Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

SUBJECT: NCD Complaint – Intraocular Lens (CMS Ruling 05-01)
Docket No. A-10-97
Decision No. 2418
October 21, 2011

DECISION

On November 22, 2010, the Departmental Appeals Board (Board) acknowledged an acceptable complaint from the aggrieved party (AP) challenging a national coverage determination (NCD) barring coverage of presbyopia-correcting intraocular lenses (PC-IOL) inserted after cataract surgery. After reviewing the NCD Record and the AP's contentions, we uphold the validity of the NCD for the reasons explained in detail below.

Procedural background

The AP originally filed an unacceptable complaint on September 9, 2010. Pursuant to 42 C.F.R. § 426.510(c), the Board provided the AP an opportunity to amend the complaint to meet the standards required for an acceptable complaint, which the AP did by submissions dated October 29, 2010 and November 9, 2010. The AP challenged Medicare's policy that denies coverage for the implantation of a "multifocal lens" or PC-IOL after cataract surgery. AP September 9, 2010 letter at 1. The AP asserted that he was in need of coverage because he chose to have multifocal lenses inserted after cataract surgeries on both eyes and found them superior in various ways. AP Letter, October 29, 2010 at 1.

The Board has jurisdiction to review NCDs under section 1869 of the Social Security Act (Act)[1] and implementing regulations at 42 C.F.R. Part 426. Consistent with the regulations, the Board ordered the Centers for Medicare & Medicaid Services (CMS) to produce the NCD Record for the AP to review.

[1] The current version of the Act is at http://www.socialsecurity.gov/OP_Home/ssact/ssact.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. A cross-reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

CMS initially moved to dismiss the appeal on the ground that the policy barring coverage of PC-IOLs is not an NCD, but rather a CMS Ruling, not subject to appeal. CMS Memorandum in support of CMS Motion to Dismiss (CMS Memo) at 1. In a ruling dated June 16, 2011, which we incorporate by reference and include as an attachment to this decision, the Board held that the definition of an NCD does not depend on its title or the process by which it is issued. Instead, the Board held, an NCD is any Secretarial determination as to "whether or not a particular item or service is covered nationally" under Medicare (except for a determination about what code to assign or the amount of payment to be made). Act § 1869(f)(1)(B); Board Ruling at 2-3. After the Board Ruling was issued, CMS produced the administrative record for CMS Ruling No. 05-01, issued May 3, 2005, CMS Manual Pub. No. 100-04 (Change Request 3927). We cite to pages in this NCD record as NCD Record at xx.

After receiving the NCD record, the AP had an opportunity to submit a statement explaining "why the NCD record is not complete, or not adequate to support the validity of the NCD under the reasonableness standard." Board Notice of Acceptable Complaint at 2. After requesting and receiving an extension of time, the AP advised the Board that he did not wish to submit any additional material and asked that the matter be decided on the record already developed before the Board. The Board therefore closed the record and determined to proceed to decision on the written record. Subsequently, on October 3, 2011, the AP filed a motion to reopen the record which we address below.

Standard of review and review process

Section 1869(f)(1)(A)(iii)(I) of the Act limits the Board's review of an NCD "to evaluat[ing] the reasonableness" of the NCD. Section 1869(f)(1)(A)(iii)(III) provides that the Board "shall defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary." This reasonableness standard requires the Board to uphold an NCD "if the findings of fact, interpretations of law, and applications of fact to law" by CMS are reasonable based on the NCD record and the relevant record developed before the Board. 42 C.F.R. § 426.110.

The regulations provide for a two-stage process before the Board: (1) If the Board finds the NCD record to be complete and adequate to support the validity of the NCD, the Board will issue a decision to that effect, ending the review process; or (2) If the Board finds the NCD record not to be complete and adequate to support the validity of the NCD, the Board will go forward with the review process by permitting discovery and the taking of evidence, including holding a hearing if appropriate. 42 C.F.R. §§ 426.525(c), 426.531.

Analysis

1. The challenged NCD states a policy that PC-IOLs are not covered by an exception to the general bar on Medicare payment for eyeglasses or contact lenses.

Section 1862(a)(7) of the Act establishes a statutory benefit exclusion precluding Medicare from covering eyeglasses or contact lenses. *See also* NCD Record at 1. Section 1861(s)(8) establishes an exception to this exclusion of eyeglasses and contact lenses by authorizing Medicare to cover "prosthetic devices . . . which replace all or part of an internal body organ . . . including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens." (Emphasis added.)

