The Administrative Law Judge (ALJ) issued a decision dated January 22, 2009, which concerned an overpayment resulting from denial of coverage for multiple claims for physician services involving eye examinations and testing of nursing home residents. The ALJ determined that the appellant was required and failed to provide an attending physician’s order for each visit with a resident and facility nursing notes documenting medical necessity for the services. The ALJ also rejected the appellant’s challenges to the statistical sampling process used and determined that the appellant was liable for the services which were not covered. The appellant has asked the Medicare Appeals Council to review this action.

The Council reviews the ALJ’s decision de novo. 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ’s action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c).

As set forth below, the Council reverses as to 19 of the 63 claims at issue, while 44 claims continue to be denied. The contractor will need to recalculate the overpayment amount to account for the percentage of the sample cases now determined to be covered.
DISCUSSION

At issue on appeal are 63 claims each representing a single visit by the appellant with a beneficiary between January 1, 2003 and December 1, 2004. The beneficiaries were all residents of nursing facilities and their examinations were performed in a licensed mobile unit operated by the appellant. The claims were among those included in a statistical sampling review resulting in an overpayment finding. The ALJ determined that none of the claims was covered and that the statistical sampling process used a reliable methodology, and found the appellant liable for the overpayment. ALJ Decision at 6-8.

In requesting Council review, the appellant argues that:

- The ALJ improperly relied on a lack of medical documentation based on the absence of nursing facility records and attending physician orders while failing to issue requested subpoenas to allow the appellant to obtain access to the confidential records.

- The ALJ incorrectly required an attending physician order where the appellant himself was a “treating physician” entitled to deference in evaluating medical necessity. Furthermore, beneficiaries have a right to optometric services “when presenting complaints or other symptoms of concern” regardless of their living situation.

- The ALJ failed to consider supplemental documentation which contained additional physician orders and nursing facility records that the appellant was able to obtain which he admitted into the record, even though the ALJ found good cause to admit the supplemental documentation into the record.

- The extrapolation of the overpayment was improper because the underlying data is flawed.

Request for Review, Attachment B (RR) at 1-2. Below, we first consider what the applicable legal standards require as documentation of medical necessity for the provisions of services by optometrists to nursing facility residents. Next, we apply those standards de novo to the documentation in the record for the 63 claims. We then address the appellant’s
assertions that he was entitled to issuance of subpoenas and that the extrapolation was improper.

1. The correct legal standard for documentation of optometric physician services to nursing facility residents requires referral/order from attending physician and evidence of need for non-routine examination or tests.

Medicare Part B pays for physicians’ services, including diagnosis and consultation, when provided by a “doctor of optometry” acting within the scope of his license.1 42 C.F.R. § 410.20(a) and (b)(4). Covered services by doctors of optometry are limited to those authorized in the relevant state and listed in section 1861(s) of the Act and section 410.10 of the regulations. 42 C.F.R. § 410.22. Section 415.102 provides, in relevant part, that physicians may be paid on a fee schedule basis for services furnished to beneficiaries in providers (which would include nursing facilities) so long as the services are “personally furnished for an individual beneficiary by a physician,” “contribute directly to the diagnosis or treatment of an individual beneficiary,” and “ordinarily require performance by a physician.” 42 C.F.R. § 415.102 (a). Furthermore, the Medicare Benefit Policy Manual (MBPM), Chapter 250 states that physicians’ services are covered under Part B, when provided to a nursing facility resident, even though the patient has Part A coverage for the facility stay.

The ALJ concluded that the appellant failed to provide the requisite documentation to support any of the challenged claims. ALJ Decision at 6. The ALJ decision rests on the following two legal conclusions:

- “The undersigned finds that it is not sufficient to perform diagnostic tests based on a signed prescription with a diagnosis, there must be an order from the attending physician in order for an outside physician to render services to a resident in a nursing home.”

- “Medical necessity for these tests is not established by nursing notes alone although the appellant argues that it does [sic].”

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1 It is not disputed that the services at issue were provided within the scope of the appellant’s license, which appears consistent with the version of the rules of the Arkansas State Board of Optometry in the record. Ex. D at 65; Ex. E at 151-82.
ALJ Decision at 6 (citations omitted). The only authorities cited for these legal assertions are the Medicare Program Integrity Manual (MPIM), Chapter 13, Section 13.5.1 and a December 2000 contractor newsletter. The MPIM section discusses what a local coverage determination should contain, which may include a description of circumstances under which services will be considered reasonable and necessary (absent a statutory exception from the reasonable and necessary requirement). Nothing in the section provides any information as to whether an outside physician requires an order from an attending physician to treat a nursing home resident or whether nursing notes are required to establish medical necessity for diagnostic tests.

