

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA**

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**AMERICAN ORTHOTIC & PROSTHETIC  
ASSOCIATION, INC.**

**330 John Carlyle Street, Suite 200  
Alexandria, VA 22314**

**Plaintiff,**

**v.**

**KATHLEEN SEBELIUS, in her official capacity as  
Secretary of the Department of Health and Human  
Services**

**200 Independence Avenue, S.W.  
Washington, D.C. 20204**

**Defendant.**

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**Case No.**

**1:13-cv-**

**COMPLAINT**

American Orthotic & Prosthetic Association, Inc. (“AOPA”) brings this action on behalf of its members seeking declaratory, injunctive, and mandamus relief against Kathleen Sebelius, Secretary of the Department of Health and Human Services (the “Secretary”), for violations of Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395iii (“the Medicare Act”); the Administrative Procedure Act, 5 U.S.C. §§ 701 *et seq.* (“APA”); the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (“BIPA”); and the Regulatory Flexibility Act, 5 U.S.C. §§ 601 *et seq.* (“RFA”).

**INTRODUCTION**

1. AOPA’s members are independent businesses who supply artificial limbs, commonly called prosthetic devices, to Medicare patients who have lost extremities to disease or injury. At issue here are rules implemented in August 2011 by the Centers for Medicare &

Medicaid Services (“CMS”), a unit of the Department of Health and Human Services (“HHS”). The CMS rules provide that suppliers of prosthetic devices will be denied payment for the devices unless they secure specific documentation from physicians who prescribed the devices. CMS and its contractors are relying on the new rules to deny AOPA members payment for the prosthetic devices the AOPA members have supplied Medicare patients, even when other documentation justifies the medical necessity for the devices.

2. The new rules are invalid for several reasons. First, CMS improperly issued the new rules in the form of a “Dear Physician” letter posted on the websites of CMS contractors rather than through the rulemaking process required by the Medicare Act and APA, thereby depriving AOPA members and the public of notice and the opportunity to provide comments.

3. Second, CMS failed to offer a reasoned basis for the issuance of the new rules or to justify its change of position on the documentation needed to support claims for prosthetic devices. With the new legal standard, CMS no longer accepts the records of prosthetists as sufficient to show the medical necessity for artificial limbs. According to the “Dear Physician” letter, only the treating physician’s records can justify payment, even though under CMS’ prior practice and its Program Integrity Manual prosthetists are professionals whose records are part of a patient’s medical record and thus entitled to the same deference as physician notes.

4. Third, CMS is applying the new rules retroactively, in contravention of the Medicare Act. CMS agents thus are rejecting claims that were submitted by AOPA members prior to the publication of the “Dear Physician” letter.

5. Fourth, the new rules are contrary to law and expressed congressional intent. Although the “Dear Physician” letter suggests that the new rules requiring documentation from physicians are necessary because suppliers allegedly have a conflict of interest, Congress did not

give the Secretary the authority to cure perceived conflicts by insisting on corroborating documentation from treating physicians. Congress instead addressed problems with unethical or unqualified suppliers by directing the Secretary to issue regulations setting minimal qualifications for suppliers of artificial limbs to Medicare patients. Even though Congress ordered that such regulations be promulgated by December 21, 2001, the Secretary still has failed to act over 11 years later.

6. Congress further has disagreed with the premise of the “Dear Physician” letter—that physician documentation prevents waste and abuse. In recognition that physician documentation often is deficient or inaccurate, Congress recently directed in the Affordable Care Act that physicians or their assistants have face-to-face meetings with Medicare patients before a physician can order certain medical equipment for the patient. Notwithstanding that directive, the Secretary has not required physicians to meet face-to-face with their patients before ordering prosthetic devices.

7. The “Dear Physician” letter also violates congressional authorization by forcing prosthetic device suppliers to bear the consequences of allegedly inadequate physician documentation. Congress directed in the Medicare Act that if documentation from a physician is needed to justify a claim for Medicare services, the physician must provide that documentation to the supplier at the time he or she issues the order. Thus, Congress has put the onus on the physician to comply. However, the new rules do not require physicians to provide the specified documentation, and provide no financial incentive for physicians to do so, as CMS does in similar situations. The new rules further do not specify any sanction for physicians who fail to fulfill their statutory duty, and CMS has taken no action to date against physicians who failed to provide the missing documentation.

