Report on
MEDICARE COMPLIANCE

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

Contents

In Appeals, 'Waiver of Liability' May Fare Better After Court Slams Mountain of Rules

In the wake of an impassioned decision from the U.S. Court of Appeals for the 10th Circuit, hospitals may win more appeals of Medicare claim denials by saying they deserve a "waiver of liability" for payment. The three-judge panel evoked the father of the constitution, James Madison, to express concern about runaway regulations, ultimately ruling that CMS applied them retroactively in a home health agency case, according to the May 31 decision.

That gives Caring Hearts Personal Home Services, a home health provider in Kansas City, Kan., a good chance to recover $800,000 worth of Medicare claims that had been denied. Its appeals failed at every turn until the home health provider reached the federal appeals court, the second highest court in the land. That's when the three judges ruled that CMS applied more stringent 2010 regulations to 2008 claims, and went with the waiver-of-liability provision (Sec. 1395pp of the Social Security Act), which lets providers and patients off the hook when they don't know, or couldn't have been expected to know, that Medicare wouldn't reimburse them for services they received.

"Caring Hearts is entitled to relief under waiver of liability because they couldn't have known the services wouldn't be payable based on rules that hadn't been written yet," attorney Jessica Gustafson said June 3 at a Finally Friday webinar sponsored by the Appeal Academy. Providers rarely make use of it in appeals, but maybe it's time to seize the waiver-of-liability day because it's relevant in many situations, said Gustafson, with The Health Law Partners in Southfield, Mich.

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QIOs to Review Denied Claims; No Example Coming for the Two-Midnight Exception

Claims for short hospital stays that were denied by Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC-QIOs) are in a state of suspended animation because they will be reviewed again. The reason for the do-over is to ensure the two BFCC-QIOs, Livanta and KEPRO, applied the two-midnight rule accurately and consistently. In the meantime, reviews of admissions under the two-midnight rule are temporarily suspended for the next 60 to 90 days. They will resume after QIOs receive more training from CMS on the two-midnight rule and its application.

"CMS is requiring the BFCC-QIOs to re-review all claims they denied in their medical review process since October 2015 to make sure medical review decisions and subsequent provider education are consistent with current policy," CMS said on its website. "The current 'pause' will allow time for the BFCC-QIOs to conduct these re-reviews." The pause was first announced in May *(RMC 5/16/16, p. 7)*, but CMS at the time said nothing about re-reviewing all claim denials. CMS also unveiled a flowchart to help QIOs improve their short-stay reviews (see box, p. 3).

continued

CMS handed QIOs the ropes in the 2016 outpatient prospective payment system (OPPS) regulation proposed on July 8, 2015 *(RMC 7/13/15, p. 1)*. There are no more probe and educate reviews by Medicare administrative contractors (MACs) or routine patient-status audits by recovery audit contractors (RACs). Instead, every year QIOs will audit 50 medical records from larger hospitals and 20 from smaller hospitals. Only repeat offenders will be sent to RACs for audits *(RMC 8/24/15, p. 5)*.

So far, QIOs have not referred any hospitals to the RACs, a CMS spokesperson says. But it's always a possibility for "consistently failing to adhere to the Two Midnight rule or failing to improve their performance after QIO educational intervention," the CMS website says.

In a hospital open-door forum on June 7, CMS officials discussed the QIO temporary pause, the two-midnight rule and the use of the JW modifier when reporting drug waste. CMS last month announced that hospitals nationally will have to use the JW modifier on all outpatient Medicare claims for discarded drugs and biologicals from single-use vials on July 1, 2016 *(RMC 5/9/16, p. 1)*, but at the open-door forum, CMS said it has decided to delay the effective date until Jan. 1, 2017. Universal use of the JW modifier for drug waste ends the Medicare administrative contractors' discretion; currently, some MACs require hospitals to use JW and some don't. The modifier doesn't apply in the physician office setting either.

