September 10, 2012

Cahaba Government Benefit Administrators, LLC
Comments for Draft LCDs
ATTN: Dr. Greg McKinney
Post Office Box 13384
Birmingham, Alabama 35202-3384

Re: LCD ID Number DL32816 / "Surgery: IRF Admission after Single Joint Replacement with CMGs A0801-A0806"

Dear Dr. McKinney:

The American Academy of Physical Medicine and Rehabilitation (AAPM&R), the American Association of Orthopaedic Surgeons (AAOS) and the American Association of Hip and Knee Surgeons (AAHKS) appreciate this opportunity to comment on Cahaba's Draft Local Coverage Determination (LCD) on IRF Admission after a Single Joint Replacement. For the reasons stated below, our organizations strongly oppose the proposed LCD and urge that it be rescinded.

The AAPM&R is the national medical society representing more than 8,000 physiatrists, physicians who are specialists in the field of physical medicine and rehabilitation. Physiatrists treat adults and children with acute and chronic pain, persons who have experienced catastrophic events resulting in paraplegia, quadriplegia, traumatic brain injury, spinal cord injury, limb amputations, rheumatologic conditions, musculoskeletal injuries, and individuals with neurologic disorders or any other disease process that results in impairment and/or disability. Physiatrists also provide rehabilitation care for patients undergoing joint replacements.

The AAOS represents 98 percent of the more than 18,000 orthopaedic surgeons practicing in the United States. Orthopaedic surgeons are Board Certified physicians with more than a decade of specialized training who provide surgical treatment for musculoskeletal conditions and disease. The AAHKS represents over 1,800 orthopaedic surgeons who specialize in total joint arthroplasty, most of whom are based in the United States.

Post-surgery rehabilitation is essential in restoring function for individuals undergoing joint replacement. Although not all joint replacement patients need inpatient hospital rehabilitation after surgery, patients who do not receive appropriate rehabilitation in the proper setting run the risk of remaining permanently impaired. Decisions about post-surgical rehabilitation should be made by patients and their physicians, not insurance companies.

Introduction

In its draft LCD, Cahaba proposes to automatically deny, as medically unnecessary, all admissions to inpatient rehabilitation facilities (IRFs) for patients undergoing single joint

replacements who fall into case mix groups (CMGs) A0801-A0806. Cahaba's stated rationale for this change in policy is that:

1) Cahaba's denial rate for such claims is in the mid to upper 90% range; and
2) Medical literature, while supporting post-joint replacement rehabilitation, does not "point to the necessity of an inpatient admission (i.e. IRF)."

Cahaba cites a number of Medicare statutory and regulatory provisions as well as CMS Manuals as apparent authority for this LCD. The Medicare regulations and manual guidance, however, clearly establish that the actions taken by Cahaba in issuing this draft LCD are in conflict with federal rules for IRF admission. The Medicare Program Integrity Manual (MPIM) requires contractors to ensure that LCDs are "consistent with all statutes, ruling, regulations, and national coverage, payment, and coding policies." (Ch. 13, §13.1.3). As set forth below, this LCD represents an unprecedented and wholesale usurpation of the judgment of the treating physician, deprives Medicare beneficiaries of their right to individualized treatment, and ignores the IRF coverage and payment rules in 42 C.F.R. §412.622, rending this draft LCD null and void.

Further, although the MPIM suggests that contractors may develop new LCDs to address frequent denials, we question Cahaba's characterization of denials as "in the mid to upper 90% range." When these denials have been appealed through the Administrative Law Judge level, they are routinely overturned in favor of IRF providers and the physicians who treat these patients in the IRF setting.

Discussion

A. The Draft LCD Provides no Role for the Judgment of the Patient's Treating Physicians

A critical decision facing physicians caring for individuals undergoing joint replacement is the appropriate setting for post-surgery rehabilitation. Although skilled nursing facilities (SNFs) may be the best setting for some patients, others may have more complex medical needs that cannot be met by the level of care provided in a SNF. These patients require the more intensive hospital level of care available only in an IRF. This decision can only be made on a case-by-case basis by the patient's treating physician who has direct knowledge of the patient's condition. The draft LCD would take that decision out of the hands of the patient's physician in favor of a one-size-fits-all approach. <u>This violates Medicare coverage rules and, as such, the LCD is invalid.</u>

When a patient undergoes joint replacement surgery, the surgeon makes the initial determination as to whether rehabilitation should take place at home, in a SNF, or in an IRF. A patient with medically complex needs may be recommended by the surgeon for admission to an IRF. If a patient is referred for IRF care, a physiatrist or rehabilitation specialist must review the patient's condition both before admission and shortly after to ensure that the patient meets the Medicare criteria for IRF admission and can benefit from care in an IRF. Medicare regulations and policy specifically assign this determination to the rehabilitation physician subject to certain clearly established criteria. Extensive documentation requirements are also in place to justify the medical necessity of the IRF admission and subsequent IRF stay.