The requirement that an optometric physician providing services to nursing home residents must do so pursuant to an order from the residents’ attending physician, on which the ALJ relied to deny all the claims across the board, is derived from the local contractor newsletter article published in December 2000. The article requires that, when requested to document “the medical necessity of a nursing home visit performed by someone other than the attending physician,” a provider is requested to submit a signed, dated written request for the specialist visit (and nursing notes if the reason for the visit is not clear in the physician’s order) along with the specialist’s own documentation of the services performed. Ex. E, at 138. (Medicare News, MCB 2000-06, December 2000). The rationale for this requirement is to ensure that services of optometrists (along with other health care providers such as podiatrists or clinical social workers) are “a reaction to a stated or suspected problem, not in response to routine screening practices.” Id.

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2 ALJ quoted and cited numerous other statutory and regulatory provisions in the legal framework section of his decision, but nowhere explained the relevance of most of them to the dispute before him. He cited 42 C.F.R. § 424.24 in setting out requirements for medical and other services furnished by providers under Part B. ALJ Decision at 5. Section 424.24 addresses certification requirements. Physicians are to play “a major role in determining utilization of health services furnished by providers” and, to that end, must order tests and treatments and certify medical necessity. 42 C.F.R. § 424.10(a). Coverage of Part B provider services requires a certification of medical necessity by a physician. 42 C.F.R. § 424.24(b)-(g). Physicians who furnish items or services under Medicare, including “doctors of optometry” acting within the scope of their licenses, however, are considered “suppliers” and not “providers of service.” Sections 1861(d), 1861(r), and 1861(u) of the Act. The regulatory provision for physician certification of the medical necessity of services furnished by a provider under Part B does not apply to services furnished by a doctor of optometry or other specialty physician services.
The article’s concern reflects Medicare’s restrictions on routine testing in general and on eye care in particular. Thus, section 411.15 of the Medicare regulations excludes from coverage routine physical checkups including examinations not performed to treat or diagnose specific illness, symptoms, complaints or injuries in general. 42 C.F.R. § 411.15(a). Furthermore, in particular, coverage is excluded for eyeglasses or contact lenses (except prostheses for those lacking a lens either congenitally or post-surgically and one pair after a cataract surgery) and eye examinations “for the purpose of prescribing, fitting or changing eyeglasses or contact lenses for refractive error only” and any refractive procedures even “in connection with otherwise covered diagnosis or treatment of illness or injury.” 42 C.F.R. § 411.15(b) and (c).^3^ The requirement for an order from the attending physician, who is required to be familiar with the resident’s overall plan of care, also ensures that the services are not duplicative and do not conflict with other medical conditions of the resident or services already being provided.

The article goes further, however, to state that the premise that medical necessity requires a showing of “an identifiable relationship” between a nursing home resident’s attending physician and any other Part B provider furnishing services “constitutes no more or no less than the requirements found in” 42 C.F.R. § 483.40. This assertion is legally incorrect. The cited provision requires that “a facility must ensure that the medical care of each resident is supervised by a physician and that physician visits must take into account the resident’s total program of care, including medication and treatments.” (Emphasis added.) On its face, the requirement is placed on the nursing home to obtain physician supervision for the medical care it provides and to inform physicians of the total plan of care. Similarly, section 483.20(d), also cited in the article, lays out the requirements for the facility to develop a

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^3^ Similarly, the Medicare Benefit Policy Manual (MBPM) makes clear that Medicare does not cover “[r]outine physical checkups; eyeglasses, contacts, and eye examinations for the purpose of prescribing, fitting, or changing eyeglasses; eye refractions by whatever practitioner and for whatever purpose performed . . .” among other routine services, including any “examinations performed without relationship to treatment or diagnosis for a specific illness, symptom, complaint, or injury . . . .” MBPM, Ch. 16, § 90 (Rev. 1, 10-1-03). On the other hand, these exclusions “do not apply to physicians’ services (and services incident to a physicians’ service) performed in conjunction with an eye disease, as for example, glaucoma or cataracts . . . .” Id.
comprehensive care plan based on a comprehensive assessment of all the resident’s medical, nursing, mental and psychosocial needs. The facility must include the attending physician in the development of the care plan, along with the nurse caring for the resident, and representatives of other disciplines as needed, but the responsibility to develop, review and carry out the care plan lies with the facility. 42 C.F.R. § 483.20. Nothing in the cited regulations creates a requirement for any particular “relationship” between a resident’s attending physician and other Part B providers from whom the facility may obtain services to implement the plan of care and the physician’s orders.