Aside from the JW modifier and a smattering of other issues, the open-door forum was devoted to reviews under the two-midnight rule and the context of the rule itself. Marc Hartstein, director of the CMS hospital and ambulatory policy group, addressed the use of the relatively new case-by-case exception to the two-midnight rule that materialized in the 2016 OPPS regulation. Although generally CMS bases its Part A payments for admissions on whether they are medically necessary and cross two midnights, it permits "Part A payment on a case-by-case basis for inpatient admissions that do not satisfy the 2-midnight benchmark, if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care despite an expected length of stay that is less than 2 midnights," according to the OPPS final rule.

Hospitals Have Been Looking for Guidance

Hospitals have been clamoring for an example of how the exception may play out so they don't rely on it only to misconstrue it, and then face QIO denials and possibly the RAC. But Hartstein said no examples will be forthcoming. "This is the kind of question we have found very difficult to answer from the central office," he said. The point of the two-midnight rule is to establish a policy calling for Medicare Part A payment when it's reasonable and necessary for patients to stay in the hospital for two midnights. If it's less than that, CMS "would rarely expect" to pay under Part A, Hartstein says. For everything in between — one to two midnights — CMS added the exception in the OPPS, effective Jan. 1, 2016, that "left it to physician judgment," he noted. "We are leaving this determination to the individual physician or practitioner to make a judgment based on the characteristics of the specific patient." CMS will not tie anything to a clinical condition à la the current "rare and unusual circumstances" exception for mechanical ventilation *(RMC 12/9/13, p. 8)*. "After further inquiries came to us," CMS decided to skip a national determination of what would qualify for short inpatient stays in favor of leaving it to physicians, he says.

However, Hartstein said, "If we see a high proportion of those types of cases where patients were admitted, QIOs will review them with the hospital."

Hospitals use this exception at their own risk, but it may come up, warns Ronald Hirsch, M.D., vice president of regulations and education at Accretive Physician Advisory Services. He has seen QIOs approve an inpatient

