



# Advocate

Newsletter of the National Assistive Technology Advocacy Project  
A Project of Neighborhood Legal Services, Inc.

237 Main Street, Suite 400, Buffalo, New York 14203 • (716) 847-0650  
FAX: (716) 847-0227 • TDD: (716) 847-1322 • Web Page: www.nls.org

Funded through a grant received from the Rehabilitation Service Administration, U.S. Department of Education, to the Rehabilitation Engineering Society of North America (RESNA) (with a subcontract to Neighborhood Legal Services, Inc.) under contract number H224B050003. The opinions expressed herein do not necessarily reflect the position of the U.S. Department of Education, and no official endorsement by the U.S. Department of Education of the opinions expressed herein should be inferred.

© Copyright 2009 - Neighborhood Legal Services, Inc.

Volume XIII Issue 1

Spring / Summer 2009

## PROCEDURES FOR CHALLENGING A MEDICARE LOCAL COVERAGE DETERMINATION

*Using the LCD Review Process; Highlights From a Successful Challenge to Medicare's Ceiling Track Lift Exclusion*

Medicaid and Medicare are likely to grow as both primary and supplemental insurances as more and more baby boomers reach retirement age, and young men and women in the military return from recent conflicts with a range of physical, sensory, and emotional disabilities. Protection and Advocacy agencies and their Protection and Advocacy for Assistive Technology (PAAT) projects will be continually challenged to find ways to serve these and other new clients with dwindling or over-stretched resources. Systemic challenges of every nature will need to be investigated and used in order to bring a better "bang for the buck" result.

This article will discuss one of these systemic challenges: Medicare's Local Coverage Determination (LCD) review using an actual LCD review as an example of the process. First, we will cover the procedural highlights of an LCD challenge: including the complaint, production of the LCD record, discovery, the reasonableness standard, and the administrative hearing. We will then use an actual LCD challenge as an example, examining the "before and after" of the old and revised LCD, the key holdings of the ALJ's Ruling Pursuant to 42 C.F.R. § 426.425, and the distinction between an LCD and a Policy Article.

As the reader will observe in going through this article, the LCD review is more demanding than most administrative hearings but will move

### IN THIS ISSUE...

What is a Local Coverage Determination? .....	427
Legal Procedure for an LCD Review .....	427
Filing the Complaint and Burden of Proof .	427
The LCD Record.....	428
The Reasonableness Standard.....	428
Discovery .....	429
The Administrative Hearing or Written Record Review.....	430
The Case of Steven Fink .....	430
Filing Mr. Fink's Complaint.....	431
The ALJ's Continuing Order to NHIC: Produce the LCD Record.....	432
The ALJ's Ruling Pursuant to 42 C.F.R. § 426.425(c) and the Order for Case Development .....	433
NHIC's Retirement of the Existing LCD; Publication of the New LCD .....	435
Mr. Fink Receives Reimbursement for His Lift .....	436
Conclusion.....	436

### SPECIAL FEATURES

Advocate Caveat: Distinguishing the LCD Review from the Traditional AdministrativeHearing .....	428
"Bridges to Better Advocacy" Conference: Join Us in Austin, Texas, October 21-23, 2009 .....	429
ALS and Military Service .....	436

more quickly and may consume less time than most systemic challenges conducted through litigation. In fact, since the LCD review process is an administrative proceeding, not involving litigation, a paralegal or advocate can assume primary responsibility on one of these cases. In fact, Marge Gustas, an experienced paralegal with New York's PAAT project, initiated the successful LCD review described below and was joined by attorney, Jim Sheldon, as co-counsel only after filing the initial complaint in the case.

## What is a Local Coverage Determination?

What advocates describe as assistive technology (AT) is primarily covered in Medicare through the Part B durable medical equipment (DME) benefit. Although DME is authorized in the Medicare Act, 42 U.S.C. § 1395x(n), and the four-part criteria for DME is spelled out in the regulations, 42 C.F.R. §§ 410.38(a), 414.202, most decision making on DME requests is governed by policy that is not found in the law or regulations. There are two major sources of policy: National Coverage Determinations (NCDs), issued by the Centers for Medicare and Medicaid Services (CMS), and Local Coverage Determinations (LCDs), issued by one of four Durable Medical Equipment - Medical Administrative Contractors (DME-MACs).

An LCD is a policy developed by a DME-MAC and governs claims for DME within its region of the country. For example, CIGNA Government Services is the DME-MAC for Jurisdiction C, covering 14 states, Puerto Rico and the Virgin Islands (go to [www.cignagovernment-services.com](http://www.cignagovernment-services.com) and use links to go to DME-MAC site and other related sites). On the LCD section of its site, we find coverage criteria for many items of DME, including Canes and Crutches (L4989), Positive Airway Pressure (PAP) devices for treatment of sleep apnea (L11518), and Patient Lifts (L11562, as revised effective 1/1/09).

Pursuant to Chapter 13 of Medicare's Program Integrity Manual, contractors (i.e., DME-MACs) are to develop LCDs that are limited to services provided within their jurisdiction (e.g., the 11 states plus District of Columbia that make up Jurisdiction A). However, as the authors learned in the context of their LCD challenge, Medicare policy requires that LCDs must be uniform throughout the country. See, e.g., Program Integrity Manual, Part 13.1.4 ("CMS requires that the recommended LCDs developed

by the DME-PSCs [Program Safeguard Contractors] be identical for each region to ensure uniformity ..."). This means that an LCD appearing on the CIGNA website must be the same as LCDs appearing on the websites of the other three DME-MACs. This also means that a successful LCD challenge, like the one described below, will have a nationwide impact.

