Report on
MEDICARE COMPLIANCE

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

Contents

Final Safe Harbor Is More Flexible on Free Transportation; OIG Revises CMPs

Hospitals can offer free or discounted transportation to patients with more peace of mind under the fraud and abuse laws, according to a regulation finalized by the HHS Office of Inspector General on Dec. 7. The regulation protects local transportation and free shuttles from kickback prosecution if they qualify for the safe harbor, and offers shelter to other kinds of arrangements as well. There are also new exceptions to the civil monetary penalty (CMP) law for beneficiary inducements. But that's not all that OIG had to say about the world of health care wheeling and dealing. In a companion regulation, OIG finalized new CMPs from the Affordable Care Act.

Transportation seemed to play a starring role in the final regulation, which had some notable changes from OIG's 2014 proposal. "It provides very clear guidance to entities that are considering providing local transportation," says Washington, D.C., attorney Heidi Sorensen, with Foley & Lardner LLP. "You want to make sure your patients are getting good care and don't have any barriers, but it's hard for a health system to commit to an expenditure they don't need to make if they also are concerned the government will penalize them."

Safe harbors shield arrangements from kickback prosecution as long as their conditions are met. Falling outside a safe harbor doesn't doom arrangements; it's up to

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MOON Is Final, With Hospital Use Required By March 8; Who Will Deliver the Form?

The Medicare Outpatient Observation Notice (MOON) is now a done deal, and hospitals are required to start giving the form to patients by March 8, CMS said on its website Dec. 8. With the clock ticking, hospitals and critical-access hospitals have to figure out the best way to deliver this new patient notification. Because CMS requires hospitals to explain to patients why they were placed in observation instead of admitted as inpatients, the MOON probably should be in the hands of a clinician, not a registrar, which may be impractical, one compliance officer says.

The MOON informs patients they are outpatients receiving observation services, not inpatients. CMS created the form in response to the Notice of Observation Treatment and Implication for Care Eligibility (NOTICE) Act, which was signed by President Obama on Aug. 6, 2015. It was supposed to take effect one year later, but there have been delays. At first things were rolling along: CMS fleshed out the law in the proposed 2017 Inpatient Prospective Payment System (IPPS) regulation released April 18 *(RMC 4/25/16, p. 1)* and posted a proposed MOON a week later *(RMC 5/2/16, p. 6)*. Then CMS revised the MOON in the final IPPS regulation and posted a draft on Aug. 1 *(RMC 8/8/16, pp. 1, 6)*, but it had to again pass muster with the Office of Management and Budget (OMB) under the Paperwork Reduction Act. OMB approved the revised form on Dec. 7.

continued

According to the NOTICE Act, hospitals are required to notify patients who receive 24 hours or more of observation services that they are not inpatients within 36 hours after physicians have written the observation order. The MOON tells patients that "You're a hospital outpatient receiving observation services. You are not an inpatient because:" followed by a blank space, where physicians or other hospital personnel will have to explain why. In instructions posted with the MOON, CMS said, "Fill in the specific reason the patient is in an outpatient, rather than an inpatient stay."

CMS said it's open to ideas on how to fill it out and promised in the final rule to consider suggestions for making the form more user friendly, such as checkboxes or narratives. Nothing more has been said about this yet.

Ronald Hirsch, M.D., vice president of education and regulations at Accretive Physician Advisory Services, thinks checkboxes will be helpful. Here is his version:

◆ ***Your doctor expects that you will need hospital care for less than a total of two days.***

◆ ***You require more care after your surgery but should be able to be discharged within a total of two days.***

◆ ***Your Medicare Advantage plan has told your doctor to place you in observation.***

◆ ***Other:***

"The question is, will CMS allow checkboxes? I think they will," Hirsch says. "But until we see additional guidance, we can't be sure."

Peter Hughes, director of corporate compliance at Hackensack Meridian Health Network, says the challenge with the MOON is finding the right people to deliver it since CMS appears to require a clinical reason for the patient status. The vast majority of observation patients come through the emergency department, but it's up to attending physicians, not ED physicians, to give a reason for placing patients in observation vs. admitting them as inpatients, he says. The problem is, attending physicians aren't always on site at the right time.