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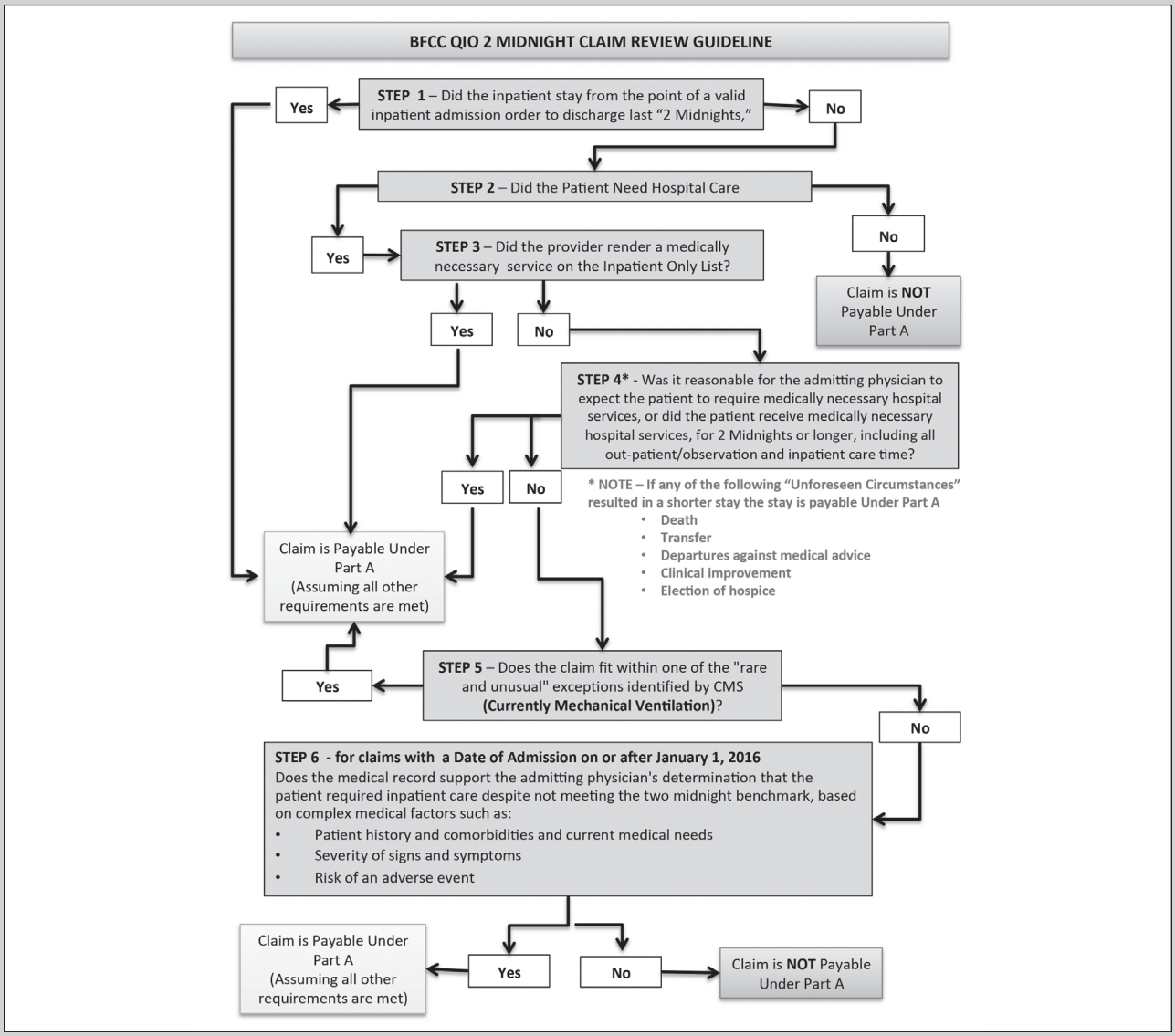
admission even though it was a one-day stay because the physicians documented the patient's high risk.

In one case, the patient came to the emergency room with a complete heart block. The patient's heart rate was 20, so a permanent pacemaker was immediately implanted and he went home the next day. "That was an inpatient whose life was in immediate jeopardy. It was very high risk and he required invasive care at that moment," Hirsch says. "Those are the types of cases, with documentation, that most likely would be acceptable for

Flow Chart for Evaluating Admissions Under the Two-Midnight Rule

CMS posted this tool June 7 to help quality improvement organizations (QIOs) determine whether inpatient admissions satisfy the two-midnight rule. There are flaws, however, with the flow chart that might undermine CMS's attempts to improve QIO reviews, says Ronald Hirsch, M.D., vice president of regulations and education at Accretive Physician Advisory Services. For example, the flow chart asks up front whether the patient was an inpatient for two midnights. If the answer is "yes," the case should not even be up for QIO review, he says. It also appears that if the QIO reviews that kind of case, it will automatically approve the admission, Hirsch says. What about medical necessity? It's only addressed in step six, when the flow chart gets useful. Hirsch has his doubts that it's going to help. Contact Hirsch at rhirsch@accretivehealth.com.



admission as an inpatient" — and the QIO agreed with the hospital in this case. But he doesn't think hospitals should use the case-by-case exception for patients who come in with high-risk chest pain; they have diabetes and hypertension and recently had a stent implanted. They need further diagnostic testing and are high risk, he says, "but I would be hesitant to use the exception for a patient like that."

Contact Hirsch at rhirsch@accretivehealth.com. View the CMS notice about the QIO pause at http://tinyurl.com/p9ha9qh. ✧

Insurer Reviews Are 'Veiled Audits'; Don't Always Hand Over Records

When a commercial insurer asked for 1,000 medical records last year from a 300-bed hospital, it flatly refused. The hospital informed the insurer that it was welcome to peruse the medical records, but it would have to come on over, make copies and pay for the privilege. The limits set by the hospital fell within the scope of its contract with the insurer, and while the hospital certainly wasn't saying "no," it simply decided to stop bending over backwards for commercial insurers that were doing a "veiled audit" of their claims, which could lead to recoupment, a consultant says.