LCDs were created by Section 522 of the Benefits Improvement and Protection Act of 2000 to replace the older Local Medical Review Policies (LMRPs). The final regulations that established LCDs were published on November 11, 2003. Effective December 7, 2003, contractors were to issue new policies as LCDs, rather than LMRPs, with all existing LMRPs converted into LCDs over a two-year period. Medicare Program Integrity Manual, Part 13.1.3.

## Legal Procedure for an LCD Review *Filing the Complaint and Burden of Proof*

LCD reviews are covered under 42 C.F.R. Part 426, Subparts A through D. (Subpart E covers National Coverage Decision reviews.) See, also Medicare Program Integrity Manual, Part 13.13. The LCD review is distinct from other appeals, such as the Medicare hearing authorized by 42 C.F.R. §§ 405.1000 *et seq.* and the Medicare court appeal authorized by 42 U.S.C. § 405(g). Although an individual may simultaneously pursue a traditional appeal and an LCD review, "the aggrieved party must notify the ALJ or the Board, as appropriate, regarding the submission and disposition of any pending claim or appeal relating to the subject of the aggrieved party's LCD . . . complaint." 42 C.F.R. § 426.310(b). Only the *aggrieved party* may initiate an LCD review by filing an acceptable complaint. There are also specific provisions for filing joint complaints. 42 C.F.R. § 426.400(d). An acceptable complaint may be filed in writing or online on the CMS website <http://www.medicare.gov/coverage/static/appeals.asp> and it must be both timely and include specific components as listed in the regulations at 42 C.F.R. § 426.400.

Timely filing of the complaint can be assured by filing within:

- (1) 6 months of the issuance of a written statement from each aggrieved party's treating practitioner, in the case of aggrieved parties who choose to file an LCD challenge before receiving the service; *or*
- (2) 120 days of the initial denial notice, in the case of aggrieved parties who choose to file an LCD challenge after receiving the

## ***Advocate Caveat: Distinguishing the LCD Review from the Traditional Administrative Hearing***

Although the LCD review culminates with an administrative hearing, there are important differences between the LCD review and what most advocates would undertake in the normal course of preparing for an administrative hearing. The ALJ hearing to contest a denial of DME through Medicare or the fair hearing to contest a denial of DME through Medicaid are geared to accept evidence and hear arguments related to the individual's request to fund a piece of equipment. By contrast, the LCD review is geared to accept evidence and hear arguments to determine the reasonableness of a Medicare contractor's policy which precludes funding of the very equipment the individual is seeking to have funded.

service. 42 C.F.R. § 426.400(b). (emphasis added)

After the complaint is filed, it is assigned to an administrative law judge (ALJ) within the Civil Remedies Division of the Departmental Appeals Board at CMS. If the ALJ finds that a complaint is unacceptable, the aggrieved party has one opportunity to amend the complaint. 42 C.F.R. § 426.410(c)(1).

“During an LCD or an NCD review, an *aggrieved party bears the burden of proof and the burden of persuasion* for the issue(s) raised in a complaint. The burden of persuasion is judged by a preponderance of the evidence.” 42 C.F.R. § 426.330 (emphasis added).

### ***The LCD Record***

If the ALJ assigned to the LCD review finds the aggrieved party's complaint (or amended complaint) to be acceptable he or she will require “CMS or the contractor to send a copy of the LCD record to the ALJ and all parties to the LCD review within 30 days of receiving the ALJ's letter, the copy of the complaint and any associated evidence . . . .” 42 C.F.R. § 426.410(d)(3).

The regulations, at 42 C.F.R. § 426.418(a), are very specific about what is to be included with an LCD record:

(a) . . . [the] contractor's LCD record consists of any document or material that the

contractor considered during the development of the LCD, including, but not limited to, the following:

- (1) The LCD being challenged.
- (2) Any medical evidence considered on or before the date the LCD was issued, including, but not limited to, the following:
  - (i) Scientific articles.
  - (ii) Technology assessments.
  - (iii) Clinical guidelines.
  - (iv) Statements from clinical experts, medical textbooks, claims data or other indication of medical standard of practice.
- (3) Comment and Response Document.
- (4) An index of documents considered that are excluded under paragraph (b) of the section.

See also, Medicare Program Integrity Manual, Part 13.7.1.

The regulations, at 42 C.F.R. § 426.418(b), are also specific about parts of the record that are not made available to the aggrieved party:

- (b) Elements of the LCD record *not furnished* to the aggrieved party. The LCD record furnished to the aggrieved party does not include the following:
  - (1) Proprietary data or privileged information.
  - (2) *Any new evidence.* (emphasis added)

The requirement of a record did not originally apply to policies created as LMRPs. However, during the changeover from LMRPs to LCDs, the contractor was required to create an LCD record to support the policy. Effective June 2004, the contractor must maintain an LCD record for all active LCDs. Medicare Program Integrity Manual, Part 13.13.2.

Once the aggrieved party has an opportunity to review the LCD record, they can file a “statement explaining why the contractor's LCD record is not complete, or not adequate to support the validity of the LCD under the reasonableness standard.” 42 C.F.R. § 426.425(a). The contractor then has 30 days to submit a response to the ALJ in defense of the LCD. After both sides have had an opportunity to present their cases, “the ALJ applies the reasonableness standard to determine whether the LCD record is complete and adequate to support the validity of the LCD.” 42 C.F.R. § 426.425(c)(1). If the ALJ finds the record to be complete and adequate that ends the LCD review process. If the ALJ determines that the LCD record is not complete and adequate to support the validity of the LCD, he or she will permit discovery and the taking of evidence. 42 C.F.R. § 426.425(c)(3).

