Department of Health and Human Service

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In re CMS LCD Complaint:	)	Date: August 11, 2009
Homeopathic Medicine and Transfer Factor (LCD Database ID No. L26134 (Retired))	)	Docket No. C-08-72
Contractor: NHIC (Carrier)	)	Decision No. CR1989
Homeopathic Medicine and Transfer Factor (LCD Database ID No. L28267 (Active))	)	
Contractor: Palmetto GBA (MAC)	)	
Oversight Region I	)	

DECISION

The record of the local coverage determination (LCD) titled "Homeopathic Medicine and Transfer Factor," LCD Database ID No. L28267 (LCD L28267), issued by the Medicare contractor, Palmetto GBA (Palmetto), which is substantially similar to the LCD titled "Homeopathic Medicine and Transfer Factor," LCD Database ID No. L26134 (LCD L26134) issued by the Medicare contractor, National Heritage Insurance Company (NHIC), is complete and adequate to support the validity of the LCD provision at issue under the reasonableness standard. Review of the challenged LCD is complete with the issuance of this decision, and the Aggrieved Parties (APs) are entitled to request further review by the Appellate Division (the Board) of the Departmental Appeals Board (DAB).

I. Procedural History

On October 31, 2007, Dorothy Calabrese, MD filed a LCD complaint as the authorized representative of one Medicare beneficiary.[1] The Civil Remedies Division (CRD) of the DAB acknowledged receipt of the complaint on November 27, 2007, and the case was assigned to me for adjudication.

I advised Dr. Calabrese by letter dated January 3, 2008, that the LCD complaint was unacceptable because she had not submitted evidence to show that her patient had been or would be denied Medicare benefits based upon the application of a LCD. I pointed out to Dr. Calabrese that she referred in the complaint to an article issued by the Medicare contractor – possibly the same policy reviewed by the Board in an earlier case – a policy that the Board found had been withdrawn by the contractor. I advised Dr. Calabrese that the Medicare Coverage Database reflected that the Medicare contractor, NHIC, had effectuated a LCD entitled "Homeopathic Medicine and Transfer Factor," LCD Identification No. L26134 and a related coding article entitled "Coding for Transfer Factor Article Identification No. A46150." I further advised Dr. Calabrese that she failed to submit any clinical or scientific evidence in support of the complaint. On January 14, 2008, Dr. Calabrese filed an amended complaint with multiple exhibits.

On January 29, 2008, Dr. Calabrese filed a "Request for Pre-Hearing Motion" in which a ruling was requested regarding "the legal validity of any and all California non-reimbursement of transfer factor LCDs and the criminal and civil violations of EDS – NHIC Dr. Bruce Quinn and their agents with respect to L26134 and the Medicare Carrier Advisory Committee."

On January 31, 2008, I issued an "Acknowledgment of Receipt of Acceptable Complaint and Order to File LCD Record" (Acknowledgment and Order) after evaluating Dr. Calabrese's amended complaint as required by 42 C.F.R. § 426.410(b), (c), and (d), and finding that the complaint was acceptable. The amended complaint alleged that since October 30, 2003, the Medicare contractor had applied a contractor-wide policy to deny payment for "transfer factor immunomodulatory therapy"[2] – a therapy required by the

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[1] The names of Medicare beneficiaries are not listed in published decisions to protect their privacy. 68 Fed. Reg. 63,691, 63,709 (2003). In August 2008, November 2008, December 2008, and January 2009, Dr. Calabrese filed documents as the authorized representative of ten additional Medicare beneficiaries making this case a joint complaint. The requirements for a joint complaint are satisfied, and all eleven beneficiaries are accepted as APs. 42 C.F.R. § 426.400(d). Dr. Calabrese is also the treating physician for all eleven beneficiaries.

[2] Hereafter referred to as "TF therapy."

APs for treatment of allergies, including allergic hypersensitivity to chemicals, and abnormal cell-mediated immunity/delayed type hypersensitivity – and that the constructive LCD continued until the contractor issued LCD No. L26134, effective October 28, 2007, which continued the policy. I advised the parties in my Acknowledgment and Order that I would proceed to review the alleged LCD. I set deadlines for either NHIC or the Centers for Medicare and Medicaid Services (CMS) to serve upon the AP and me the LCD record for LCD L26134, and any predecessor constructive contractor-wide policy to deny Medicare coverage for TF therapy. I also set deadlines for the AP (there was only one at the time) to file her statement as authorized by 42 C.F.R. § 426.425(a), and for NHIC to file its response as authorized by 42 C.F.R. § 426.425(b).

On February 15, 2008, Dr. Calabrese filed a "Motion that the NHIC Carrier Advisory Committee record and membership list be included in the LCD Docket."

On February 27, 2008, the Medicare contractor, NHIC, filed a motion requesting an indefinite extension of time to file the LCD record on grounds that NHIC was being replaced as the Medicare contractor by Palmetto GBA effective March 5, 2008, and that Palmetto was required to review all LCDs and might elect to withdraw LCD L26134, thereby mooting the pending complaint. On February 29, 2008, I denied the motion for extension noting that NHIC, by its own admission, remained responsible for the LCD record until March 3, 2008 the date it was due to be filed. I directed that Palmetto file a notice of substitution of party when it became the responsible party.

On February 29, 2008, NHIC filed a "Memorandum Regarding Nonexistence of LCD That Transfer Factor Was Not Reasonable and Necessary Prior to LCDs 26134 and Submission of LCD Record Pursuant to January 31, 2008 Order." On March 12, 2008, NHIC was advised that it had not filed the required number of copies of the LCD record and the LCD record would not be treated as filed until the proper numbers of copies were received at the CRD. NHIC submitted additional copies of the LCD record on April 21, 2008. On March 31, 2008, Dr. Calabrese filed a response to the NHIC memorandum. On April 30, 2008, NHIC filed a reply to Dr. Calabrese's response. NHIC filed a further reply on June 3, 2008.

On March 31, 2008, Dr. Calabrese filed: (1) a "Motion that LCD L26134 is Not Legally Valid & Should be Nullified;" (2) a motion for expedited review; (3) a motion that the decision of an ALJ in the prior LCD complaint be removed from the HHS website; (4) a "Motion Challenging Article A38251/A38252 & NHIC Non-reimbursement of TF Policy Prior to LCD L26134;" and (5) a motion that NHIC identify the physician who prepared a certain exhibit. On April 30, 2008, NHIC filed oppositions to all motions filed by Dr. Calabrese on March 31, 2008.

On April 4, 2008, Dr. Calabrese file a "Motion for Ruling of Fraud, Gross Negligence and Reckless Disregard Against EDS – NHIC & Dr. Bruce Quinn & Request for Referral to CMS for Independent Investigation." NHIC filed an opposition to the motion on May 2, 2008. On May 4, 2008, Dr. Calabrese filed "Appellant Request for Copies of Dr. Lewis Kanter's Confidentiality Agreements for His: a) Medicare CAC Participation & b) NHIC Medical Expert Participation." NHIC filed a response to Dr. Calabrese's request for information related to Dr. Kanter on June 3, 2008.

On August 25, 2008, counsel for CMS filed a notice of appearance in this case.

By Order dated October 3, 2008, I advised the parties that: LCD No. L26134 for Northern and Southern California were retired on September 1, 2008; that the new Medicare contractor, Palmetto GBA, had issued a new LCD No. L28267, titled "Homeopathic Medicine and Transfer Factor," with an effective date of September 2, 2008; and that my comparison of the retired and new LCDs caused me to believe the two were substantially similar. I ordered that: on or before October 20, 2008, the contractor or CMS file the LCD record for LCD No. L28267; that the APs file any supplemental statement on or before November 10, 2008; and that the contractor or CMS file a response not later than November 24, 2008.[3]

On October 10, 2008, Dr. Calabrese filed a motion for expedited hearing and ruling on the Aggrieved Parties' Complaint. CMS filed an opposition to the motion for expedited hearing and ruling and moved to dismiss the complaint on October 31, 2008. On November 3, 2008, Dr. Calabrese filed an opposition to the CMS motion to dismiss.

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[3] The regulations require that a contractor notify an ALJ within 48 hours of retiring or revising an LCD. 42 C.F.R. § 426.420(c). No notice was received from NHIC, Palmetto, or CMS. The regulations provide that retiring or revising an LCD to remove the provision requires dismissal of the complaint. 42 C.F.R. § 426.420(e)(1). The regulation also provides that if revision of the LCD does not result in eliminating the provision in question completely, the ALJ must continue the review, including requiring the contractor to file the supplemental LCD record and permitting the aggrieved party to file an additional response. 42 C.F.R. § 426.420(e)(2). Although NHIC withdrew the LCD originally challenged before me, Palmetto immediately reissued the LCD with substantially the same provisions. Rather than dismiss the complaint, I concluded it more appropriate to treat the change in LCDs upon the change of contractors as a revision – a revision that only significantly impacted the name of the contractor on the LCD.

On October 21, 2008, CMS filed the supplemental LCD record for LCD No. L28267 and admitted that the retired and new LCDs were substantially similar, stating:

> [T]his supplement to the Local Coverage Determination ("LCD") record which documents the transition of the retired LCD No. L26134, *Homeopathic Medicine and Transfer Factor*, issued by National Heritage Insurance Company ("NHIC"), the outgoing carrier to the status of an active LCD No. 28267, *Homeopathic Medicine and Transfer Factor*, effective September 2, 2008, by the incoming Medicare Administrative Contractor ("MAC") Palmetto GBA. The Palmetto GBA LCD is substantially similar to the LCD retired by NHIC, which was in effect for the period October 28, 2007 through September 1, 2008.

On October 21, 2008, Dr. Calabrese filed a response to my order of October 3, 2008, in which she waived further response on behalf of the APs and requested a ruling on the merits.

On October 24, 2008, I ordered that CMS advise me whether NHIC or its counsel remained a party to this proceeding. CMS advised me by letter dated October 31, 2008, that NHIC was no longer a party effective September 1, 2008, as its Medicare contract expired on that date and that CMS would continue as the real party in interest in this proceeding.

On October 29, 2008, I directed that CMS properly mark and file the LCD record as exhibits. On November 7, 2008, CMS filed the LCD record marked as exhibits and its exhibit list. On November 10, 2008, Dr. Calabrese filed objections to certain CMS exhibits and requested discovery regarding certain CMS exhibits. On December 3, 2008, I directed that Dr. Calabrese file missing exhibits and a proper exhibit list. Dr. Calabrese filed the missing AP exhibits and a corrected exhibit list on December 8, 2008.

On December 8, 2008, Dr. Calabrese filed a motion for a hearing on whether the CMS attorney should be replaced or sanctioned.

Dr. Calabrese submitted 235 exhibits, which are marked as Aggrieved Party (A.P.) Exs. 1-235.[4] CMS has not objected to any of the exhibits offered by Dr. Calabrese, and A.P.

[4] When Dr. Calabrese submitted exhibits with her amended complaint (A.P. Exs. 1-193), she had not marked them in accordance with CRD procedures. My office therefore marked the first page of each exhibit using the designation "A.P. Ex.," followed by the exhibit number (e.g., "A.P. Ex. 1"). Dr. Calabrese submitted more exhibits with subsequent filings. She identified these exhibits with the designation "A. Ex." Because this is not the proper exhibit designation, I have replaced "A. Ex." on her exhibits with the designation "A.P. Ex." On December 8, 2008, Dr. Calabrese filed a corrected exhibit list with A.P. Exs. 1 through 228 listed and she also filed copies of A.P. Exs. 167, 180, 182, 195, 207 through 211, and 224 through 228. The description of A.P. Ex. 3 on the exhibit list filed December 8, 2008, is in error. A.P. Ex. 3 should be listed as *In Vitro Methods in Cell-Mediated Immunity*, 95-150, (Barry R. Bloom & Philip R. Glade, eds., Academic Press 1971), which is the text of a presentation by H. Sherman Lawrence entitled *Factors and Activities Produced In Vitro by Lymphocytes.*

The exhibit list filed December 8, 2008, also includes the following errors which are corrected as indicated: D.G. Jose, *Transfer Factor in Children with Infection and Malnutrition*, 1 The Lancet, No. 7954, 263-66 (1976), currently listed under A.P. Ex. 59, is actually A.P. Ex. 60 and should be listed as such; documents currently listed as being A.P. Exs. 59 (referring to the erroneous second use of "A.P. Ex. 59") through A.P. Ex. 68, should be listed as A.P. Exs. 61 through 70; the identifiers A.P. Ex. 75, A.P. Ex. 76, and A.P. Ex. 77 are erroneously used twice, and the second use of those identifiers in the exhibit list are corrected to be A.P. Ex. 78, A.P. Ex. 79, and A.P. Ex. 80; A.P. Exs. 78 through 90 listed on the exhibit list filed December 8, 2008, are corrected to read A.P. Exs. 81 through 93; the description of A.P. Ex. 147 is corrected by the addition of "6th ed. 2003;" T. Fukuyama, et. al., *Use of Long Term Dermal Sensitization followed by Intratracheal Challenge Method to Identify Low-Dose Chemical-Induced Respiratory Allergic Responses in Mice*, 181 Toxicology Letters, No. 3, 163-170 (2008) is listed as A.P. Ex. 226 but marked A.P. Ex. 227 and the exhibit list is corrected accordingly; T. Fukuyama, et. al., *Detection of Low-Level Environmental Chemical Allergy by a Long-Term Sensitization Method*, 180 Toxicology Letters, No. 1, 1-8 (2008), is listed as A.P. Ex. 227 but marked A.P. Ex. 226 and the exhibit list is corrected accordingly. Two documents marked A.P. Ex. 195 were received. A complaint for injunctive and declaratory relief in the U.S. District Court for the Central District of California, SACV08-00633 is listed on the exhibit list as A.P. Ex. 195. The other document marked A.P. Ex. 195, Appellants' Informal Reply Brief, U.S. Court of Appeals for the Ninth Circuit, 07-56622, is remarked A.P. Ex. 229. The declaration of Beverly Patricia Meyer

(...continued)

Exs. 1 through 235 are admitted. On December 7, 2007, Dr. Calabrese sent a copy of a declaration of Bruce Quinn, M.D., the Medical Director of NHIC, to my office by facsimile, but then requested in a telephone conversation with the staff attorney assigned to assist me that the declaration be disregarded. Dr. Quinn's declaration is dated December 5, 2007, and includes relevant information regarding the adoption of the NHIC LCD originally challenged, it provides information regarding the history of the case, and also has at least minimal relevance to the challenges to my jurisdiction in this case. I have marked Dr. Quinn's declaration Court Exhibit 1, pages 1 through 18, and it is admitted and considered as evidence.[5]

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[4](continued...)

dated December 13, 2007 (on the exhibit list) and the First Amended Complaint for Injunctive Relief and Review of Administrative Record in SACV08-00633 were both marked A.P. Ex. 207, and the second document is remarked as A.P. Ex. 230. On June 7, 2008, Dr. Calabrese submitted a document marked A. Ex. 209 which was a "Status Report on OMHA Appeal 1-185294748" filed in the U.S. District Court, Central District of California. On December 8, 2008, she filed another document marked as A. Ex. 209, I. Kimber and R.J. Dearman, *The Mechanisms and Evaluation of Chemically Induced Allergy*, 64/65 Toxicology Letters 79-84 (1992). The former is remarked A.P. Ex. 235. W. Rea, 4 *Chemical Sensitivity, Tools of Diagnosis and Methods of Treatment*, 2721-70 (1997) (on the exhibit list) and the declaration of Marylin Clark-Koenig dated March 25, 2008, were both marked A.P. Ex. 211, and the second document is remarked A.P. Ex. 231.

Also submitted unmarked were the following that are now marked as indicated: A.P. Ex. 232 – M. Heyman, et. al., *Hypersensitivity Reaction in an Infant Fed Hydrolyzed Lactalbumin Contained in Semielemental Formula*, 10 Journal of Pediatric Gastroenterology and Nutrition 253-56 (1990); A.P. Ex. 233 – OMHA Appeal 1-185294748, Hearing Brief, December 18, 2007; A.P. Ex. 234 – Declaration of Douglas Sandberg, M.D., dated December 15, 2007.

[5] Evidence is generally admissible in an administrative hearing if it is relevant to an issue that requires resolution and it is authentic. 5 U.S.C. § 556. In a normal LCD review, not all the documents offered in this case would necessarily be relevant due to the limited scope of review. However, in this case, issues raised regarding my jurisdiction, the fact that there was a prior appeal related to the same or similar policy of the contractor, and the change in contractor and LCD during the pendency of this complaint increased the breadth of potentially relevant material. Dr. Calabrese marked and offered as evidence various pleadings filed in the U.S. District Court, Central District of

(...continued)

CMS submitted 22 exhibits, marked as CMS Exs. 1-22.[6] Dr. Calabrese objected on November 10, 2008, to the admissibility of CMS exhibits 1, 2, 3, 4, 10, 18, and 22 on grounds that they were fraudulent.[7] Objections To and Motion for Discovery Regarding CMS Exhibits Filed November 7, 2008. Dr. Calabrese objects generally that the LCD record for L28267 submitted by CMS was a collection of documents assembled by the CMS attorney to justify the LCD and not a proper LCD record assembled by Palmetto after September 2, 2008. Dr. Calabrese cites no evidence in support of her assertion. Dr. Calabrese also cites no authority for what process is required to compile a LCD record for what is, in fact, a revision of an earlier LCD that was retired. The regulation refers to

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[5](continued...)