8. Instead, the consequences for a physician's failure to provide the specified documentation fall solely on the suppliers, including AOPA's members, and on Medicare patients. Despite the AOPA members' lack of any contractual or practical ability to induce the physicians to honor their statutory duty to provide documentation, the Secretary is denying the AOPA members payment for artificial limbs and related services they provide to Medicare patients if CMS contractors deem the physician's documentation to be inadequate. Compounding the arbitrariness of the new rule is that AOPA members cannot submit a claim for payment until they have provided the artificial limb to the patient.

9. CMS' enforcement of the new rules is equally arbitrary and capricious. Relying on the "Dear Physician" letter, CMS contractors increasingly are making independent medical judgments and overruling determinations by physicians and prosthetists as to the appropriate type of artificial limb needed by Medicare patients. These reversals are based solely on the contractors' review of the medical records and without even examining the patient or consulting with the prosthetist or treating physician. The CMS contractors further are denying claims in full if they think the patient could get by with a less sophisticated prosthetic device than the one ordered by the patient's physician in consultation with the prosthetist. Even though AOPA members have secured a large number of reversals of these decisions on appeal, CMS has failed to rein in the contractors' abuses and modify or withdraw the "Dear Physician" letter.

10. Aside from violating the Medicare Act, APA, and BIPA, the Secretary also has violated the RFA. CMS never has acknowledged, much less quantified, the significant adverse financial and regulatory impact the new rules and CMS' enforcement of them could be expected to have on AOPA's members, many of whom are small businesses.

## **PARTIES**

11. Plaintiff AOPA is a not-for-profit corporation organized under the laws of Delaware with its principal place of business in Alexandria, Virginia. AOPA is a trade association whose stated mission includes working for the favorable treatment of the orthotic and prosthetic business in laws, regulations, and services. According to AOPA's bylaws, one of the purposes of the corporation is "[a]rticulating and advocating the needs and interests of the O&P industry before legislative, administrative and judicial branches of local, state and national governments." AOPA's bylaws authorize it to do "anything necessary and proper for the accomplishment" of that purpose.

12. AOPA brings this action as a representative of its members. The 816 members of AOPA, operating from 2,009 locations, are businesses and organizations which provide orthotic and prosthetic care and supplies to patients, including patients covered by the Medicare program. AOPA members, as suppliers under the Medicare program, would have standing to bring individual claims against the Secretary; however, the relief sought here does not require their participation.

13. Defendant Kathleen Sebelius is the HHS Secretary with authority over the Medicare program. She is sued in her official capacity. CMS, a subunit of HHS, acts as the Secretary's designee in overseeing the Medicare program.

14. The Secretary maintains the headquarters of HHS in Washington, D.C.

## **JURISDICTION AND VENUE**

15. This Court has jurisdiction over this case pursuant to 42 U.S.C. §§ 405, 1395ff, and 1395hh; 5 U.S.C. §§ 702 and 706; and 28 U.S.C. §§ 1331 and 1361. The Court may issue declaratory relief under 28 U.S.C. §§ 2201 and 2202.

16. Venue in this Court is proper under 42 U.S.C. § 405 and 28 U.S.C. § 1391(e).

### **FACTUAL ALLEGATIONS**

17. Under Medicare Part B, Medicare patients are entitled to receive artificial limbs that are medically reasonable and necessary for the treatment of injury or to improve the functioning of a malformed body member.

18. Medicare patients often must undergo amputations of limbs because of disease or accident. Many of those patients require artificial limbs to regain the ability to ambulate or to maintain some degree of mobility and independence. Active patients are especially reliant on prosthetic devices to maintain functioning in their daily lives.

19. Prosthetic devices must be specifically fitted to each patient to take into account the nature of the injury or disease, the point of amputation, and the patient's size, weight, age, and mobility.

20. Prosthetists are individuals who have been trained to measure, design, fabricate, and fit prosthetic devices after examining patients and assessing what device would best serve the patient's needs. A certified prosthetist is one who has satisfied educational criteria and passed certification tests.

21. Prior to 2011, CMS looked at a Medicare patient's entire medical record to evaluate whether a prosthetic device was medically necessary to improve the functioning of amputated limbs. CMS' Program Integrity Manual sets forth the relevant legal standard: "The patient's medical record is not limited to the physician's office records. It may include hospital, nursing home, or HHA records and records from other health care professionals." Consistent with the Program Integrity Manual, CMS routinely paid claims submitted by AOPA members where prosthetist notes demonstrated the medical necessity of the prosthetic device.