As noted in the administrative hearing section, below, the ALJ has discretion to decide the case through an administrative hearing or without a hearing, upon the record only. 42 C.F.R. § 426.431(a)(2).

If a reader is considering an LCD review to challenge an exclusion of a whole class of equipment through an LCD, there may be a significant likelihood that the contractor (i.e., the DME-MAC) has not met its burden of supporting the LCD through an LCD record that meets these stringent requirements. We believe that the failure to develop an adequate record, or failure to develop any record at all (see discussion of Steven Fink case, below) is most likely if the current policy being challenged, like the ceiling track lift exclusion in Mr. Fink's case, was originally within an LMRP that was then converted to an LCD.

### ***The Reasonableness Standard***

The "reasonableness standard" is defined at 42 C.F.R. § 426.110 - *Definitions*:

[It means] the standard that an ALJ or the Board must apply when conducting an LCD or an NCD review. In determining whether LCDs or NCDs are valid, the adjudicator must uphold a challenged policy (or a provision or provisions of a challenged policy) if the findings of fact, interpretations of law, and applications of fact to law by the contractor or CMS *are reasonable based on the LCD . . . record and the relevant record developed before the ALJ or the Board.* (Emphasis added)

Pursuant to the reasonableness standard, an ALJ must:

- (1) Confine the LCD review to the provision(s) of the LCD raised in the aggrieved party's complaint.
- (2) Conduct a hearing, unless the matter can be decided on the written record.
- (3) Close the LCD record to the taking of evidence. 42 C.F.R. § 426.431(a).

### ***Discovery***

The good news is that discovery is permitted, pursuant to the ALJ's order, once the ALJ determines that the LCD record is not complete and adequate to support the validity of the LCD. However, the right to discovery is extremely limited. Accordingly, anyone who is planning to challenge an LCD through this process would be wise to think through what documents they might need and what unanswered questions might impact on the LCD review. Since you will not have the broad discovery options that you would have in litigation, you should obtain

as many of the needed documents and answers to questions by informal investigation before you file your complaint (or before the discovery phase of the LCD review begins).

In general, "[i]f the ALJ orders discovery, the ALJ must establish a reasonable time frame for discovery." 42 C.F.R. § 426.432(a). A party may make a request for the production of documents and/or submit up to 10 interrogatory questions, relating to the specific LCD. 42 C.F.R. § 426.432 (c). "The term documents includes relevant information, reports, answers, records, accounts, papers, and other data and documentary evidence." 42 C.F.R. § 426.432(d). However, "[r]equests for admissions, depositions, or and other forms of discovery, other than those permitted under paragraph (c) of this section are not authorized." 42 C.F.R. § 426.432 (e). Additionally, the ALJ cannot order the disclosure of privileged or proprietary information filed under seal "without the consent of the party who possesses the right to protection of the information." 42 C.F.R. § 426.432 (f). "The ALJ notifies all parties in writing when the discovery period closes." 42 C.F.R. § 426.432 (g).

### ***"Bridges to Better Advocacy" Conference: Join Us in Austin, Texas, October 21-23,***

Our 13<sup>th</sup> annual "Bridges" conference will take place again at the Hilton Garden Inn in Austin, Texas. Our traditional two-day event will take place on October 22<sup>nd</sup> and 23<sup>rd</sup> (Thursday-Friday). An optional pre-conference is scheduled for Wednesday, October 21<sup>st</sup> and will focus on preparation for a Medicaid durable medical equipment hearing. Many great presentations are planned, including a presentation by Marge Gustas and Jim Sheldon on the subject of this newsletter.

A flyer and registration form is available as an insert to this newsletter or is available on the National AT Advocacy Project's website, [www.nls.org/natmain.htm](http://www.nls.org/natmain.htm).

### ***The Administrative Hearing or Written Record Review***

The ALJ is required to conduct a hearing, "unless the matter can be decided on the written record." 42 C.F.R. § 426.431(a)(2). "Upon agreement of the parties, any conferences, argu-

ments or hearings may be held in person, via telephone, or via any other means.” Medicare Program Integrity Manual, Part 13.13.2. Once a case gets to this stage, it can be resolved in one of two ways: through the voluntary retirement of all or part of the LCD being challenged; or through a final ALJ decision rendered with or without an evidentiary hearing.

**Voluntary retirement of LCD.** This could occur at any time following the commencement of the LCD challenge and before the ALJ issues a final decision. “Retiring an LCD or LCD provision under review has the same effect as an ALJ decision.” 42 C.F.R. § 426.420(a). The contractor may also revise the LCD “to remove or amend the LCD provision listed in the complaint through the reconsideration process before the date the ALJ issues a decision regarding that LCD.” Revising an LCD has the same effect as an ALJ decision. 42 C.F.R. § 426.420(b). However, if the contractor retires the LCD or revises it to completely remove the section at issue, “the ALJ must dismiss the complaint and inform the aggrieved party(ies) who sought the review that he or she or they receive individual claim review without the retired/withdrawn provisions.” 42 C.F.R. § 426.420(e)(1). Should the contractor revise the LCD, but not remove it altogether, before the ALJ issues a decision, the ALJ must continue the review *under the revised LCD*. “In this case, the contractor must send a copy of the supplemental record to the ALJ and all the parties. In that circumstance, the ALJ permits the aggrieved party to respond to the revised LCD and supplemental record.” 42 C.F.R. § 426.420(e)(2).