An intraocular lens (IOL) is a disk inserted into the eye after the removal of a cataract to replace the "distance focusing power" of the natural lens. NCD Record at 2. Presbyopia is "an age-associated and progressive loss" of the ability to focus on objects close up. *Id*. A PC-IOL corrects for this loss of ability to focus on close-up objects. *Id*. The policy in CMS Ruling No. 05-01 provides that Medicare will not pay for (and the beneficiary is responsible for payment of) any additional facility charges and physician services for insertion of a PC-IOL exceeding the charges for resources required for insertion of a conventional IOL. *Id*. at 4.

CMS Ruling No. 05-01 recognizes that a single PC-IOL "essentially provides what is otherwise achieved by two separate items: an implantable conventional IOL . . . and eyeglasses or contact lenses." *Id*. at 3. The NCD concludes that the statute provides for coverage of a lens to replace the one removed by surgery and for a single pair of eyeglasses or contact lenses but not for coverage of insertion of a lens to perform both functions. *Id*. The NCD permits beneficiaries to elect insertion of PC-IOLs during surgery but provides that the beneficiary will be responsible for the cost of the lens and the additional facility or physician charges exceeding the charges for conventional lens insertions. *Id*. at 4.

2. The NCD Record is complete and adequate.

As we have noted, the AP chose not to respond to the NCD Record provided to him, electing to rest on the arguments and materials he had already submitted. We have reviewed the NCD Record and the AP's submission in order to make our initial determination as to whether that Record is complete and adequate to support the validity of the NCD or whether it is necessary to go forward to accept new evidence.

The NCD Record provided by CMS includes Food and Drug Administration approval letters and labeling information for specific PC-IOL models (NCD Record at 7-13, 47-125); internal CMS e-mail discussion about whether the insertion of the new type of lens is non-covered as a refractive service (*id*. at 14-15); a legal brief arguing that beneficiaries should be allowed to pay out of pocket for the selection of PC-IOLs (which seems to have been allowed under the NCD as issued)(*id*. at 20-26); correspondence to and from manufacturers, patients, and congressional offices (*id*. at 18-19, 27-33, 42-48, 52); and a journal article addressing the issue of "balance billing" for Medicare beneficiaries opting for the PC-IOL (*id*. at 34-37).

We see nothing in the NCD Record itself that demonstrates that CMS's interpretation of the statutory exclusion as barring coverage of intraocular lenses is unreasonable. Indeed, the submissions made to CMS by various correspondents do not focus on the question of extending Medicare coverage to pay for such lenses or their insertions. The focus instead was on whether the method of payment for cataract surgery treating the lenses as "bundled" with the surgery in some situations should be changed to permit patients to pay separately for the PC-IOL option if they chose to while Medicare covered the costs that would be incurred had the conventional lens been inserted.

The AP did not submit anything that undercuts the reasonableness of CMS's statutory interpretation either. The materials submitted by the AP include patient information relating to one brand of PC-IOL. AP Letter, October 29, 2010, attached Exs. 2, 3, and 4. The primary benefit promoted for selecting PC-IOLs is "the opportunity for freedom from reading glasses and bifocals." AP Letter, October 29, 2010, attached Ex. 2 at 1. If anything, this material substantiates CMS's conclusion that PC-IOLs amount to refractive correction treatments that do not meet the statutory exception of being a pair of eyeglasses or contact lenses supplied after cataract surgery.

3. <u>The AP's legal arguments lack merit.</u>

The AP raised both legal and factual arguments in his various submissions which we address in turn. As to legal issues, the AP contends that the reasonableness standard set out in 42 C.F.R. § 426.110 "is legally invalid because it lacks a value standard, or touchstone" and may be "legally void for vagueness" and that the NCD violates statutory prohibitions against interference with the practice of medicine. AP Letter, October 29, 2010 at 2-3.

The reasonableness standard set out in the regulations merely tracks the wording of the Act. *See* Act § 1869(f)(1)(A)(iii)(I) and (III); 42 C.F.R. § 426.110. Thus, any argument about vagueness amounts to an attack on the validity of a federal statute, a subject beyond the scope of our review.