### Posting of the “Dear Physician” Letter

22. In August 2011, CMS’ four Medicare Administrative Contractors (“MACs”) posted on their websites a form letter titled “Dear Physician.” The “Dear Physician” letter is signed by the medical directors for the four MACs. A copy of the letter is attached as Exhibit A.

23. Although the letter is titled and addressed “Dear Physician,” CMS has not stated what efforts, if any, it made to actually disseminate the letter to physicians enrolled in the Medicare program. MACs instead have recommended that artificial limb suppliers bring the letter to the attention of physicians.

24. The “Dear Physician” letter demands that suppliers obtain documentation from treating physicians to justify the payment of claims for prosthetic devices. According to the letter, “It is the treating physician’s records, not the prosthetist’s, which are used to justify payment.”

25. The “Dear Physician” letter also specifies the documentation that CMS is now requiring treating physicians to provide. The letter says that “it is critical that physicians thoroughly document the functional capabilities of their patients, both before and after amputation.” According to the letter, a physician’s records “must document the patient’s current functional capabilities and his/her expected functional potential, including an explanation for the difference.” The “Dear Physician” letter requires the physician to grade the patient’s functional capability on a K-0 to K-4 scale.

26. The “Dear Physician” letter identifies 11 categories of information that the medical record should “typically” include. Those categories, which the letter characterizes as “not all-inclusive,” include items such as (1) a description of activities of daily living, (2) musculoskeletal examination, and (3) neurological examination. The letter urges the physician

to clearly describe “the pre and post-amputation capabilities of the patient” and to write a medical history that paints a picture of the “patient’s functional abilities and limitations on a typical day.”

27. Typically, the physician prescribing a prosthetic device is either the surgeon who performed the amputation or the patient’s general practitioner. In most cases, neither physician has been trained to assess the patient’s pre- and post-amputation capabilities, where the patient ranks on a K-level functionality scale, and what type of artificial limb is best suited for the patient. Medical schools usually provide students only a few hours of training on prosthetics and no training on K-levels. Upon information and belief, neither the Secretary nor CMS has ever provided medical schools with course materials or training instructions on how physicians should determine an amputee’s K-level.

28. Many prescribing physicians are aware of their limited ability to make K-level determinations and to assess the patients’ pre- and post-amputation capabilities, and thus traditionally have relied on prosthetists to make these assessments. Prosthetists generally will make a recommendation regarding a prosthetic device in a work order that the prescribing physicians review and sign.

#### Payment Standard Prior to the “Dear Physician” letter

29. Prior to posting the “Dear Physician” letter on the MAC websites, CMS recognized the prescribing physician’s limited training and experience in gauging the patient’s functional abilities and what type of artificial limb would be optimal for the patient. CMS accordingly did not require prescribing physicians to undertake separate assessments of their patients’ functional capabilities, to grade those capabilities on a K-0 to K-4 scale, or to evaluate how those capabilities could be improved by an artificial limb. CMS allowed the assessment to



be made by either the treating physician or the prosthetist. Reflecting this policy, MAC documentation checklists (1) refer to the “reasonable expectations of the prosthetist and treating physician” regarding the patient’s potential function and (2) state that the prosthetic device should be selected by the “treating physician and/or prosthetist.” An example of a MAC documentation checklist is attached as Exhibit B.

30. For many years, CMS paid claims submitted by prosthetists and other prosthetic suppliers for artificial limbs as long as the prosthetist’s or supplier’s files had sufficient documentation of the assessment of the patient’s functional levels consistent with Exhibit B. CMS did not require that physicians provide the documentation identified in the “Dear Physician” letter as a condition of AOPA members receiving payment for the artificial limbs they provided to Medicare patients. CMS further did not insist that physician notes corroborate prosthetist notes before the claims of AOPA members could be paid.

31. The posting of the “Dear Physician” letter reflected a significant change of position by CMS regarding the documentation required for claims for artificial limbs. CMS did not provide any explanation for the change in legal standards reflected in the “Dear Physician” letter. CMS further did not make a corresponding change to its Program Integrity Manual, which still provides today that “The patient’s medical record is not limited to the physician’s office records. It may include hospital, nursing home, or HHA records and records from other health care professionals.”