**The ALJ decision.** If the ALJ conducts a hearing, the ALJ is responsible for the hearing record and must ensure that “all hearings are open to the public.” 42 C.F.R. § 426.446. He or she is responsible for issuing, within 90 days of the closing of the LCD review record, either: a written decision; or, a written notification that a decision is pending and an approximate decision date. 42 C.F.R. § 426.447. The ALJ’s decision must include one of the following findings:

- (1) A determination that the provision of the LCD is valid under the reasonableness standard.
- (2) A determination that the provision of the LCD is not valid under the reasonableness standard.
- (3) A statement dismissing the complaint regarding the LCD and a rationale for the dismissal.
- (4) A determination that the LCD record is

complete and adequate to support the validity of the LCD provisions under the reasonableness standard. 42 C.F.R. § 426.450(a).

The decision must also include other information pursuant to 42 C.F.R. § 426.450(b) (e.g., a summary of the evidence reviewed, findings of fact, interpretations of law, and appeal rights).

However, the ALJ’s decision may not do any of the following:

- (a) Order CMS or its contractors to add any language to a provision or provisions of an LCD.
- (b) Order CMS or its contractors to pay a specific claim.
- (c) Set a time limit for CMS or its contractors to establish a new or revised LCD.
- (d) Review or evaluate an LCD other than the LCD under review.
- (e) Include a requirement for CMS or its contractors that specifies payment, coding or systems changes for an LCD or deadlines for implementing these types of changes.
- (f) Order or address how a contractor(s) must implement an LCD. 42 C.F.R. § 426.455.

### **The Case of Steven Fink**

*We would not ordinarily mention an individual client by name. However, Mr. Fink has agreed to allow us to use his name in this publication.*

Steven Fink needed a ceiling track lift so that he could get from his bed to his power wheelchair. Mr. Fink is in his sixties with a diagnosis of multiple sclerosis that severely limits the use of his arms and legs. He resides in a wheelchair-accessible home with his son (who works full-time and has a bad back) and his 85 year old mother-in-law. A local charity provides some personal care, but most of his care needs are met by his aged and frail mother-in-law. Medicare purchased a manually-operated hydraulic lift for Mr. Fink, but he could not use it since there was no one able to assist him with getting into the sling. Nor was there anyone available to actually work the lift. Mr. Fink also tried, without assistance, to use a simple sliding board. That resulted in his falling off the board onto the floor where he would lay until help arrived. Mr. Fink modified his sliding board use to include carrying a cell phone with him so that if he fell he could at least call the police or fire company.

Mr. Fink found a ceiling track lift, known as the “SureHands Lift and Care System,” that he could use independent of any additional assistance. This particular lift was designed so that

an individual with Mr. Fink's condition could place himself in the lift with minimal trouble and hang his arms and legs over the appropriate rests on the lift. The lift would move along the ceiling track, activated by Mr. Fink, using an electronic control that was attached directly to the lift.

Mr. Fink requested prior approval for the device through his Medicare Managed Care Organization (MCO). The MCO, in denying the request, informed Mr. Fink that Medicare never paid for these lifts and provided him with several reasons for their decision: the lift, in question, was not considered to be DME; and/or the lift was electric; and/or the lift was a convenience; or all of the above. The MCO did not specifically mention the LCD governing patient lifts in New York (L5064) in its denial notice.

Following the denial, Mr. Fink pursued, simultaneously, two courses of action: a traditional appeal through an ALJ hearing; and an LCD review to challenge the validity of a policy that precluded funding for his ceiling track lift. Although our State Protection and Advocacy for Assistive Technology (PAAT) Project did not represent Mr. Fink at the ALJ hearing, we did agree to pursue the LCD review on his behalf. Mr. Fink was allowed to use and complete the LCD review process even though he lost his individual appeal at the ALJ level and did not appeal the unfavorable decision.

Since Mr. Fink's prior approval request was denied and he would be confined to his bed without the requested lift, he thereafter purchased and had the Sure Hands lift installed while his traditional appeal was pending and immediately began using it. This battery-operated ceiling track lift that Mr. Fink now uses does not require any assistance from care givers or anyone else. He safely uses it, independently, to go from bed to wheelchair, from wheelchair to commode, and from wheelchair to bed. Because the lift allows him to access his power wheelchair, Mr. Fink can then access food in his kitchen, a sink where he can shave and brush his teeth, his urinal and toilet, and the main rooms of his house.

### ***Filing Mr. Fink's Complaint***

Our New York PAAT Project opted for filing a written complaint on Mr. Fink's behalf, in June 2007, since tracking the delivery of the complaint via Federal Express assured proof of receipt. Mr. Fink understood that this LCD challenge was systemic in nature and, even if successful, would not guarantee payment for his ceiling track lift. Nevertheless, Mr. Fink was

anxious to show that the ceiling track lift, as purchased and installed while his traditional appeal was pending, was more than a convenience. In fact, the written statements provided by Mr. Fink and his doctor (and alleged in the complaint) supported Mr. Fink's contention that if he could not get the requested ceiling track lift, he would be confined to his bed and not able to participate in his mobility related activities of daily living.

Our LCD review concerned the LCD for Patient Lifts (L5064), as published and maintained by NHIC, Corp., the DME-MAC for Jurisdiction A (11 states and the District of Columbia). When we filed the complaint the LCD read, "An electric lift mechanism is not covered; it is a convenience feature. When code E0635 or E0636 is billed, if coverage criteria for a patient lift are met, payment is based on the least costly alternative, E0630." The Policy Article read, "E0639 and E0640 are non-covered. These items do not meet the statutory definition of durable medical equipment."