CCO: Case Managers Don't Work 24/7

Staff nurses on the unit floor or observation unit are another option for explaining the MOON, but they don't want to get entangled in conversations with patients about patient status and its financial obligations, and case management nurses don't always work 24/7, so timely delivery of the MOON can be an issue for them, Hughes says. The form would be a natural job for registrars, who review other paperwork with patients, but Hughes questions whether that's possible. It wouldn't be appropriate for registrars to document a clinical reason for patient status, such as "we have to monitor your triglyceride levels as part of tracking any cardiac issues." But registrars could fill out the MOON if the explanation were more general, Hughes says, such as "your attending physician has determined your current condition indicates keeping you at the hospital to be monitored to see if admission as an inpatient is necessary/appropriate. For additional information, speak to your emergency department doctor." (These are hypotheticals, Hughes emphasizes.)

"There is still uncertainty about who will do this and how patients will react," Hirsch notes.

Hospitals also must walk patients through the form orally, document the oral explanation and get patients to sign and time it, according to CMS instructions provided with the MOON. The time is critical to compliance because the form must be given to patients within 36 hours of when their observation order was written, Hirsch says. "We never know how much auditing will happen," he says. "Will this be a big target when the Joint Commission shows up at hospitals? We don't know."

Contact Hirsch at rhirsch@accretivehealth.com and Hughes at Peter.Hughes@hackensackmeridian.org. View the forms at http://tinyurl.com/hob5k6k. ✧

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CMS Shines Light on Hospice Elections; Area Is Under Scrutiny

Hospices have been put on notice their election statements aren't up to snuff, which could put their reimbursement in jeopardy. Between new CMS guidance, an HHS Office of Inspector General report and an upcoming OIG audit, hospital-owned and freestanding hospices may want to revisit their certifications.

CMS states that "a written certification must be on file in the hospice beneficiary's record prior to submission of a claim to your Medicare Administrative Contractor (MAC)," according to a Nov. 22 *MLN Matters* (SE1628). The guidance focuses on physician certification of the patient's eligibility for hospice services. This is nothing new, although CMS revised the requirements for hospice certifications in the fiscal year 2015 hospice payment regulation, which took effect Oct. 1, 2014. Apparently many hospices are out of compliance with the certification requirement, which attests to the patient's election of hospice benefits and the physician's confirmation the patient has a life expectancy of six months or less and therefore is qualified for Medicare coverage of hospice services. OIG said in a September evaluation that one third of election statements were missing required information or "had other vulnerabilities" and will now audit hospices' compliance with Medicare requirements, according to the 2017 Work Plan *(RMC 11/14/16, p. 1)*.

Forms Lacked 'Appropriate Information'

That's unnerving for compliance officers who are finding gaps on their election statements. At one health system where problems surfaced with its hospice election statements, the compliance officer has been scouring OIG and CMS materials. "We had acquired a hospice as part of a hospital acquisition and found that our forms do not have appropriate information," says the compliance officer, who asks not to be identified. "We were debating, does that mean we have to pay everything back?"

In the *MLN Matters*, CMS explained what documentation would support the certification requirements:

(1) "A simple statement on the certification/recertification that states the beneficiary has a medical prognosis of 6 months or less if the terminal illness runs its normal course."

(2) "The certification should give specific clinical findings, for example, signs, symptoms, laboratory testing, weights, anthropomorphic measurements, oral intake."

(3) "The signature(s) of the physician(s), the date signed, and the benefit period dates that the certification or recertification covers."

CMS elaborated on other requirements of election statements in a 2014 *MLN Matters* (MM9114). Hospice patients have the right to choose their attending physicians, and their election statements must state the patient's choice of attending physician, including the name, office address and national provider identifier.

The compliance officer tells *RMC* that the certifications at the hospice acquired by the health system lacked the physician designation and the patient acknowledgement that the attending physician was the patient's choice. Although the health system did its due diligence before buying the hospital and its hospice, the election statements were overlooked, the compliance officer said.

"If you don't have the right language in your certification, technically you are out of compliance, and you don't warrant any of the Medicare hospice payment," the compliance officer said. "To me, that's ridiculous because the care was provided — quality care — and it met the spirit of what was [intended]." The health system fixed its hospice election statements, but decided not to return payments for historical hospice services. It's taking its cue from the OIG report, which doesn't direct CMS to recover money stemming from inadequate certifications, and from CMS, which focuses on improving compliance in the *MLN Matters* articles. "CMS is making it clear now. I think what they are doing is giving us a break," the compliance officer says. "But I am always wary."