Because the hospital didn't make it easy, the insurer moved on, says Christopher Baggott, president of Medlinks Inc., in Brentwood, Calif. "1,000 pieces of PHI were not sent out into the world and potentially 1,000 DRGs were not changed," Baggott tells *RMC*. "You have to be willing to defend your right to your dollars, and not just roll over."

Hospitals may find that if they don't send their medical records to commercial insurers — and instead invite them over at the insurers' expense — they'll face fewer audits, he says. This is a different world than Medicare, which is entitled to medical records, because commercial payers pre-authorize services. Unless contracts with commercial payers require hospitals to turn over medical records on demand, hospitals can resist them and insist they come on-site and pay the cost of copying the records and the cost of assigning staff to shadow auditors as they review records, Baggott says.

"Across the country, this release of records situation is so rote," he says. "Everyone does it the same way and no one is challenging these contractual situations." Commercial payers contend they have the right to audit, but he says that's not often the case. Baggott has rarely seen commercial insurer contracts that require providers to produce medical records at their own expense for purposes of an audit. However, insurers are welcome to conduct quality of care reviews, and hospitals will turn over medical records for that purpose, he says.

Baggott considers audits to be "double dipping" in commercial contracts. *The reason:* admissions are preauthorized by commercial payers. For example, when the physician wants to admit a patient with apparent pneumonia, the hospital calls the insurer for approval to admit the patient for a certain number of days. When the insurer asks for medical records later, they are essentially trying to sneak in an audit of a hospital stay that's already been authorized, Baggott says. Or the insurers will try to use their record requests to downsize the MS-DRG or hit hospitals for poor documentation, he says.

How Should Hospitals Deal With Insurers?

Again, he isn't suggesting that hospitals withhold records. But if commercial insurers want them, let them come on-site and pay for the privilege of reviewing them for cases they have already authorized. And he urges hospitals to adjust their accommodating attitude. Baggott has watched facilities with virtual private networks turn over their VPN access to auditors from commercial payers so they don't have to come on-site.

"It's a great point for facilities to understand," he says. They may have tunnel vision about recovery audit contractors. But "that's just one segment of auditing. Commercial-payer auditors have a new list of audits we have never seen before — medical necessity reviews, DRG validation, level of care audits and technical denials based on [providers] not sending them medical records."

Pulling off this strategy will require coordination between people at the hospital who work on appeals and people who work on insurance contracts, Baggott says. "You have to be careful about this," he notes. "You don't want to violate the contract." But a lot of money is at stake, and it's time to break down the walls between compliance/case management/physician advisers/appeals management on the one hand, and contracting on the other. Probably the only thing being violated "is a cultural standard."

Contact Baggott at cbaggott@medlinksinc.com. ✧

Updated OIG Work Plan Hits Outliers, Provider-Based Space

Provider-based space is getting another look-see from the HHS Office of Inspector General, according to the mid-year update to its annual Work Plan, which was released June 7. This time, OIG is eyeing provider-based space through a somewhat different lens.

The revised item says OIG will determine how many provider-based facilities are owned by hospitals, and evaluate compliance with certain provider-based requirements, as well as "challenges associated with the provider-based attestation review process." In addition, OIG also will assess how well CMS oversees provider-based compliance.

"It implies OIG will audit more attestations for accuracy," says San Francisco attorney Judy Waltz, who is with Foley & Lardner LLP. "If OIG reviews and finds attestations misleading, they could collect provider-based overpayments, which would be a lot of money," she adds.

This area has already taken a big hit, with the Balanced Budget Act of 2015 ending the creation of new provider-based space as of Nov. 2, 2015, with some exceptions *(RMC 11/2/15, p. 1, 11/23/15, p. 1)*.