California and the U.S. Court of Appeals for the Ninth Circuit that are admitted not because they are evidence relevant to the reasonableness standard, but rather because they shed additional light upon Dr. Calabrese's theory in this case. The evidence relevant to a particular issue is generally discussed with that issue. The absence of specific discussion may not be construed as a failure to consider the evidence as all the documents offered and admitted were carefully reviewed and assessed for whatever relevant material they contained.

[6] The exhibits submitted by CMS comprising the LCD record include materials originally submitted by NHIC as well as the supplemental LCD record filed by CMS related to the revised LCD issued by Palmetto.

[7] It is clear from the various pleadings of Dr. Calabrese that she alleges "fraud" or "fraudulent actions" by the Medicare contractor, its employees, CMS, CMS employees, and counsel for CMS, in the sense of a criminal or tortious conduct. I have no jurisdiction to address such allegations. Nevertheless, I do consider whether the various documents submitted by the government are authentic. I also consider whether each document submitted by the government is credible and whether the document is entitled to weight in applying the reasonableness standard or rendering various rulings in the context of this decision. Dr. Calabrese requested discovery as to the documents and that sanctions be imposed against CMS. Discovery is not provided for and it is not necessary in this first phase where I am required to apply the reasonableness standard to the LCD. Accordingly, discovery is not ordered. Dr. Calabrese's request for sanctions is unfounded and is unsupported by any evidence that would support sanctions – mere allegations are not a sufficient basis for sanctions. Furthermore, as discussed hereafter, the LCD against coverage for TF therapy at issue in this case satisfies the reasonableness standard and to the extent that there was any irregularity in the adoption of the policy, Dr. Calabrese cites no authority for the proposition that such irregularity either invalidates the policy or provides a basis for remedy for the APs or for sanctions against counsel for CMS, CMS, or its contractor.

a "supplemental record" for a revised LCD that is under review, clearly suggesting that review continues based upon the record for the LCD prior to revision plus the supplemental record related to the revision. The Social Security Act (Act) specifies no procedures for the adoption of a LCD. Act § 1869(g). The Act did not require that the Secretary of Health and Human Services (Secretary) issue regulations that establish a procedure for the adoption of LCDs, and no regulations exist that establish a procedure or specify the contents of a LCD record. CMS has provided guidance to its contractors regarding adopting LCDs in the Medicare Program Integrity Manual (MPIM), Publication No. 100-08, Chapter 13, which is not a regulation and establishes no rights or remedies for the APs. Section 13.7 of the MPIM, which describes the LCD development process, directs that when a new or revised LCD is needed, the contractor is to "[a]dopt or adapt an existing LCD, if possible." Thus, it was not improper for CMS to submit the LCD record for L26134 supplemented by any additional evidence considered when L28267 was adopted, if any additional record material was received and considered at the time of adoption.

Dr. Calabrese objects to CMS Ex. 1 on grounds that the decision was signed by the Office of Medicare Hearings and Appeals (OMHA) Managing Administrative Law Judge (MALJ) rather than the administrative law judge (ALJ) who conducted the hearing in the case. It is not necessary for me to explore or address the reasons the MALJ signed for the ALJ or the lawfulness of such action. The decision is simply not relevant to the issue I am required to decide, i.e., whether the LCD meets the reasonableness standard. Therefore CMS Ex. 1 is not admitted. CMS Ex. 1 does provide some insight into the history of this case and it is cited hereafter in that context only.

Dr. Calabrese objects to CMS Exhibit 2, arguing that it was obtained by NHIC essentially by trick or misrepresentation. It is not necessary for me to inquire further as the document bears no signature and I do not consider it to be authentic in light of Dr. Calabrese's objection. Accordingly, CMS Ex. 2 is not admitted.

Dr. Calabrese objects to CMS Exhibit 3, arguing that it was obtained by NHIC essentially by trick or misrepresentation. It is not necessary for me to inquire further as the document bears no signature and I do not consider it to be authentic in light of Dr. Calabrese's objection. Accordingly, CMS Ex. 3 is not admitted.

Dr. Calabrese objects to CMS Exhibit 4 on grounds that it was removed from the American Academy of Allergy Asthma & Immunology (AAAAI) website, "Allergy & Asthma Disease Management Center," prior to December 19, 2007, and therefore it could not be part of the LCD record for L28267. However, as already discussed, the record for the retired LCD L26134 and any documents NHIC relied upon for a constructive LCD may properly be considered part of the LCD record for the revised LCD currently in effect, L28267. The date on the copy is May 29, 2003, which is consistent with the document being considered by NHIC in adopting a non-coverage policy prior to adoption

of L26134. Dr. Calabrese does not object to the authenticity of the document but concedes that it was previously posted on the AAAAI website. Dr. Calabrese's objection that the author of the document is unknown goes to the weight of the document and not its admissibility. However, the fact that the article was admittedly published on the AAAAI website reflects that the article is entitled to some weight. Accordingly, CMS Ex. 4 will not be excluded.

Dr. Calabrese objects to CMS Ex. 10 on grounds that it is fraudulent. CMS Ex. 10, pages 1 and 2 is a memorandum by Donald Adams, M.D. dated January 14, 2004. The memorandum provides no evidence related to whether or not the LCD meets the reasonableness standard. The memorandum is not relevant to any issue I may decide and is not admitted. Pages 3 through 8 of CMS Ex. 10 appear to be handwritten notes of Dr. Adams from February and March 2004, recording various conversations he had regarding TF. Dr. Calabrese does not argue that Dr. Adams did not make the notes or that they do not reflect information related to TF. Thus, CMS Ex. 10, pages 3 through 8 are authentic and relevant and admissible. However, the pages contain Dr. Adams' summary of statements made by others during Dr. Adams' interviews of the declarants. The summary of statements are clearly offered by CMS for the truth of the matter asserted and are hearsay. I have no way of judging the reliability of Dr. Adams' summary or the reliability of this hearsay; accordingly, I give the evidence no weight.

Dr. Calabrese objects to CMS Ex. 18 on grounds that it is a fraud, and that TF and homeopathic medicine are not the same. This document purports to be a summary of the public comments considered by NHIC associated with the development of LCD L26134. The document contains relevant information, and Dr. Calabrese has not cited any grounds for me to conclude that it is not what it purports to be. Accordingly, the document will not be excluded.

Dr. Calabrese did not discuss her objection to CMS Ex. 22 in detail. CMS Ex. 22 is a copy of LCD L28267. The document is both relevant and authentic. The document is available at http://www.cms.hhs.gov/mcd/indexes.asp by selecting "Search" and entering the LCD identifier, "L28267." CMS Ex. 22 is not excluded. The retired LCD L26134 is also available at the same web address.

CMS Exs. 4 through 9, CMS Ex. 10, pages 3-8, and CMS Exs. 11 through 22 are admitted and considered as evidence.

I advised the parties in the Acknowledgment and Order that, after receiving the LCD record and their briefs, I would conduct the review specified by 42 C.F.R. § 426.425. I advised that, upon completion of my review, I would either issue a decision or issue further orders for discovery and the preparation of this case for hearing. As discussed

hereafter, the LCD record is complete and adequate to support the validity of the LCD provisions at issue under the reasonableness standard and no further proceedings or review is required.

II. Discussion

A. Applicable Law

Section 1831 of the Act (42 U.S.C. § 1395j) establishes the supplementary medical insurance benefits program for the aged and the disabled known as Medicare Part B. Qualified individuals must elect to participate in the Medicare Part B program, which is funded by enrollees' premiums and appropriations from the federal government. The coverage or benefits of Medicare Part B are described in sections 1832, 1833, and 1834 of the Act (42 U.S.C. §§ 1395k, 1395l, and 1395m). However, section 1862 of the Act (42 U.S.C. § 1395y), which is applicable to both Medicare Part A and Part B, provides that no payment may be made for items or 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 Secretary has provided by regulation that any services not reasonable and necessary for one of the purposes listed in the regulations are excluded from coverage under Medicare. 42 C.F.R. § 411.15(k). The Medicare Benefit Policy Manual, CMS Publication 100-02, Chapter 16, §§ 10 and 20 provide that no payment may be made for items and services that 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 administration of Medicare Part B is through contractors. Act §§ 1842, 1874A (42 U.S.C. §§ 1395u, 1395kk-1). The Act provides for both National Coverage Determinations (NCD) and LCDs. Act § 1869(f)(1)(B) and (2)(B) (42 U.S.C. §1395ff(f)(1)(B) and (2)(B)). A LCD is a determination by a Medicare contractor, either a fiscal intermediary or a carrier, applicable to the area served by the contractor "respecting whether or not a particular item or service is covered," i.e., whether or not the item or service is reasonable and necessary within the meaning of section 1869(a)(1)(A) of the Act. Act § 1869(f)(2)(B). CMS instructs its contractors that they will consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational . . .; and
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:

- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the functioning of a malformed body member;
- Furnished in a setting appropriate to the patient's medical needs and condition;
- Ordered and furnished by qualified personnel;
- One that meets, but does not exceed, the patient's medical need; and
- At least as beneficial as an existing and available medically appropriate alternative.

MPIM § 13.5.1. The MPIM § 13.3 provides:

> Contractors may review claims on either a prepayment or postpayment basis regardless of whether a NCD, coverage provision in an interpretive manual, or LCD exists for that service. However, automated denials can be made only when clear policy or certain other conditions (see chapter 3, §3.5.1) exist. When making individual claim determinations, the contractor shall determine whether the service in question is covered based on an LCD or the clinical judgment of the medical reviewer. A service may be covered by a contractor if it meets all of the conditions listed in §3.5.1, Reasonable and Necessary Provisions in LCDs below.

In the absence of a NCD or a LCD, individual claim determinations are made based upon an individual beneficiary's particular factual situation. 68 Fed. Reg. 63,691, 63,693 (2003) citing *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); 42 C.F.R. §§ 426.420(a), (b), (e)(1), 426.460(b)(1), 426.426.488(b).

Review of a LCD is distinct from review of an individual claim determination. 68 Fed. Reg. 63,691, 63,692-94 (2003). The right to administrative and judicial review of individual claims determinations is established by sections 1869(a) through (d) of the Act, and the regulations of the Secretary governing review are at 42 C.F.R. §§ 405.1000 through 405.1140. Individual claim determinations are not subject to review under the LCD process. 68 Fed. Reg. 63,691, 63,707 (2003). Pursuant to the Act and the Secretary's implementing regulations, the DAB has the authority to review NCDs, ALJs

assigned to the CRD have the authority to review LCDs subject to further review by the DAB, and individual claim determinations are reviewed by ALJs assigned to the OMHA subject to further review by the Medicare Appeals Council and the DAB.[8]

Section 1869(f)(2)(A) of the Act (42 U.S.C. §1395ff(f)(2))[9] provides for the review of a LCD by an ALJ subject to the limitations that (1) a complaint must be filed by an aggrieved party; (2) the ALJ must review the record of the LCD; (3) only if the record is determined by the ALJ to be incomplete or to lack adequate information to support the validity of the LCD, will the ALJ permit discovery and the taking of evidence to evaluate the reasonableness of the LCD; (4) the ALJ may consult appropriate scientific and clinical experts; and (5) the ALJ will "defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary." Act § 1869(f)(2)(A)(i)(III). An aggrieved party may request that the Board review an adverse ALJ determination. Act § 1869(f)(2)(A)(ii).

An aggrieved party is one who has standing within the meaning of section 1869(f)(5) of the Act:

> An action under this subsection seeking review of a national coverage determination or local coverage determination may be initiated only by individuals entitled to benefits under Part A, or enrolled under part B, or both, who are in need of the items or services that are the subject of the coverage determination.

The Secretary promulgated regulations pursuant to sections 1102 and 1871 of the Act (42 U.S.C. §§ 1302 and 1395hh), implementing sections 1869(f)(1) and (f)(2) of the Act for the review of NCDs and LCDs. 68 Fed. Reg. 63,691 (2003); 42 C.F.R. § 426.100. The regulations are found at 42 C.F.R. Part 426. The procedures for review of a LCD are in 42 C.F.R. Part 426, Subpart D (42 C.F.R. § 426.400 *et. seq.*). The regulatory history for

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[8] Benefit appeals under Medicare Parts A, B, and C were previously adjudicated by ALJs assigned to the Social Security Administration (SSA). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. Law 108-173, § 931(a) and (b) required that the Secretary and the Commissioner of Social Security transfer the responsibility for adjudicating such appeals from SSA to HHS. OMHA was the result. 70 Fed. Reg. 36,386 (June 23, 2005) (Office of Medicare Hearings and Appeals; Statement of Organization, Functions, and Delegations of Authority).

[9] Provisions for the review of NCDs and LCDs were added to section 1869 of the Act by the Benefit Improvement and Protections Act of 2000 (BIPA), Pub. L. 106-554 § 522.

the regulations states that the regulations expanded the definition of an aggrieved party "to include a beneficiary who received a service, but whose claim for the service was denied extending an opportunity to that beneficiary" to file a complaint for a NCD or LCD review. 68 Fed. Reg. 63,691, 63,693-95 (2003).

Section 1869(f)(2) of the Act establishes a two-phase LCD review process by the ALJ. The ALJ reviews the LCD record, and, if he or she determines that the record is complete with adequate information to support the validity of the LCD, review is complete. If the ALJ reviews the record and determines that the record is incomplete or lacks adequate information to support the validity of the determination, then further process is required, although that process is not specified by the statute. The Secretary's regulations establish a review procedure consistent with that specified by Congress. The regulations provide that after the aggrieved parties file a statement as to why the LCD is not valid[10] and the contractor responds, "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). "Issuance of a decision finding the record complete and adequate to support the validity of the LCD ends the review process." 42 C.F.R. § 426.425(c)(2). If the ALJ does not determine that the LCD record is complete and adequate to support the validity of the LCD, then the regulation provides for discovery and the taking of additional evidence. No hearing was intended by the drafters or required by the language of the regulation for the first phase review. 68 Fed. Reg. 63,691, 63,700, 63,710 (2003).

The reasonableness standard is defined at 42 C.F.R. § 426.110, as:

> [T]he 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 or NCD record and the relevant record developed before the ALJ or the Board.

Further clarification of the reasonableness standard intended by the drafters is provided by the notice of final rule-making at 68 Fed. Reg. 63,691, 63,703-04 (2003). The drafters of the regulation discussed the reasonableness standard adopted as follows:

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[10] The aggrieved party may file copies of clinical or scientific evidence in support of his or her complaint that a LCD is not reasonable. 42 C.F.R. §§ 426.400(c)(6), 426.403.

We are using the statutory language from sections 1869(f)(1)(A)(iii) and (f)(2)(A)(i) of the Act, which instructs adjudicators to defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary.

The logical corollary is that the ALJs and the Board must accord deference if the contractor's or CMS's findings of fact, interpretations of law, and application of fact to law are reasonable. The concept of deference is one that is generally applied by courts to administrative decisionmaking, in recognition of the expertise of a program agency. Thus, we view the statute as setting out a reasonableness standard that recognizes the expertise of the contractors and CMS in the Medicare program--specifically, in the area of coverage requiring the exercise of clinical or scientific judgment.

So long as the outcome is one that could be reached by a rational person, based on the evidence in the record as a whole (including logical inferences drawn from that evidence), the determination must be upheld. This is not simply based on the quantity of the evidence submitted, but also includes an evaluation of the persuasiveness of the material. If the contractor or CMS has a logical reason as to why some evidence is given more weight than other evidence, the ALJs and the Board may not overturn the determination simply because they would have accorded more weight to the evidence in support of coverage. In some situations, different judgments by different contractors may be supportable, especially if explained by differences such as the ready availability of qualified medical professionals in one contractor's area, but not in another. Moreover, an ALJ or the Board may not determine that an LCD is unreasonable solely on the basis that another Medicare contractor has issued an LCD that permits coverage of the service at issue, under the clinical circumstances presented by the complaint.

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. So long as an interpretation is one of

> the readings permitted by the plain language of the law and can be reconciled with relevant policy, however, it must be upheld, even if the ALJ or the Board might have reached a different result if interpreting the statute or regulation in the first instance.

68 Fed. Reg. 63,691, 63,703-04 (2003).

Pursuant to 42 C.F.R. § 426.330, the aggrieved party bears the burden of proof and persuasion, which is judged by a preponderance of the evidence.

B. Issue

At this phase in the review process, the issue is whether or not the LCD record is complete and adequate to support the validity of the challenged LCD provisions under the reasonableness standard.[11]

C. Historical Context

This statement of historical context is not relevant to the issue of whether or not the present LCD satisfies the reasonableness standard and does not affect my decision in that regard. This information is included to provide the reader some perspective on the history leading to the present active LCD and Dr. Calabrese's determination to ensure she is compensated by Medicare for her treatment of her patients with TF therapy.

> 1. TF was found reasonable and necessary by a SSA ALJ in the appeal of an individual Medicare beneficiary.