The complaint first asserted that the LCD, as written, was narrower than National Coverage Decision (NCD) 280-1, a policy published through CMS (available on the CMS website at: [www.cms.hhs.gov/manuals/downloads/ncd103c1\\_part4.pdf](http://www.cms.hhs.gov/manuals/downloads/ncd103c1_part4.pdf)) and providing that "patient lifts" are "covered if contractor's medical staff determines patient's condition is such that periodic movement is necessary to effect improvement or to arrest/retard deterioration in condition." NCD 280-1, known as the "Durable Medical Equipment Reference List," does not limit the coverage of a patient lift to a hydraulic lift, nor is there any language that excludes battery, electric, ceiling or wall mounted lifts. Further, NCD 280-1 does not refer the contractor to any other NCD specifically relating to patient lifts.

The complaint then asserted that if the contractor was not sure how to handle a request for a ceiling track lift, such as the one sought by Mr. Fink, pursuant to NCD 280-1 the contractor had the "authority and responsibility for deciding whether [that] item is covered under the DME benefit." NCD 280-1 advises the contractor to make its coverage decision based on the following: the Medicare Claims Processing Manual (which includes the four-part DME definition); whether the item has been approved by the Food and Drug Administration (FDA) and is otherwise considered to be safe and effective for the purpose intended; and whether the item is reasonable and necessary for the individual patient.

The complaint also challenged the Policy Article language, contending it was part of the challenged LCD, since it was within the “four corners” of the document and appeared to be directly related to the reason for the MCO’s denial in Mr. Fink’s case. The Policy Article stated that the requested lift was not DME, but did not provide any reasoning to support that conclusion. (The purpose of the Policy Article and its relationship to the LCD will be discussed below.) Attached to the complaint were all the documents required by the regulations and any evidence readily available to support Mr. Fink’s claims.

The Civil Remedies Division, within the CMS Departmental Appeals Board, notified us that the complaint had been accepted, assigned a docket number, and assigned to an ALJ. Next, we received a copy of the order from the ALJ, finding the complaint to be acceptable and ordering the contractor to file the LCD record with the Civil Remedies Division with copies to the ALJ and Mr. Fink’s representative.

***The ALJ’s Continuing Order to NHIC:  
Produce the LCD Record***

As the case moved forward, it became evident that, with one exception, the only record that existed to support the LCD and its exclusion of ceiling track lifts was seven exhibits that were little more than a history of the different formats in which the LCD and prior LMRP were published over the years. The contractor offered no documentation of medical evidence considered before or after the LCD was issued. No scientific articles, technology assessments, claims data, or other indication of medical standard or practice was supplied, as contemplated by the regulations. Instead, the contractor suggested multiple reasons for why an LCD record was not required.

The eighth exhibit submitted was an something known as a “Comment and Response Document” (i.e., a summary of comments received by the contractor concerning the draft LCD) and is part of what the regulations contemplate for the LCD record. 42 C.F.R. § 426.418(a)(3). This excerpt is from a document which summarizes comments and responses in connection with draft DME polices from 1993 which, presumably, included the patient lift policy that became the LCD being challenged. Apparently, some commenters expressed concern about the exclusion of an electric lift mechanism since it presumed the availability of care givers who might not be present for many

Medicare beneficiaries. The summary response states that equipment which is primarily for the “convenience” of the care giver does not constitute medical equipment and would not be covered as DME. As noted below, the ALJ ultimately rejected the contractor’s contention that “convenience” is part of the definition of DME.

**The Record that Never Was!** One over-used bit of bureaucratic wisdom that we as advocates see repeatedly dragged out and dusted off when there is nothing else to be said is: “If nothing exists to support or refute our actions, then we are free to do whatever we please.” And so went the response from the contractor to the ALJ’s order to produce a record. Basically, their defense went something like this. Way back when LCDs were LMRPs (Local Medical Review Policies) local contractors did not have to build a record showing any evidence that would support the reasoning and effect of the LMRP. Now that LMRPs have been converted to LCDs, as required by law, we still do not have a record and do not need to make one at this time. Why not, you might ask? Well, they claimed, because they did not have to make one for the LMRP. However, in 2004 contractors were instructed to prepare, retroactively, LCD records for already finalized LCDs, including those converted from LMRPs. Medicare Program Integrity Manual, Part 13.13.2. Therefore, at least in this case, this defense was not acceptable.

**The nature, purpose and the contractor’s inappropriate use of the Policy Article.** Between 2003 and 2005 LMRPs were converted to LCDs and separate Policy Articles, typically appearing as a combined document. The regulations state that Policy Articles are not part of the LCD, and therefore, not subject to challenge. 42 C.F.R. § 426.325. LCDs only address what is reasonable and necessary. Medicare Program Integrity Manual, Part 13.1.3. Any other information regarding the devices listed, their coding information, etc., belongs in the Policy Article.

In its brief, the contractor argued that the HCPCS code assigned to the device Mr. Fink requested was listed on the LCD but, the determination that it did not meet the DME definition, was listed in the Policy Article, and therefore, could not be challenged. So, they argued, since Mr. Fink was denied coverage for the lift under a Policy Article that could not be challenged, Mr. Fink did not have standing as an “aggrieved party.” In essence, since Mr. Fink’s claim was not based on the LCD itself but on a separate

Policy Article, the contractor argued that Mr. Fink was not permitted to seek review of an exclusion contained in a Policy Article.

