Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of: LCD Appeal of Non-Coverage of Transfer Factor	DATE: October 12, 2006 Civil Remedies CR1396 App. Div. Docket No. A-06-43 Decision No. 2050

FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION

Dorothy Calabrese, M.D., filed an appeal of the decision of Administrative Law Judge (ALJ) Richard J. Smith, dismissing a complaint in which she represented multiple aggrieved parties challenging an article which she alleged contained a Local Coverage Determination (LCD) under the federal Medicare program. In re CMS LCD Complaint: Non-Coverage of Transfer Factor, DAB CR1396 (2006) (ALJ Decision).

The ALJ dismissed the complaint on two grounds. First, he held that the article at issue, which was posted on the website of the relevant Medicare contractor, National Heritage Insurance Company (NHIC), did not constitute an LCD within the meaning of the applicable law and regulations. ALJ Decision at 2, citing section 1862(a)(1)(A) of the Social Security Act and 42 C.F.R. § 400.202.[1] Second, he held that, even if the article were

[1] The current version of the Social Security Act can be found at www.ssa.gov/OP_Home/ssact/comp-ssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross reference

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considered to be an LCD, he was required to dismiss the complaint under 42 C.F.R. § 426(e)(1) because the policy reflected in the article was changed to withdraw the challenged provision. ALJ Decision at 3.

For the reasons discussed below, we conclude that the ALJ was correct in dismissing the complaint because the relevant provision was withdrawn. We disagree with the ALJ about whether the original policy constituted an appealable LCD, but conclude that any error in that regard is harmless, given the withdrawal of the original policy.

Case Background

NHIC is the Medicare Part B contractor for the Centers for Medicare & Medicaid Services (CMS) for California, the state in which Dr. Calabrese practices medicine. Dr. Calabrese specializes in the care of patients suffering from a pattern of symptoms known as severe "multiple chemical sensitivity syndrome." In the course of the care, Dr. Calabrese employs custom-prepared transfer factor, an extract derived from dialyzed human leukocytes as part of an immunotherapy regime. In 2004, NHIC ceased covering the costs of transfer factor treatment for Dr. Calabrese's Medicare patients.

Dr. Calabrese originally sought relief by a complaint filed with the Civil Remedies Division of the Departmental Appeals Board (DAB) on February 8, 2005. Hers was among the first challenges citing section 1869(f)(2) of the Social Security Act (Act), which permits an aggrieved party to file a complaint seeking review of a Medicare contractor's LCD. The final procedural regulations for LCD hearings and appeals are set out at 42 C.F.R. Part 426 and became effective December 8, 2003.

Dr. Calabrese's complaint sought to challenge NHIC's noncoverage of "transfer factor immunomodulatory reagent" on behalf of 32 named patients. The ALJ permitted Dr. Calabrese an opportunity to amend the complaint to meet the criteria in the regulations for an acceptable complaint, including establishing whether any of the named persons was an "aggrieved party" as defined at 42 C.F.R. § 426.110. ALJ Initial Procedural Order, March 16, 2005. The amended complaint and supporting documentation persuaded the ALJ that 26, of the original 32, individuals were entitled to act

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[1](...continued)
table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

as aggrieved parties pursuing a joint complaint. ALJ Order, October 12, 2005, at 4. The ALJ also ordered NHIC to produce its record for the transfer factor LCD. Id. at 5.

NHIC responded that it had no transfer factor LCD. Instead, NHIC asserted that it followed the policy of a National Coverage Determination (NCD) stating that transfer factor is not covered for treating multiple sclerosis. NHIC stated that it published articles "based on the NCD" in its resource guide of June 2004 and on its website. Id. Thus, NHIC did not consider its explanatory articles to constitute an LCD.

The ALJ dismissed the case on January 24, 2006. ALJ Decision. Dr. Calabrese appealed the dismissal by submission dated February 2, 2006.[2]

Applicable legal authority

Section 1869(f)(2) of the Act created a new channel for review of LCDs issued by Medicare contractors.[3] Under that section, an ALJ reviewing any LCD is to defer to "reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law" by CMS and its contractors. Section 1869(f)(2)(A)(i)(III) of the Act. This deference standard is sometimes referred to as the reasonableness test. Where the ALJ determines that the LCD record "is incomplete or lacks adequate information to support the validity" of the LCD, the ALJ shall then permit discovery and the taking of evidence. Section 1869(f)(2)(A)(i)(I) of the Act.