On April 25, 1989, ALJ Stanley Sadur, who was assigned to the SSA's Office of Hearings and Appeals, issued a decision in which he found that the "immunomodulatory reagent" is covered by Medicare and he directed that the Medicare contractor determine the reasonable charge and make appropriate payment. The beneficiary in that case was treated by Dr. Ewing with TF for multiple allergies and chemical sensitivity. Dr. Ewing represented to the ALJ in a letter that the beneficiary had shorter and less severe reactions due to treatment with TF. The Medicare contractor had refused to pay for the cost of the TF treatments because the treatment was considered to be experimental and was not reasonable and necessary. ALJ Sadur stated in his decision that a Medicare contractor physician who reviewed the case stated that he could find no controlled studies of the

[11] I have shortened the statement of the issue to "whether the LCD satisfies the reasonableness standard" throughout the decision. The short-form of the issue is for ease in drafting and reading only and the correct characterization of the issue is as stated here.

usefulness of TF for the treatment of allergies. ALJ Sadur cited evidence submitted by the beneficiary regarding chemical sensitivity, which he characterized as a relatively recent field of research but increasingly being accepted as a legitimate concern. He cited evidence that some private insurers were covering TF. He cited a study conducted by Said Youdim, Ph.D., of the Environmental Health Center in Dallas that reported that half of 50 patients had positive responses to TF. ALJ Sadur reasoned that the Medicare contractor had denied coverage because there was no clear evidence of safety and effectiveness, but risky and less documented treatments may be acceptable when a beneficiary's life or health is seriously threatened and no better or safer treatment is available. ALJ Sadur concluded that the beneficiary in the case before him benefited from TF treatment, that TF was safe and effective for that beneficiary, and that it was reasonable and necessary and subject to Medicare coverage for that beneficiary. A.P. Ex. 183. Although there is a reference to a decision by ALJ Arthur Cahn finding TF therapy reasonable and necessary in the case of an individual beneficiary in 2003, that decision is not in evidence before me. A.P. Ex. 185, at 2.

2. NHIC post-payment review of claims for TF treatments by Dr. Calabrese during the period January 1, 2001 through February 28, 2003.

CMS Ex. 1 is a decision signed by MALJ E. M. Koldewey for ALJ Richard B. Gould dated June 3, 2008. Dr. Calabrese has indicated in various pleadings that this decision is being challenged administratively and judicially and I am not aware of the status of review of that decision. I declined to admit the decision as evidence on any issue before me, but find that it does provide some enlightening history. The case involved an appeal by Dr. Calabrese challenging a post-payment claim review by NHIC of claims submitted by Dr. Calabrese for TF or TF-related services.

According to the decision, NHIC notified Dr. Calabrese in December 2002 that she was selected for post-payment claim review due to possible over-use of a particular procedure code. CMS Ex. 1, at 4, 9. The post-payment claim review was eventually expanded to cover claims paid to Dr. Calabrese from January 1, 2001 through February 28, 2003, on behalf of 37 beneficiaries, 1,115 claims, and 47,125 units of service, of which 1,733 were actually reviewed. CMS Ex. 1, at 9.

Due to the results of the post-payment review, Dr. Calabrese was placed on prepayment claims review and required to submit supporting documentation with each claim submitted to the Medicare contractor for payment. In November 2004, NHIC advised Dr. Calabrese that she had been overpaid $308,311.36 and that she would have to refund that amount to Medicare. Dr. Calabrese received an unfavorable decision by a Medicare Hearing Officer and requested ALJ review in July 2007. CMS Ex. 1, at 5.

The issues addressed by the decision (CMS Ex. 1) are whether TF is a medically recognized and accepted standard of treatment; whether TF was reasonable and necessary for the beneficiaries; and whether payment could be made by Medicare. CMS Ex. 1, at 7. The decision states that Dr. Calabrese argued that "[b]ecause the claims for the services at issue had been processed and paid by Medicare, . . . NHIC inappropriately overturned its prior coverage on the transfer factor services used . . . to treat allergies" and chemical sensitivity. CMS Ex. 1, at 10. The decision also indicates that the Hearing Officer hearing was delayed to permit Dr. Calabrese to complete the LCD complaint then pending at the DAB. CMS Ex. 1, at 10. The decision indicates that Dr. Calabrese admitted in her testimony that TF was a blood-based item that was not approved by the Food and Drug Administration (FDA); that TF was self-administered by the beneficiaries; and, therefore, the majority of the TF treatments (those billed under CPT code 95165) would not be covered by Medicare. The decision also states that Dr. Calabrese failed to show that TF was effective and a standard treatment for the diagnoses for which she administered TF. The decision states that even if TF was found medically necessary, Dr. Calabrese failed to provide documents sufficient to verify medical necessity for the individual beneficiaries to which TF was administered. CMS Ex. 1, at 23.

My reading of the decision is that it turns on lack of adequate documentation by Dr. Calabrese and not the issue before me. The decision states "[Dr. Calabrese's] documentation failed to demonstrate medical need for any of the services denied by the contractor and, thus, the services at issue are not covered [by] [sic] Medicare benefits." CMS Ex. 1, at 33. Based upon the foregoing finding of fact, the conclusion of law articulated was that all the services denied by NHIC were not "medically reasonable or necessary." CMS Ex. 1, at 33. Dr. Calabrese was found not without fault for the overpayment and she did not present evidence that she advised the beneficiaries that the TF treatment was not likely to be covered by Medicare; therefore, she was held to be liable for repaying the improper payments. CMS Ex. 1, at 24, 33.

> 3. Dr. Calabrese's first LCD complaint filed in 2005 on behalf of 32 aggrieved parties resulted in dismissal of the complaint because, if the language of the policy in issue was a LCD, it was withdrawn by NHIC and CMS.

On February 8, 2005, during the pendency of the overpayment case described above, Dr. Calabrese, as representative for 32 aggrieved parties, filed a LCD complaint at the CRD. The complaint challenged a policy on the NHIC website that stated TF was not covered by Medicare. NHIC denied it had a LCD that stated that TF was not covered. ALJ Richard Smith dismissed the case on January 24, 2006. Judge Smith cited two alternative grounds for dismissal. First, he held that the article at issue that had been posted on the NHIC website was not a LCD within the meaning of the applicable law and

regulations and he had no subject matter jurisdiction. In the alternative, Judge Smith held that, even if the article was a LCD, dismissal was required under 42 C.F.R. § 426.420(e)(1) because the policy reflected in the article was changed to withdraw the challenged provision. *In re CMS LCD Complaint: Non-Coverage of Transfer Factor*, DAB CR1396 (2006). Judge Smith noted that Dr. Calabrese never addressed NHIC's assertion that it determined to deny the aggrieved parties' claims in that case on a case-by-case basis, and, on that basis found that TF was not reasonable and necessary, rather than by application of a LCD. Judge Smith concluded that:

> The responses from NHIC and CMS establish that the coverage decisions were not made on a carrier-wide, but on a claim-by-claim basis, and were on that basis determined to be not reasonable and not necessary. Thus, the coverage decisions were not an LCD.

Id. at 2. As I read Judge Smith's holding, he concluded that Dr. Calabrese did not satisfy her burden to show that the aggrieved parties' claims were denied based on a LCD; rather, the NHIC and CMS evidence was persuasive that the aggrieved parties' claims received case-by-case review. Thus, he concluded that evidence did not show that the aggrieved parties' claims were denied based on the application of a LCD. Judge Smith also found that the language that was alleged to reflect a policy to deny coverage for TF therapy on a contractor-wide basis was removed by the contractor at the direction of CMS. Because the language alleged to be a LCD was removed, Judge Smith concluded that pursuant to 42 C.F.R. § 426.420(e)(1), he had no jurisdiction to conduct further review and dismissal was required. He commented, citing 42 C.F.R. § 426.420(e)(1), that removal of the LCD language required that claim-by-claim review be done. *Id.* at 3.

> 4. Dismissal of Dr. Calabrese's first LCD complaint was affirmed on appeal to the Board because the LCD had been withdrawn.

On February 2, 2006, Dr. Calabrese appealed the ALJ decision to the Board. The Board affirmed the ALJ's dismissal on grounds that the language alleged to be a LCD in the NHIC policy was removed. *LCD Appeal of Non-Coverage of Transfer Factor*, DAB No. 2050, at 2 (2006). The Board found that NHIC replaced the TF article on its website with a revised statement that did not include the language challenged as a LCD, entitled "Article for Transfer Factor - Correct Coding and Recent Medical Reviews - Revised (A38251/A38252)," with an effective date of February 9, 2006. *Id.* at 12. Despite finding that the ALJ properly dismissed the complaint on grounds that the NHIC policy was revised, the Board discussed at length its disagreement with the ALJ's conclusion that the LCD did not constitute a LCD and stated that it concluded that the policy statement was actually a LCD. *Id.* at 6-11. As already noted, my reading of the ALJ's decision is that Dr. Calabrese did not meet the burden to show that a LCD was applied to deny the aggrieved parties' claims. The Board did not defer to, but rejected the ALJ's

factual finding that the evidence did not show that the offending language had been applied to deny claims automatically rather than after a case-by-case review. Rather, the Board concluded that the offending language sounded as if it constituted a LCD, i.e., a contractor- adopted policy to deny claims for TF automatically. *Id.* at 10-11. Unfortunately, the Board's dictum[12] regarding whether or not the offending language of the NHIC policy constituted a LCD seems to have been misleading or confusing for Dr. Calabrese. A brief discussion is therefore deemed appropriate here to aid Dr. Calabrese's and the APs' understanding of the rationale underlying my decision. The Board states in its decision that NHIC ceased covering the costs of TF for Dr. Calabrese's Medicare patients in 2004, which is consistent with the April 1, 2004 original effective date of the NHIC policy article under review by the Board. *Id.* at 2; CMS Ex. 19. The OMHA decision at CMS Ex. 1 discussed above reflects that prior to the post-payment review, Dr. Calabrese was paid for claims for TF for her Medicare-eligible beneficiaries. However, based on the results of the post-payment review, most of the claims were found to be improper and not subject to payment by Medicare; an overpayment was declared; and Dr. Calabrese was placed on prepayment review. CMS Ex. 1.

The Board commented that whether or not a policy is a LCD is "a legal issue based on the substance and content of the policy, not the label or characterization of the policy by the contractor." DAB No. 2050, at 10. The Board did not specifically mention that to be a LCD, a policy must also be applied or used by a contractor to automatically deny claims for benefits for treatment or service rather than conducting case-by-case medical review for whether treatment or service is reasonable and necessary. *See* MPIM § 13.3. However, that seems to be what the Board intended by the use of the word "active" in the following passage from its decision:

> 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 website. The regulatory exclusion [from review as a LCD] 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.

[12] Dictum is opinion on a question that is directly involved, briefed, argued, and passed on by the court, but not essential to the decision. *Blacks Law Dictionary* 485 (8th ed. 2004). The Board characterizes its conclusion that the policy was a LCD as having "little practical significance." *Id.* at 11.

Id. at 10-11 (emphasis added). The Board recognizes by this language that a statement on a carrier website or documents that claims for TF are never granted by the contractor may not be a LCD, if the statement is merely educational or has some similar purpose and is not relied upon by contractor staff as the basis for claim denial in lieu of individual case-by-case review. Nevertheless, the Board concluded that the language of the NHIC policy was a LCD even in the absence of evidence that the language was intended to be the basis for automatic claims denial or was ever used in that manner.[13] CMS and Dr. Calabrese were the real parties in interest before the Board, as they are before me. Further, the issue of whether NHIC was following a policy to automatically deny claims for TF prior to issuing L26134 is the same before me as it was before the Board, though some of the facts are different. Because the parties are identical, and, to the extent the issue before me is the same, i.e., whether a contractor-wide policy to deny coverage for TF therapy satisfies the reasonableness standard, I find the Board's prior legal conclusion that NHIC applied its policy as a LCD binding in the case before me pursuant to the doctrine of res judicata and the law of the case doctrine. *See* 2 Am. Jur. 2d Administrative Law § 579 (2009); *c.f.* 42 C.F.R. § 426.431(a)(4) (prior Board decision involving the same LCD provision, issues, facts, and clinical condition to be treated as precedential). The Board did not address the issue before me of whether or not a contractor-wide policy to automatically deny claims for TF satisfied the reasonableness standard as it concluded that the offending policy had been withdrawn by revision of the NHIC article. DAB No. 2050, at 11-14, 16, 19. The Board also did not address whether or not TF is reasonable and necessary for the treatment of any diagnosis.

The Board's discussion of other arguments raised by Dr. Calabrese is illuminating. Regarding Dr. Calabrese's argument that NHIC should be required to create a general policy subject to a single challenge rather than conducting a case-by-case review that every beneficiary must appeal if denied, the Board found no authority for such a requirement. The Board noted that the LCD appeal provisions of the Act do not require that a contractor issue a LCD when denying claims on the basis that a service is not reasonable and necessary even though that may not be efficient and could be burdensome for physicians and beneficiaries. The Act provides a right to challenge a LCD if the contractor chose to issue one to permit automatic denials for a particular service rather than conducting a case-by-case medical review for each claim. The Board noted that its interpretation is consistent with the legislative history of the change to the Act that

[13] The Board states that "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." *Id.* at 11. However, earlier in its decision the Board indicated that NHIC urged that the policy was simply intended to give direction regarding proper coding. *Id.* at 10. Thus, it may also be correct to say that there was no admission by NHIC or CMS that the policy was ever applied as a LCD and that there was no affirmative evidence that it was so applied.

permitted LCD complaints. The Board also pointed out that Dr. Calabrese could request a NCD that would be binding upon contractors and ALJs that would provide for coverage of TF. *Id.* at 15-16.

Dr. Calabrese alleged before the Board that the change in the revised article was merely cosmetic and that NHIC would effectively continue to have a secret noncoverage LCD to automatically deny all TF claims. Dr. Calabrese argued that the statement of NHIC that it was unaware of any recent case in which TF was found to be reasonable and necessary to treat a disease indicated that NHIC would continue to deny all claims for TF even on case-by-case review. The Board rejected Dr. Calabrese's argument, stating that it did not agree that the new policy was effectively the same as the old. The Board recognized that the NHIC statements regarding past denial of claims for TF indicated that NHIC was unlikely to grant coverage for future TF claims. But, the Board said that the new NHIC article did not "constitute a policy that NHIC will deny every claim for transfer factor" and it did not preclude granting coverage for TF where the beneficiary's circumstances or the state of medical science supported granting coverage, which distinguished the new NHIC policy from a LCD. DAB No. 2050, at 16. The Board rejected Dr. Calabrese's argument that it should conclude or presume that NHIC was acting in bad faith with the intent to continue to automatically deny claims for TF. The Board noted that it may be difficult to distinguish between multiple claim denials based on case-by-case review and the effect of application of a LCD. But the Board expressed confidence that NHIC would follow the regulations, which require that when a LCD is invalidated by an ALJ or the LCD provision under review is retired or withdrawn, the contractor must reopen the claim of the aggrieved party and conduct a medical review without applying the LCD. The contractor is also required to conduct case-by-case medical review on future claims rather than apply the invalidated, retired, withdrawn, or revised LCD.

Unfortunately, the Board chose the language "in addition to providing individual claim relief" in discussing what the contractor must do pursuant to the regulations following invalidation, retirement, withdrawal, or revision of a LCD. *Id.* at 18. Arguments of Dr. Calabrese in the case before me suggest that she misconstrued the language of the Board in this regard. Her arguments suggest that she believed that the Board's decision amounted to a determination that TF should be a covered service for the Medicare beneficiaries involved in the TF complaint and/or that NHIC should have paid for TF services. *See eg.*, APs' January 29, 2008 "Request for a Pre-Hearing Motion." However, that interpretation is incorrect. As the Board went on to explain, "the aggrieved parties are entitled to have their prior claims reopened and readjudicated with no regard given to the withdrawn policy and . . . 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." DAB No. 2050, at 18. Stated even more simply, in the absence of a LCD, NHIC was required to do case-by-case medical review of each claim for TF rather than apply a LCD to automatically deny the claims. *See also* 68 Fed. Reg. 63,691, 63,698 (retiring or withdrawing a LCD results in the AP receiving

individual claim review) 63,712 (if the AP has not already done so, may receive service and file claim that will receive individual review) (2003).

Finally, the Board advised that if NHIC ever adopted a contractor-wide policy to automatically deny coverage for TF, a new LCD complaint could be initiated to challenge the policy – and, in accordance with the Board's advice, Dr. Calabrese has brought the case before me.

> 5. The Medicare contractor, NHIC, issued LCD L26134 applicable to TF services performed after October 28, 2007.