Those criteria, established in 2010 after an extensive review and rulemaking process, were intended to replace more subjective standards with comprehensive and objective policies. See 74 Fed. Reg. 39,762 (Aug. 7, 2009). Those new standards, set forth at 42 C.F.R. §412.622 (a)(3)(i-iv) and reiterated in Section 110 of the Medicare Benefit Policy Manual (MBPM), require that there be a reasonable expectation that the patient meet the following specific criteria:

1. *The patient must require the active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics), one of which must be physical or occupational therapy.*

2. *The patient must generally require an intensive rehabilitation therapy program, as defined in section 110.2.2. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy per day at least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a 7 consecutive day period, beginning with the date of admission to the IRF.*

3. *The patient must reasonably be expected to actively participate in, and benefit significantly from, the intensive rehabilitation therapy program that is defined in section 110.2.2 at the time of admission to the IRF. The patient can only be expected to benefit significantly from the intensive rehabilitation therapy program if the patient's condition and functional status are such that the patient can reasonably be expected to make measurable improvement (that will be of practical value to improve the patient's functional capacity or adaptation to impairments) as a result of the rehabilitation treatment, as defined in section 110.3, and if such improvement can be expected to be made within a prescribed period of time.*

4. *The patient must require physician supervision by a rehabilitation physician, defined as a licensed physician with specialized training and experience in inpatient rehabilitation. The requirement for medical supervision means that the rehabilitation physician must conduct face-to-face visits with the patient at least 3 days per week throughout the patient's stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.*

5. *The patient must require an intensive and coordinated interdisciplinary approach to providing rehabilitation, as defined in section 110.2.5.*

As noted, the regulations also specify detailed documentation requirements that must be met by the IRF to prove that these criteria are present. Requirements include a comprehensive preadmission screening by a licensed clinician designated by a rehabilitation physician (with whom the rehabilitation physician must concur), a post-admission evaluation by a rehabilitation physician that must take place within 24 hours of admission to the IRF, and an individualized overall plan of care developed by a rehabilitation physician with input from an interdisciplinary care team (412. 622(a)(4)(E) (ii),(iii)). Thus, Medicare rules require physician involvement at each phase of the admission decision and, by the time a joint replacement patient has been

admitted to an IRF, at least two physicians (the patient's surgeon and the rehabilitation physician) have concluded that an IRF admission is necessary.

As physicians, we are ethically bound to make recommendations that we believe are in the best interest of our patients. The draft LCD would deprive surgeons and other physicians responsible for patients during their acute hospital stays of the ability to refer patients to an IRF even if, based on their medical judgment and experience, they believe such a referral is appropriate and meets Medicare's coverage criteria set forth in 42 CFR § 412.622(a)(3). This puts physicians in the untenable position of having to refer a patient to a less intensive care setting that may jeopardize their recovery and bypasses the medical judgment of the rehabilitation physician – the very physician to whom CMS has given a special role in evaluating the patient, both pre-and post-admission. One likely consequence of the draft LCD is that patients ineligible for IRF care would undergo longer lengths of stay in the acute care setting which could result in outlier payments and recalibration of the DRG rates, thereby driving up program costs and delaying rehabilitation.

In summary, if the CMS regulatory criteria are met and properly documented, this establishes that IRF care is medically necessary and covered. Cahaba has no authority to impose additional local coverage restrictions in contravention to the federal regulations promulgated by CMS. In particular, Cahaba cannot simply rule that an entire class of patients (those in CMGs A0801-A0806) are ineligible for IRF care. In so doing, Cahaba attempts to substitute its judgment for the judgment of the patient's treating physicians in direct contravention of Medicare regulations and guidance.