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[2] We note that Dr. Calabrese attached to her submission of March 20, 2006, to the Board letters from the Association of American Physicians and Surgeons and the Center for Medicare Advocacy. The regulations provide for limited participation by non-parties in NCD appeals but do not provide for such an amicus curiae role in the LCD appeal process. 42 C.F.R. § 426.513; see also 68 Fed. Reg. 63,694, 63,697 (Nov. 7, 2003). We therefore do not accept these letters as statements of the signatories in an amicus curiae role. Since Dr. Calabrese included them with her statement and referenced them in her statement, however, we have reviewed the contents as part of the record in support of the joint complaint. Nothing in the letters alters the analysis set forth below.

[3] Section 1869(f) was added to the Act by section 522 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.

The Act defines LCD as "a determination by a fiscal intermediary or a carrier under part A or part B [of the Medicare program], as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A)."[4] With certain exceptions not relevant here, section 1862(a)(1)(A) of the Act specifies that no Medicare payment may be made for items and services which "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." The coverage exclusion in section 1862(a)(1)(A) is sometimes referred to as the "medical necessity" standard. An LCD applying the medical necessity standard is not binding beyond the issuing contractor, whereas a national coverage determination (NCD) issued by CMS is binding nationwide and can be challenged only through the NCD appeal process set out in section 1869(f)(1) of the Act.

Standard of Review

The Board reviews ALJ decisions on LCD appeals to determine whether the ALJ decision contains any material error. 42 C.F.R. § 426.476(b). Harmless error is not a basis for reversing an ALJ decision under the regulations. 42 C.F.R. § 426.472(b)(4).

Analysis

1. Preliminary discussion of history and scope of issues before the Board

The dispute here arises from a long history reflected in the record developed before the ALJ. The record indicates that a minority of allergy-immunology specialists have, for some time, treated patients who present with a spectrum of symptoms described as "multiple chemical sensitivity syndrome" with approaches that are not accepted by the majority of opinion in the field.[5] It is not disputed that the appellants here have

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[4] Fiscal intermediaries and carriers are collectively referred to here as Medicare contractors.

[5] On this basis, Dr. Calabrese views the issue as part of an ongoing "turf war" among various groups of physicians driven by anti-competitive motives. See, e.g., Calabrese Statement, June 6, 2005, at 7-9, 33-54, 76-78. In addition to her professional interest, Dr. Calabrese explained her personal perspective based on her own medical difficulties and her tragic

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medical records of such symptoms including extensive allergies, sensitivity to various chemicals, and abnormal cell-mediated immunity. The minority-opinion treatment includes the clinical use of parenteral transfer factor (an extract of human leukocytes prepared from blood) intended to serve as an immunomodulatory reagent to reduce the excessive broad reactivity of their immune systems.

Dr. Calabrese states that her practice which includes these beneficiaries is exclusively focused on treating carefully-selected patients with refractory illnesses relating to allergies and chemical sensitivities using custom biological reagents. Calabrese Statement, June 6, 2005, at 5. Dr. Calabrese's various statements submitted in the course of this matter contain wide-ranging assertions about bad faith on the part of various physicians or professional organizations. See, e.g., Calabrese Statement, June 6, 2005, at 8. She also contends that NHIC acted improperly in the process that led to its issuance of the disputed policy explanation and to denial of claims submitted by Dr. Calabrese. Id. Further, Dr. Calabrese provides a large selection of articles from medical literature to establish her position that NHIC's policy of denying coverage for the use of transfer factor treatment in circumstances like those presented by the beneficiaries fails under the reasonableness standard set out in the statute and regulations. Id. at 1-13, and articles in record cited therein. According to Dr. Calabrese, it would be unreasonable to demand a higher standard of clinical research given the lack of economic incentives to drug testing and development for an "orphan illness" affecting relatively few persons and given the present state of the art. Id. at 11-12.