Dr. Calabrese alleged in the complaint filed on October 31, 2007, that NHIC was following a "*sub rosa*"[14] policy to automatically deny all TF claims. In my January 3, 2008 letter advising Dr. Calabrese that the LCD complaint was not acceptable as filed, I noted that NHIC had issued LCD L26134 titled "Homeopathic Medicine and Transfer Factor" applicable to services performed after October 28, 2007.[15] The significance of the issuance of the LCD, though not specifically mentioned in my letter, was that it was no longer subject to dispute that NHIC was following a policy to automatically deny claims for TF therapy rather than providing case-by-case review. Thus, review of the

[14] *Sub rosa* is literally translated from Latin as "under the rose." In modern legal use, the Latin phrase is commonly used as an adjective meaning "confidential, secret, or not for publication." *Blacks Law Dictionary* 1468 (8th ed. 2004). Often the phrase is used with a negative connotation, which seems to be Dr. Calabrese's intent from her pleadings. Because a Medicare contractor is not likely to keep secret that it is automatically denying all claims of a particular type based on a policy rather than review of individual claims, *sub rosa* is inapt. More appropriate is the term "constructive," which I use in lieu of *sub rosa* when addressing Dr. Calabrese's argument. A "constructive LCD" as used in this decision is one that may be legally imputed from the facts though, as a matter of fact, no LCD was actually issued. *See Black's Law Dictionary* (8th ed. 2004) ("Constructive" is an adjective which means "[l]egally imputed; having an effect in law though not necessarily in fact.")

[15] This LCD is not in evidence before me. However, it may be viewed at http://www.cms.hhs.gov/mcd/indexes.asp by selecting "Search" in the left menu box and entering the LCD number as "L26134."

LCD could proceed upon LCD L26134 without the need for Dr. Calabrese to prove the existence of a constructive policy.[16]

> 6. The Medicare contractor that replaced NHIC issued a LCD applicable to TF therapy services performed on or after September 2, 2008, the day after NHIC retired its LCD that was substantially similar.

Palmetto GBA replaced NHIC as the Medicare contractor responsible for California in September 2008. NHIC retired LCD L26134 effective September 1, 2008. Palmetto issued LCD L28267, "Homeopathic Medicine and Transfer Factor," effective September 2, 2008. CMS does not dispute that the two LCDs are substantially similar, stating in the document "Supplemental LCD" filed on October 21, 2008:

> Pursuant to this tribunal's order of October 3, 2008, [CMS] submits for filing this supplement to the [LCD] record which documents the transition of the retired LCD No. L26134, *Homeopathic Medicine and Transfer Factor*, issued by [NHIC], the outgoing carrier to the status of an active LCD No. L28267, *Homeopathic Medicine and Transfer Factor*, effective September 2, 2008, by the incoming Medicare Administrative Contractor ("MAC") Palmetto GBA. The Palmetto GBA LCD is substantially similar to the LCD retired by NHIC, which was in effect for the period October 28, 2007 through September 1, 2008.

Dr. Calabrese objected to having to "litigate" either L26134 or L28267. Motion for Expedited Hearing & Ruling On Our 10-31-07 Filing, filed October 10, 2008. Her objection reflects a fundamental misunderstanding of the issue before me, i.e., whether the LCD satisfies the reasonableness standard. The issuance of LCD L26134 by NHIC

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[16] For claims of any of the APs denied before October 28, 2007, it may have been necessary to consider whether there existed a constructive LCD to automatically deny claims for TF services rather than denials based upon case-by-case review. I specifically advised Dr. Calabrese in my January 3, 2008 letter to submit evidence that her clients had been denied benefits based upon application of a LCD. Dr. Calabrese has submitted no evidence related to specific claims of the APs that were denied. Thus, while the APs have satisfied the standing requirement as discussed hereafter, I have no evidence of any specific claim of an AP being denied prior to October 28, 2007, but after the Board decision in DAB No. 2050. Therefore, it is unnecessary to consider whether NHIC was following a constructive LCD to automatically deny all TF claims without case-by-case review prior to issuance of L26134.

actually relieved Dr. Calabrese of a significant burden to demonstrate by competent evidence the existence of a constructive LCD. Therefore, her objection to proceeding upon LCD L26134 is unfounded and overruled. Her objection to addressing L28267 is also without merit and contrary to the interests of the Medicare beneficiaries she is representing. The regulations are clear that a contractor has the discretion to retire a LCD or an offending provision of a LCD under review by an ALJ at anytime prior to issuance of a decision by the ALJ. 42 C.F.R. § 426.420(a). The contractor is required to notify the ALJ within 48 hours that the LCD or LCD provision being reviewed has been retired or a revision issued, and, if a revision is issued, the revision must be provided to the ALJ.[17] 42 C.F.R. § 426.420(c) and (d). The regulation also requires that I dismiss the LCD complaint if the offending LCD is retired or the offending provision of the LCD is removed. 42 C.F.R. § 426.420(e)(1). Both ALJ Smith and the Board discussed this requirement in detail in their respective decisions discussing the prior LCD complaint filed by Dr. Calabrese. However, when the contractor merely revises a LCD and does not completely remove the challenged provision, then the ALJ must continue the review based on the LCD record as supplemented. 42 C.F.R. § 426.420(e)(2). The situation in this case, i.e., the contractor's contract is not renewed, the contractor retires its LCDs, and the new contractor issues new LCDs, is not addressed by the regulation. However, CMS admits that the two policies are substantially similar. Further, my comparison of L26134 and L28267 reveals that the challenged LCD provision, i.e., "Medicare does not cover transfer factor therapy or services primarily based to support transfer factor therapy" is identical in both LCDs. Therefore, I conclude that the facts of this case are more analogous to a revision that requires I continue review of the LCD, rather than a true retirement of the LCD, which would deprive me of jurisdiction. Viewed another way, the Medicare contractors' contractor-wide policy to automatically deny claims for TF services without case-by-case medical review – the LCD challenged – continued without change after October 27, 2007, despite the change in contractor on September 1 and 2, 2008. Accordingly, despite Dr. Calabrese's objections, I complete review of the LCD.

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[17] Dr. Calabrese complains in her "Motion for Expedited Hearing & Ruling On Our 10-31-07 Filing," at 2-3, and her "Declaration" regarding "Appellants' 'Class of One' due process and equal protection under the 5th Amendment to the US Constitution," at 5-6, both filed on October 10, 2008, that I did not sanction NHIC for failure to provide me notice as required by the regulation. Whether or not NHIC, Palmetto, or CMS should have provided me with notice of the revision of the LCD is not clear from the regulation. However, with two contractors and a government agency involved, it is understandable that the ball was dropped and I was not notified. No sanction was issued here as CMS promptly and professionally remedied the problem, and it is clear that the failure to comply with the procedural requirement of the regulation was merely an oversight and not evidence of contumacy. I further note that there is no evidence of any prejudice to the APs due to the oversight and Dr. Calabrese cites none.

D. Jurisdiction

My jurisdiction or authority in this case is clearly delineated at 42 C.F.R. §§ 426.405, 426.450, and 426.455. I am limited to addressing the issues of whether or not the LCD record is complete and adequate to support the validity of the LCD under the reasonableness standard and whether the LCD is valid or invalid under the reasonableness standard. 42 C.F.R. § 426.450(a).

Dr. Calabrese filed numerous motions for relief that are listed in the procedural history of this case. Following are my rulings on the motions. The CMS motion to dismiss the complaint is also addressed here due to jurisdictional implications.

1. APs' January 29, 2008 motions.

On January 29, 2008, Dr. Calabrese filed a "Request for a Pre-Hearing Motion" (Prehearing Motion). Dr. Calabrese stated that she requested a "pre-hearing motion regarding the legal validity of any and all California non-reimbursement of transfer factor LCDs and the criminal and civil violations of EDS - NHIC Dr. Bruce Quinn and their agents with respect to L26134 and the Medicare Carrier Advisory Committee." Dr. Calabrese summarized her legal arguments as follows:

> a. Article A38251/2 cannot be used as a LCD as there is no LCD docket
> b. The LCD L26134 does not have a legally valid docket.
> c. Without a legally valid LCD docket the federal code in BIPA 2000 Sec 522 states that reimbursement is reinstated
> d. the DHHS DAB Civil Remedies Division has jurisdiction to order NHIC [sic] reinstate reimbursement
> e. there is no appealable LCD

Prehearing Motion at 1.

Dr. Calabrese also requested that she receive the LCD record, including "Medicare CAC transcripts, rules and members;" she requested full discovery, including "witnesses and evidence to properly adjudicate whether EDS-NHIC, Dr. Bruce Quinn and their agents committed fraud, gross negligence and reckless disregard with respect to LCD L26134;" that LCD L26134 be ruled illegal and that NHIC be ordered to reinstate reimbursement; and that Dr. Bruce Quinn be referred to the U.S. Department of Justice for investigation regarding alleged criminal offenses. Prehearing Motion at 7.

Dr. Calabrese's requests and arguments are addressed as follows.

> a. Article A38251 was not a LCD and Dr. Calabrese has submitted no evidence that it was used as such after the Board decision in DAB No. 2050.

In its decision ruling on the appeal from the dismissal of the prior LCD complaint, the Board concluded that the NHIC policy article entitled "Article for Transfer Factor – Correct Coding and Recent Medical Reviews – Revised (A38251/A38252)," with an effective date of February 9, 2006, was not a LCD. DAB No. 2050, at 12-16. I am bound by the Board's decision. The APs' assertion that the policy article may not be used as a LCD because there is no "LCD docket" is not pertinent. The article was found not to be a LCD as it did not include language that amounted to a contractor-wide policy to automatically deny coverage for TF therapy.

Dr. Calabrese alleges that Article A38251/A38252 was used to "retroactively deny reimbursement to three dozen Medicare beneficiaries." However, Dr. Calabrese has presented no evidence that NHIC denied any claims for TF without case-by-case review based upon A38251/A38252 after the Board decision in DAB No. 2050; thus, there is no evidence upon which a constructive LCD might be found. Because I have no evidence to show that NHIC was following a constructive LCD to automatically deny claims for TF therapy rather than on a case-by-case basis, I also have no jurisdiction to inquire further into events between October 12, 2006, the date of the decision in DAB No. 2050, and October 28, 2007, the effective date of LCD L26134.

> b. Dr. Calabrese erroneously asserts as a basis for review that there was no "LCD docket" for either Article A38251/A38252 and LCD L26134, and that the Act requires that reimbursement be reinstated.

I understand Dr. Calabrese's argument to be that Article A38251/A38252 and LCD L26134 were not properly developed as LCDs and that they are therefore invalid. Her further argument is that because Article A38251/A38252 and LCD L26134 were not properly developed, reimbursement must be made for claims denied based upon either. Both arguments are in error.

An aggrieved party has no standing to challenge a LCD on the basis that it was not properly developed. Section 1869(f)(2) of the Act established an aggrieved party's right to review of a LCD by an ALJ and also provided that an unfavorable decision was subject to further review by the Board and judicial review. The Act does not establish a procedure for development and issuance of a LCD. Section 1869(f)(2) of the Act also limits the review available to the issue of the reasonableness of the LCD. The Act does not provide for review of the process by which a LCD is developed. However, I

recognize that the adequacy of the development of a LCD may impact upon the determination of whether the LCD meets the reasonableness standard, i.e., the evidence cited as the basis for the LCD may not be sufficient to support its reasonableness in the face of evidence presented by an aggrieved party. The Secretary's regulations also do not establish a procedure for the development of a LCD or grant an aggrieved party the right to challenge a LCD on the basis that it was not properly developed. 42 C.F.R. § 426.325. The procedure for development of a LCD is established by CMS as a policy in the MPIM § 13.7. The procedure is detailed but establishes no right for an aggrieved party to challenge a LCD based upon the procedure by which it was developed and it recognizes no such right. Accordingly, I conclude that an aggrieved party has no right to challenge a LCD on the basis that it was not properly developed and that I have no jurisdiction to review a LCD on that basis. *LCD Appeal of Non-coverage of Intravenous Immunoglobulin (LCD Database Id. No. L9245)*, DAB No. 2059 (2007).

Dr. Calabrese is also incorrect to the extent that she intends to assert that there is no LCD record for LCD L26134. In fact, NHIC filed the LCD record for LCD L26134, and CMS subsequently filed the supplemental record for the Palmetto LCD L28267. The LCD records filed were reviewed to decide the issue of whether or not the LCD record is complete and adequate to support the validity of the challenged LCD provisions under the reasonableness standard.

Dr. Calabrese's argument that reimbursement must be made for a claim denied based on an invalid LCD is in error. If a LCD is found invalid or it is withdrawn, the relief to which an aggrieved party is entitled is individual claim review without application of the invalidated LCD. Individual claim review is subject to the "reasonable and necessary" standard established by section 1862(a)(1) of the Act and individual claim review may or may not result in reimbursement. Invalidation of a LCD does not automatically result in reimbursement for claims denied based upon the LCD or that would have been denied based upon the LCD. Section 1869(f)(2) of the Act creates the right to review of a LCD upon a complaint by an aggrieved party. The Act does not, however, specify the relief to which an aggrieved party is entitled if a LCD is invalidated by an ALJ, the Board, or a court. The Secretary's regulation, however, is very clear on the relief available to an aggrieved party. If an ALJ determines that a LCD is invalid under the reasonableness standard, an aggrieved party whose claim was denied based on the invalid LCD is entitled to have his or her claim reopened and adjudicated without application of the invalid LCD. 42 C.F.R. § 426.460(b)(1)(i) and (iv); DAB No. 2050, at 18. For an aggrieved party who had not yet submitted a claim, the contractor adjudicates the claim without applying the invalid LCD. 42 C.F.R. § 426.460(b)(1)(iii) and (iv). Relief available from the Board is similarly limited. 42 C.F.R. § 426.488. ALJs and the Board are specifically prohibited from ordering that CMS or its contractors pay a specific claim. 42 C.F.R. §§ 426.455(b) and 426.486(b). Accordingly, I conclude that invalidation of a LCD does not alone require reimbursement for a claim of an aggrieved party whose claim was denied or would have been denied. I further conclude that I have no authority to

order reimbursement for any individual's claim. Finally, I see nothing in the decision of the Board in DAB No. 2050 that suggests that the Board intended to order reimbursement for previously denied claims in excess of its regulatory authority.

c. Dr. Calabrese is in error arguing that there is no appealable LCD.

If I accepted Dr. Calabrese's argument that there is no appealable LCD, then the Medicare beneficiaries she represents would have no right to review, and I would have no jurisdiction to review the LCD at issue in this case under section 1869(f)(2) of the Act. The gist of Dr. Calabrese's argument is that the LCD subject to my review is invalid because the Medicare contractor engaged in improper conduct with improper motives when developing and issuing LCD L26134, and that it is, therefore, invalid. The issue I may decide is whether or not the LCD record is complete and adequate to support the validity of the challenged LCD provisions under the reasonableness standard. In this case, Dr. Calabrese alleged that NHIC had a contractor-wide policy to deny claims for TF therapy that was applied to cases after the Board decision in DAB No. 2050. However, she offers no evidence to support her allegation and there is no constructive LCD for me to review, even if I had the jurisdiction to do so. As I have already discussed, before the initial complaint was filed in this case, NHIC did, in fact, effectuate LCD L26134 that included a contractor-wide policy to automatically deny claims for TF without case-by-case review. When LCD L26134 was retired by NHIC when its contract ended on September 1, 2008, the new contractor, Palmetto, effectuated LCD L28267, which contained the identical contractor-wide policy to deny claims for TF therapy and related services. My jurisdiction in this case is premised upon the existence of LCD L26134 and the revision to LCD L28267, and the identical contractor-wide policy to deny claims for TF therapy and related services found in both. My jurisdiction is limited to reviewing the LCD record and supplemental records presented by CMS and its former contractor, NHIC, and the evidence submitted by the APs in support of their position, to decide the issue presented. If I find that the LCD is valid under the reasonableness standard, then my jurisdiction is further limited by the regulatory requirement that I cease further review. 42 C.F.R. § 426.425(c)(2).

d. Other requests and arguments.

Dr. Calabrese requested that I order that NHIC produce certain witnesses to provide testimony. During this first phase of LCD review, the issue is whether or not the LCD record is complete and adequate to support the validity of the challenged LCD provision under the reasonableness standard. The issue is resolved based upon the documentary record and testimony is not required or relevant at this stage. Therefore, the request for witnesses is denied.

Dr. Calabrese requested that I order that NHIC produce records regarding non-reimbursement of TF. At this stage of the LCD review, the only relevant records are those that constitute the LCD record, and NHIC and CMS were ordered to produce and did produce what is alleged to be the LCD record for both L26134 and L28267. To the extent Dr. Calabrese seeks records in addition to the LCD record, discovery is not available at this stage as the additional records are not relevant.

Dr. Calabrese argues in this motion and other pleadings that NHIC and its employees engaged in criminal or tortious conduct. I have no authority or jurisdiction granted by the Act or regulations to inquire into such allegations and I do not address them further.

Dr. Calabrese also requested that if I ruled that I did not have jurisdiction to grant her requests, that I explain what remedies are available to the APs. An aggrieved party denied coverage based upon a LCD is entitled to challenge the denial and show that TF therapy is reasonable and necessary before an OMHA ALJ and the MAC, as they are not bound to follow a LCD. Act § 1869(a) through (d); 42 C.F.R. §§ 405.1000 through 405.1140.

2. APs' February 15, 2008 motion.

On February 15, 2008, Dr. Calabrese filed a "Motion that the NHIC Carrier Advisory Committee record and membership list be included in the LCD Docket." The documents requested are not part of the LCD record and are not relevant to the issue before me. The LCD record for the purposes of my review is the contractor's LCD record as defined by 42 C.F.R. § 426.418. A.P. Ex. 208 indicates that Dr. Calabrese was provided the list of members on April 1, 2008, in response to a Freedom of Information Act request. On April 4, 2008, Dr. Calabrese filed a "Motion For Ruling Of Fraud, Gross Negligence And Reckless Disregard Against EDS - NHIC & Dr. Bruce Quinn & Request for Referral to CMS For Independent Investigation" in which she admits that she received the requested documents on April 4, 2008, rendering this motion moot.