The AP also seems to misunderstand the role of the reasonableness standard, arguing that it is "*defined* by reference to Board action involving evidence to be adduced." AP Letter, October 29, 2010, at 2 (emphasis in original). Board action does not define the standard. Congress has effectively instructed the Board to defer to CMS's factual findings, legal interpretations, and applications of law unless the Board concludes that they cannot reasonably be upheld. Our review is de novo in that we may take new evidence if we find that the NCD record is not complete and adequate, but the standard to be applied in our review is highly deferential to CMS as the agency directly charged with implementing Medicare law. This standard of review is simply one of the various appellate standards, such as "clear error," or "substantial evidence," which are familiar to jurisprudence. We therefore find no basis for the contention that a specific "touchstone" of some kind is required in order to understand how to apply it.

The AP cites the following Medicare provision in arguing that the NCD interferes improperly in medical practice:

> Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

Act § 1877. The AP argues in essence that the NCD allows "government bureaucrats" to deny medical care that a physician believes is reasonable and necessary. AP Letter, October 29, 2010, at 3. This argument is without merit.

First, as explained above, the NCD is not based on a determination about medical necessity at all, but rather is an interpretation and application of a statutory benefit exclusion. Second, the NCD does not supervise or control any medical practice or provision of medical services. Instead, the NCD explains the scope of coverage for which the federal government will make payment under the Medicare program. Moreover, reading section 1877 as mandating that Medicare pay for all possible services and items in order to provide incentives for medical research and development, as the AP

suggests, would be inconsistent with the Medicare statutory scheme as a whole which contemplates coverage of specific benefit categories and exclusions to them. *Cf.* AP Letter, September 9, 2010, at 1. (Notably, for example, Medicare generally does not cover investigational and experimental devices. *See* 42 C.F.R. Part 405, subpart B). Thus, even if we accepted the AP's claims that non-coverage interferes with medical practice generally by deterring advances in lens technology, that would not, by itself, be a basis for finding the NCD invalid.

4. The AP's factual and policy arguments are unsupported.

The AP argues that CMS has unreasonably denied coverage for "the best available lens given the patient's need, because of cost, without making a study and evaluation of the actual lower costs resulting from covering the lens." AP Letter, October 29, 2010, at 3. The AP does not provide any documentation supporting the claim that the determination not to cover PC-IOLs was made because of cost or that an evaluation that determined the actual cost of PC-IOLs to be lower would necessarily alter that determination.

The NCD does not reference comparative cost as a reason for restricting coverage to conventional IOLs. Instead, the NCD relies on an interpretation of the statutory benefit categories. Specifically, the NCD notes that Medicare coverage is available for insertion of a lens when a cataract is removed as part of treating illness or injury or "improving the functioning of a malformed body part" (Act § 1862(a)(1)(A)) but that the statute bars any coverage of eyeglasses or examinations or procedures to determine the refractive state of the eyes. NCD Record at 2; Act § 1862(a)(7). Section 1861(s)(8) makes an exception to this bar for coverage of a single pair of conventional glasses or contact lenses after cataract surgery. The rationale for the non-coverage NCD is that, while PC-IOLs provide the same functionality as a pair of glasses or lenses in terms of refractive correction, they are not eyeglasses or contact lenses within the meaning of section 1861(s)(8). A conventional IOL merely replaces part of an internal body organ that is malformed – PC-IOLs go beyond that replacement to also correct refractive vision. Hence, they do not fall into the single exception to the coverage restriction on refractive corrective devices or services.

The AP also complains that Medicare's requirement that requests for payment of claims for PC-IOLs must be submitted by the provider or supplier, rather than the patient, is an attempt to ensure that the AP is unable to obtain coverage from a secondary carrier for lack of a Medicare claims denial for the service. AP Letter, October 29, 2010, at 3. He contends that this requirement is unreasonable because the physician is prohibited from claiming payment for the PC-IOL under the NCD. *Id*. This argument is undercut by the claims denial form submitted by the AP himself, which indicates not only that the

supplier had to submit the claim but also that "Medicare does not pay for this item or service" in reference to the intraocular lens inserted. AP Letter, October 29, 2010, attached Exs. 5 and 6. In any case, the prohibition against a Medicare supplier seeking payment for inserting a PC-IOL merely implements the determination that such items and services are not covered under Medicare and hence cannot properly be paid as claims. The AP himself submitted patient information from an eye care center explaining that "lifestyle lens implants," while they often benefit patients by reducing dependence on glasses, are "not covered" by Medicare and most insurance companies and that patients will be billed directly for the additional costs. AP Letter, October 29, 2010, attached Ex. 1, at 3. Thus, the unavailability of coverage from other carriers is not a function of the lack of claims denial letters from Medicare.