B. The Draft LCD Deprives Patients of their Right to an Individualized Decision

The draft LCD deprives Medicare patients of their right to an individualized coverage determination. The Medicare Benefits Policy Manual (MBPM) requires that the IRF admission and coverage criteria be applied on an individual case-by-case basis: "Medicare requires determinations of whether IRF stays are reasonable and necessary to be based on an assessment of each beneficiary's individual care needs." (MBPM, Ch. 1, Se. 110). This policy reflects CMS' clear intent, as stated in the Final Rule for the FY 2010 IRF PPS, "that each patient in an IRF requires an individualized standard of care." (74 Fed. Reg. 39,762, 39,796 (August 7, 2009)).

However, under the draft LCD, decisions would not be based on the beneficiary's individual care needs. Instead, patients would be treated as numbers and those assigned to CMGs A0801-A0806 would be denied coverage without regard to their medical and rehabilitative needs. This policy would prevent Medicare patients from receiving medically necessary care to which they are entitled by law and is the type of "rule of thumb" that has been rejected by CMS and the courts.

In the Final Rule for the FY 2010 IRF PPS, CMS stated that "rules of thumb cannot serve as a basis of a coverage denial." (74 Fed. Reg. 39,794). This same conclusion was reached by a federal district court, over twenty years earlier, in Hooper v. Sullivan, 1989 WL 107497 (D. Conn. 1989). In that case, the court specifically concluded that denials of Medicare coverage "based on numerical utilization screens, diagnostic screens, diagnosis, specific treatment norms,

'the three hour rule', or other 'rules of thumb' are not appropriate." Basing a coverage decision on a patient's CMG classification is precisely what the court and CMS have declared to be impermissible.

C. The Draft LCD's Reliance on CMGs to Define Coverage is Based on a Misunderstanding of the IRF PPS Payment System and is Clinically Inappropriate

The draft LCD states that Cahaba would deny coverage for IRF care for single joint replacement patients who fall into CMGs A0801-A0806, noting that Tier A represents patients with "no co-morbidities." This is incorrect. In fact, patients assigned to Tier A often have significant co-morbid conditions that are simply not recognized by the IRF PPS as necessitating additional payment for these patients. Cahaba's attempt to use CMGs as a basis for coverage reflects a complete misunderstanding of the IRF Prospective Payment System (PPS). CMGs are payment classifications. They are not clinical diagnoses. When the CMGs were developed in their current form, co-morbidity tiers were established using four tiers. Tiers B, C, and D represent successively increasing costs based on the presence of certain co-morbidities or other complicating factors that were determined to add to the cost of care – thus justifying additional reimbursement. Tier A means only that the patient does not have one of the co-morbidities determined to justify an increase in payment. It does not mean that the patient has no co-morbidities.

As already stated, patients assigned to Tier A may be clinically complex and have a number of serious co-morbidities. According to our expert physician members, co-morbidities that do not result in classification to Tiers B-D and which can (and often are) present in patients assigned to Tier A include the following:

Hypertension
Post-op Anemia
Depressive & anxiety disorders
Coronary Artery Disease
Congestive Heart Failure
Atrial Fibrillation
Chronic Obstructive Pulmonary Disease
Urinary Tract Infections
Asthma
Hypothyroidism
Chronic Kidney Disease
Obstructive Sleep Apnea
Neuropathy

In a November 2009 CMS Conference Call on Inpatient Rehabilitation Facility Coverage Requirements, Susan Miller, MD, in the Office of Clinical Standards and Quality, walked through some clinical examples to illustrate how the new IRF coverage criteria should be

applied.[1] Some of the types of patients that CMS used to illustrate when IRF admission would be appropriate would not be permitted admissions to an IRF under the Cahaba draft LCD.

For example, in one case study, Dr. Miller related the case of an 80-year-old woman who underwent a bilateral knee replacement and who, post-operatively, experienced a myocardial infarction complicated by congestive heart failure. After 10 days in the acute care hospital, her medical condition began to stabilize although her medications were still changing. The patient was otherwise able and motivated to participate in rehabilitation. Dr. Miller explained that this patient would qualify for IRF admission because of the need for blood pressure and heart rate monitoring by therapists before, during and after therapies, and the need for EKG monitoring and frequent physician consultation. The conditions justifying IRF admission (i.e., need for monitoring of cardiovascular function during therapy and availability of the physician for consultation, plus the ongoing changes being made to heart medication) would be equally relevant to a patient undergoing single joint replacement with the same history of congestive heart failure and myocardial infarction. However, neither of those co-morbidities are considered "tier co-morbidities" under the CMG system and, consequently, this patient would not be eligible for IRF admission under the draft LCD.