Accordingly, the motion is denied.

3. APs' March 31, 2008 motions.

On March 31, 2008, Dr. Calabrese filed the following motions:[18]

[18] Dr. Calabrese characterized these pleadings as "declarations" and certified them as true and correct subject to penalty for perjury. However, there is no requirement that pleadings be verified or attested in this forum. The pleadings are treated as motions filed by Dr. Calabrese in her representative capacity and not as evidence.

a. "Motion That LCD L26134 Is Not Legally Valid & Should Be Nullified: EDS - NHIC Violations of: (a) 18 U.S.C. § 1035(a) False Health Care Statements to Medicare Part B CAC (b) 42 C.F.R. § 426.463 (c) Medicare Program Integrity Manual Ch. 13."

b. "Motion for Expedited Review that LCD No. L26134 is Not Legally Valid & Not Appealable Based on EDS - NHIC Violations of a) 42 C.F.R. § 426.463 b) 18 USC § 1035(A)"

NHIC filed a consolidated opposition to both motions on April 30, 2008. Dr. Calabrese filed a consolidated response to the NHIC filings in opposition to all her motions on May 4, 2008.

Dr. Calabrese argues that LCD L26134 must be nullified as it is not legally valid and fraudulent because "legal requirements for writing and executing" the LCD were not met. Dr. Calabrese cites no authority for the proposition that an aggrieved party may seek and obtain review of the procedures by which a LCD is adopted. Rather, as previously discussed, the Act and the Secretary's regulations provide a limited right to challenge and review a LCD based upon whether or not the LCD record is complete and adequate to support the validity of the challenged LCD provisions under the reasonableness standard. Whether or not the contractors failed to follow the procedure in MPIM Chapter 13, for issuing a LCD, is not an issue before me. *LCD Appeal of Non-coverage of Intravenous Immunoglobulin (LCD Database Id. No. L9245)*, DAB No. 2059 (2007). As discussed hereafter, the contractor-wide policy adopted by NHIC in LCD L26134 and subsequently adopted by Palmetto in L28267, to automatically deny coverage for TF therapy rather than provide case-by-case review, does meet the reasonableness standard.

Dr. Calabrese argues that NHIC's medical director made false statements relating to health care matters in violation of 18 U.S.C. § 1035. I have no criminal jurisdiction and do not address the allegations further.

Dr. Calabrese argues that the NHIC's medical director violated 42 C.F.R. § 426.463, which provides that a "contractor may not reinstate an LCD provision(s) found to be unreasonable unless the contractor has a different basis . . . ." Neither ALJ Smith nor the Board reached the issue of whether or not the non-coverage of TF therapy satisfied the reasonableness standard or was unreasonable. Thus, 42 C.F.R. § 426.463 has no application to this case.

Dr. Calabrese alleges that the NHIC medical director violated MPIM Chapter 13, which establishes the procedures to be followed in developing a LCD. Dr. Calabrese cites no authority for the proposition that an aggrieved party may challenge a LCD on this basis and I am aware of no authority that permits me to conduct such a review. I recognize,

however, that inadequate development of a LCD may impact whether or not a LCD meets the reasonableness standard.

Accordingly, Dr. Calabrese's motions are denied.

c. "Motion That DHHS DAB Remove Judge Smith's 01-24-06 Ruling from the DHHS DAB Internet Site"

On January 24, 2006, ALJ Smith issued his decision dismissing Dr. Calabrese's previous LCD complaint in *In re CMS LCD Complaint: Non-Coverage of Transfer Factor*, DAB CR1396, which is available at www.hhs.gov/dab/decisions/CR1396.htm. Dr. Calabrese requests that the decision be removed from the website because it was legally incorrect and misleading to Medicare Part B physician providers and beneficiaries. NHIC filed its opposition to the motion on April 30, 2008. I have no authority to review ALJ Smith's decision or to order the relief that Dr. Calabrese requests. I do note that Dr. Calabrese did appeal ALJ Smith's decision to the Board and the Board upheld the dismissal on grounds that the LCD was withdrawn by NHIC, though it disagreed in dictum with ALJ Smith's conclusion that there was no LCD. I have already discussed in detail the Board's decision in DAB No. 2050 and Dr. Calabrese's misconception of the import and impact of that decision. The APs' right to obtain Board review of ALJ Smith's decision was exercised and review was granted. The motion is denied.

d. "Motion Challenging Article A38251/A38252 & NHIC Non-Reimbursement of TF Policy Prior to LCD L26134."[19]

The gist of this motion is found on page 4, ¶ 9, where Dr. Calabrese states:

> We respectfully ask this Court to rule that EDS – NHIC policy of non-reimbursement of TF continued illegally after DHHS DAB final agency decision, when Article A38251/A38252 replaced the 04-01-04 NHIC non-reimbursement of TF LCD.

As I have already discussed, Dr. Calabrese has not presented evidence that even one claim by a beneficiary or on a beneficiary's behalf for TF therapy was denied by NHIC between the issuance of the Board's decision and the effective date of LCD L26134. Indeed, Dr. Calabrese admitted in one pleading that no claims for TF therapy were filed after October 30, 2003. Motion That LCD L26134 Is Not Legally Valid & Should Be Nullified, filed March 31, 2008, at 12, ¶ 21.

[19] NHIC filed its opposition on April 30, 2008.

However, in her motion, she cites to her exhibits, arguing that the exhibits show that an Independent Hearing Officer delayed or denied review of claims as late as March 28, 2007. Motion at 3, ¶¶ 3, 4, 5. Dr. Calabrese argues that her exhibits show that NHIC continued to automatically deny claims for TF therapy after the Board issued DAB No. 2050 on October 12, 2006, and before LCD L26134 was effective on October 28, 2007. Motion at 2-3, ¶¶ 1-2. The facts are not as alleged by Dr. Calabrese. The exhibits cited by Dr. Calabrese, A.P. Exs. 202-205, actually relate to the post-payment review of claims for TF treatments by Dr. Calabrese during the period January 1, 2001 through February 28, 2003, and the related overpayment that was the subject of the June 3, 2008 decision signed by MALJ Koldewey at CMS Ex. 1 discussed above.[20] As the phrase "post-payment review" indicates, the claims involved were actually paid and thus, no LCD was applied to deny those claims. However, based upon the post-payment review, the NHIC determined that claims were paid that should not have been paid and an overpayment was declared. CMS Ex. 1, at 1-6, 9-10. Therefore, there is no evidence that the overpayment case against Dr. Calabrese involved the application of a LCD, i.e., a contractor-wide policy to automatically deny claims for TF therapy and services.

The exhibits Dr. Calabrese cites do not show that NHIC applied any contractor-wide policy to automatically deny coverage of TF therapy to any claim rather than conduct an individual review after the Board decision or before the LCD was issued. Dr. Calabrese's assertion that no claims for TF therapy were filed after October 30, 2003,[21] is more consistent with the complete absence of any evidence before me that any claim was filed after that date. Accordingly, I conclude that the evidence does not show that NHIC was following a constructive LCD to automatically deny on a contractor-wide basis any claim for TF between October 12, 2006 and October 28, 2007. Furthermore, I am bound by the Board decision in DAB No. 2050 that Article A38251/38252 was not a LCD.

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[20] Dr. Calabrese reveals later in the motion that she is actually referring to the overpayment case rather than any new claims. Motion at 9, ¶ 12-13. Her assertion that the Independent Hearing Officer did not do a single claim review is misleading. The ALJ decision at CMS Ex. 1 shows that the claims involved actually received extensive case-by-case review.

[21] This date is significant as Dr. Calabrese was placed on 100% pre-payment review effective October 31, 2003. One impact of pre-payment review is that claims were no longer automatically paid. The other impact was that Dr. Calabrese had to submit medical records with each claim to "substantiate the reasonableness and necessity for all her services." Claims submitted without documentation were to be denied. A.P. Ex. 205.

Dr. Calabrese also included in her motion a list of alleged criminal violations by NHIC or its employees that I have no jurisdiction to address.

> e. "Motion That The Contractor Identify Their Physician Who Wrote Exhibit 196 & The Source of His Evidence."

Dr. Calabrese seeks the identity of the author of A.P. Ex. 196, a copy of a one-page, handwritten document with the title "Medical Advisor's Overall Summary," dated February 3, 2003, and with an indecipherable signature. Dr. Calabrese represents in her motion that the document was received in another agency proceeding. NHIC filed an opposition on April 30, 2008, on grounds that the document is not part of the LCD record, and the opposition was supported by the Declaration of Annette Kazmerski, dated April 30, 2008. Dr. Calabrese has not shown that the document is part of the LCD record or that it has any relevance to the issue before me. Accordingly, her motion is denied.

4. APs' April 4, 2008 motion.

On April 4, 2008, Dr. Calabrese filed a "Motion For Ruling Of Fraud, Gross Negligence And Reckless Disregard Against EDS - NHIC & Dr. Bruce Quinn & Request for Referral to CMS For Independent Investigation." Dr. Calabrese admits that she received the list of the Carrier Advisory Committee members in response to her Freedom of Information Act request. She alleges that NHIC or its medical director exercised "undue coercion" over one or more committee members regarding development of LCD L26134. Motion at 2, ¶ 3. Dr. Calabrese requests as relief that I refer her allegations to CMS for an independent investigation. Motion at 8. NHIC filed a brief in opposition on May 2, 2008. I deny this motion. It is not within my jurisdiction to grant the relief requested. Furthermore, based upon the multitude of pleadings and allegations filed by Dr. Calabrese in this case and the pleadings she has filed with me from various cases she has pursued in the U.S. District Court, Central District of California and the Ninth Circuit Court of Appeals, I have little doubt that CMS is aware of her allegations against NHIC and its employees. I also am unaware of any impediment to Dr. Calabrese taking her complaints directly to CMS officials or the Inspector General for HHS.

5. APs' May 4, 2008 motion.

On May 4, 2008, Dr. Calabrese filed "Appellant Request for Copies of Dr. Lewis Kanter's Confidentiality Agreements for His: a) Medicare CAC Participation & b) NHIC Medical Expert Participation." NHIC filed a brief in opposition on June 3, 2008. The issues raised and the information Dr. Calabrese seeks to obtain by her motion is simply not relevant to the issue before me and the motion is denied.

6. APs' October 10, 2008 motion.

On October 10, 2008, Dr. Calabrese filed a "Motion for Expedited Hearing & Ruling On Our 10-31-07 Filing" and her "Declaration" regarding "Appellants' 'Class of One' due process and equal protection under the 5th Amendment to the US Constitution." On October 31, 2008, CMS filed a consolidated opposition to the APs' motion and a motion to dismiss the complaint, which is discussed hereafter.

I have already ruled upon the APs' motion in the discussion of "Historical Context," Part II.C.6 of this decision, *supra*. The motion and my denial of the motion require some additional discussion of the jurisdictional aspect. I have already discussed in detail that, contrary to the repeated assertions of Dr. Calabrese, the Board decision in DAB No. 2050 did not have the effect of requiring that TF therapy and services be covered by Medicare or that reimbursement be reinstated (to use Dr. Calabrese's characterization). I have already also discussed my conclusion that Dr. Calabrese has failed to present any evidence that, after the Board decision and before LCD L26134 was issued, NHIC followed a contractor-wide policy to automatically deny claims for TF therapy and services. Thus, my review is limited to whether the LCD set forth in LCD L26134 and LCD L28267 satisfies the reasonableness standard. The practical impact of limiting my review to the LCD language found in LCD L26134 and LCD L28267 is virtually nil for the APs and Dr. Calabrese. The impact is virtually nil for two reasons: (1) despite having sufficient time to do so, Dr. Calabrese has presented no evidence that any submitted claim for TF therapy and services was denied based on a LCD after October 30, 2003, and she has admitted no claims were filed after that date; and (2) for claims for service with dates of service after October 30, 2003 and before October 28, 2007 (the effective date of LCD L26134), the APs and Dr. Calabrese have a judicial admission by CMS and its contractor that the claims are entitled to case-by-case review, albeit on a prepayment basis.

Dr. Calabrese also misstates the issues before me. She asserts that the two primary issues are whether NHIC's "non-reimbursement of transfer factor immunomodulatory therapy . . . sub rosa policy is legally valid" and whether LCD L26134 was legally valid. She also incorrectly asserts that the case covers a finite period from October 12, 2006 to September 1, 2008. The issue I am authorized by law to address is whether or not the LCD record is complete and adequate to support the validity of the challenged LCD provisions under the reasonableness standard. As previously discussed, I am only granted jurisdiction to inquire regarding existing LCDs.

Dr. Calabrese alleged in her Declaration at pages 5-6 that the DAB is biased in favor of the contractor. Dr. Calabrese cites as evidence that no sanction was imposed against NHIC for failing to provide notice that LCD L26134 was retired on September 1, 2008. As I have explained, the regulation does not specify whether the responsibility to report was upon NHIC, CMS, or Palmetto. However, CMS quickly remedied the oversight

when I called it to their attention and no sanction was necessary. Dr. Calabrese complains because Palmetto has been added to the case as the current contractor. I have explained that it is in the best interest of the APs for me to address the LCD rather than dismiss the complaint because the transition from NHIC to Palmetto resulted in a revision of the LCD, not a retirement which would require dismissal. Thus, adding Palmetto to this case is to the benefit of the APs. Dr. Calabrese also alleges that NHIC and its counsel lied to me, in other proceedings, and to CMS, and no sanction was imposed. I have no jurisdiction to review any other proceedings or NHIC's communications with CMS. However, in the case before me, the evidence does not show that NHIC lied or misrepresented in the manner alleged by Dr. Calabrese and there is no basis for any sanction.

Dr. Calabrese alleges in her Declaration at pages 6-10, that the DAB is biased against the APs. She complains that she was threatened with sanctions for failure to follow the rules. Dr. Calabrese was not threatened, but rather, warned that if she failed to comply with the rules, particularly that against ex parte communications, she would be sanctioned. No disrespect was intended by the warning; rather, a warning is generally deemed appropriate prior to imposing a sanction. Because Dr. Calabrese has made an effort to comport with the rules, she has not been sanctioned. Dr. Calabrese complains that NHIC and its counsel violated her and her patients' right to confidentiality and that I have failed to take action to prevent it. Allegedly NHIC gave information to a competing local allergist. However, it is clear from the ALJ overpayment decision at CMS Ex. 1, at 16, that the "competing local allergist" was also an expert witness who testified against Dr. Calabrese in that proceeding and likely had access to information through that proceeding rather than this, as neither party in this proceeding has been directed to prepare witnesses for a hearing. Furthermore, while I have authority to control the proceedings of the case before me, I have no general authority in the context of this case to investigate or remedy any perceived violation of Dr. Calabrese's or her patients' confidentiality. Dr. Calabrese argues that as a non-attorney representative, she should be given more leeway than an attorney. The record speaks for itself. Dr. Calabrese has not been held to the standards and norms of conduct that are expected of a practitioner. More importantly, her minor procedural irregularities and tone are not permitted to put at a disadvantage the APs that she has undertaken not only to treat but to represent. This substantive decision is based strictly upon the evidence, or the lack thereof, and the conduct of Dr. Calabrese is not a factor I have considered. There is no bias for or against Dr. Calabrese, the APs, or the governmental parties in this case.

7. CMS's motion to dismiss filed October 31, 2008.

On October 31, 2008, CMS filed a pleading titled "CMS' Opposition to Motion for Expedited Hearing and Ruling and Motion to Dismiss Complaint." Dr. Calabrese filed an opposition to the motion on November 4, 2008.

CMS objected to Dr. Calabrese listing three APs in her October 10, 2008 Motion for Expedited Hearing on grounds that only one of the three had been found to have filed an acceptable complaint. The CMS objection was technically correct. However, as I have indicated in footnote 1 of this decision, all 11 of the beneficiaries that Dr. Calabrese has sought to add as joint complainants are accepted as APs.[22]

CMS moved to dismiss the complaint on grounds that: (1) the beneficiaries are not aggrieved parties and lack standing to maintain the complaint; and (2) NHIC retired LCD L26134 and dismissal is required by 42 C.F.R. § 426.420(e)(1). The motion to dismiss is denied.

Section 1869(f)(5) of the Act defines standing as follows:

> An action under this subsection seeking review of a national coverage determination or local coverage determination may be initiated only by individuals entitled to benefits under Part A, or enrolled under part B, or both, who are in need of the items or services that are the subject of the coverage determination.