Therefore, we conclude that the AP's legal and policy arguments are unpersuasive.

5. The AP provided no basis for reopening the record before the Board**.**

The AP moved to reopen the record based on his receipt of a "CMS Medicare Summary Notice" dated September 13, 2011 concerning a Medicare Part B reimbursement determination on his individual claim for his cataract surgery and lens implants. Citing the notice's reference to "L26853," a local coverage determination (LCD), the AP alleges that this notice constitutes a "unilateral fact change" and a basis for reopening the record in the NDC case.

We reject the AP's argument. First, the bases for the payment determinations for services the AP received on May 27, 2010 in this notice are identical (including L26853) to those set out in a notice dated September 14, 2010, a notice that the AP submitted for the record on December 1, 2010. Therefore, the 2011 notice does not present a "unilateral fact change" or alter the facts relevant to our determination that the NCD Record is complete and adequate to support its validity. Moreover, our review under 42 C.F.R. Part 426, subpart E is not a review of the denial of the AP's individual claim but of the validity of the challenged NCD based on our application of the reasonableness standard. As we stated in our letter of October 4, 2010 to the AP, his initial filing before the Board indicated that he understood that the individual claim process was "distinct from the process to challenge an NCD" and that he was (as the 2010 and 2011 notices reflect) separately requesting review of his individual claim by the Medicare contractor. Therefore, nothing submitted by the AP, including the references to an LCD in the 2010 and 2011 notices, justifies reopening our record or delaying our resolution of the limited question before us -- whether the Record is complete and adequate to support the validity of the challenged NCD.

Conclusion

We conclude that the NCD Record is complete and adequate to support the validity of the NCD under the reasonableness standard. The AP has shown no basis for the Board to conduct further proceedings. This decision ends the NCD review, and therefore constitutes the final decision of the agency for purposes of judicial review. 42 C.F.R. § 426.566.

/s/
Judith A. Ballard

/s/
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/s/
Leslie A. Sussan
Presiding Board Member

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Re: NCD Complaint – Intraocular Lens [CMS Manual System Pub. 100- 04, Chapter 32, Section 120]
Board Docket No. A-10-97

RULING DENYING MOTION TO DISMISS AND ORDERING NCD RECORD TO BE FILED

On September 17, 2010, the Departmental Appeals Board (Board) received a letter from Paul G. Fargo, Esq. seeking to challenge the validity of Medicare national policy denying coverage of multifocal intraocular lens (IOL) implants. The complaint as submitted was unacceptable, but on November 3, 2010, the Board received an amended complaint with attachments. By letter dated November 22, 2010, the Board acknowledged receipt of an acceptable complaint and notified the parties of the further steps in the process, including ordering the Centers for Medicare & Medicaid Services (CMS) to produce the record of the applicable national coverage determination (NCD) within 30 days. Thereafter, CMS requested repeated extensions of time in which to comply with that order, which were granted in the absence of opposition by Mr. Fargo. On May 17, 2011, in lieu of submitting the NCD record, CMS filed a motion to dismiss the complaint. For the reasons explained below, we find no merit to CMS's arguments and deny the motion to dismiss.

Sources of Denial of Coverage Policy

Mr. Fargo submitted a Medicare Summary Notice regarding claims processed October 19, 2010 denying coverage for specialized IOL implants citing the Medicare Claims Processing Manual (MCPM), Publication No. 100-04, chapter 32, section 120.4. Letter from Paul G. Fargo to Board, received December 6, 2010, Attachments, unnumbered p. 6. The manual section provides that "[w]hen a beneficiary requests insertion of a P-C [presbyopia-correcting] or A-C [astigmatism-correcting] IOL instead of a conventional IOL following removal of a cataract and that procedure is performed, the beneficiary is responsible for payment of facility and physician charges for services and supplies attributable to the P-C or A-C functionality of the P-C or A-C IOL . . . ." MCPM, Pub. No. 100-4, ch. 32, § 120.4; s*ee also* MCPM, Pub. No. 100-4, ch. 32, § 120 (Medicare will allow beneficiary to opt for and pay for additional charges relating to use of specialized IOL implant during cataract survey based on CMS Ruling 05-01, issued May 3, 2005, but will not cover those additional charges under Medicare.).