Dr. Calabrese also asserts that the treatments involved here had been covered by the previous Medicare contractor for her region, Transamerica Occidental, before NHIC sought to retroactively deny reimbursement for the treatments provided to all of her patients. Id. at 47. She asserts that the disorder being treated is recognized as disabling by various authorities, including the Social Security Administration, and that no other effective treatment is available for the patients with severe symptoms such as the beneficiaries here. Id. at 79-81. She further asserts that other Medicare contractors and other third party insurers

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[5](...continued)
loss of her own two children. Calabrese Statement to NHIC, Nov. 20, 2003 (included with Calabrese Statement, June 6, 2005) at 21-31.

all provide coverage for transfer factor in circumstances in which NHIC is now denying it.

She also alludes to an ALJ decision reversing a denial of coverage for this treatment for one beneficiary (listed as one of the aggrieved parties) on the grounds that transfer factor was reasonable and necessary for treatment of that individual's condition. Id. at 80-81.[6] According to Dr. Calabrese, NHIC should be bound by this decision to permit coverage for transfer factor.

Whatever the merits of these assertions,[7] they do not address the narrower issues presented to us for decision, however. Neither the ALJ nor the Board can reach the substantive merits of the medical treatment and whether non-coverage was based on reasonable findings of fact, reasonable conclusions of law, and reasonable applications of the one to the other by NHIC, i.e., whether the LCD met the reasonableness standard, without first establishing that certain preliminary conditions exist. Specifically, the preliminary question that is decisive in this case is whether NHIC has in fact established and maintained a carrier-wide LCD barring coverage of transfer factor treatment for patients with the clinical conditions of the aggrieved parties. The ALJ concluded that the online article published by NHIC explaining coverage and coding policies for transfer factor did not constitute an LCD within the meaning of the LCD appeal statute. The ALJ further concluded that, even if the article constituted an LCD, NHIC had withdrawn the non-coverage provisions to which the aggrieved parties objected.

While we conclude that the published article was an LCD, we agree with the ALJ that any non-coverage LCD provision contained in the article was revised and withdrawn by NHIC's replacement article. Below, we discuss our reasons for concluding that the article was

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[6] Dr. Calabrese mischaracterizes individual ALJ decisions as representing Federal Court of Appeals case precedent. See, e.g., Calabrese Statement, June 6, 2005, at 80. While this confusion is understandable in a non-lawyer, the error is nevertheless important to point out because it arises from a misunderstanding of the various sources and authority for Medicare coverage decisions.

[7] Many of the factual allegations are indeed scantily documented at this point. Given the posture of the case when dismissed, the ALJ did not develop the record he would have needed to resolve them had he reached the merits.

an LCD and then discuss our reasons for concluding that the non-coverage LCD was withdrawn. We also discuss the effect of the withdrawal on the aggrieved parties' past and prospective individual coverage for transfer factor treatments and on the future handling of claims by NHIC.

2. The policy statement posted on NHIC's website constituted an LCD.

The policy statement from which the aggrieved parties in this matter appealed appeared in an article on NHIC's website at http://www.medicarenhic.com/ as of December 23, 2004. The article states that it "updates and expands upon" an earlier "non-coverage notification on transfer factor" published in April 2004. NHIC Letter, Nov. 17, 2005, attachment at 2. The new policy statement read, in relevant part, as follows:

> **Noncoverage of transfer factor**
>
> NHIC has been asked to review noncoverage of transfer factor. NHIC has confirmed the rationale for its noncoverage policy. "Transfer Factor" is a non-specific term that refers to an extract derived from dialyzable human leukocytes. There are not Food and Drug Administration approved preparations of this substance. The use of parenteral "Transfer Factor" to treat any illness is not a recognized treatment modality accepted by the scientific and medical community, and may be dangerous. The use of parenteral "Transfer Factor" is not a covered benefit under Medicare.

NHIC Letter, Nov. 17, 2005, attachment at 3.

NHIC responded to the ALJ's order to provide a copy of the record on which its transfer factor LCD was based by asserting, as mentioned above, that no such LCD existed. Instead, NHIC characterized its transfer factor policy as governed by an NCD which denies coverage for transfer factor for multiple sclerosis because its use for that purpose is still experimental.[8] NHIC Letter, November 17, 2005, citing NCD at Section 160.20 in the Medical Manual, Pub. No. 100-3.

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[8] The beneficiaries involved in the joint complaint here do not seek coverage for multiple sclerosis, but rather for different conditions characterized by multiple chemical sensitivity. NHIC does not argue that the NCD directly bars coverage for those conditions.