**Enter, The Constructive LCD.** While the contractor made its best effort to persuade the ALJ that the Policy Article was insulated both from challenge and review, he found that position to be reaching, at best. The ALJ initially ruled on March 4, 2008, in response to the contractor's arguments, that the contractor's Policy Article amounted to a "constructive LCD." (Later, in his ruling and order of October 7, 2008, the ALJ elaborates on this conclusion.)

The ALJ ordered the contractor to now produce a record for the constructive LCD. In response, the NHIC again stated that the Policy Article could not be challenged because the ceiling tract lift did not meet the definition of DME. They also argued that it did not have to construct a record for the prior LMRP so, therefore, it did not have to have a record for either the LCD or the constructive LCD. Finally, they now argued that while the lift's sling might be DME, the ceiling tract part of the device is not a medical intervention. No additional record was produced by NHIC to support the exclusion found in the Policy Article.

***The ALJ's Ruling Pursuant to  
42 C.F.R. § 426.425(c)  
and the Order for Case Development***

Following the filing of multiple briefs, exhibits, and what purported to be the LCD record for L5064, the ALJ issued his ruling and order for case development on October 7, 2008. First, the ALJ concluded that the LCD record is not complete and adequate to support the challenged LCD. He then ordered a very brief period for discovery and briefing to be followed by an administrative hearing that was to occur in 2009.

The ALJ's 22-page decision focused on four primary areas: 1) the "reasonableness standard" that governs this review; 2) the Policy Article as a rule and its effects on a recipient's benefits; 3) what he believes to be CMS's misapplication of the term "convenience item," as a basis for coverage exclusion; and 4) the relationship of both the LCD and the constructive LCD to the controlling National Coverage Determinations (NCD), 280.1 and 280.3. Page number references are to the ALJ ruling and order of October 7, 2008.

**The reasonableness standard.** Pursuant to 42 C.F.R. § 426.425(c) "the ALJ applies the reasonableness standard to determine whether the LCD record is complete and adequate to

support the validity of the LCD." The reasonableness standard must be distinguished from the "reasonable and necessary" standard that governs whether a piece of covered DME is medically necessary for the Medicare recipient who is seeking it.

In setting the stage for his decision the ALJ relied of the definition of an LCD from the Medicare Act, i.e., "a determination by a [contractor] . . . respecting whether or not a particular item or service is covered," 42 U.S.C. § 1395ff(f)(2)(B), and the reasonableness standard as defined at 42 C.F.R. § 426.110. (pp. 3-4) For a fuller understanding of the reasonableness standard, he relied on the notice of final rule making at 68 Fed. Reg. 63,693, 63,703-04 (2003), where for the most part, the drafters acknowledge and encourage agency deference in day-to-day program activity. His quoted provisions make clear that so long as the interpretation is "one of the readings permitted by the plain language of the law," it must be upheld even if the ALJ or Appeal Board might have reached a different conclusion. (p. 5) However, as the ALJ points out, the same passage in the Federal Register makes it clear that this deference is not absolute: "For legal interpretations, the reasonableness standard would not be met if an interpretation is in direct conflict with the plain language of the statute or regulation being interpreted. Moreover, an interpretation in an LCD would not meet the reasonableness standard if it directly conflicts with an NCD or with a CMS Ruling." (pp. 4-5)

**The Policy Article as a Rule or "Constructive LCD."** As stated by the ALJ, "the issue for this ruling is whether the record produced shows that LCD 5064 or Policy Article 23657 meet the reasonableness standard, when subject to review." (p. 10) The ALJ relied on a decision, "LCD Appeal of Non-Coverage of Transfer Factor, DAB No. 2050 (October 12, 2006) (available at [www.hhs.gov/dab/decisions/dab2050.pdf](http://www.hhs.gov/dab/decisions/dab2050.pdf)), to find that the Policy Article in question created a constructive LCD. He wrote (pp. 8-9):

The Departmental Appeals Board determined in LCD Appeal of Non-Coverage of Transfer Factor, DAB No. 2050 (October 12, 2006), that a contractor may not avoid review of a general policy to deny coverage by the simple expedient of failure to promulgate the policy as a local coverage determination (LCD). Based upon the [contractor] characterization of its policies in its reply, it is clear the [contractor] has adopted a gen-

eral policy or policies that have the effect of an LCD that would operate to deny the Aggrieved Party's request for coverage. Accordingly, the policy or policies are subject to review as a constructive LCD.

Relying on the *Transfer Factor* holding, the ALJ points out the "neither the form nor the characterization by a Medicare contractor or CMS controls in deciding whether a policy is an LCD and subject to review [under the Act]." He further points out that the Departmental Appeal Board suggests "that whether a policy is a LCD is a legal issue to be decided based upon the substance and content of the policy, i.e., a policy to deny coverage for a particular item or service on a contractor-wide basis." (p. 14) Upon review of the contractor's (NHIC's) characterization of its Policy Article, the ALJ found that NHIC had adopted a policy to deny electric lifts, including battery operated lifts, and this policy had the effect of an LCD. (p. 8)

**Whether the Policy Article addresses "reasonable and necessary" issues.** The contractor, NHIC, also argued that the Policy Article is not a constructive LCD because it does not involve a coverage exclusion based on a determination of whether the device is reasonable and necessary. See, e.g., Program Integrity Manual, Part 13.5.1 ("Only reasonable and necessary provisions are considered part of the LCD.")