This definition of standing has only two elements necessary for standing: (1) an individual must be a qualified Medicare beneficiary under Part A or B or both; and (2) they must be in need of services that are subject to the coverage determination. There is no requirement that the individual have applied for and been denied benefits based on the coverage determination. The drafters of the regulation expanded the definition of an aggrieved party, i.e., one with standing, "to include a beneficiary who received a service, but whose claim for the service was denied extending an opportunity to that beneficiary" to file a complaint for a NCD or LCD review. 68 Fed. Reg. 63,691, 63,693-95 (2003). Thus, the definition of "aggrieved party" at 42 C.F.R. § 426.110 was not intended to limit the beneficiaries who could maintain a LCD complaint to those who had a claim denied based upon application of a LCD. Rather, a Medicare beneficiary has standing as an aggrieved party if: (1) he or she provides evidence of a need for a service by submitting a timely document from a treating physician stating that the service is needed; and (2) the service would be denied based upon the LCD challenged. CMS acknowledges that when there is "an active LCD, it would be sufficient for the purported aggrieved party to establish that coverage had been or would be denied based upon the LCD." Motion at 6. CMS argues, however, that the complaint must be dismissed because NHIC is no longer the Medicare contractor; LCD L26134 issued by NHIC was retired on September 1, 2008, when NHIC was replaced by Palmetto; and there is no evidence that any claim was

[22] The eleven APs are listed on the correspondence transmitting this decision to the parties, but their identities are not revealed in the decision to protect their privacy.

denied based on LCD L26134. CMS does not cite any authority for this construction of the statutory or regulatory requirement for standing or aggrieved party status. I do not find the argument persuasive.

When CMS filed its supplemental LCD record, prior to filing its motion to dismiss, CMS explicitly stated, "*[t]he Palmetto GBA LCD is substantially similar to the LCD retired by NHIC, which was in effect for the period October 28, 2007 through September 1, 2008.*" (Emphasis added). I compared the language of the two LCDs that state that TF therapy and services are not covered and find that the language is identical. As discussed above, I conclude that the change from LCD L26134 to LCD L28267 was really a revision of the LCD to reflect the transition from NHIC to Palmetto and not a substantive change to the LCD that amounted to a retirement or withdrawal. Pursuant to 42 C.F.R. § 426.420(e)(2), I must continue review of a LCD if it is merely revised and the substantive provision in question is not removed. Accordingly, the CMS motion to dismiss is denied, and I complete the LCD review specified by 42 C.F.R. § 426.425.

8. APs' November 10, 2008 motion.

On November 10, 2008,[23] Dr. Calabrese filed a submission titled "Objections to & Motion for Discovery Regarding CMS Exhibits Filed 11-07-08." Dr. Calabrese's objections to CMS exhibits are discussed above. I deny the motion for discovery. Discovery is not available to the parties at this phase of the review process. The regulations provide for discovery and the taking of additional evidence only if I determine that the LCD record is not complete and adequate to support the validity of the LCD.

9. APs' December 8, 2008 motion.

On December 8, 2008, Dr. Calabrese filed a "Motion for Hearing that CMS Region IX Attorney Angela Belgrove a) Be Replaced b) Be Sanctioned." CMS did not file a response. Dr. Calabrese alleges that Attorney Belgrove, who represents CMS in this case, is a witness in two cases Dr. Calabrese has pending in the U.S. Court of Appeals for the Ninth Circuit and that she will be named as a co-defendant in those cases. Dr. Calabrese also alleges that Attorney Belgrove "introduced fraudulent documents into this case and misled [me] with respect to OMHA decision 06-03-08 [CMS Ex. 1] and NHIC's Theresa DeBell, R.N.'s e-mail." Dr. Calabrese requests that I convene "a full evidentiary

[23] The motion is dated November 3, 2008; however, the proof of service is dated November 10, 2008.

hearing to preserve Appellants' constitutional rights." Dr. Calabrese's motion for an evidentiary hearing or that Attorney Belgrove be replaced or sanctioned is denied.

The fact that Attorney Belgrove may be called as a witness in a proceeding in the Ninth Circuit by Dr. Calabrese or that Dr. Calabrese may name her a co-defendant in those cases is not grounds for Attorney Belgrove being disqualified to represent CMS in this case. If simply calling opposing counsel as a witness or naming them a co-defendant were grounds for disqualification, it would encourage the unscrupulous and further disrupt the judicial process.

Dr. Calabrese's allegations that Attorney Belgrove introduced a fraudulent document or misled me, is frivolous. I am well aware of Dr. Calabrese's arguments regarding the legitimacy of the OMHA decision dated June 3, 2008, that was signed by MALJ Koldewey for ALJ Gould. CMS Ex. 1. I am aware that Dr. Calabrese disagrees with the decision. Nevertheless, the decision is an official record of the United States and it will remain so, even if Dr. Calabrese is successful at some time in the future overturning the decision. The document clearly reflects some of the history leading to the adoption of the LCD at issue in this case. However, the decision was not admitted as evidence as it does not help me resolve the only issue before me. Based upon my review of CMS Ex. 1, Attorney Belgrove made no misrepresentation about what the document is or says in the October 31, 2008 "CMS' Opposition to Motion for Expedited Hearing and Ruling and Motion to Dismiss Complaint."

Dr. Calabrese does not clearly describe the e-mail of RN Theresa DeBell about which she complains. However, the supplemental LCD record filed by CMS included an email that reflects it was from Theresa DeBell. Attorney Belgrove as counsel for CMS filed the supplemental record on October 21, 2008, pursuant to my order of October 3, 2008. My order did not grant CMS discretion to produce less than the whole supplemental record that was the basis for the adoption of LCD L28267. Furthermore, Attorney Belgrove has not advanced any argument citing to the Theresa DeBell email or offered it as an exhibit[24] in support of the CMS position that the LCD is reasonable.

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[24] On February 29, 2008, NHIC produced the LCD record for LCD L26134. The documents that comprised the record were not marked as evidence. On October 21, 2008, CMS produced the supplemental LCD record. My review of the documents submitted revealed that many were not relevant to or weighty on the issue before me. Accordingly, on October 29, 2008, I directed by letter that CMS mark as evidence the documents from the LCD record and supplemental record that it considered relevant to the issue before me at this phase of the proceedings, and resubmit the documents. CMS did not mark the entirety of the record and supplemental record as evidence, and I consider only those portions that are marked as evidence. I note that both the record and supplemental record were served on Dr. Calabrese.

Attorney Belgrove has signed only five documents in this case: her notice of appearance, the pleading accompanying the supplemental LCD record, the cover letter for the marked CMS exhibits and exhibit list, the CMS exhibit list, and the CMS "Opposition to Motion for Expedited Hearing and Ruling and Motion to Dismiss Complaint." I have carefully reviewed all the documents signed by Attorney Belgrove and find no statement that suggests fraud or an attempt to mislead.

10. APs' allegations of Constitutional violations.

Dr. Calabrese asserts in several pleadings that the APs' rights to equal protection and due process have been violated. To the extent that Dr. Calabrese intends to challenge either the Act or the Secretary's regulations, I have no jurisdiction to address her challenge. 42 C.F.R. § 426.405(d)(13). To the extent that Dr. Calabrese intends to challenge the conduct of the Medicare contractors or CMS, I also have no jurisdiction. Rather, my jurisdiction is limited to deciding the issue specified above. As already noted, the procedures for adopting a LCD are not established by the Act or the regulations. Rather, the procedures are specified in the MPIM, Chapter 13, and the APs have cited no authority that they have any right to challenge the procedures followed in adopting the LCD before me and I am aware of no such authority. Finally, to the extent that Dr. Calabrese challenges the process accorded her by this proceeding, I have accorded the APs the process due them under the Act and regulations.

E. Findings, Conclusions, and Information Required by 42 C.F.R. §§ 426.450.

1. Based upon the evaluation required by 42 C.F.R. § 426.425(c)(1), I conclude that the LCD record is complete and adequate to support the validity of the LCD provision at issue under the reasonableness standard. 42 C.F.R. § 426.450(a)(4).

2. The evidence does not establish that the APs have filed claims that have been denied based upon the LCD provision challenged.

3. No proprietary or privileged data was submitted under seal or considered in this case.

The regulation provides that after receiving the LCD record; the aggrieved party's statement of why the LCD is not valid, including evidence submitted in support of that position; and the contractor's response to the aggrieved party's statement, I am to apply 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). In this case, after thoroughly reviewing the LCD record as supplemented; Dr. Calabrese's

submissions discussing why the LCD is not valid and her supporting evidence; and the CMS response, I conclude that the LCD record is complete and adequate to support the validity of the LCD. Accordingly, the LCD review process ends with this decision, subject to any further appeal to the Board. 42 C.F.R. §§ 426.425(c)(2); 426.465.

The issue is whether or not the LCD record is complete and adequate to support the validity of the challenged LCD provision under the reasonableness standard. 42 C.F.R. § 426.425(c)(1). The specific LCD provision challenged is stated in LCD L28267 as follows:

> **Non-coverage of transfer factor**
> Taken as a whole, the review does not support transfer factor as a well-accepted therapy for any specific illnesses. In addition, the outgoing contractor contacted a senior practicing allergist and a number of leading university directors of allergy-immunology, none of whom supported transfer factor therapy. In addition, the American Academy of Allergy, Asthma, Immunology specifically wrote the outgoing contractor that there is no good evidence for use of transfer factor therapy (10/2007). Therefore, Medicare does not cover transfer factor therapy or services primarily based to support transfer factor therapy.

CMS Ex. 22, at 5. The contractor-wide statement of the policy of non-coverage of TF therapy and services, i.e., the LCD provision currently in effect and subject to challenge, is the last sentence of the foregoing passage.[25] I construe the preceding three sentences of the passage to be a summary of the basis for the policy decision.

Dr. Calabrese is the treating physician for the 11 APs in this case. She provided a physician's statement for each of the 11 APs certifying that each presents clinically with extensive allergies, including allergic hypersensitivity to chemicals, and abnormal cell-mediated immunity due to hereditary combined Th1 – Th2 immunoregulatory defect. Dr. Calabrese asserts that the APs responded "dramatically clinically to transfer factor immunomodulatory therapy . . . [Th1 specific] and/or preservative-free antigen immunotherapy [Th2 specific]." "Declaration of Dorothy Calabrese, M.D. on Appellants' 'Class of One' due process and equal protection under the 5th Amendment to

[25] LCD L26134 contains a similar passage, the last sentence of which is identical to the LCD provision in LCD L28267.

the US Constitution," at 4.[26] For purposes of a decision at this phase in a LCD complaint, I accept Dr. Calabrese's assertions regarding her treatment of her patients as true as they are uncontested. But the fact that Dr. Calabrese reports success with her patients is not sufficient evidence to show that the LCD is unreasonable for the same reason other anecdotal reports of positive results in individual patients are insufficient. However, I do not mean to suggest that, in the event of a claim denial based upon LCD L28267, an individual beneficiary could never prevail before an ALJ arguing that TF therapy and services are reasonable and necessary for that individual beneficiary, just as a beneficiary did before Judge Sadur. Dr. Calabrese opines and argues that "injections of transfer factor immunomodulatory reagent" are safe, effective, and medically necessary for the treatment of the clinical conditions of the APs. She asserts that "[t]he scientific and clinical evidence on TF meets and exceeds Medicare requirements for coverage." Opposition to CMS Motion to Dismiss Appellants LCD Complaint, dated November 3, 2008. I do not accept her opinions and arguments as statements of undisputed fact, as they are the heart of the issue I must decide and are subject to being weighed in light of the other evidence of record. Though I find Dr. Calabrese's opinions weighty, I do not find that they outweigh the other evidence of record that supports the validity of the LCD.

In deciding the issue, I am required to consider the contractor's findings of fact, interpretations of law, and application of fact to law when applying the reasonableness standard. 42 C.F.R. § 426.450(b)(4). Under the reasonableness standard, I am required to uphold a challenged LCD if the contractor's or CMS's "findings of fact, interpretations of law, and applications of fact to law" are reasonable based upon the LCD record and the relevant record developed before me. 42 C.F.R. § 426.110. The drafters of the regulations explained that legal interpretations of the Act or regulations by CMS or the contractor must be upheld so long as their interpretation is one possible reading of the plain language of the law and can be reconciled with policy, even if the ALJ or the Board may have reached a different result. For factual issues, the drafters expressed the intent that so long as the factual finding by the contractor or CMS "is one that could be reached by a rational person, based upon the evidence in the record as a whole (including logical inferences drawn from that evidence), the determination must be upheld." 68 Fed. Reg. 63,691, 63,703-04 (2003). The drafters specified that so long as the contractor and CMS have some logical reason for the weight they assign certain evidence, I may not overturn that determination simply because I disagree. The drafters also recognized that different judgments by different contractors may be supportable and the mere fact that another contractor has issued a LCD to permit coverage is not reason to find a LCD denying coverage unreasonable. Dr. Calabrese argues in various pleadings in this case that

[26] Dr. Calabrese emphasizes that she does not treat patients with Multiple Chemical Sensitivity Syndrome, contrary to past statements of NHIC staff and the Board in DAB No. 2050, at 4. Declaration, at 4.

initially NHIC and now Palmetto are the only Medicare contractors to issue a LCD denying coverage from TF therapy. However, as the drafters made clear, that is not a basis to find the LCD before me unreasonable.[27]

My review of the LCD record begins with the LCD itself. The active LCD is L28267 and that is the document to which I refer unless otherwise indicated. CMS Ex. 22. The "Definition" section of LCD L28267 states that TF is a term "used in at least four different ways in allopathic and natural medicine," but, for purposes of the LCD, TF "refers to substances in dialyzed leukocyte extracts which affect cellular but not humoral immune function in experimental animals such as mice and in man." CMS Ex. 22, at 4.

The contractor provides a detailed statement of its basis for the conclusion that TF therapy is not reasonable and necessary under Medicare. In the section titled "Literature review," Palmetto discusses the extensive review of scientific and clinical literature on the subject of TF relied upon by the "outgoing contractor" (i.e., NHIC) when promulgating the LCD.[28] Palmetto notes that NHIC reviewed five major clinical immunology journals (*Journal of Clinical Immunology*; *Allergy*; *Clinical and Experimental Allergy*; *Journal of Allergy and Clinical Immunology*; and *Journal of Clinical and Laboratory Immunology*) for articles dealing with TF as a current clinical treatment regimen for any allergy or immunology condition. NHIC found only "[three] very minor clinical research articles" dealing with TF, and "[n]one had convincing clinical results." As stated in the LCD, no TF article had appeared in any of the leading allergy/immunology journals in nearly 20 years, and most were from the early 1980s. CMS Ex. 22, at 4.

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[27] CMS Ex. 1 and Ct. Ex. 1 both indicate that NHIC adopted LCD L26134 due to Dr. Calabrese's post-payment review and overpayment related to many claims she submitted in 2001 and 2002. Adopting a LCD to address a validated problem or anticipated frequent denials is within the discretion of a contractor under MPIM § 13.4B. Thus, it is possible that other contractors identified no need for a similar LCD because few or no claims for TF therapy are filed by or on behalf of Medicare beneficiaries. Dr. Calabrese presented no evidence that claims for TF therapy are paid by other Medicare contractors or insurers.

[28] I find it acceptable for Palmetto to rely upon the prior research of NHIC when promulgating its LCD. The fact that Palmetto relies upon the research of NHIC supports my prior conclusion that the Palmetto LCD is a revision and continuation of the prior NHIC LCD, LCD L26134.

The prior contractor also reviewed over 100 article citations, "2/3 of which were general reviews mentioning transfer factor or basic science publications, with most publications occurring in the 1970s." What NHIC found were very early speculative articles that suggested that TF had "broad benefits." CMS Ex. 22, at 4. According to a statement taken from articles authored in 1973, immunologists had been interested since 1970 in the therapeutic benefits of TF and were using it at the time in a variety of disorders associated with defects in cellular immunity. There were pilot studies that looked at TF "for cancer, neurologic disease such as multiple sclerosis, and leprosy." However, the results were far from promising:

> [P]ositive or weakly positive studies were offset by entirely negative studies (in cancer, multiple sclerosis, atopic dermatitis, etc.) and clinical research dwindled sharply within a decade of the initial speculative clinical interest.

CMS Ex. 22, at 4.

Palmetto states that, to put the studies from the older articles in perspective, NHIC also reviewed 32 textbooks in allergy and immunology published in the USA or U.K. between 1979 and 2004. NHIC found no mention of TF either as a treatment or as a concept in 27 of the textbooks. One textbook cited TF only negatively, and four cited TF "en passant, by definition, or mildly positively." One review chapter in one of the textbooks (Fudenberg, 1989) was "generally positive," but contained a statement by the author that there was skepticism among most physicians as to the efficacy of TF. It is noted that the studies discussed in the chapter were not of high quality; there were many references to "unpublished findings" of the 1970s or 1980s, and there was a dearth of clinical acceptance of TF. Palmetto notes that NHIC also reviewed other titles, abstracts, and full publications. CMS Ex. 22, at 5.

Palmetto concluded that what NHIC found were speculative articles, small pilot studies, studies contradicted by later findings, and, in some cases, withdrawn studies. CMS Ex. 22, at 5. Palmetto's discussion of NHIC's review of the literature on TF therapy indicates that, while there was much early clinical interest in the subject resulting in many speculative studies, the efficacy of TF therapy was never conclusively determined. Palmetto concludes that the sources cited above show that TF therapy is not recognized as accepted therapy for any illnesses. Both conclusions are reasonable based upon the literature reviewed as summarized by Palmetto. Dr. Calabrese admits that the LCD record served upon her includes the clinical and scientific articles that she relies upon in support of using TF therapy for her patients. Motion at 19, ¶ 40.