In September 27, 2004, the contractor issued an online provider information notice entitled “Podiatrists and Optometrists Billing for Nursing Facility Assessments.” Ex. E, at 139. This notice indicated that optometrists could not bill as physicians for purposes of reviewing comprehensive assessments and care plans for nursing facilities, because areas of the total care are outside the scope of their licenses. Id. Instead, optometrists may bill for consultation visits “when the primary care physician has ordered . . . optometry services,” in which case the documentation must include a signed order from the attending physician. Id. No mention is made in this later document of any requirement that the optometrist not only obtain an attending physician’s order and document that the services are medically necessary and otherwise covered under Medicare (i.e., not routine screening examinations or excluded eye care), but also that the optometrist must obtain nursing notes from the facility showing the reason for the visit.

We conclude that the ALJ could, and we do, properly defer to the contractor’s requirement, repeated in two communications from the contractor of which the appellant had constructive notice under 42 C.F.R. § 411.406(e), that an attending physician’s order must be produced.4 It is further clear that the appellant

4 Unfortunately, it is not clear to what the ALJ was in fact deferring. He included a list of local coverage determinations supposedly “[s]pecific to the instant case” which he asserts that he “considered and gave substantial deference to,” but which appear completely irrelevant, dealing with evaluation of veins and arteries in the extremities, pulmonary function, and nerve conduction studies, while providing no reference to any policy dealing with services of doctors of optometry or services by external physicians to nursing home residents. ALJ Decision at 5-6. In our de novo review, however, we have considered both the 2000 and 2004 contractor communications and give substantial (though not complete) deference to them, as explained in the text.
bears the burden of documenting that the services provided were reasonable and necessary to diagnose or treat specific complaints or illnesses presented by the individual patients and not merely screening, routine examinations, or related to eye refractions or the provision of glasses or contacts. We do not, however, agree with the ALJ that the only potential documentation adequate to establish medical necessity would be nursing notes maintained by the nursing facility.\(^5\)

The ALJ gave as an alternative basis for denying the claims that the medical documentation was inadequate to show medical necessity. ALJ Decision at 6. We agree with the ALJ that the appellant was required to document why an individual beneficiary required the eye examinations and diagnostic tests which he performed. The ALJ failed, however, to discuss any of the specific medical documentation on which the appellant relied. Instead, the ALJ simply repeated that the documentation was inadequate because there were “no nursing notes or attending physician orders to show that the residents needed eye services.” \(\text{Id.}\) This assertion is not an independent basis for his non-coverage conclusions and is, in any case, an inaccurate description of the record since physician orders do appear in many of the beneficiary exhibits and some contain nursing notes.

We therefore next review the medical documentation de novo to determine whether it is adequate to show that the services provided were reasonable and necessary.

2. Evaluation of medical necessity documentation in individual claims

The Council has reviewed the recording of the ALJ hearing, the exhibits and declarations, and the entire record on appeal. In each case, our review included the appellant’s supplemental beneficiary statement (prepared at the request of the ALJ at the hearing), the individual beneficiary medical exhibits (Exhibit 2 in each file), the index of documentation prepared by the appellant as revised exhibit H, and the supplemental documentation for each beneficiary submitted as exhibit J.

\(^{5}\) Notably, the ALJ did not actually hold that that nursing notes were required but rather that nursing notes alone were insufficient. ALJ Decision at 6 (language quoted supra). He proceeded, nevertheless, to treat the absence of nursing notes as fatal to coverage.
As discussed above, optometric services must be based on a specific problem or complaint relating to an eye disease, such as cataracts or glaucoma; general screening examinations or services related to visual acuity or need for eyeglasses are excluded from coverage. It is not sufficient to merely list diagnoses, such as depression, dementia, or hypertension that may relate to the reasons for the beneficiary’s nursing home placement, without an indication that some complaint or symptom occurred which was related in time and reason to the optometric services provided on the dates at issue. Therefore, we deny claims where the presenting complaint is loss of visual acuity or inadequate glasses.

Attending physician orders that either do not mention optometric services at all or that are undated or dated months before or after the dates of service cannot provide evidence of medical necessity for these services. See, e.g., File of M.M., Ex. 2. In addition, many cases involve only a complaint of watery eyes or dry eyes with evidence that the resident was already being treated with eye lubricants and no evidence of any recent exacerbation or new development. In addition, general statements by the facility, even if signed by the medical director, that Dr. Daniel provided services to residents over the course of three years that were done “for the benefit of residents” do not establish a physician’s order for or a need by a particular resident to receive an examination or services on at particular date. See, e.g., File of W.F., Ex. 2.