The ALJ then determined that his jurisdiction extended only to appeals of LCDs, but that the issue of what constitutes an LCD did not depend on NHIC's characterization of the policy. The ALJ therefore issued an order directing further submissions from the parties for the purpose of determining the legal question of whether NHIC's policy statements on transfer factor met the regulatory definition of an LCD. ALJ Order, Dec. 12, 2005.[9]

The regulations expand on the statutory definition of an LCD, as follows:

> *Local coverage determination (LCD)* means a decision by a fiscal intermediary or a carrier under Medicare Part A or Part B, as applicable, whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with section 1862(a)(1)(A) of the Act. An LCD may provide that a service is not reasonable and necessary for certain diagnoses and/or for certain diagnosis codes. An LCD does not include a determination of which procedure code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

42 C.F.R. § 400.202.[10]

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[9] The order also specifically requested that CMS submit a written response explaining its view of whether the policy on transfer factor constituted an LCD. ALJ Order, Dec. 12, 2005, at 2.

[10] The term "LCD" was not consistently applied in this way by CMS or its contractors before section 1869(f)(2) of the Act went into effect. Thus, the preamble to the regulations explains that many contractors had policies, known as local medical review policies (LMRPs), which included not only determinations about whether certain services were reasonable and necessary under section 1862(a)(1)(A) of the Act, but also provisions on proper coding, benefit categories and statutory exclusions. 68 Fed. Reg. 63,707, at 63693. CMS explained the intended treatment of LMRP provisions as follows:

> We intend to work with contractors to divide LMRPs into separate LCD and non-LCD documents; however, it is likely that LMRPs will continue to exist for the next several years. During this time, the term LCD will refer to both of the following:

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Dr. Calabrese responded that NHIC's policy met both criteria which the ALJ extracted from this definition, i.e., that the coverage policy is applied on a carrier-wide basis and that it is based on a determination that the service is not reasonable and necessary. Calabrese Statement, Jan. 4, 2005, at 2. She argued essentially that posting a policy statement that transfer factor is an unrecognized and potentially dangerous treatment modality implies an intention to deny coverage to all claims for it made to that carrier. Id. Further, the implication is that such treatment cannot be medically necessary if it is not medically recognized and cannot be reasonable if it is dangerous. Id. Consistent with those inferences, NHIC "wrote denials for all transfer factor . . . stating 'not medically necessary." Id. In addition, Dr. Calabrese asserted that an NHIC representative postponed all claims appeal proceedings until the resolution of this LCD challenge but never suggested that NHIC did not have such an LCD. Id. at 3-4.

CMS agreed that an LCD is not defined by how the contractor labels a policy but by whether the policy represents a decision whether to cover a particular service on a contractor-wide basis. CMS letter to ALJ, Jan. 3, 2005. CMS contended, however, that the policy here was not an LCD because the regulations excluded certain items from LCD challenges, including "[c]ontractor bulletin articles, educational materials, or Web site frequently asked questions," as well as "individual claim determinations." 42 C.F.R. § 426.325(b)(9) and (11). Nevertheless, CMS acknowledged that the article contains "some misleading language" that might "lead readers to believe it is an LCD." CMS letter to ALJ, Jan. 3, 2005. CMS would therefore "instruct the contractor to revise the article in order to make clear that the intent of

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[10](...continued)

- Separate, stand-alone documents entitled "LCDs" that contain only reasonable and necessary language; and
- The reasonable and necessary provisions of an LMRP.

Id. The policy statement in the NHIC article on the website was in the nature of an LMRP in that it combined statements about whether coverage was reasonable and necessary with statements about coding and other information. It is thus consistent with the intention of the preamble to treat the reasonable and necessary provisions of the policy as an LCD.

this article is to educate providers on billing and coding; not to influence coverage decisions." Id.

NHIC stated that it deferred generally to the CMS letter. NHIC noted that, in practice, situations could be "problematic." NHIC letter, Jan. 5, 2006, at 1. Here, NHIC stated that it had found transfer factor to have been miscoded and also found "that it was not payable as not reasonable and necessary in any case we reviewed." Id. at 1.[11] The "dilemma" was to "explain correct coding in a coding article," where there might be a misleading implication of coverage history. Id. NHIC noted that it did not follow the process for issuing a new LCD set out in CMS's Program Integrity Manual, and that it had now revised the article to focus on the definition and proper coding of transfer factor therapy, along with "recent utilization findings." Id. at 2.