Some other examples of elderly Medicare patients who would fall into CMGs A0801-A0806 and would thus be ineligible for IRF care under Cahaba's draft LCD might include:

- A patient with Parkinson's or multiple sclerosis whose neurological disease is compounded by the joint replacement;
- A patient with a joint infection or other complex wound care issues;
- A patient with post-operative encephalopathy who requires careful medical supervision;
- A patient with congestive heart failure who experiences an MI post-surgery;
- A patient who experiences atrial fibrillation post-operatively and is placed on new cardiac medications which require close monitoring.

It is inconceivable to us that patients with these types of co-morbidities or medical complications could not even be considered for admission to an IRF. Instead, these patients would be sent to a SNF—where a physician is only required to visit once every 30 days—or they may be sent home with care to be provided by a home health agency.

The draft LCD mistakenly uses a payment policy as a proxy for medical decision-making. The fact that the co-morbidities listed above were determined not to justify additional payment to an IRF should have no relevance to whether admission to an IRF is medically necessary for a specific patient. Individuals with any of the above co-morbidities may, depending on the number of conditions present and their severity, require the more intensive medical supervision available in an IRF. This is precisely the type of decision that CMS determined should be made by physicians.

[1] See transcript of Provider Conference Call of November 12, 2009 at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Coverage.html

In fact, the very existence of Tier A CMGs for joint replacement in the IRF PPS indicates that individuals falling into these CMGs may be appropriate for covered IRF care. In contrast, CMS created six Health Insurance Prospective Payment System ("HIPPS") codes that are not permitted to be billed by IRFs, but these codes are only used for administrative purposes.[2] If CMS had intended to foreclose IRF coverage for single joint replacement patients without co-morbidities, it would have assigned these cases to non-covered codes.

D. The Draft LCD Conflicts with Medicare's 60 Percent Rule

The draft LCD would deny coverage for patients that fall within one of the 13 conditions identified as meeting the 60 percent rule such as patients undergoing bilateral knee or hip replacements, any lower extremity joint replacements if over age 85, or patients who have a body mass index of 50 or greater. (42 C.F.R. § 412.29(b)). Thus, patients whom CMS clearly intended to be eligible for IRF carecould be disqualified under the draft LCD by the policy of automatic denial.

As physicians, we cannot imagine, for example, that an 86 year-old patient with atrial fibrillation and congestive heart failure who undergoes a single joint replacement could not even be considered for admission to an IRF. Yet that would be the result of the draft LCD.

We also note that the CMGs identified in the draft LCD as not eligible for coverage apply to both single and bilateral joint replacement surgery since there are no CMGs specifically limited to single joint replacements.

E. The Draft LCD Is Not Supported by the Medical Literature

Cahaba cites four articles in support of its decision that Medicare does not cover IRF care for single joint replacement patients in CMGs A0801-0806 stating:

> "The literature is replete with articles supporting post-joint replacement rehabilitation; however, the environment in which this can occur does not point to the necessity of an inpatient admission (i.e. IRF)."

We do not dispute that *some patients* undergoing single joint replacement can receive appropriate rehabilitation and medical care in a SNF or even at home with outpatient therapy, and that the outcomes for those patients may be just as satisfactory as in an IRF. However, we strongly disagree that Cahaba should be permitted to make this decision for *all* patients just because they happen to fall within a particular payment category. Nothing in the literature cited in the draft LCD supports a conclusion that *every* patient, regardless of co-morbidities or other medical needs, can be treated just as successfully in a SNF. None of the cited articles justifies eliminating the physician's judgment in favor of a CMG classification.

[2] The six HIPPS codes referred to here are meant to be assigned by the intermediaries or Medicare Administrative Contractors, when applicable, rather than billed by the IRFs themselves.