The Work Plan is OIG's roadmap of audits, evaluations and inspections for the coming year. Health care organizations use it to inform their annual compliance work plans *(RMC 11/9/15, p. 3)*. Recently, OIG has been posting additions, revisions and deletions along the way.

Work Plan Has New Items

The mid-year OIG Work Plan has some brand-new items. For example, there's an intriguing audit of outpatient outlier payments for short-stay claims that is due out next year. OIG says it will "determine the extent of potential Medicare savings if hospital outpatient stays were ineligible for an outlier payment. CMS makes an additional payment (an outlier payment) for hospital outpatient services when a hospital's charges, adjusted to cost, exceed a fixed multiple of the normal Medicare payment (Social Security Act (SSA) § 1833(t)(5))."

Another new item has to do with the nexus of skilled nursing facilities (SNFs), the three-day qualifying rule and the prospective payment system (PPS). In this review, which is slated for publication this year, OIG says it will examine compliance with the SNF PPS requirement connected to the three-day qualifying hospital stay. Medicare covers SNF admissions only if patients are discharged from the hospital after an inpatient, medically necessary stay that lasted three consecutive days.

Contact Waltz at jwaltz@foley.com. View the Work Plan update at http://go.usa.gov/chqr5. ✧

Waiver of Liability Wins the Day

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"This case has broad implications," added former Administrative Law Judge (ALJ) Bob Soltis. Waiver of liability is "sort of an afterthought," but he urged providers to "consider every possible arrow in your quiver. It is half of every hearing."

The judges in the 10th circuit decision raised the question of whether myriad regulations — "37,000 separate guidance documents can be found on CMS's website" — are too hard for the government, and by extension providers, to keep track of.

"This case has taken us to a strange world where the government itself — the very 'expert' agency responsible for promulgating the 'law' no less — seems unable to keep pace with its own frenetic lawmaking," the judges ruled in the case. "A world [James] Madison worried about long ago, a world in which the laws are 'so voluminous they cannot be read' and constitutional norms of due process, fair notice, and even the separation of powers seem very much at stake. But whatever else one

CMS Transmittals and *Federal Register* Regulations

June 3 – June 9

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. 100-02, Medicare Benefit Policy Manual

- Update to Chapter 11 End-Stage Renal Disease for Calendar Year 2016, Trans. 224BP, CR 9541 (June 3; eff. Jan. 1; impl. Sept. 6, 2016)

Pub. 100-20, One-Time Notification

- Coding Revisions to National Coverage Determinations (R), Trans. 1672OTN, CR 9631 (June 3; eff. Oct. 1; impl. Oct. 3, 2016)
- Payment Change for Group 3 Complex Rehabilitative Power Wheelchairs Accessories and Seat and Back Cushions under Section 2 of the Patient Access and Medicare Protection Act for Home Health Claims (R), Trans. 1671OTN, CR 9586 (June 2; eff. Oct. 1; impl. Oct. 3, 2016)

Federal Register Regulations

Correction

- Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2017 Rates; Quality Reporting Requirements for Specific Providers; Graduate Medical Education; Hospital Notification Procedures Applicable to Beneficiaries Receiving Observation Services; and Technical Changes Relating to Costs to Organizations and Medicare Cost Reports, 81 Fed. Reg. 37175 (June 9, 2016)

might say about our visit to this place, one thing seems to us certain: an agency decision that loses track of its own controlling regulations and applies the wrong rules in order to penalize private citizens can never stand."

The case focused on whether certain patients met the Medicare definition of "homebound" and therefore were eligible to receive home health services, and whether skilled nursing services and physical therapy were medically necessary for homebound patients. About two dozen claims were denied by a CMS benefit integrity contractor, which meant an overpayment of $63,153, but that turned into $855,000 because the errors were extrapolated to a larger universe of claims, according to court papers. On appeal to the Medicare administrative contractor, Caring Hearts lost for the most part, but the overpayment amount was revised to $800,000. At the next level, the qualified independent contractor upheld the overpayment, including the extrapolation, and on and on it went as Caring Hearts traveled the appeals route, with the ALJ and Medicare Appeals Council more or less ruling against it. The HHA also was shot down by the U.S. District Court for the District of Kansas City.