Palmetto also indicates in the LCD that NHIC contacted a senior practicing allergist and several leading university directors of allergy-immunology, none of whom supported TF therapy. In addition, the American Academy of Allergy, Asthma, and Immunology specifically wrote NHIC, stating that there is "no good evidence for use of transfer factor therapy." Palmetto states that no Blue Cross Blue Shield Technology assessments or positive coverage positions of major insurers were found. No requests for a NCD for coverage of TF or for clinical or basic scientific research studies were found. All Palmetto's findings are consistent with its conclusions based upon the literature view.

In producing the LCD record, CMS submitted over 40 articles from scientific journals, symposiums, and textbooks that discuss experiments and research investigating the nature of TF, as well as clinical studies evaluating the therapeutic efficacy of TF. CMS Exs. 7-9, 12-15, and 17. In addition, CMS submitted over 600 citations to articles and studies involving the therapeutic use of TF. CMS Exs. 11, 16.

What is clear from the LCD record submitted by CMS is that, while researchers initially believed that TF showed promise as a potential form of treatment for various diseases, they also recognized that understanding the role of TF presented many questions. One early article from the 1970s, Huntington Potter et al., *Transfer Factor*, 81 Annals of Internal Medicine 838, 839 (1974) (CMS Ex. 17, at 104-113), stated:

> The potential application of transfer factors to the treatment of diseases rests on the assumption that many diseases are associated with the appearance of new antigens in the body (for instance, leprosy bacilli or tumor antigens). In essence the individual is not responding adequately to these antigens. It is hoped that transfer factors will be found that can stimulate the individual's immune system to recognize and combat the foreign agent.

CMS Ex. 17, at 105.

The article also stated:

> The essence of transfer factors seems to be their ability to mobilize the immune system for response to a specific antigen. This poses the long-range challenge of harnessing these substances for therapeutic use. . . . If the patient is unable to mount a cell-mediated response against the disease-causing agent, it is hoped that transfer factor from a sensitized individual may provide the necessary stimulation.

CMS Ex. 17, at 111-12.

In a 1980 article, Charles H. Kirkpatrick, M.D., *Therapeutic Potential of Transfer Factor*, The New England Journal of Medicine, 390 (1980) (CMS Ex. 17, at 86-87), the author stated:

> The ability of a low-molecular-weight material from sensitized lymphocytes to transfer cell-mediated immune responses to previously unreactive recipients was reported many years ago. During the past decade, there have been several investigations into the possibility that this form of passive sensitization might be efficacious in patients with cancer, autoimmune diseases, immunodeficiency syndromes, or a variety of inflammatory disorders of uncertain origin. The reports have been promising but inconclusive; either too few patients were studied or the "transfer factor" was used in combination with other agents that may have produced similar results. It is still too early to state that transfer factor is appropriate therapy for any of the above diseases.

CMS Ex. 17, at 86.

The author concludes the article with a note of caution:

> Investigators must also recall that treatment with transfer factor has had adverse effects. Even though the relations between transfer-factor therapy, the underlying disease, and the adverse reactions are still unclear, we must be alert to the possibility of adverse effects if an immunologically active agent is administered to patients with abnormal immune systems.

CMS Ex. 17, at 87.

The Third International Symposium on Transfer Factor was held on October 12 through 14, 1978, in Dallas, Texas. CMS submitted as CMS Ex. 13, a collection of papers that were presented at that symposium. The papers cover experimental methods to examine the nature of TF and also discuss patient studies using TF therapy for diseases such as herpes simplex, hepatitis, Behcet's syndrome, chronic mucocutaneous candidiasis, and cancer, among others. The preface states:

> The molecules regulating immune responses are an active area of research in immunology. Transfer factor, a dialyzable component of leukocyte lysates, contains several immune regulators. The isolation and characterization of the immunologically active molecules is being accomplished, and tests for *in vitro* and *in vivo* are being developed. The spectrum of clinical trials ranges from phase I studies to randomized controlled trials.

CMS Ex. 13, at 10 (emphasis in original).

On February 25, 1981, the Immunology, Allergic and Immunologic Diseases Program of the National Institute of Allergy and Infectious Diseases, National Institutes of Health convened a workshop on TF. The workshop had two objectives: "(1) to review the state of the art of transfer factor and (2) to suggest future directions for research in this area, specifically in regard to the prophylactic use of transfer factor for varicella-zoster in leukemic children." CMS Ex. 17, at 59. A workshop paper, Judith G. Massicot, Ph.D. and Robert A. Goldstein, M.D., Ph.D., *Transfer Factor*, 49 Annals of Allergy, 326, 328 (1982) (CMS Ex. 17, at 59-62), concluded by stating:

> For those who have not abandoned the idea that TF, whether an entity or collection of heterogeneous molecules, can have a place in the armamentarium of immunotherapy many nagging questions remain to be answered. While 28 years of intriguing observations have not provided an explanation of the basic mechanisms of TF, some newer developments may present proponents with the opportunity to explore possibilities for investigations to add to the scientific documentation.

CMS Ex. 17, at 61.

The Fourth International Workshop on Transfer Factor was held on October 3 through 6, 1982, in Aspen, Colorado. CMS has submitted as CMS Ex. 14, a collection of papers presented during the workshop. The papers describe the body of knowledge regarding TF at that time and scientific experiments to further understand the nature and mode of action of TF. The papers also discuss studies in which patients with herpes infections and lung cancer, among other diseases, were given TF, both human and bovine. CMS Ex. 14.

The article by David W. Talmage, *The Acceptance and Rejection of Immunological Concepts*, 4 Ann. Rev. Immunol. 1, 9 (1986) (CMS Ex. 17, at 27-32), stated, "[o]ne problem with the concept of transfer factor is that a clear picture of what it is and how it works is lacking. Immunologists are unable to connect it with what is known about

immunoglobulins and T-cell receptors." CMS Ex. 17, at 31. The author stated further, "I am convinced that [transfer factor and suppressor T-cells] are real, but until their recognition systems and the mechanisms of their action are clearly elucidated, I will be skeptical of their physiological significance." CMS Ex. 17, at 31.

Another article on TF published in 1988, Charles H. Kirkpatrick, M.D., *Transfer factor*, 81 J. Allergy Clin. Immunol. 803 (1988) (CMS Ex. 17, at 16-26), discussed the research on TF and described the efficacious clinical effects of TF treatment on patients with certain viral and fungal infections. The author stated, "little is known about the mechanisms of these effects." CMS Ex. 17, at 24.

Among the 36 scientific articles and letters to the editor that comprise CMS Ex. 17, there are 20 articles discussing patient studies that were conducted to determine the efficacy of TF treatment on various diseases and disorders. I have reviewed these studies, and they show that, over the years, researchers have used TF therapy to treat patients suffering from a broad range of diseases and disorders: atopic dermatitis, Hodgkin's disease, chronic mucocutaneous candidiasis, herpes simplex, Epstein-Barr virus/cytomegalovirus infection, Wiskott-Aldrich syndrome, asthma associated with frequent infections, infection and malnutrition in children, leprosy, chronic active Type B hepatitis, multiple sclerosis, leukemia patients with susceptibility to varicella-zoster infection, cutaneous leishmaniasis, Behcet's syndrome, and cancer. *See also* CMS Ex. 8 (H. Hugh Fudenberg, M.D. and H. Haskell Fudenberg, *Transfer Factor: Past, Present and Future*, 29 Annual Rev. Pharmacol. Toxicol., 475, 489-99 (1989) (contains summary of the results of TF therapy in various categories of diseases). The clinical findings reported in these patient case studies showed varying outcomes. I do not discuss any of the patient case studies in detail, but will briefly describe a few.

A study that began in 1976 involved a controlled trial of 15 patients who suffered from frequent infections from severe asthma. Four patients were in the placebo control group, and eleven were in the TF treatment group. The patients, who ranged in age from 3 to 70 years old, were observed from 13 to 22 months. According to the researchers, "[m]arked decrease in respiratory infections and striking improvement in asthma resulted." CMS Ex. 17, at 71 (Amanullah Khan, M.D., F.A.C.A., et al., *The Usefulness of Transfer Factor in Asthma Associated with Frequent Infections*, 40 Annals of Allergy, 229, 229 (1978)). The researchers opined that TF treatment "represents a safe method of reconstituting cellular immunity." CMS Ex. 17, at 74 (Amanullah Khan, M.D., F.A.C.A., et al., *supra* at 232). Although the authors represent in the introduction that this was a controlled study, in fact, only 4 of the 15 received a placebo and then for only one month when the code was broken and all the patients began receiving TF. Supervision for the study was by the patients' physicians and family members who maintained records of drugs, asthma scores, and infections, and provided them to the researchers. CMS Ex. 17, at 71. The researchers indicate that fewer asthma attacks were the result of a decrease in the number of respiratory infections due to that administration of TF. CMS Ex. 17, at 73.

I do not find this study particularly weighty as the control was not maintained, it is not a double-blind study, the results are reported in a very conclusory fashion, e.g., observed decline in infections due to TF without analysis of other possible causes; it is not clear how well patients were supervised; and I do not find a similar study related to infections or asthma that replicates the results alleged.

In a study of 32 patients suffering from Wiskott-Aldrich syndrome, patients were treated with TF. The author reported that clinical benefit was seen in 14 of the 32 patients (44%). The author concluded that TF resulted in "apparent clinical benefit and prolonged survival in some, but not all, patients with the Wiskott-Aldrich syndrome." CMS Ex. 17, at 63 (Lynn E. Spitler, M.D., *Transfer Factor Therapy in the Wiskott-Aldrich Syndrome*, 67 The American Journal of Medicine 59 (1979)).

Several studies involved patients with atopic dermatitis. A 1982 double-blind study involved 12 patients (six men and six women) with severe atopic dermatitis who received TF every other week for one year. The researchers concluded that the results did not show any clinical benefits of TF therapy. CMS Ex. 17, at 33 (Marie Cramers, et al., *Transfer Factor in Atopic Dermatitis*, 164 Dermatologica 369, 369-70 (1982)); see also CMS Ex. 17, at 51 (H. Thulin, et al., *Long-Term Transfer Factor Treatment in Severe Atopic Dermatitis*, Acta Allergologica, 236, 246 (1977)) (Researchers noted "slight improvements," but concluded "no convincing effect of [TF] therapy was encountered in immune parameters and no major alterations were found in the status of the patients' atopic dermatitis.")

In a controlled randomized study, 47 patients with Hodgkin's disease undergoing treatment were given TF to determine if it would enhance their immune status and reduce the incidence of infection – 22 patients received TF; 25 received a placebo. Researchers concluded that TF had no effect in preventing infections (including varicella/zoster). CMS Ex. 17, at 11-15 (B.W. Hancock, et al., *Transfer Factor in Hodgkin's Disease: a Randomized Clinical and Immunological Study*, 24 Eur. J. Cancer Clin. Oncol. 929-33 (1988)).

Another disease treated with TF therapy was chronic mucocutaneous candidiasis, a fungal disease. In a 1974 article, Huntington Potter, et al., *Transfer Factor, supra*, the authors noted that 25 patients had been treated with TF, and that 14 "showed marked clinical improvement with eradication of the disease or sustained remission." CMS Ex. 17, at 112. In a 1988 article, Charles H. Kirkpatrick, *Transfer Factor, supra*, the author noted that more than 60 patients with chronic mucocutaneous candidiasis have been treated with TF. The author described one study of 12 patients, and stated that patients received monthly injections of TF for four months, after which TF was given at two to four month intervals. The author stated that "[i]n spite of the fact that all patients developed cellular immune responses . . . to *Candida*, there was no evidence that treatment with [TF] alone provided clinical benefits." CMS Ex. 17, at 22. Another study

was conducted to evaluate the effects of TF on the durations of remissions that were induced with intravenous amphotericin B. The author concluded that the results indicated that "combination of treatment with both antifungal and immunologic therapy provides the best long-term results." CMS Ex. 17, at 23.

The patient studies are enlightening regarding clinical investigation of TF but show that TF therapy has raised more questions than were answered. Where certain patient studies indicated that TF might have played a role in easing symptoms or the progression of disease, it is clear that researchers remained cautious about making any conclusive pronouncements as to its efficacy.

None of the patient studies discussed in the articles or papers submitted by CMS involved patients receiving TF therapy for the clinical indications Dr. Calabrese seeks to treat – allergies, including allergic hypersensitivity to chemicals, and abnormal cell-mediated immunity/delayed type hypersensitivity. The absence of evidence of studies showing the efficacy of TF for allergies, including allergic hypersensitivity to chemicals, and abnormal cell-mediated immunity/delayed type hypersensitivity, is consistent with the Palmetto and CMS position that TF has not been shown to be efficacious or safe and effective for those diagnoses.

After considering the rationale set forth in LCD L28267 and the LCD record, I cannot conclude that the contractor's findings of fact, interpretations of law, and applications of fact to law are unreasonable. The absence of scientific evidence is a basis upon which a rational person may conclude that TF therapy has not been shown to be safe and effective for the treatment of allergies, including allergic hypersensitivity to chemicals, and abnormal cell-mediated immunity/delayed type hypersensitivity or any other diagnosis.

However, it is also necessary to consider the extensive collection of scientific articles produced by Dr. Calabrese before it can be decided whether or not the LCD is valid. The regulations provide that the APs have the burden of proof and persuasion on the issues raised by the complaint. 42 C.F.R. § 426.330.

To counter CMS's position that TF is not safe and effective, Dr. Calabrese submitted 304 articles and letters from scientific and medical journals and extracts from textbooks in support of her position that TF is a safe and effective treatment for those with allergies, or allergic hypersensitivity to chemicals. I have reviewed all of the scientific and medical literature submitted by Dr. Calabrese. I conclude that the materials submitted by Dr. Calabrese do not show unreasonable, the decision of the Medicare contractor that TF therapy and services are not reasonable and necessary and not covered by Medicare.

Included among the exhibits submitted by Dr. Calabrese are over 30 exhibits containing scientific case studies in which researchers conducted TF experiments on animal models. TF experiments were conducted on rhesus monkeys (A.P. Exs. 16, 65); mice (A.P. Exs. 20, 58, 65, 66, 92, 96, 99, 107, 111, 127, and 132); guinea pigs (A.P. Exs. 22, 34, 90, 125, 130, and 133); non-human primates (chimpanzee, two baboons) (A.P. Ex. 37); dogs (A.P. Ex. 120); and rats (A.P. Ex. 121).[29] Inasmuch as these studies are not human studies, they are wholly inadequate as support for Dr. Calabrese's position and are an insufficient basis for finding TF to be an effective, reasonable, or necessary treatment for humans.

Dr. Calabrese also offered articles of experimental mice studies in the area of chemical allergy, a significant occupational health issue. A.P. Exs. 152, 209, 210, 223, 224, 226, 227. In these studies, usually using a method called cytokine profiling, researchers exposed mice to various chemical allergens to examine their immune responses and attempted to discriminate between contact and respiratory allergens. A.P. Ex. 152. The researchers did not use TF in these experiments and made no mention of TF in any of the articles. As with the other animal studies submitted by Dr. Calabrese, I find these mice studies to be an insufficient basis for finding TF to be an effective, reasonable, or necessary treatment for humans.

Dr. Calabrese also offered 27 exhibits comprising research on the effects of exposure to environmental pollutants, particularly diesel exhaust particulates (DEP), on respiratory function. A.P. Exs. 153-79. In these studies, researchers exposed both animals (mice and rats) and humans to DEP to explore the correlation between DEP and allergic respiratory disease. These studies of DEP exposure did not involve TF and contained no discussion related to TF. I find these studies to be an insufficient basis for finding TF to be an effective, reasonable, or necessary treatment for humans.

Included among the other exhibits submitted by Dr. Calabrese are articles discussing over 60 patient case studies in which TF was used to treat the following diseases and disorders: agamma globulinemia (A.P. Ex. 139); asthma (A.P. Ex. 64); atopic dermatitis (A.P. Exs. 57, 59, 115); Behcet syndrome (A.P. Ex. 41); bullous pemphigoid (A.P. Ex. 64); chorioretinitis (A.P. Ex. 69); chronic mucocutaneous candidiasis (A.P. Exs. 15, 18, 29, 31, 40, 55, 60, 65, 72, 74, 75, 77, 89, 97, 108, 110, 135, 136, 225); coccidioidomycosis (A.P. Ex. 25); cryptococcus (A.P. Ex. 53); cytomegalovirus retinitis (A.P. Ex. 101); herpes (A.P. Exs. 24, 33, 113, 134); Hyperimmunoglobulin E syndrome (A.P. Exs. 42, 63); lupus vulgaris (A.P. Ex. 57); multiple sclerosis (A.P. Ex. 17); mycosis fungoides (A.P. Ex. 138); otitis media (A.P. Ex. 61); paracoccidiomycosis (A.P. Ex. 82); protein-calorie malnutrition (A.P. Exs. 60, 128); respiratory tract infections in children (A.P. Exs. 52, 132); rheumatoid arthritis (A.P. Ex. 43); sarcoidosis (A.P. Ex. 57);

[29] Researchers also conducted TF experiments involving human lymphocytes and guinea pig, rabbit, and sheep erythrocytes. A.P. Ex. 80; *see* A.P. Exs. 56, 106.

subacute sclerosing panencephalitis (A.P. Ex. 126); tuberculosis (A.P. Exs. 100, 118, 131, 133, 140); uveitis (A.P. Ex. 8); and Wiskott-Aldrich syndrome (A.P. Exs. 28, 75, 109, 112, 112). The patient case studies listed above, some of which are included in the LCD record, reflect mixed results at best. The case studies did not involve and thus do not provide a scientific basis to conclude that TF therapy is efficacious for patients who suffer from allergies, or allergic hypersensitivity to chemicals.