CMS provided a copy of CMS Ruling 05-01 (CMS Ruling) as Attachment 1 to its motion to dismiss. This ruling states that it "sets forth CMS policy concerning the requirements for determining payment for insertion" of P-C IOL lenses following cataract surgery. CMS Ruling at 1. The ruling explains that Medicare covers insertion of a conventional lens following removal of a cataract to replace the cloudy or opaque lens. *Id.* at 3. Medicare expressly excludes coverage for eyeglasses or contact lenses, but a statutory exception allows coverage for one pair of eyeglasses or contact lenses "as a prosthetic device" after cataract surgery. *Id*.; Social Security Act (Act) §§ 1861(s)(8), 1862(a)(7). The ruling further states that, although P-C IOL provides "what is otherwise achieved by two separate items: an implantable conventional IOL . . . and eyeglasses or contact lenses," such P-C IOLs are "neither eyeglasses nor contact lenses." CMS Ruling at 2. The ruling concludes that no benefit category exists for Medicare to pay for the "presbyopia-correcting functionality of an IOL implanted following cataract surgery," or for facility or physician services or resources related to that added functionality. *Id.* at 3.

Definition of an NCD

The Act defines NCD to mean –

> A determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title, but does not include a determination of what code, if any, is assigned to a particular item or service covered under this title or a determination with respect to the amount of payment made for a particular item or service so covered.

Act § 1869(f)(1)(B). The regulations similarly define NCD to mean "a decision that CMS makes regarding whether to cover a particular service nationally" under Medicare, excluding coding and amount of payment. 42 C.F.R. § 400.202 ("service" in this context includes both items and services. 68 Fed. Reg. 63,692, at 63,707 (Nov. 7, 2003). The

Act provides that, upon "the filing of a complaint by an aggrieved party, such a determination shall be reviewed" by the Board. Act § 1869(f)(1)(A)(iii); 42 C.F.R. § 426.300(b).

CMS argues that the ruling and manual provisions referenced above that preclude coverage of P-C IOLs do not constitute an NCD because they were "not adopted through the precise process required by the Medicare statute . . . ." Motion to Dismiss at 10. As CMS recognizes, section 1862(l) of the Act requires CMS (acting for the Secretary) to follow a specific process within a set timeframe to promulgate certain NCDs (specifically those relating to whether an item or service is reasonable and necessary) upon receipt of a public request. Language at the end of section 1862(a) requires similar notice and comment procedures for development of NCDs (as defined in paragraph (1)(B) of section 1869(f)) initiated internally by CMS.

Under the statute, however, the definition of an NCD for purposes of review by the Board is not governed by the method through which CMS promulgates the policy determination but its content. The Board does not review whether CMS followed proper procedural steps in adopting an NCD. Indeed, the statute expressly excludes from the review of the NCD any challenge to the lawfulness of the notice and comment and publication process. Act § 1869(f)(1)(A)(ii). The statute states, however, that the Board "shall review" any NCD upon filing of a proper complaint.

The issue is therefore not how the ruling (and implementing manual provision) was adopted but whether the substance and content of the policy meet the statutory definition of an NCD. *Cf. LCD Appeal of Noncoverage of Transfer Factor*, DAB No. 2050 (2006) ("[W]hether a policy is an LCD is a legal issue based on the substance and content of the policy, not on the label or characterization of the policy by the contractor"). We must therefore ascertain whether the challenged policy here meets the content requirements of the NCD definition. The part of the ruling entitled "coverage policy" is on its face a determination by the Secretary that a particular item (P-C IOLs) and related services are not covered nationally. Other parts of the ruling that address coding or go to the proper amount of payments to be made are not NCD provisions.

In adopting the regulatory definition of NCD, CMS observed that it was following the statute in expanding the definition beyond earlier meanings. 68 Fed. Reg. at 63,694. In particular, the definition of NCD is broader than the corresponding definition of local coverage determinations that is limited to determinations about coverage made "in accordance with section 1862(a)(1)(A)," often referred to as the medical necessity provision. Act § 1869(2)(B). Thus, Board review is available for NCDs addressing the scope of statutory benefit coverage as well as medical necessity-based determinations. 68 Fed. Reg. at 63,694. The policy at issue here squarely fits within that definition.