The ALJ concluded that the policy was not an LCD because "the responses from NHIC and CMS establish that the coverage decisions were made not on a carrier-wide, but on a claim-by-claim basis, and were on that basis determined to be not reasonable and not necessary. ALJ Decision at 2.

We agree with the ALJ, as did all parties, that whether a policy is an LCD is a legal issue based on the substance and content of the policy, not on the label or characterization of the policy by the contractor. CMS relied on regulatory language listing some contractor documents and actions that are not LCDs, including "Contractor bulletin articles, educational materials, or Web site frequently asked questions." 42 C.F.R. § 426.325(b)(9). As the preamble to the regulations makes clear, the purpose of excluding certain documents and actions from LCD review was to limit challenges only to LCDs as defined in the Act and regulations by excluding those that do "not meet the definition of an LCD." 68 Fed. Reg. 63,707 (Nov. 7, 2003). The focus is on the substance and not the form of the policy. Thus, an active contractor-wide noncoverage policy is not insulated from challenge merely because it is placed in a coding article or on a

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[11] On appeal, Dr. Calabrese argues that Dr. Bruce Quinn, who wrote this letter on behalf of NHIC, deliberately misled the ALJ by suggesting that the article addressed only coding rather than coverage policy. Calabrese Declaration, May 29, 2006, at 1-2, 8. On that ground, she requested imposition of unspecified sanctions on Dr. Quinn. Id. We do not find evidence of a "fraud" or "cover-up" as alleged by Dr. Calabrese, and hence need not consider what sanctions might be available in such a situation.

website. The regulatory exclusion was clearly directed at contractor statements that did not set out coverage policy but were educational in nature or addressed simply to correct coding practices. By the same token, contractor policies on proper coding, or other interpretative policies not related to medical necessity, do not become subject to challenge as LCDs even when they are contained in the same document.

The language of the NHIC article at issue here is unequivocal in stating that NHIC has reviewed and "confirmed the rationale for its noncoverage policy." The article concludes that "use of parenteral 'Transfer Factor' is not a covered benefit under Medicare." While the article contains additional discussion of proper coding of claims for transfer factor (which is not subject to LCD review), the quoted sections plainly state a prospective position by the contractor that no such claims are covered under Medicare.

We can find no support for the ALJ's conclusion that, despite this explicit noncoverage policy, NHIC actually made its coverage decisions on transfer factor claims on a case-by-case basis. NHIC explains that it did not believe the circumstances set out in the Program Integrity Manual for promulgating an LCD applied, i.e., a widespread problem or a need for automated denials. NHIC does not, however, deny Dr. Calabrese's allegation that the noncoverage policy set out in the article was used as a basis for blanket denials of claims. CMS states that coverage "<u>will</u> be determined on a claim by claim basis by the carrier" subject to individual claims appeals," but nowhere avers that NHIC had been making such individualized determinations in the past.

We therefore would consider the noncoverage policy set out in the article on NHIC's website to constitute an appealable LCD. Our conclusion, however, has little practical significance here, given that NHIC complied with CMS's instruction to revise the article. Since we proceed to uphold the ALJ's conclusion that the revision effectively withdrew the LCD, any error by the ALJ in characterizing the policy is harmless.

3. <u>The revised article withdrew the provisions of the LCD barring coverage</u>.

The ALJ's second ground for dismissing the case was that, even if the article was considered an LCD, the provision barring coverage

of transfer factor had been retired. ALJ Decision at 3.[12] As noted, following the instructions of CMS, NHIC replaced the transfer factor article with a revised statement, entitled "Article for Transfer Factor - Correct Coding and Recent Medical Reviews - Revised (A38251/ A38252)" with an effective date of February 9, 2006.[13] The revised article reads (in pertinent part), as follows:

> This article updates and expands upon information in an original Transfer Factor article published in March 2004.
>
> This article discusses coding and local utilization of services.
>
> 1. What is transfer factor?
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> Transfer factor is a term used in at least four different ways in allopathic and natural medicine. (1) Transfer factor refers to bacterial proteins which facilitate gene transfer and insertion;