The ALJ disagreed with NHIC that "no reasonable and necessary determination" underlies its Policy Article provision or LCD L5064. "I have received no evidence that shows that patient lifts subject to CPT Code E0640 were ever evaluated by CMS or a contractor and a determination made that such lifts are not DME or that such lifts may never be considered reasonable and necessary." "I also do not accept that NHIC can avoid review by simple expedient of characterizing the blanket non-coverage determination for lifts subject to CPT Code E0640 as a determination that such lifts are not DME particularly because the lifts clearly fall within the broad definition of DME under the ACT." (p. 9) Therefore, "because policy article A23657 establishes a rule of general application in the area serviced by the contractor that fixed patient lifts are never reasonable and necessary because they are convenience items, the language that establishes the rule is a constructive LCD." (p. 13)

In the Fink case, NHIC and its predecessors determined that Medicare does not cover electric lifts and now does not cover fixed patient

lifts. The ALJ found that NHIC's position rests "on the determination that patient lifts are never reasonable and necessary because they are convenience items." (p. 12)

The ALJ also explained that NHIC and CMS incorrectly applied the definition of DME, which does not include an element that considers convenience.

Whether an item is a convenience or not is not a consideration in the determining whether a[n] item of equipment is DME under the statutory or the regulatory definitions. (p. 13)

CMS use of the phrase "comfort or convenience" rather than "primarily and customarily used to serve a medical purpose" was imprecise, inaccurate, and in error. (p. 15)

The determination . . . that the item of equipment is a convenience item is actually a determination that the item of equipment is not "reasonable and necessary". . . . (p. 16)

The contractor and CMS have also failed to produce any record that supports a conclusion that an electric, fixed lift system, such as the SureHands system, is never reasonable and necessary. (p. 17)

Digging even deeper into this issue, the ALJ reasoned that the former Health Care Financing Administration (HCFA, now CMS) used an open ended definition for DME rather than "providing a specific and exhaustive list or very precise definition." HCFA Ruling 96-1 at 3. "HCFA also commented that its long-standing policy of broadly construing the DME benefits category is consistent with Congressional intent." *Id.* at 6. (p. 15) He chastises both NHIC and CMS for their use of the term convenience in determining whether or not a device meets the DME definition by stating that, ". . . adding an element related to convenience is inconsistent with a broad construction intended by Congress and overly restrictive." By way of analogy to further clarify his argument, the ALJ reasons that "not all equipment that provides convenience is excluded under Act. Consider the convenience provided by a power wheelchair over a manual wheelchair, yet power wheelchairs are not excluded." (pp. 15-16)

The ALJ goes on to conclude that construing the definition of DME to include an element or criteria related to convenience is in direct conflict with the Medicare Act and regulations and is not permissible.

The absence of an element of convenience in either the statutory or regulatory definition for DME, and the fact that an electric, fixed lift system such as the SureHands lift meets the four criteria to be DME supports my conclusion that the determination not to cover electric lifts and fixed lifts under CPT Code E0640, was based on a reasonable and necessary determination, and as such is properly subject to review as a LCD, even though found in a policy article. (p. 16)

Accordingly, the ALJ concluded that the exclusion of electric lifts and fixed patient lifts from the DME category is inconsistent with the statute and regulation that define DME and cannot stand.

**The application of NCDs 280.1 and 280.3.**

NCD 280.1 includes both Mobility Assistive Equipment (MAE) and patient lifts, with NCD 280.3 detailing the criteria for MAE coverage. The ALJ agreed with our position, as stated in the complaint, that NCD 280.1 “does not preclude coverage of fixed or electric (battery or household current) lifts.” NHIC had argued that the track function of the requested lift is not a medical intervention. However, according to the ALJ, the track portion of the device met the definition for MAE pursuant to NCD 280.3 and the MAE, as described in 280.3, is not an exhaustive list. In support of this new position, interjected by the ALJ himself, the ALJ reasoned that MAE may be required for a number of reasons including a person’s living situation. He then found that the SureHands lift system is a “hybrid consisting of both an electric lift and a personal mobility system.” (p. 18)

The ALJ concluded that the LCD under review was inconsistent with the NCD governing mobility assistive equipment.

The LCD at issue precludes coverage of fixed electric lift systems that permit personal mobility such as the SureHands lift based on the determination that such a lift and MAE system is a convenience without individual case review to determine whether such a system is reasonable and necessary, is inconsistent with NCD 280.3 and its presumption that MAE is reasonable and necessary when the MAE criteria are met. Because the LCD is inconsistent with an NCD, it does not meet the reasonableness standard. (p. 18)

***NHIC’s Retirement of the Existing LCD;  
Publication of the New LCD***

**NHIC’s retirement of the existing LCD.**

After so many offers by the ALJ to produce a record, and with none forthcoming, the October 7, 2008 ruling in this case appeared to be a strong hint of the ALJ’s leaning. And, while we did make an actual demand for discovery and had scheduled time for briefing, we were notified by NHIC’s attorney, in mid-December, that NHIC would retire the LCD. Shortly thereafter, NHIC published a new LCD L5064 that would be effective on January 1, 2009.

**NHIC’s revised LCD for patient lifts.**

When we filed the complaint on behalf of Mr. Fink, the LCD read, “An electric lift mechanism is not covered; it is a convenience feature. When code E0635 or E0636 is billed, if coverage criteria for a patient lift are met, payment is based on the least costly alternative, E0630.” The Policy Article read, “E0639 and E0640 are non-covered. These items do not meet the statutory definition of durable medical equipment.”