On the face of it, providers have to report and return Medicare overpayments within 60 days of identifying them, according to the 60-day rule. "But what is an overpayment? It's not that well-defined," says Boston attorney Larry Vernaglia, with Foley & Lardner LLP. Before they write a check, providers should make certain they were overpaid and carefully quantify the amount. CMS's final regulation gives providers six months to investigate "credible information" on overpayments before the 60-day clock starts ticking *(RMC 2/15/16, p. 1)*. "This needs to happen before your duty per the regulation kicks in," he notes. Compliance with the 60-day rule may be complicated by the U.S. Supreme Court's June decision in *Universal Health Services v. United States ex rel. Escobar*, which addressed implied certification in a False Claims Act case *(RMC 6/20/16, p. 1)*, Vernaglia says. The decision stated that false claims liability can attach "when the defendant submits a claim for payment that makes specific representations about the goods or services

provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement."

Knowingly retaining an identified overpayment beyond 60 days can be alleged to be a "reverse false claim," and Vernaglia figures there will be false claims cases based on noncompliance with technical requirements, such as hospice election statements. "Can a reverse false claim be based on failure to refund an overpayment based on an immaterial regulatory violation? That would be inconsistent with the court's holding in *Escobar*," he says.

Contact Vernaglia at lvernaglia@foley.com. View the *MLN Matters* at http://tinyurl.com/jso5u5o. ✧

Complying With Hospice Certification Requirements

To improve compliance with certification requirements, CMS on Nov. 23 published a sample hospice notice of election (*MLN Matters* SE1631). "This sample includes the necessary elements that assure the beneficiary understands the nature of hospice care and makes an informed decision," CMS says. Visit http://tinyurl.com/jsmht3h.

Medicare Hospice Notice of Election Statement

Draft Sample

I, _____ choose to elect the Medicare hospice benefit and receive Hospice services from
(Beneficiary Name)
_____.
(Hospice Agency)

Hospice Philosophy
I acknowledge that I have been given a full explanation and have an understanding of the purpose of hospice care. Hospice care is to relieve pain and other symptoms related to my terminal illness and related conditions and such care will not be directed toward cure. The focus of hospice care is to provide comfort and support to both me and my family/caregivers.

Effects of a Medicare Hospice Election
I understand that by electing hospice care under the Medicare Hospice Benefit, I am waiving (give up) all rights to Medicare payments for services related to my terminal illness and related conditions and I understand that while this election is in force, Medicare will make payments for care related to my terminal illness and related conditions only to the designated hospice and attending physician that I have selected. I understand that services not related to my terminal illness or related conditions will continue to be eligible for coverage by Medicare.

Right to choose an attending physician
I understand that I have a right to choose my attending physician to oversee my care. My attending physician will work in collaboration with the hospice agency to provide care related to my terminal illness and related conditions.

❑ I do not wish to choose an attending physician

I acknowledge that my choice for an attending physician is:
Physician Full name: _____ NPI (if known) _____
Office Address: _____

I acknowledge and understand the above, and authorize Medicare hospice coverage to be provided by
_____ to begin on _____
(Hospice Agency) (Effective Date of Election)

Note: The effective date of the election, which may be the first day of hospice care or a later date, but may be no earlier than the date of the election statement. An individual may not designate an effective date that is retroactive.

_____ _____
Signature of Beneficiary/Representative (Date)

❑ Beneficiary is unable to sign -
Reason:_____

_____ _____
Signature of Beneficiary/Representative (Date)

Execs, MDs Accused of Kickbacks At Out-of-Network Texas Hospital

Three years after a Dallas hospital settled a false claims case and entered a non-prosecution agreement for alleged kickbacks, its owners and some managers and physicians have been charged with felonies in a complex kickback and bribery scheme, the U.S. Attorney's Office for the Northern District of Texas said Dec. 1.

The allegations center on payments to physicians and others to induce referrals of certain patients to physician-owned Forest Park Medical Center, which was an out-of-network hospital. In a nutshell, physicians allegedly were paid kickbacks to refer patients "with high reimbursing out-of-network private insurance benefits or benefits under certain federally-funded programs," the U.S. attorney's office said, and to "sell" Medicare and Medicaid patients to other hospitals, according to the indictment. It alleged that $40 million in bribes were paid from 2009 to January 2013. The hospital is not being prosecuted.