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[12] Neither CMS nor the contractor raised any objection to Dr. Calabrese seeking Board review of the ALJ's determination that the action by NHIC constituted a withdrawal or revision of an LCD. The ALJ, however, stated in his decision that the aggrieved parties did not have the right to appeal his decision that their complaint was subject to dismissal because the LCD was retired. ALJ Decision at 4. He based this assertion on a provision in the regulations that an ALJ's dismissal may not be appealed in the circumstance where the "contractor has retired the LCD provision(s) under review." 42 C.F.R. § 426.465(d)(1). We do not interpret this provision as barring an appeal challenging whether the circumstance cited, i.e., that the contractor has retired the LCD provision, actually exists. We interpret it to bar challenging the ALJ's decision to dismiss when the circumstance does exist, because, in that situation, the regulations make dismissal mandatory. If we find that the contractor has retired the LCD provision, then we too are bound to dismiss. 42 C.F.R. § 476(d); see also 68 Fed. Reg. at 63,713.

[13] Actually, NHIC indicated in its submission on appeal that the article was revised "sequentially in December, January, and February," with the final version being that issued February 6, 2006 (presumably to be effective on February 9, 2006), set out in the text. NHIC Response, May 6, 2006, at 1.

(2) Transfer factor is a term in pulmonary physiology to describe speed or ratio of gas transfers;
(3) Transfer factor is very widely used in holistic and naturopathic medicine to describe cow colostrum extracts and other natural food preparations which typically may be used orally or topically. Numerous internet websites sell "transfer factor" as a natural supplement in this sense; and
(4) Transfer factor refers to substances in dialyzed leukocyte extracts which affect cellular but not humoral immune function in experimental animals such as mice and in man.[14]

This article is limited to the use of transfer factor only in the situation described in definition number 4.

2. Coding and billing guidelines for transfer factor

Claims for transfer factor usage may be submitted to NHIC for individual review, for denial purposes for secondary insurers, in conjunction with an Advance Beneficiary Notice (ABN), or to initiate appeal rights. An ABN is appropriate when there is a benefit category (physician services) but a particular service is likely to be considered not reasonable and necessary by Medicare.

Transfer factor should be billed as CPT code 95199, Unlisted allergy/clinical immunologic service or procedure, with “transfer factor” inserted in the comment field.

Transfer factor should not be coded as CPT code 95165, Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy. Additionally, none of the codes within the 95115 - 95180 range should be used, since dialyzed donor white cell factors are not an environmental allergen against which the patient had become allergic. The CPT manual defines immunotherapy (desensitization, hypersensitization) as parenteral administration of allergenic extracts, typically by increasing dosages. Transfer factor is not an allergenic extract.

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[14] It is undisputed that the first three definitions are not involved in the present matter.

> 3. Local utilization of transfer factor in California
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> NHIC Medical Review noted a clinic in which a high intensity of services for transfer factor were billed as allergy injections. **Therefore, NHIC undertook case-by-case individual review of claims and supporting medical records for this therapy. In this series of cases, NHIC determined that transfer factor had not been a reasonable and necessary treatment for disease. NHIC is unaware of any recent case where we have determined upon medical review that transfer factor was reasonable and necessary to treat disease.** Correct coding for transfer factor therapy for Medicare, as presented above, will allow us to review additional cases and better assess the incidence of transfer factor therapy for Medicare Part B patients in California.

NHIC Letter, Jan. 6, 2005, Attachment 1, also available online at http://www.medicarenhic.com/cal_prov/articles/transferfactor_0206.htm (accessed August 28, 2006)(emphasis added). The article as revised no longer contains the paragraph entitled "noncoverage of transfer factor" and no longer states that transfer factor is not a covered benefit under Medicare. For that reason, the ALJ concluded that the revision eliminated the provision being challenged. ALJ Decision at 4.

On appeal, however, Dr. Calabrese disputes both NHIC's authority to conduct case-by-case claims appeals instead of a creating a general policy subject to a single challenge on behalf of all her patients and NHIC's integrity in claiming not to have a de facto noncoverage LCD still in effect.

On the first point, she asserts that CMS and NHIC "wish to wind the clock back to before this [LCD appeal] law when they could assess every case and use medical necessity as a gatekeeper." Calabrese Declaration, Feb. 4, 2006, at 2. She reads the intent of the LCD appeal provisions as providing that "beneficiaries with a similar clinical diathesis, medically requiring the same therapy, should not be forced as individual beneficiaries to all go to beneficiary appeals to make the same case." Id. at 3.