But the Court of Appeals for the 10th Circuit saw things differently. It determined that CMS "applied the

Example of Non-Retaliation Policy

Here is the non-retaliation policy in effect at Broward Health, a public hospital district in Florida. Implementing and enforcing non-retaliation policies is at the heart of compliance programs because employees must feel confident they won't suffer consequences for reporting potential compliance problems. Broward Health has experienced some fallout recently in this area after board members tried to identify the person who sent an anonymous email that complained about the integrity of the independent review organization hired to conduct reviews under Broward Health's corporate integrity agreement, and about the behavior of general counsel *(RMC 6/6/15, p. 1)*. Contact Donna Lewis, chief compliance and privacy officer, at dlewis@browardhealth.org.

I. SCOPE

This policy applies to all Broward Health-affiliated entities including, but not limited to: hospitals, ambulatory surgery centers, hospices, home health agencies, physician practices, outpatient centers, clinics, and all Broward Health departments, groups, and divisions.

This policy applies to all Workforce Members, which include employees, independent contractors, agents, volunteers, trainees, or other persons who perform work for or on behalf of Broward Health. This includes full-time, part-time, and pool employees; associates; directors; officers; managers; supervisors; volunteers; members of the Board and members of standing committees; medical staff employed by or otherwise affiliated with Broward Health; medical students and all other affiliated students or others receiving training at any Broward Health facility; and others who provide goods or services to Broward Health.

II. PURPOSE

This policy establishes a policy and procedure to encourage Broward Health's Workforce Members to report Compliance Issues or Ethics Issues and to prevent, detect, and address retaliation in the event that a Broward Health Workforce Member reports a Compliance Issue or an Ethics Issue.

III. POLICY

It is Broward Health's policy that retaliation is prohibited against a Broward Health Workforce Member, who in good faith reports to Broward Health a Compliance Issue, an Ethics Issue, or a violation of Broward Health Corporate Compliance and Ethics Requirements or Applicable Federal and State Requirements. Making a good faith report means that the Broward Health Workforce Member has reasonable cause to make such report.

Neither Broward Health nor any Broward Health Workforce Member will discharge, demote, suspend, threaten, harass, condone or in any other manner discriminate against another Broward Health Workforce Member regarding his or her employment or engagement terms and conditions, because the Workforce Member has acted in accordance with his or her lawful rights, including but not limited to those rights under a federal or state False Claims Act action, including but not limited to investigation of, initiation of, testimony for, or assistance in an action filed or to be filed under the Federal False Claims Act, 31 U.S.C. § 3730, or other applicable federal or state fraud, waste, and abuse laws.

Any Broward Health Workforce Member who is involved in any act of retaliation against a Broward Health Workforce Member may be subject to prompt disciplinary action, up to and including termination.

Retaliation may include, but is not limited to, the following:

- Reducing or restricting a Broward Health Workforce Member's duties or responsibilities;
- Demoting, failing to promote, decreasing or failing to increase a Broward Health Workforce Member's compensation;
- Terminating a Broward Health Workforce Member; and
- Taking any action against a Broward Health Workforce Member that is intended as retribution or "pay back."

Corrective action may be taken against anyone who knowingly makes false reports of Compliance Issues or Ethics Issues.