The indictment charges 21 people, including surgeons and primary care physicians, but the corporate entity was not charged, and that "indicates strong adherence by the Department of Justice to the principles articulated in the Yates memo," says Denver attorney Greg Goldberg, with Holland & Hart. "This indictment would suggest that DOJ clearly is focusing on individual culpability, namely, who — specifically — did what and when and why. " The 2015 Yates memo, also known as the Individual Accountability Policy, is the DOJ blueprint for nailing "culpable" individuals as part of corporate civil and criminal fraud cases *(RMC 10/3/16, p. 1; 9/14/15, p. 1)*.

Hospital Resolved Earlier Case for $258,000

Forest Park Medical Center was already on DOJ's radar screen because of the 2013 fraud case. The hospital agreed to pay the government $258,000 to settle false claims allegations that it violated the anti-kickback statute. According to the U.S. Attorney's Office, the hospital allegedly "offered and paid excessive remuneration and other things of value to actual and potential referring physicians or others, including amounts for 'marketing' or 'advertising.' Payments also were made in the form of cash and gift cards/coupons for luxury items." These kickbacks were targeted at getting TRICARE referrals, DOJ alleged.

Forest Park Medical Center also entered into a non-prosecution agreement with the government and accepted a federally imposed monitor for not more than 24 months. The monitor will review and evaluate inpatient and outpatient claims submitted to all payers, not just federal programs. The non-prosecution agreement with the hospital didn't release any individual from liability, and the government said it was continuing to investigate certain individuals involved with the scheme. Non-prosecution agreements give defendants a chance to comply with reforms and escape prosecution.

Out-of-network hospitals don't accept reimbursement rates set by insurers. They're free to set their own prices "and were generally reimbursed at substantially higher rates than in-network providers," according to the indictment. Patients who use out-of-network hospitals generally pay much more of their bills — "generally 20% to 50% of the hospital's total charges."

Forest Park Medical Center was founded by Richard Ferdinand Toussaint Jr., an anesthesiologist; Wade Neal Barker, a bariatric surgeon; Alan Andrew Beauchamp, chief operating officer; and Wilton McPherson Burt, a managing partner — all of whom were charged — and was managed by Burt and Beauchamp, according to the indictment.

continued

CMS Transmittals and *Federal Register* Regulations

Dec. 2–Dec. 8

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. 100-01, Medicare General Information, Eligibility and Entitlement Manual

- Update to Medicare Deductible, Coinsurance and Premium Rates for 2017, Trans. 103GI, CR 9902 (Dec. 2; eff. Jan. 1; impl. Jan. 3, 2016)

Pub. 100-04, Medicare Claims Processing Manual

- HCPCS Code Update for Preventive Services, Trans. 3669CP, CR 9888 (Dec. 2; eff. Jan. 1; impl. Jan. 3, 2016)
- Update to Editing of Therapy Services to Reflect Coding Changes (R), Trans. 3670CP, CR 9698 (Dec. 1; eff. Jan. 1; impl. April. 3, 2017)
- CY 2017 Update for Durable Medical Equipment, Prosthetics, Orthotics and Supplies Fee Schedule, Trans. 3671CP, CR 9854 (Dec. 5; eff. Jan. 1; impl. Jan. 3, 2016)

Pub. 100-20, One-Time Notification

- Changes to the End-Stage Renal Disease Facility Claim (Type of Bill 72X) to Accommodate Dialysis Furnished to Beneficiaries with Acute Kidney Injury (R), Trans. 17590TN, CR 9598 (Dec. 6; eff. Jan. 1; impl. Jan. 3, 2016)

Federal Register Regulations

Final Rules

- Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Civil Monetary Penalty Rules, 81 Fed. Reg. 88334 (Dec. 7, 2016)
- Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368 (Dec. 7, 2016)

They are accused of illegally enriching themselves and others "through the submission of private, out-of-network claims, and [Federal Employee Compensation Act] and TRICARE claims, for services provided to beneficiaries" at Forest Park Medical Center. The Federal Employee Compensation Act provides medical care and rehab to federal employees, including postal workers.