One exhibit submitted by Dr. Calabrese, A.P. Ex. 211, at 5-20 (4 William J. Rea, M.D., *Chemical Sensitivity* 2721-42 (1997)), does discuss a study undertaken at the Environmental Health Center in Dallas, Texas, of "50 chemically sensitive patients" who were administered TF for 6 to 12 months. The authors state that the participants were 8 males and 42 females, ranging from 7 to 75 years. They state that prior to and concurrent with receiving TF therapy, a "large number of the patients" were on "antigen immunotherapy and adopted environmentally less-toxic or less-allergenic living habits, both of which were required criteria" in order to participate in the study. A.P. Ex. 211, at 14. The purpose of having these criteria, according to the authors, was to allow them to have "a steady-state environment in order to evaluate TF therapy more thoroughly." A.P. Ex. 211, at 14. Explaining the criteria further, the authors state that the patients were advised to eliminate carpet, natural gas fuel, and create an oil-free environment, and were required to "use chemically less-contaminated food and water." A.P. Ex. 211, at 6. A majority of the patients received supportive immunotherapy "for sensitivity reactions to biological inhalants, foods, and/or chemical sensitivities." A.P. Ex. 211, at 6.

The authors note that these patients had failed to improve after receiving other treatments. The authors state that the TF was prepared using blood from 30 to 40 random healthy donors obtained from a blood bank. A.P. Ex. 211, at 6, 19. The patients were given blood tests in order "to develop laboratory criteria for treatment and for monitoring" their treatment. A.P. Ex. 211, at 6. Also, the patients' "delayed-type hypersensitivity responses" to seven antigens were tested using a cell-mediated immunity (CMI) test kit, which contained the antigens tetanus, diphtheria, streptococcus, tuberculin, candida, trichophyton, and proteus. The authors state that they read the number of positive dermal reactions at 48 hours, and a "reaction was considered positive if the average diameter was greater than 2 mm." If the reaction was negative or less than 2 mm in diameter, it was scored as zero. The authors state that they periodically measured, approximately every three months, the patients' T and B lymphocytes and CMIs to determine whether there were any changes. A.P. Ex. 211, at 7. According to the authors, they divided the patients in the study into four groups "[i]n order to establish their immune differences": (1) those with "normal T and B lymphocyte numbers and normal CMI response"; (2) those with "abnormal T and B lymphocyte numbers and abnormal CMI response"; (3) those with "normal T and B lymphocyte numbers and abnormal CMI response"; and (4) those with "abnormal T and B lymphocyte numbers and normal CMI response." A.P. Ex. 211, at 7.

The authors state that each patient received one unit of TF twice a week, either via subcutaneous or intramuscular administration. A.P. Ex. 211, at 7. They explain that the dosage was arbitrarily picked "on the basis of previous studies by others of nonchemically sensitive patients." They chose the frequency of administration "based on the observation that most of our patients did well on food injections every 4 days rather than longer and the observation in 12 hours of study of chemically sensitive patients that they did do as well with administration at 7-day intervals." A.P. Ex. 211, at 7. Each patient kept a symptom score sheet, which he or she was required to fill out before and after the six to twelve months of TF therapy. They were asked to note the frequency and severity of the following symptoms: "hypersensitivity reactions to incitants, cephalgia, recurrent infections, fatigue, gastrointestinal problems, depression, and lack of concentration." A.P. Ex. 211, at 7. The patients gave responses based on a scale of 1 to 5, and based on their scores, they were categorized as "improved" or "no change" in their symptoms. A.P. Ex. 211, at 7. In analyzing the results, the authors "examined the correlation of improved clinical status to the increase in the number of WBC [white blood cells], lymphocytes, T cells, T cell subpopulations, B cells, and CMI response in TF recipients." A.P. Ex. 211, at 8.

The authors report that 39 of 50 patients (78%) showed some improvement with TF therapy in one or more of their symptoms. A.P. Ex. 211, at 8. According to the authors, the study results showed that the patients improved in eight clinical parameters. A.P. Ex. 211, at 14. The authors report that "the cumulative data indicated that a substantial portion of the patients (73.5%) exhibited an increase in their CMI, in the number of the B and T lymphocytes (62.1%), and in both of these parameters (95.5%)." A.P. Ex. 211, at 8-9. The authors note that TF seemed to have the most effect in providing relief from severe fatigue (69.4% of the patients), and from frequent, recurrent infections (70.6% of the patients). The symptoms that were the least affected by TF were arthritis and gastrointestinal problems. A.P. Ex. 211, at 8. The authors state that "22% of the patients demonstrated no improvement in their clinical status, and a minor population showed no change or a decrease in their immune parameters." A.P. Ex. 211, at 8. According to the authors, there was an increase in numbers of lymphocytes and T cells (T11, T4, and T8) in 18 patients. The authors report that, in every category of cell population, except for T8 cells, there was a substantial, statistically significant increase. A.P. Ex. 211, at 13. They state, however, that the increases "were not universal." They note that two patients had a decrease in lymphocyte numbers, one had a decrease in total T cells, and another had a decrease in T4 cells. In four patients, the total number of T8 cells went down. The authors state that the decreases occurred inconsistently, in different patients and cell populations, and opine that TF therapy could not be directly responsible for the results. A.P. Ex. 211, at 14. In examining the results according to patient category (four categories as described above), the authors report the following:

> There were 11 of 14 patients (78.6%) on TF who demonstrated no tested immunologic abnormalities at the start of the trials and reported clinical improvement, while 3 of 14 (21.4%) perceived no change; . . . 16 of 17 (94%) patients who exhibited numerical abnormalities of their lymphocytes or T-cells as well as impaired CMI response reported clinical improvement, while the remaining patient (6%) experienced no change. . . . Of those patients who had normal numbers of lymphocytes but had abnormal CMI response, 10 of 13 (77%) showed no improvement while 3 of 13 (23%) reported no change. . . . The sample size in the category of patients who had abnormal numbers of lymphocytes or lymphocyte subpopulations and normal CMI was too small for drawing statistical conclusions in this study.

A.P. Ex. 211, at 14. The authors note that the TF preparation was chemically complex, "with over 100 different molecules," and that it is therefore "difficult to assign specific functional activity to each molecule." A.P. Ex. 211, at 18. They state that all of the various TF components "appear to modulate biological and immunoregulatory functions and may be responsible for the changes observed in our patients." A.P. Ex. 211, at 18. They state that a small number of patients were taken off TF therapy because they did not tolerate it and experienced adverse symptoms such as muscle and joint aches, "cold or flu-like" symptoms, slight fever, and local swelling or pain where they were injected. A.P. Ex. 211, at 18. To explain these symptoms, the authors state that the patients may have reacted to interferon or had other sensitivity reactions. A.P. Ex. 211, at 18. The authors conclude that "[f]or the vast majority of our patients, TF therapy was utilized without complications and proved to be quite safe as well as effective." A.P. Ex. 211, at 18. In their concluding comments about this study, the authors further note that they had subsequently treated an additional 1000 chemically sensitive patients with TF, and obtained results from that study similar to those of their 50-patient study. A.P. Ex. 211, at 14, 20.

I do not find this 50-patient study or the authors' conclusion that TF was safe and effective for many of the patients, weighty for the following reasons. In describing the parameters of the study, the authors gave no indication that they conducted a placebo-controlled, double-blind clinical trial. They stated that 50 patients participated in the study and were divided into four groups, and all 50 received TF therapy. There is no indication that a control group was part of the study. A more credible scientific study would have used a separate control group, consisting of people who would have been given a placebo instead of receiving actual TF treatment. Having a control group allows a comparison of the results obtained from those receiving the treatment with those who did not receive the treatment. The authors' failure to conduct the study as a double-blind trial, though not required, further indicates that their results are subject to researcher

bias.[30] The authors stated that for the 50 patients the duration of participation varied from 6 to 12 months. However, the authors do not explain how they determined how long each patient would receive TF therapy. Moreover, the authors stated that "[a] large number of the patients previously and concurrently used antigen immunotherapy and adopted environmentally less-toxic or less-allergenic living habits, both of which were required criteria for entering the study." A.P. Ex. 211, at 14. Earlier in the article, the authors stated that "[f]ifty patients who intended to undergo treatment with TF were advised to adopt environmentally safe practices, eliminating carpet and natural gas fuel and creating an oil-free environment. Also, they were required to use chemically less-contaminated food and water." A.P. Ex. 211, at 6. Based on the authors' remarks, it is apparent that the patients' environments and other therapy likely played a role in this study. However, their report does not distinguish the effect of environmental changes and other therapy from the effect of TF therapy and there is no evidence that the study was designed to permit such discrimination. The report suggests that study participants lived in their homes with minimal supervision to ensure compliance with study protocol. The authors of the study claim to have had a "steady-state environment," but there is no evidence in the report to support that they actively ensured that each patient's environment was controlled throughout the study, and that all patients' environments were the same or consistent. Accordingly, I do not find the 50-patient study sufficiently credible or weighty to provide a basis for finding the challenged LCD provision invalid.

In A.P. Ex. 211, following the discussion of the 50-patient study, there is a case study report of a 37-year-old chemically sensitive woman with eczema who was treated with TF, and showed clinical improvement. A.P. Ex. 211, at 20-24. The patient had had eczema and asthma as a child, experienced skin flare-ups from foods, detergents, and other products, and also had severe urticaria from foods. The patient had tried different types of therapy and was resistant to most treatment, except steroids. Initially, bathing in sea water helped in healing, but at the time of the study, she could no longer tolerate it. A.P. Ex. 211, at 20. The patient exhibited a scaly rash over her upper trunk and upper extremities and upper legs. She was admitted to an environmentally clean room made of tile. She fasted for four and one-half days and noted that her symptoms, while not clearing completely, did lessen. Tests indicated that she "had sensitivity to 50 foods, molds, lake algae, T.O.E., candida, dust, mites, smuts, histamine, serotonin II, trees, weeds, terpenes, fluogen, MRV, Nystatin, orris root, newsprint, perfume, formaldehyde, and phenol." A.P. Ex. 211, at 21. In tests of chemical exposure, the patient exhibited symptoms to phenol, insecticide, chlorine, formaldehyde, and natural gas. She did not exhibit symptoms to ethanol and normal saline. A.P. Ex. 211, at 21. The study states that the patient was treated with "an environmentally clean oasis at home, chemically less-contaminated foods and water, as well as injections for sensitivity to foods and

[30] In a double-blind trial, neither the participants nor the researchers know who is in the treatment group and who is in the placebo group.

inhalants." A.P. Ex. 211, at 22, 24. As a result of this treatment, she improved somewhat and discontinued taking steroids. Because hot weather aggravated her, she moved from New Orleans to Chicago. The patient discovered that living in the North, and continuing to receive injections, helped her control her food sensitivity. A.P. Ex. 211, at 24. In October 1986, the patient began receiving two units of TF a week, and continued on this schedule for two years. The study reports that her skin cleared, and she showed an increased number of lymphocytes, total T cells, T helper, and T suppressor cells. The study states that "[h]er cell-mediated immunity improved markedly," she felt much better, and her skin remained clear as of July 19, 1990. A.P. Ex. 211, at 24. The study does suggest that TF was beneficial in treating the patient's skin; however, the authors do not distinguish between the effects of TF therapy and the other changes in the patient's environment and other therapies. I do not find this anecdotal report of beneficial effect of TF adequate to show that TF therapy is safe and effective. Accordingly, I do not find the case study to be sufficiently weighty to provide a basis for finding the challenged LCD provision invalid.

In addition to the host of articles she submitted, Dr. Calabrese also points to the 1989 decision issued by ALJ Sadur in support of her position. A.P. Ex. 183. As I previously discussed, in that case, Judge Sadur considered an individual beneficiary's Medicare Part B claim and found that TF immunomodulatory reagent was medically reasonable and necessary to treat the beneficiary's allergies. Judge Sadur's decision indicates that the Medicare contractor denied the claim for TF because it was experimental and not reasonable and necessary with no controlled studies of the usefulness of TF for treatment of allergies and possible undesirable side effects. A.P. Ex. 183, at 2. Judge Sadur's decision indicates that he found the evidence showed that the individual beneficiary in that case had experienced beneficial effects from TF therapy and concluded that TF therapy was reasonable and necessary for that beneficiary. A.P. Ex. 183, at 4. Judge Sadur's decision is not binding precedent and does not control the decision in this or any other case. 42 C.F.R. § 405.1062. Further, the issues in Judge Sadur's case and the matter before me are completely different. The issue before Judge Sadur was whether or not it was reasonable and necessary at the time he decided the case of that individual beneficiary, for that beneficiary to have TF therapy and receive coverage for such treatment. Typically in individual Part A and B cases, neither CMS nor the contractor is present or provides any evidence in addition to the file related to the denied benefit, and the ALJ gives significant, if not controlling weight, to the opinion of the treating source, at least to the extent it is supported by the beneficiary's clinical record. Judge Sadur's decision reflects no consideration of evidence submitted by the contractor or CMS and turns on the fact that the beneficiary was reported to have benefited from TF therapy. In the matter before me, the issue is whether or not the LCD record is complete and adequate to support the validity of the challenged LCD provisions under the reasonableness standard, and I must uphold the validity of the LCD if the contractor's

findings, interpretations of law, and application of fact to law are reasonable in light of the LCD record and the evidence submitted by the APs. Though Judge Sadur's opinion reflects that the appeal of an individual beneficiary can result in a finding that TF is reasonable and necessary, it is not weighty evidence that the LCD in this case is not valid.

Dr. Calabrese has also offered the statement of Dr. Alan S. Levin (A.P. Ex. 184), the declaration of Dr. Douglas Sandberg (A.P. Ex. 184), and the affidavit of Dr. Gerald Ross (A.P. Ex. 185) for my consideration. Each of these physicians opined that TF therapy is safe and effective for the treatment of allergies. However, other than citing to studies of other diseases where TF therapy was shown to be efficacious or making general and conclusory statements, none of their statements cited or discussed any published studies in scientific or medical literature where TF treatment was used to treat patients with allergies or allergic hypersensitivity to chemicals. Therefore, their opinions are unsupported and not weighty.[31]

Based upon my evaluation of the LCD record and the voluminous record submitted by Dr. Calabrese, I conclude that the contractor's findings of fact, interpretations of law, and applications of fact to law are reasonable. 42 C.F.R. § 426.450(b)(4). I am required to uphold a challenged LCD if the contractor's or CMS's "findings of fact, interpretations of law, and applications of fact to law" are reasonable based upon the LCD record and the relevant record developed before me. I have no hesitation upholding the LCD as reasonable in this case. Dr. Calabrese has presented no evidence that tends to show that TF is efficacious for the treatment of allergies, including allergic hypersensitivity to chemicals, and abnormal cell-mediated immunity/delayed type hypersensitivity.[32]

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[31] Dr. Calabrese often refers to her experts, particularly Dr. Levin, as being "Daubert qualified." Dr. Calabrese's use of the phrase "Daubert qualified" is apparently intended to indicate that the individuals have previously been qualified to testify to their opinions as scientific experts in other proceedings. In *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), the Supreme Court addressed the standard for admitting expert scientific testimony in a federal trial, rejecting the "general acceptance" test from *Frye v. United States*, 54 App. D.C. 46, 293 F. 1013 (1923), and holding that the standard for admissibility is that stated in Federal Rule of Evidence 702. The fact that one may be found qualified under Rule 702 to render opinions as a scientific expert in a proceeding does not mean that the opinions rendered are necessarily credible.

[32] Dr. Calabrese has not even presented evidence that TF was efficacious for the 11 APs or her other patients except for some testimonial letters of her patients (A.P. Ex. 193) that give no insight into their actual treatment so that one could credibly draw conclusions regarding the efficacy of TF therapy.

4. Pursuant to 42 C.F.R. § 426.425(c)(2), the review process is complete upon issuance of this decision.

The LCD record is complete and adequate to support the validity of the challenged LCD provisions under the reasonableness standard. "Issuance of a decision finding the record complete and adequate to support the validity of the LCD ends the review process." 42 C.F.R. § 426.425(c)(2).

5. Appeal rights. 42 C.F.R. §§ 426.462, 426.465.

Pursuant to 42 C.F.R. § 426.465(a), an aggrieved party may request review by the DAB. Except upon a showing of good cause, a request for review by the DAB must be filed within 30 days of the date of this decision (42 C.F.R. § 426.465(e)) and must comply with the requirements of 42 C.F.R. § 426.465(f).

III. Conclusion

The LCD record is complete and adequate to support the validity of the LCD provisions at issue under the reasonableness standard and review of the challenged LCD is complete.

/s/ Keith W. Sickendick
Administrative Law Judge