Any Broward Health Workforce Member who self-reports misconduct in which he or she has engaged will not be exempted from potential appropriate disciplinary action. However, such self-reporting may be considered as a mitigating factor when determining the appropriate course of subsequent action.

considerably more onerous regulations" to the home health claims that were adopted years later — "regulations that Caring Hearts couldn't have known about at the time it provided its services," according to the court decision. That's why the home health provider argued it was entitled to a waiver of liability, which CMS disputed The appeals court sided with Caring Hearts — noting it "knew or should've known its conduct was unlawful only in light of regulations that were then but figments of the rulemakers' imagination, still years away from adoption" — and vacated the earlier rulings against the home health provider.

This wasn't an abstract legal ruling. The appeals court explained its reasoning through some of the patients in the case.

On the homebound requirement, the judges described "a typical example" of a Caring Heart patient: an 85-year-old man who weighed 352 pounds, had diabetes and high blood pressure, and spent most of his time in a wheelchair. "Despite these documented facts, CMS adopted the ALJ's judgment that [the patient] wasn't homebound and Caring Hearts could not have reasonably thought otherwise," the appeals court stated. CMS figured there wasn't enough evidence to prove that leaving his home required "'considerable and taxing effort.'"

The glitch: in 2008, that wasn't exactly how CMS defined "homebound." Medicare regulations indicated patients would be considered homebound if they generally couldn't leave their homes without help from an assistive device, such as crutches or wheelchairs.

"And it seems pretty clear from the record before us that [the patient] qualified as homebound under this more generous definition" because he couldn't leave his house without a wheelchair, the court stated. Years later, CMS tightened the definition of "homebound," removing fuzzy terms, such as "generally speaking."

CMS also argued it relied on the home health statute, which should have made it clear to Caring Hearts that its claims were improper. The statute said, in part, that "while an individual does not have to be bedridden to be considered 'confined to his home,' the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual" (42 U.S.C. § 1395f(a)).

Even throwing in statutory language, the appeals court is dubious that Caring Hearts could have known this patient wouldn't satisfy the definition of "homebound." The meaning of the statute isn't obvious "without the added gloss of CMS's current regulations," the decision stated.

continued

Example of Non-Retaliation Policy (continued)

IV. ENFORCEMENT

All Workforce Members whose responsibilities are affected by this policy are expected to be familiar with the basic procedures and responsibilities created by this policy. Failure to comply with this policy will be subject to appropriate remedial and/or disciplinary action, up to and including termination of any employment or other relationship, in accordance with the Enforcement of Disciplinary Standards Policy, Policy No. GA-004-238.

V. DOCUMENT RETENTION

Broward Health will retain all documents relating to this policy, and implementation of this policy, for a period of seven (7) years after their creation. Documents may be considered a public record under Chapter 119, Florida Statutes and may be subject to disclosure, unless otherwise exempted.

VI. EXCEPTIONS

There are no exceptions to this policy.

VII. INTERPRETATION AND ADMINISTRATION OF POLICY

This policy will be assessed and updated at least annually (and more frequently, if appropriate) and revised as necessary. Within 30 days of the effective date of any revisions or additions to this policy, a description of the revisions will be communicated to all affected responsible persons at Broward Health and a copy of the revised policy will be made available. The Chief Compliance Officer and Chief Ethics Officer will monitor Broward Health's adherence to this policy and make routine, but no less than quarterly, reports to the Board.

Administration and Interpretation of this policy is the responsibility of the General Counsel, in conjunction with the Chief Compliance Officer and the Chief Ethics Officer, as necessary.

VIII. RELATED POLICIES

Disclosure Program Policy, Policy No. GA-004-233;
Open Lines of Communication Policy, Policy No. GA-004-234;
Response and Prevention of Offenses, Policy No. GA-004-242;
Enforcement of Disciplinary Standards Policy, Policy No. GA-004-238.

IX. REFERENCES

- Department of Health and Human Services, Office of Inspector General, Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987 (Feb. 23, 1998).
- OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4858 (Jan. 31, 2005).
- 31 U.S.C. § 3730(h).
- 45 C.F.R. §164.530(g).
- U.S. Sentencing Guidelines Manual § 8B2.1 (2014).