For example, Beauchamp, Toussaint, Barker and Burt allegedly paid surgeons for referring patients to the hospital for procedures, with an emphasis on high-paying surgeries, such as spine and bariatric surgeries, the indictment alleges. Surgeons were asked how many procedures they did a month and the number of out-of-network cases they could steer to the hospital. According to the indictment, the surgeons spent most of the bribe money marketing their own practices and on personal expenses, including cars, diamonds, and payments to family members. About 40 primary care physicians also allegedly received $500 a month in kickbacks from the "certain coconspirators" to refer their patients to the surgeons or the hospital, the indictment states.

Physicians were not the only people who allegedly received kickbacks for referring patients to Forest Park Medical Center. Workers' compensation preauthorization specialists, attorneys and chiropractors, among others, allegedly were paid as well, the indictment states. Some of them had clinics and allegedly received money for sending patients to the hospital or surgeons who performed procedures there, the indictment contends.

The defendants were charged with violating anti-kickback law, the conspiracy statute and violations of the Travel Act, which bars traveling interstate to commit crimes.

"This is a relatively complicated indictment to begin with and the inclusion of the Travel Act — which is taken out of the Racketeering chapter of the federal criminal code — heaps on more complexity, particularly in terms of proof at trial," Goldberg notes.

Forest Park Medical Center is now closed.

Contact Goldberg at GGoldberg@hollandhart.com. Visit http://tinyurl.com/hwtxckp. ✧

Court Gives HHS Deadlines for Clearing Medicare Appeals Backlog

Administrative law judges (ALJs) now have a deadline for disposing of Medicare appeals in the pipeline after a hard-fought battle between HHS and the American Hospital Association (AHA).

In a Dec. 5 ruling, the U.S. District Court for the District of Columbia granted AHA's motion for summary judgment, and set a series of staggered deadlines for clearing the decks by 2020 (*American Hospital Association et al. v. Sylvia Burwell*, No. 14-851).The court left it up to CMS and the Office of Medicare Hearings and Appeals (OMHA) to figure out how to meet the deadlines for appeals of Medicare claim denials.

The deadlines are:

- ***By Dec. 31, 2017,*** a 30% reduction in the backlog of cases pending before ALJs;
- ***By Dec. 31, 2018,*** a 60% reduction in the backlog of cases pending before ALJs;
- ***By Dec. 31, 2019,*** a 90% reduction; and
- ***By Dec. 31, 2010,*** the backlog would be gone.

The reductions were suggested by AHA in a writ of mandamus, which means it asked the court to compel CMS to resolve the backlog on a court-ordered schedule.

There's a 90-day statutory deadline for ruling on appeals filed by providers and suppliers with OMHA, but ALJs, who are swamped with cases, virtually never rule that fast. According to OMHA's fiscal year 2017 report on justifications for estimates to the appropriations committee, the average processing time for cases was 661 days in 2015, and it had increased to 935 days as of October 2016. To ease the backlog, CMS and OMHA have implemented a number of initiatives, including the 2014 hospital appeals settlement process *(RMC 9/15/14, p. 1)*, which CMS revived on Dec. 1. CMS is now offering hospitals 66% of the net allowable amount of denied patient-status claims if they withdraw their appeals *(RMC 11/21/16, p. 1)*.

"The judge's ruling is broad enough that it allows CMS and OHMA to use a variety of methods to obtain the case-reduction requirements outlined in the judge's order," says attorney Andrew Wachler, with Wachler & Associates in Royal Oak, Mich. He doubts CMS will cut back on audits to comply with the deadlines, but thinks it would be effective to extend the hospital appeals settlement offer to other types of providers, such as home health agencies and durable medical equipment suppliers. Also, more money to double the number of ALJs, as called for in the bipartisan Audit and Appeals Fairness, Integrity and Reforms in Medicare Act (AFIRM) of 2015 approved by the Senate Finance Committee *(RMC 6/8/15, p. 4)*, "would help considerably," Wachler says.

The court's decision to set deadlines came after months of wrangling between AHA and HHS *(RMC 11/21/16, p. 6; 9/26/16, p. 8; 11/16/15, p. 8)*. It's over for now, but the federal court said it will keep an eye on things. "Although the Court will administratively terminate the case, it will retain jurisdiction in order to review the required status reports and rule on any challenges to unmet deadlines," according to the decision.