#### CMS’ Failure to Follow Rulemaking Procedures

32. CMS did not give AOPA members, physicians, or other members of the public advance notice of the “Dear Physician” letter before it was put into effect or provide the AOPA

members, physicians, and other members of the public with an opportunity to comment on the changed legal standard set forth in the letter.

33. Neither the MACs nor CMS explained why the new documentation requirement was being announced in a “Dear Physician” letter, rather through a rulemaking process. Neither CMS nor the Secretary claimed that the new documentation requirement fell within any of the categories exempt from the rulemaking process under the Medicare Act.

34. CMS’ failure to issue the “Dear Physician” letter through a rulemaking was not consistent with its prior practice. In the mid-2000s, CMS imposed documentation requirements on suppliers of durable medical equipment that called for physicians to generate entries in their medical record to justify an order for such equipment. In that case, CMS chose to promulgate those requirements in regulations that were issued after public notice and a comment period. CMS further amended those regulations in response to the comments it received.

35. CMS also followed a formal rulemaking process when promulgating rules in 2012 requiring that physicians have a face-to-face encounter before prescribing durable medical equipment. CMS revised the initial proposed regulations after receiving a number of comments from the public.

#### CMS’ Lack of Justification for the New Rules and Failure to Implement BIPA

36. CMS did not offer a written rationale for the new documentation requirement set forth in the “Dear Physician” letter. CMS has suggested in recent correspondence that its reversal of position reflected in the “Dear Physician” letter is justified because prosthetists are suppliers who may have a conflict in deciding what prosthetic device is best suited for a patient.

37. Thousands of professionals, including physicians, daily prescribe medical products or services for Medicare patients under circumstances in which they may be perceived

as having a conflict. CMS nevertheless routinely pays claims for such products or services without requiring that the prescription be independently corroborated.

38. Congress did not authorize CMS to pay claims for prosthetic devices only if documentation from treating physicians, as opposed to documentation from prosthetists, justified payment.

39. Congress instead directed CMS to take other steps to deter unethical or unqualified prosthetists from fitting Medicare patients with unnecessary prosthetic devices.

40. Congress acted after a 2000 Office of Inspector General (“OIG”) report found that qualifications of orthotic suppliers varied, with noncertified suppliers being the ones most likely to provide inappropriate items and services. In response to the OIG report, Congress included in Section 427(a) of BIPA a prohibition on Medicare payments for prosthetics and custom-fabricated orthotics unless the devices were (1) furnished by a qualified practitioner and (2) fabricated by a qualified practitioner or supplier.

41. Congress defined a “qualified practitioner” as a (a) qualified physical therapist or occupational therapist, (b) an individual licensed in prosthetics or orthotics in the state in which the prosthetic or orthotic device is supplied, or (c) in states lacking licensing, an individual certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or the Board for Orthotist/Prosthetist Certification or under an equivalent program. Most, if not all, of the prosthetists working for AOPA members are “qualified practitioners.”

42. Congress defined a “qualified supplier” as an entity that is accredited by the American Board for Certification in Orthotics and Prosthetics, Inc. or the Board of Certification/Accreditation, International or under an equivalent program. Most, if not all, AOPA members are “qualified suppliers.”

43. Section 427(b) of BIPA directed the Secretary to promulgate regulations to carry out the qualification requirements of Section 427(a). Congress directed that the regulations be promulgated no later than one year after enactment of BIPA.

44. The one-year anniversary of BIPA was December 21, 2001.

45. The Secretary has not promulgated regulations to implement Section 427(a) of BIPA, even after the OIG brought this failure to the Secretary's attention in an October 2012 report.

46. In 2010 CMS paid almost 1,000 claims for prosthetics and custom-fabricated orthotics from practitioners and suppliers who did not appear to meet the certification standards set forth in BIPA.

47. The Secretary's failure to promulgate regulations has enabled unqualified competitors of AOPA members to secure payments for artificial limbs to Medicare Patients, resulting in monetary loss to AOPA members. In addition, unqualified suppliers have continued to provide unsuitable artificial limbs, thereby damaging the overall image of the industry and triggering excessive audit scrutiny by CMS contractors of all claims for artificial limbs.

48. If the Secretary had promulgated regulations under BIPA as directed by Congress, such regulations would have prevented waste and abuse in the Medicare program in a far more effective and far less arbitrary manner than the "Dear Physician" letter.