The new LCD reads “A patient lift is covered if transfer between bed and chair, wheelchair, or commode is required and, without the use of the lift, the patient would be bed confined. A patient lift as described by codes E0630, E0635, E0639, or E0640 is covered if the basic coverage criteria are met. If the coverage criteria are not met, the lift will be denied as not medically necessary.” The Policy Article now reads, “E0639 describes a device in which the lift mechanism is part of a floor-to-ceiling pole system that is not permanently attached to the floor and ceiling and which is used in a room other than the bathroom. The lift/transport mechanisms may be mechanical or electric. No separate payment is made for installation. All costs associated with installation are included in the payment for the device. When a device is only used in a bathroom, it is coded E0625. Code E0640 describes a device in which the lift mechanism is attached to permanent ceiling tracks of a wall mounting system and which is used in a room other than the bathroom.” Pursuant to the Policy Article, modifications to the home such as structural changes or remodeling for installation of a lift system will not be paid. The new LCD appears on the NHIC website at: <http://www.medicarenhic.com/dme> (use the links for LCD/Medical policies).

### **Nationwide coverage of ceiling track lifts.**

The authors knew that, if successful, a revised coverage decision would affect all Medicare beneficiaries in New York, the District of Columbia, and the 10 other states that make up the Jurisdiction A region covered by NHIC, Corp., as the DME-MAC for the region. What we did not realize is that conforming LCD changes would be required in the other regions.

Identical patient lift LCDs have now been published by the three other DME-MACs: National Government Services ([www.ngsmedicare.com](http://www.ngsmedicare.com)), covering Jurisdiction B (see LCD L27218); CIGNA ([www.cignagovernmentservices.com](http://www.cignagovernmentservices.com)), covering Jurisdiction C (see LCD L11577); and Noridian ([www.noridianmedicare.com](http://www.noridianmedicare.com)), covering Jurisdiction D (see LCD L27218). Follow the search function on each site to view the new LCD.

### **Mr. Fink Receives Reimbursement for His Lift**

As required by the LCD review regulations, now that the original LCD was retired and a newly revised LCD published, Mr. Fink was entitled to have his original claim reviewed under the new LCD. 42 C.F.R. § 426.460(b). The new claim review took place in early 2009, the MCO approved his claim, and the full cost of the ceiling track lift and installation (approximately \$10,000) was covered, subject to the Part B co-payment requirements.

### **CONCLUSION**

The LCD review can be a tremendous tool for doing systemic Medicare work without the necessity of litigation. For further information about the LCD review process or about the Fink case, you can contact either Marge Gustas (716-847-0650 ext. 256 or [mgustas@nls.org](mailto:mgustas@nls.org)) or Jim Sheldon (ext. 262 or [jsheldon@nls.org](mailto:jsheldon@nls.org)).

## ***ALS and Military Service***

Amyotrophic Lateral Sclerosis (ALS), commonly known as Lou Gehrig's disease, was identified about 135 years ago. We still do not know its cause, how to cure it and, most importantly, how to prevent it. ALS is a progressive disease that attacks the voluntary and involuntary muscles, but not the brain. "The average life expectancy for a person with ALS is two to five years from the time of diagnosis." (See *ALS in the Military: Unexpected Consequences of Military Service* (May 12, 2009), available at: [http://www.alsa.org/files/pdf/ALS\\_Military\\_Paper.pdf](http://www.alsa.org/files/pdf/ALS_Military_Paper.pdf).)

Acquiring knowledge of prevention of the disease is of the utmost importance when one considers that a study done by Harvard found that "men with any history of military service in the last century are at nearly a 60% greater risk of ALS than men who did not serve in the military." Studies done by the Department of Veteran's Affairs found that "those deployed to the Southwest Asian theater of operations during the Gulf War are at an increased risk of ALS – that Gulf War veterans are approximately twice as likely to develop ALS as those not deployed to the Gulf." In response to these findings, the VA has now defined ALS as a service connected disability if, "the development of ALS manifested at any time after discharge or release from active military, naval, or air service . . ." (38 C.F.R. § 3.318 (a)) The veteran will enter into the system at a Group 2 level.

What is of significant importance for any Protection and Advocacy (P&A) agency is that as more men and women return from the Gulf, traditional veteran advocates are becoming increasingly overwhelmed. This means the P&As will need to stay aware of changes in the law in all areas related to armed forces personnel and their dependents so that we will be ready to accept the overflow of these populations (or at least provide them with quality information). For those involved in AT advocacy, there is a strong likelihood that those newly diagnosed with ALS will seek AT devices, such as power wheelchairs and augmentative and alternative communication (AAC) devices.

The **AT Advocacy Project** will provide nationwide services to PAAT projects including technical assistance to advocates wanting to access funding for assistive technology for individuals with disabilities.



**If you would like the  
AT Advocate Newsletter  
sent to you in a large-print  
or other alternative format,  
please let us know.**

### **Update on The National Assistive Technology Resource Library**

We have designed a word-searchable digest, using computer technology, to store and retrieve hearing decisions and other administrative documents. We also have indexed nearly 700 documents from more than 125 pending and decided court cases. All documents are available through our AT Resource Library. Please send us your hearing decisions, briefs and other documents involving AT.

**Please send information to:**

Attn.: Jim Sheldon  
Neighborhood Legal Services, Inc.  
237 Main Street, Suite 400  
Buffalo, NY 14203

TEL: (716) 847-0650  
FAX: (716) 847-0227  
TDD: (716) 847-1322  
e-mail: [jsheldon@nls.org](mailto:jsheldon@nls.org)

**Web Page:** [www.nls.org](http://www.nls.org)

RETURN SERVICE REQUESTED

NON-PROFIT  
ORGANIZATION  
U.S. POSTAGE  
**PAID**  
BUFFALO, N.Y.  
PERMIT NO. 743

NEIGHBORHOOD LEGAL SERVICES, INC.  
237 Main Street, Suite 400  
Buffalo NY 14203

**AT**  
Advocate