Contact Wachler at awachler@wachler.com. Read the decision at http://tinyurl.com/zsfzmoa. ✧

Transportation Safe Harbor Is Final

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providers to decide whether they fall comfortably enough within the fraud and abuse laws. Or they may prefer a definitive answer from an OIG advisory opinion, but "it's not binding unless you're the requestor" and "it's a long process," Sorensen says.

If they want immunity, providers may now look to the transportation safe harbor, which will insulate health systems that offer "local" transportation for "established" patients, terms that are spelled out in the rule. The transportation goes both ways, from the patient's home to the provider and back for medically necessary services. But forget the fancy stuff; transportation cannot "take the form of air, luxury, or ambulance-level service," OIG explained.

Only "eligible entities" may provide free transportation, according to the rule. That "excludes only suppliers of items," such as pharmacies and durable medical equipment suppliers. OIG went out of its way to welcome home health agencies into the transportation safe harbor, but the invitation came with a warning. "Patients eligible for home health services may be particularly in need of transportation, which home health agencies may be in a unique position to provide. We are aware, however, that home health agencies have historically posed a heightened risk of program abuse, and take this opportunity to remind all eligible entities that, to be protected by this safe harbor, the provision of transportation must be for medically necessary services and comply with all other conditions of the safe harbor," the rule states.

Transportation Is Not for 'Recruiting'

Also, eligible entities can't make transportation available based on the volume or value of referrals. For example, when hospitals offer discharged patients a ride to a follow-up visit with the cardiologist, they have to come through even if the patient chooses a cardiologist who isn't affiliated with the hospital. However, hospitals may limit transportation in some ways (e.g., only for visits included in the discharge plan), the rule states.

Hospitals and other organizations are eligible for safe harbor protection only if they offer free or discounted transportation to established patients. The definition in the proposed rule — which said free transportation wouldn't be protected if it were offered to new patients who hadn't yet attended an appointment — came under fire. People commented that "many newly insured patients may need help getting to their first appointment, and that in some cases, the first appointment may be critical or urgent." In response, OIG changed its tune, saying a patient may be "established" after scheduling an appointment with a provider.

However, OIG warned, "transportation cannot be used as a recruiting tool." And health systems shouldn't assume the safe harbor is a green light for all its entities to give patients a free ride. "OIG is saying the 'established patient' criteria doesn't apply across an integrated health system," Sorensen says. "It's probably a nuanced point that has to be worked out." However, the final rule gives more leeway to accountable care organizations, noting "an ACO or similar entity may assist its affiliates in providing transportation (e.g., by having a fleet of vehicles available for the use of its affiliates in transporting their patients)" — as long as the affiliates pay for it.

OIG also massaged its definition of "local" transportation for purposes of meeting the safe harbor. Giving patients a ride to health care services is protected only if it's local, and the proposed rule defined that as no more than 25 miles. But OIG has now drawn a distinction between urban and rural areas in response to comments.

"This final regulation maintains the proposed 25-mile distance for patients in an urban area but expands the definition of 'local' to 50 miles for patients in a rural area, as defined in this rule. The mileage can be measured directly (i.e., 'as the crow flies'), which would include any route within that radius (even if such route is more than 25 or 50 miles when driven)," OIG said.

More Wiggle Room in CMP

Shuttle services also come under the wing of the transportation safe harbor. Unlike a free ride for a specific patient, shuttles run from set locations (e.g., subway stops to the hospital) and are available to everyone (e.g., family members visiting patients), Sorensen says. Some of the safe-harbor requirements are the same. For example, shuttle services can't be marketed or advertised, and their costs must be borne by the health care entities providing them. But the established patient requirement isn't relevant.

The final rule also makes changes to the beneficiary inducement CMP, which prohibits giving free items or services the provider knows may influence Medicare beneficiaries to choose a particular provider. OIG gave providers some wiggle room if there's a low risk of fraud and abuse by creating an exception to allow incentives that promote access to care, says Cincinnati attorney Claire Turcotte, with Bricker & Eckler. "The beneficiary inducement area is really significant," she says. "Making some exceptions signals that OIG is trying to bring the rule into the 21st century in terms of making it flexible so people can develop programs that further the goals of the triple aim" — better patient experience, improved health across a population, and lower costs.