The LCD appeal provisions nowhere impose a requirement that contractors issue LCDs when denying claims on the basis that the

service involved does not meet the medical necessity standard.[15] The LCD appeal provisions apply where a contractor chooses to make a blanket policy denying coverage for a particular service for all beneficiaries in a particular category, rather than making individual case assessments as to medical necessity and reasonableness. Individual case determinations remain available to the contractor as a means of resolving individual coverage disputes, with each beneficiary having a right to appeal denied claims under the claims appeal process. The preamble reiterates this continuing authority in contractors, as follows:

> In addition to policy determinations, contractors may make individual claim determinations, even in the absence of an NCD, LMRP, or LCD. In circumstances when there is no published policy on a particular topic, decisions are made based on the individual's particular factual situation. See Heckler v. Ringer, 466 U.S. 602, 617 (1984) (recognizing that the Secretary has discretion to either establish a generally applicable rule or to allow individual adjudication).

63 Fed. Reg. at 63,693. As Dr. Calabrese points out, a proliferation of individual claims appeals on the same coverage question, especially in the case of a service provided on a repeated or ongoing basis to the patients, may well be inefficient and burdensome to the beneficiaries, their providers and the appeal system itself. Calabrese Declaration, Feb. 4, 2006, at 3. Nevertheless, nothing in the LCD appeal provisions gives us the authority to force a contractor to issue a single

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[15] Indeed, it appears that this was a decision by the legislative drafters rather than a mere oversight. During the hearings that led to the creation of section 1869(f) of the Act, Congress heard testimony about the difficulties caused by multiple beneficiaries having to appeal adverse claims determinations on the same issues. See, e.g., Medicare Coverage Decisions and Beneficiary Appeals, 106th Cong. 80-87, 129 (2000). Congress was aware that ALJ decisions resulting from such claims appeals might well be inconsistent and, in any case, would not bind the contractor to treat future claims favorably. Congress nevertheless chose to limit LCDs subject to challenge to prospective contractor-wide policy statements and not to define LCD in a way that would encompass repeated or consistent negative individual claims determinations by a contractor or in some other manner remove the possibility that multiple beneficiaries would have to appeal multiple claim denials in the absence of an LCD policy.

contractor-wide policy rather than repeated individual determinations.

Furthermore, CMS has implemented a process to request consideration or reconsideration of an NCD which is available to anyone, including Dr. Calabrese and any of the aggrieved parties here. An NCD is binding on all contractors and ALJs and thus eliminates the problem of repetitive claims appeals. The benefits of the reconsideration process, as described in the preamble, are the opportunity for all interested parties to submit scientific and medical evidence for review and the ability to obtain evaluation of possible policies by CMS experts in the first instance. 68 Fed. Reg. at 63,694. Information about how to initiate a request for an NCD or for reconsideration of an existing NCD can be found online at http://www.cms.hhs.gov/DeterminationProcess/. See also 68 Fed. Reg. 55,635 (Sept. 26, 2003).

The second point Dr. Calabrese raises is that the revision here is essentially cosmetic - a change without a real difference. Id. at 3-5. The report that NHIC is "unaware of any recent case" in which transfer factor was "reasonable and necessary to treat disease," according to Dr. Calabrese is effectively another formulation aimed at continuing to deny coverage to all patients whom she treats with this modality. She asserts that this amounts to a contractor-wide policy since it is "statistically impossible to be more carrier-wide" than a denial of all cases. Id. at 2.

We do not agree that the revised policy is effectively the same as the previous policy. The discussion of utilization history does indeed suggest that coverage of transfer factor in future cases by NHIC is unlikely based on its past experience. Nevertheless, the article does not constitute a policy that NHIC will deny every claim for transfer factor or that precludes NHIC from granting coverage where a beneficiary's circumstances or the state of medical art call for a different result. This factor distinguishes the article from an LCD, which predetermines prospectively for the issuing contractor whether a particular service can ever meet the medical necessity test for beneficiaries with a particular clinical condition.