Further, and more specifically, the studies discussed in the articles have a number of flaws and limitations. Both of the studies by DeJong et al[3] included a sample selection bias acknowledged by the authors with respect to the SNFs participating in the study. Those SNFs are not typical of the over 15,000 SNFs in the United States; rather they are leaders in the area of rehabilitation and are capable of providing intensive therapy and increased nursing oversight. Moreover, the results of that study were not unequivocal. IRF patients who presented with more severe medical and functional issues actually experienced greater functional gains in a shorter period of time than SNF patients. Further, the metric used to assess outcomes was the motor Functional Independence Measure (FIM), a measure used in IRFs but not in SNFs.

The study by Cook et al[4] excluded medically complex patients who would be more likely to benefit from IRF services. Further, this study was simply a descriptive study of SNF care patients only; there was no control group and no basis for comparing one setting to another.

There are many other studies that support the effectiveness and superior outcomes of patients admitted to IRFs. For example, a 2011 study by Herbold, et al[5] matched IRF and SNF patients with hip fracture, total knee replacement, and total hip replacement, from a free-standing IRF and 5 free-standing SNFs, based on age, sex, diagnosis, severity index, and ambulation FIM on admission. That study demonstrated shorter lengths of stay and significantly better functional outcomes for the patients treated in the IRF. Other studies provide similar support for superiority of IRF care. [6]

Cahaba's statement that the studies do not "point to the necessity of an inpatient admission" misses the point. Whether IRF care is "necessary" or not depends on whether the patient meets the criteria set forth in 42 C.F.R. §412.66(c). Federal regulations firmly dictate that these decisions are made by physicians.

---

[3] DeJong G, Horn SD, Smout RJ, Tian W, Putman K, Gassaway J., *Joint Replacement Rehabilitation Outcomes on Discharge from Skilled Nursing Facilities and Inpatient Rehabilitation Facilities* Archives of Physical Medicine and Rehabilitation; 2009, 90:1284 – 1296; DeJong G, Tian W, Smout R, Horn S, Putman K, Hsiegh CH, Gassaway J, Smith P. *Long-Term Outcomes of Joint Replacement Rehabilitation Patients Discharged from Skilled Nursing and Inpatient Rehabilitation Facilities,* Archives of Physical Medicine and Rehabilitation; 2009, 90:1306 – 1316.

[4] Cook JR, Warren M, Ganley KJ, Prefontaine P, Wylie JW. *A comprehensive joint replacement program for total knee arthroplasty: a descriptive study,* BMC Musculoskeletal Disorders; 2008, 9:154.

[5] Herbold JA, Bonistall K, Walsh MB. *Rehabilitation Following Total Knee Replacement Total Hip Replacement, and Hip Fracture: A Case-Controlled Comparison,* Journal of Geriatric Physical Therapy; Oct-Dec 2011, 34 4:155 -160

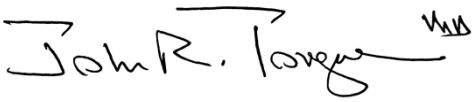
[6] Walsh MB, Herbold J. *Outcome After Rehabilitation for Total Joint Replacement at IRF and SNF: A Case-Controlled Comparison* Archives of Physical Medicine and Rehabilitation; 2006, 85:1 – 5. Munin MC, Seligman K, Dew MA, Quear T, Skidmore ER, Gruen G, Reynolds CF, Lenze EJ. *Effect of Rehabilitation Site on Functional Recovery After Hip Fracture* Archives of Physical Medicine and Rehabilitation; 2005, 86:367 – 372. Munin MC, Begley A,, Skidmore ER, Lenze EJ. *Influence of Rehabilitation Site on Hip Fracture Recovery in Community-Dwelling Subjects at 6-month Follow-Up.* Archives of Physical Medicine and Rehabilitation; 2006, 87:1004 – 1006

F. Conclusion

The Draft LCD constitutes an unprecedented and unwarranted elimination of the role of orthopaedic surgeons and rehabilitation physicians in determining medical necessity of an IRF admission for an entire class of patients based solely on the payment classification of the procedure that they underwent. The draft LCD is contrary to established Medicare regulations, is unsupported by clinical evidence, and deprives patients of their right to individualized consideration for IRF admission. We urge that it be rescinded and not implemented in final form.

Sincerely,

David L. Bagnall, MD
President, Board of Governors
American Academy of Physical Medicine and Rehabilitation (AAPM&R)



John R. Tongue, MD
President
American Association of Orthopaedic Surgeons (AAOS)

Thomas Vail, MD
President
American Association of Hip and Knee Surgeons (AAHKS)