But it's not a free pass, Turcotte cautions. "They drew a distinction between giving a beneficiary something that

would enable them to access care versus giving them something that could be viewed as a reward for completing treatment," she says. For example, a provider could offer patients free babysitting to allow them to attend a smoking cessation program under the exception if it were relevant to the patient's health condition. "But the provider could not give the patient movie tickets or any other reward for attending a session or series of sessions. A patient might not be able to attend the appointment without child care assistance, but the movie tickets do not improve the patient's ability to attend the appointment," according to the regulation.

Whether goods and services qualify for the exception to the beneficiary inducement CMP requires new thinking. Medical necessity is not the magic phrase anymore; "we believe a necessary safeguard to protect both patients and Federal health care programs is to limit the scope of the exception to remuneration that promotes access to items and services that are payable by Medicare or a State health care program," OIG states.

The proposed change to the gainsharing CMP was not finalized because the 2015 Medicare Access and CHIP Reauthorization Act (MACRA) pretty much made it moot. The CMP penalizes hospital payments to doctors to reduce services, and MACRA exempted gainsharing from the CMP as long as it doesn't lead to a reduction in medically necessary services *(RMC 4/20/15, p. 1)*. "This statutory provision is self-implementing, and no regulatory action is required to make the change enacted in MACRA effective," the final rule stated.

But it does finalize other safe harbors that, for example, protect certain copay waivers, including pharmacy waivers for financially needy patients and emergency ambulance services provided by states or municipalities.

In a separate regulation, OIG finalized new CMPs on failure to give OIG timely access to records; ordering or prescribing services while excluded; making false statements on enrollment applications; failure to report and return overpayments; and making a statement that's material to a false claim *(RMC 2/16/15, p. 4)*.

Contact Sorensen at HSorensen@foley.com and Turcotte at cturcotte@bricker.com. View the safe harbor/beneficiary inducement CMP rule at http://go.usa.gov/x8mCk and the revisions to the CMPs at http://go.usa.gov/x8mCk. ✧

NEWS BRIEFS

◆ **In a Dec. 7 policy statement, the HHS Office of Inspector General (OIG) increased the dollar value of goodies that providers can give Medicare and Medicaid patients without running afoul of the civil monetary penalty law that prohibits beneficiary inducements.** OIG is now interpreting "nominal value," which hasn't been updated since 2000, "as having a retail value of no more than $15 per item or $75 in the aggregate per patient on an annual basis." Visit http://go.usa.gov/x8m7R.

◆ **Rideout Health in California agreed to pay $2.425 million to resolve allegations that three of its facilities violated the Controlled Substances Act,** the U.S. Attorney's Office for the Eastern District of California said Dec. 6. Rideout Health also agreed to a three-year compliance plan. The settlement resolves allegations that the facilities — Rideout Memorial Hospital, Fremont Medical Center and Feather River Surgery Center — "failed to properly record and maintain thousands of transactions involving controlled substances," the U.S. attorney's office said. The settlement stems from an investigation that began when the Drug Enforcement Administration allegedly learned that Fremont Medical Center's DEA registration had expired, "and that from October 23, 2012, to October 23, 2014, pharmacy technicians at Rideout Memorial Hospital were transporting controlled substances between Rideout Health facilities with little or no security controls in place," the U.S. attorney's office alleged. Visit http://tinyurl.com/gtdyhsv.

◆ **The U.S. Senate passed the 21st Century Cures Act on Dec. 7, six days after it was passed by the House of Representatives.** The legislation, which President Obama has promised to sign, allows some "mid-build" off-campus provider-based departments to bill the outpatient prospective payment system as long as they had a binding, written agreement for construction when Sec. 603 of the 2015 Bipartisan Budget Act cracked down on provider-based space on Nov. 2, 2015 *(RMC 12/5/16, p. 3)*. They also have to jump through other hoops.

◆ **Medicare overpaid hospitals $2.7 million over three years for manufacturer credits for replaced cochlear implants,** OIG said in a new report. OIG audited 149 outpatient claims for replaced cochlear devices at 78 hospitals and found they didn't always comply with Medicare rules for reporting replaced cochlear implants. Visit http://go.usa.gov/x8EPZ.

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