4. The record does not justify a presumption that NHIC will continue the LCD sub rosa.

At its core, the continuing concern of the beneficiaries and their representative on appeal seems to be that no patient will be covered for transfer factor because the wording change is a

mere subterfuge to retain the contractor-wide noncoverage policy in a form inaccessible to challenge. Given the long and bitter history of Dr. Calabrese's differences with this contractor over transfer factor as recounted in her various declarations, this concern is understandable. Nevertheless, in effect, Dr. Calabrese asks us to presume in advance that NHIC is acting in bad faith and will continue the LCD in effect secretly. We are not willing to go so far on this record.

It is difficult to distinguish between a series of individual determinations that yield the same result because the reasoning in each case leads to the same conclusion and a situation where no case can ever yield any different result because an unacknowledged and unstated policy bars it. The preamble to the regulations recognized that merely dismissing an appeal upon withdrawal or revision of a coverage determination might create a situation where beneficiaries prevailed in appearance but lost in reality. In response to this concern, the preamble makes clear that the prior policy may not be used for any purpose and that any new policy on the same topic must be issued through normal public channels, as follows:

> Comments: One commenter agreed that, if an NCD is withdrawn, the purpose for the review has been eliminated and the claims can be adjudicated without consideration of the repealed NCD, but objected to the statement that the repeal will have the same effect as a decision under § 426.560(b). The commenter, however, interpreted section § 426.560(b) as permitting a contractor to continue to rely on a withdrawn NCD.
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> Response: Retiring an LCD or withdrawing an NCD would result in the retired/withdrawn policy no longer applying in the claims adjudication process for services rendered on or after the date that the policy is retired/withdrawn. Moreover, the aggrieved party would be granted individual claim review. Since a claimant would receive the same relief that would have been available had the adjudicator found that the relevant LCD or NCD was not valid, there would be no reason to continue the appeal.
>
> Comment: One commenter recommended against automatic dismissal if a policy were retired or withdrawn. As an alternative, the commenter suggested giving the adjudicator discretion to dismiss "where the decision normally occurs" and opined that since a retired or withdrawn policy may be reconsidered or reaffirmed, the

> automatic dismissal provision effectively nullifies the entire policy appeal process.
>
> Response: When we retire/withdraw an LCD/NCD we will not apply those policies for services furnished after the retirement/withdrawal date and we will reprocess the aggrieved party's affected claims without applying the retired/withdrawn policy. If, in the future, the contractor or CMS issues a new LCD/NCD on that subject the change would be adopted after an opportunity for public comment. Any such change would be prospective in nature, and a new LCD/NCD would be subject to challenge under this final rule.

68 Fed. Reg. 63,707, at 63,698; see also 68 Fed. Reg. at 63,712.

The final regulations provide that retiring or withdrawing an LCD under review "has the same effect as a decision under § 426.460(b)." 42 C.F.R. § 426.420(a). The effect for individual beneficiaries of an ALJ decision finding an LCD invalid under section 426.460(b) is that the contractor "must reopen the claim of the party who challenged the LCD and adjudicate the claim without using the provision(s) of the LCD that the ALJ found invalid," if a claim was previously denied, and must adjudicate any claims not yet submitted without relying on such provisions, and, in "either case, the claim and any subsequent claims for service provided under the same circumstances is adjudicated without using the provision(s) of the LCD that the ALJ found invalid." 42 C.F.R. § 426.460(b)(1). Furthermore, in addition to providing individual claim relief, the contractor must implement the decision "prospectively to requests for services or claims filed with dates of service after the implementation of the ALJ decision." 42 C.F.R. § 426.460(b)(2). In the situation here where a complaint is dismissed because the LCD is withdrawn, the "same effect" thus means that the aggrieved parties are entitled to have their prior claims reopened and readjudicated with no regard given to the withdrawn policy and that future claims by them or by other beneficiaries (after the effective date of the withdrawal) must be decided by NHIC without any reliance on the withdrawn policy.

If NHIC were to reinstitute or rely on a prospective policy that transfer factor is not reasonable and necessary for any condition, such a policy would be subject to challenge under the LCD appeal process. We have no basis here, however, to presume that the contractor will fail to comply with its responsibilities under the regulations.

Conclusion

For the reasons set out in detail above, we affirm the ALJ's dismissal of the joint complaint pursuant to 42 C.F.R. § 426.420(e)(1), on the ground that the challenged LCD provision has been retired or withdrawn prior to a decision on the merits. The appeal is dismissed.

Donald F. Garrett

Leslie A. Sussan

Judith A. Ballard
Presiding Board Member