The regulations also provide examples of documents that cannot be challenged under the LCD/NCD review process. 42 C.F.R. § 426.325. These provisions affirm that "currently effective" NCDs "may be challenged," but state that pre-decisional materials or retired or revised NCDs may not. 42 C.F.R. § 426.325(a), (b)(1)-(3). In addition, "[i]nterpretive policies that are not an . . . NCD" are not reviewable. 42 C.F.R. § 426.325(b)(4). CMS suggests that the ruling is not an NCD because it contains statements of interpretation and policy. Motion to Dismiss at 11-12. This suggestion misunderstands the regulation. Section 426.325(b)(4) does not make policies unreviewable whenever they contain interpretation. It makes unreviewable those interpretive policies that are not NCDs, i.e., that do not set out a CMS determination regarding whether to cover a particular service nationally.[1] The ruling at issue here does set out such a determination and is therefore NCD and subject to challenge as to the NCD provisions it contains.

The CMS ruling at issue here determines on a national basis whether a particular item or service is covered under Medicare. It is therefore an NCD under the definition set forth in section 400.202 (as well as the statutory definition).

Board authority to review NCDs

As explained above, the statute expressly empowers the Board to hear challenges to NCD policies and determine their validity under the reasonableness standard set out in the statute and regulations. Act § 1869(f)(1)(A)(iii); 42 C.F.R. § 426.300(b).

CMS nevertheless suggests that the Board is divested of authority to review this NCD because CMS has embodied it in a ruling which, CMS argues, is binding on the Board. Motion to Dismiss at 12. CMS is mistaken. The Board is not, and has never been, bound by CMS Rulings. CMS Ruling 05-01 itself sets out the scope of its authority as "binding on all CMS components, Medicare contractors, the Provider Reimbursement Review Board, the Medicare Geographic Classification Review Board and Administrative Law Judges who hear Medicare appeals." Ruling at 1.

The Departmental Appeals Board is not part of or subject to CMS and is not part of the Medicare claims appeal process, although it houses the Medicare Appeals Council. The Board thus does not "adjudicate matters under the jurisdiction of CMS" (42 C.F.R. § 401.108(c)) but rather provides independent adjudication at the Departmental level. For the same reason, the Board, unlike the Medicare Appeals Council, is not bound by NCDs and is entrusted with statutory authority to review their validity.

We therefore reject the assertion that the Board's statutory review authority is defeated because the NCD is in the form of a CMS Ruling.

[1] Similarly, the NCD review provisions do not provide for challenges to "[a]ny other policy that is not . . . an NCD as set forth in § 400.202 . . . ." 42 C.F.R. § 426.325(b)(12).

The complainant's status as aggrieved party

MS also argues that Mr. Fargo is not an aggrieved party and therefore not entitled to pursue an NCD challenge. Motion to Dismiss at 12, citing 42 C.F.R. § 426.320(a). An aggrieved party under 42 C.F.R. § 426.110 is a Medicare beneficiary (or the estate of one) who is "in need of coverage for a service that is denied based on . . . an NCD, regardless of whether or not the service was received . . . ." CMS argues that Mr. Fargo was denied coverage based on the ruling and implementing manuals, that the ruling was not adopted through notice and comment publications requirements applicable to NCDs, and that therefore Mr. Fargo was not denied coverage based on an NCD. This argument fails for the same reasons we set out above, i.e., the ruling is an NCD and was the basis for the denial coverage.

While we have dismissed a complaint where CMS demonstrated that the NCD at issue did not in fact bar the coverage sought by complainant, this case is not analogous. *Cf.* Board's Ruling on Motion to Dismiss NCD Complaint re: Carcinoembryonic Antigen, Docket No. A-07-106 (April 15, 2008)(redacted version available from the Board's website at http://www.hhs.gov/dab/divisions/appellate/ncdappeals/complaints.html). In the present case, CMS does not dispute that the policy at issue bars the coverage sought. We have already rejected CMS's assertion that the ruling barring the coverage is not an NCD.

We therefore conclude that Mr. Fargo is an aggrieved party within the meaning of the statute and regulations.

Next steps

By letter dated November 22, 2010, CMS was instructed to produce the record supporting its NCD within 30 days. In requesting extensions of that time, CMS counsel represented that counsel was receiving documentation from the agency and investigating and researching the matter. E-mail communication from CMS counsel to Board, February 7, 2011. Therefore, CMS should be prepared to submit the record at this point once informed of the denial of its motion to dismiss without needing an additional 30-day period. **CMS is ordered to produce the NCD record to the Board and the aggrieved party within two weeks of its receipt of this ruling**.

The remaining steps of the proceeding will follow the same schedule set out in the communications sent to the parties from the Board on November 22, 2010.

/s/
Leslie A. Sussan
Presiding Board Member