Some of the disputed claims were for services provided to patients who were acknowledged as homebound. Auditors contended that Caring Hearts couldn't prove its skilled nursing services or physical therapy were reasonable and necessary. For example, physicians prescribed physical therapy for a 71-year-old woman with diabetes, degenerative joint disease, chronic obstructive pulmonary disease, and uncontrolled pain in her lower back, hips, and right leg. Because of the physical therapy, she was able to walk 50% more and reported less back pain.

But CMS contended the documentation didn't support the medical necessity of the physical therapy, according to the court decision. Again, CMS relied on more exacting 2010 regulations, "well after events in question," the appeals court stated. It required documentation of "'objective evidence or clinically supportable statements of expectation that the patient can continue to progress toward the treatment goals and is responding to therapy,'" the decision noted. At the time the physical therapy was provided, Medicare only said that "services must be considered under the accepted standards of medical practice to be a specific, safe, and effective treatment for the beneficiary's condition."

So what happens now? The 10th Circuit sent the case back to district court to move forward consistent with the decision, which means Medicare must follow through with the conclusion that Caring Hearts complied with 2008 regulations when it submitted its claims, says Kansas City attorney Donald McLean, who represents Caring Hearts. "What the court is really saying is [CMS] has to pay the money," he says. "The thrust of the decision is that my client is without fault. If Medicare doesn't know what its laws mean, how do you expect the provider to know?"

When providers appeal to ALJs, "an elevator pitch would be helpful," Soltis said. Mention a few details about the patient — he's homebound because he weighs 350 pounds and is confined to a wheelchair — and use the patient's name to personalize the case, Soltis suggested. Then cut to the chase, explaining simply that CMS is applying new rules to historical claims. "Right there you have woken up the ALJ," he said.

Contact Gustafson at JGustafson@thehlp.com, McLean at dmcleanlaw@outlook.com and Soltis at advocacyakademie@gmail.com. Read the opinion at https://www.ca10.uscourts.gov/opinions/14/14-3243.pdf. ✧

NEWS BRIEFS

◆ **CMS is test-driving prepayment reviews of claims for home health services, according to a June 10 announcement in the Federal Register.** The agency said it's running with a five-state demonstration project in "Illinois, Florida, Texas, Michigan, and Massachusetts where there have been high incidences of fraud and improper payments for these services." The implementation dates are staggered, but it will start in Illinois sometime after Aug. 1. Visit http://tinyurl.com/z8j86eq.

◆ **HHS has delayed the expected release date for 340B drug pricing program rules and guidance.** The proposed rule on the administrative dispute resolution process (RIN 0906-AA90) will now be released in September instead of May, according to the Office of Management and Budget (OMB). The rule addresses how to resolve claims brought by both covered entities and manufacturers. The release of the final rule *340(B) Civil Monetary Penalties for Manufacturers and Ceiling Price Regulations* (RIN 0906-AA89) is now scheduled for November; it originally was slated for May. The rule addresses the situation when a drug manufacturer enters into a pharmaceutical pricing agreement with HHS agreeing not to charge more than defined 340B ceiling prices for covered outpatient drugs, but it "knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price." And the omnibus guidance (RIN 0906-AB08) that "addresses key policy issues raised by stakeholders for which HHS does not have statutory rulemaking authority" — the so-called "mega reg" — that was set for September publication has been pushed back to December. View OMB's spring rule list at http://tinyurl.com/oonsrlj.

◆ **The work of the incumbent recovery audit contractors (RACs) is winding down in preparation for the next five-year contracts.** On June 2, CMS alerted providers to a series of deadlines for documentation requests and overpayment recoveries. July 29 is the last day that RACs can send a notification letter to providers of improper payments. RACs must finish discussion periods by Aug. 28, although they're required to hold claims for 30 days "starting with the date of the improper payment notification (via letter or portal) to the provider, to allow for discussion period requests," CMS says. Visit http://tinyurl.com/zzgqwh4.

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