While, as stated above, we will accept documentation other than nursing notes to show the precipitating need for optometric services, the documentation must demonstrate a reason that an examination was needed when performed. Furthermore, where nursing facility records were provided in the supplemental exhibits, they often consisted of admission assessments or medication records lacking any information about specific complaints or symptoms relevant to eye disease or merely mentioning that the beneficiary wears glasses.

Based on our review of the entire clinical records provided by the appellant, we reach the following conclusions as to the documentation of medical necessity:

The following beneficiaries’ claims remain denied because, although an attending physician’s order was produced, neither nursing notes nor other clinical documentation indicates that the beneficiary was seen for any specific complaint other than routine examination, or else the only complaint, diagnosis and/or treatment related to refractive measurements or need for eyeglasses or contacts: T.A.; C.A.; G.A.; T.B.; D.B.; V.B.; E.B.; O.B.; H.F.; I.M.; M.M.; G.P.; and L.S. (13 claims total).

The following beneficiaries’ claims are covered because their files contain both attending physician’s orders and adequate documentation that the services provided were medically necessary and not merely routine examinations or provision of excluded eye care services: R.A. (glaucoma diagnosis); J.B. (blurred vision; medication for blepharitis); I.B. (dry age-related macular degeneration (ARMD) with blepharitis, sicca, and suspected glaucoma); M.B. (post-corneal transplant, medication for blepharitis, cataract evaluation); C.B. (cataracts); L.B. (blurred vision; levator disinsertion evaluation); V.H. (blurred vision; moderate cataracts and ARMD); L.H. (eye discharge; trichiasis, monitor other conditions); *** H. (blurred vision; severe ARMD); *** H. (blurred vision; moderate cataracts); A.K. (eye pain; cataracts and blepharitis); R.M. (inflammatory glaucoma, medication for blepharitis); W.M. (blurred vision; glaucoma); L.N. (eye pain; blepharitis, ARMD, optic nerve atrophy); B.P. (crusted lids; medication for glaucoma, cataract); E.P. (blurred vision; cataracts, optic atrophy); C.S. (blurred vision; cataracts, ARMC, optic atrophy); J.W. (blurred vision and watery eyes; cataracts, sicca); and *** W. (eye pain and inflammation; medication for blepharitis).

In summary, 19 claims are covered, while 44 claims continue to be denied. Attached to this decision is an annotated list of beneficiaries with the outcome as to each claim.

3. We deny the subpoena request.

Before the ALJ and again before the Council, the appellant sought issuance of subpoenas in order to compel nursing facilities to provide documentation of the medical necessity of his services. RR at 2. The ALJ failed to rule on the subpoena request. We deny the subpoena request. Since we have found that the appellant had notice (either actual or constructive) of
the contractor’s requirement to document orders from the attending physician when seeing nursing facility residents, the appellant should have already had such orders in his records. Since we have not required that medical necessity be documented by facility nursing notes, and since the appellant was obliged to be able to document the medical necessity of any services he provided, the appellant should not have required retrospective access to nursing facility records to obtain such documentation. We therefore conclude that the appellant has failed to demonstrate that subpoenas are necessary.

4. We reject appellant’s argument on statistical sampling and extrapolation.

The percentage of sample claims from the two-year period which were determined to be not covered by Medicare was the basis for an extrapolation for a total overpayment. The ALJ found that the appellant was provided with all materials concerning the sampling methodology and concluded that the process was “sufficiently reliable to withstand scrutiny under a due process analysis.” ALJ Decision at 7.

On appeal to the Council, the appellant argues that the extrapolation of the reviewed claims was “conducted by applying the erroneous standard of presenting an attending physician’s order” and that the “calculation is flawed in its reliance upon data based on this erroneous threshold requirement.” RR at 2.

This argument fails to identify any deficiency in the statistical sampling methodology. Instead, the appellant essentially takes the position that, if the individual sample claims were wrongly denied, then the extrapolation is flawed. This argument provides no basis to find the statistical sampling process or the extrapolation methods improper.

Furthermore, we have already rejected the appellant’s argument that attending physician referrals were unnecessary. As to those 19 claims which we have found had physician orders and were otherwise covered, however, we agree that the corresponding amount of the overpayment that reflected the noncoverage of those cases must be adjusted. The requirement to adjust the overpayment accordingly is a proper application of, not a rejection of, the extrapolation method used here.

We note that we do not address liability since the appellant did not challenge that aspect of the ALJ Decision on appeal.
DECISION

It is the decision of the Medicare Appeals Council that the 19 claims identified above are covered, while the remaining 44 are not. The overpayment amount should be adjusted accordingly.

MEDICARE APPEALS COUNCIL

/s/ Leslie A. Sussan, Member
Departmental Appeals Board

/s/ Clausen Krzywicki
Administrative Appeals Judge

Date: December 3, 2009