49. Nowhere in BIPA did Congress authorize CMS to use physician documentation as a substitute for quality standards. Moreover, CMS' reliance on physician documentation to prevent waste and abuse also is contrary to Congress' expressed concern over the adequacy of such documentation. In recognition that physician documentation frequently does not give an accurate assessment of a patient's condition, Congress specified in Section 6407(b) of the

Affordable Care Act, 42 U.S.C. § 1395m(a)(11)(B), that for items of medical equipment for which a physician's order is a condition of payment, the ordering physician must document that either he, a nurse practitioner, or a clinical nurse specialist had a face-to-face encounter with the patient prior to the physician submitting the written order. In 42 U.S.C. § 1395m(h)(3), Congress indicated that the face-to-face requirement specified in subsection (a)(11) applied to artificial limbs and other prosthetic devices.

50. The Secretary promulgated regulations in 1992 that allow MACs to require a physician to submit a written order to a supplier before the supplier may deliver and be paid for artificial limbs. MACs have published instructions on their websites directing suppliers to secure a written order from a physician before proceeding to fit a Medicare patient with an artificial limb.

51. Given the requirement for a written order for an artificial limb, the Affordable Care Act contemplates that the physician, nurse practitioner, or clinical nurse specialist will meet face-to-face with the Medicare patient prior to delivery of the written order to the supplier.

52. Notwithstanding the language in the Affordable Care Act, the Secretary has chosen to exempt physicians who issue orders for artificial limbs from the face-to-face requirement. The Secretary announced in final regulations issued on November 16, 2012, that she will address in a future rulemaking which, if any, prosthetic devices should be the subject of the face-to-face encounter requirement.

53. There is no medical need for physicians to issue a dispensing order for an artificial limb for a Medicare patient. Prosthetists almost always have greater training and experience than physicians in assessing what artificial limb would best serve an individual Medicare patient. Moreover, prosthetists already meet with patients for the express purpose of

assessing the patients' condition and prosthetic needs. CMS thus could reasonably direct its MACs to cease requiring that physicians prepare written orders for artificial limbs and thereby obviate the face-to-face encounter obligation.

CMS' Failure to Follow 42 U.S.C. § 1395u(p)(4)

54. The only statutory support cited by the Secretary for issuing the "Dear Physician" letter is Section 1842(p)(4) of the Medicare Act, 42 U.S.C. § 1395u(p)(4). This statute provides that if the Secretary requires documentation from a physician as a condition of a supplier receiving payment for medical equipment ordered by the physician, the physician must provide that documentation to the supplier at the time he or she issues the order.

55. However, 42 U.S.C. § 1395u(p)(4) neither gives the Secretary blanket authority to demand further documentation nor allows the Secretary to impose documentation requirements without going through the rulemaking process mandated by the Medicare Act and APA.

56. The Secretary further has failed to comply with 42 U.S.C. § 1395u(p)(4). Contrary to the statute, the "Dear Physician" letter does not require that a physician provide the information identified in the letter to a supplier at the time the physician places an order for an artificial limb. The "Dear Physician" letter also does not state that a physician who fails to provide the identified documentation will be subject to any sanction. The letter instead states that if physicians do not provide the requested documentation to the supplier, the supplier may not be compensated for the artificial limbs they furnish.

57. AOPA members lack any practical or legal means of inducing physicians to comply with their statutory duty to provide the documentation specified in the "Dear Physician" letter. AOPA members have no contractual relationship with treating physicians, and treating physicians are unaffected if CMS denies a claim by an AOPA member for an artificial limb.

58. CMS has provided no financial incentive to physicians to generate the additional documentation listed in the “Dear Physician” letter. By contrast, CMS compensates physicians to prepare additional entries in their medical records justifying prescriptions of power wheelchairs or scooters, in recognition of the additional work and resources required to document the need for the wheelchair or scooter. Furthermore, CMS grants additional compensation for physicians to reflect the work in documenting the face-to-face encounter required by Section 6407(b) of the Affordable Care Act.

59. CMS has offered no explanation for why it is willing to compensate physicians to prepare the paperwork needed to justify orders for power wheelchairs or scooters, but is not willing to compensate physicians for generating the paperwork CMS now asserts is needed to justify an order for an artificial limb.

60. AOPA members are encountering many physicians who refuse or fail to provide the documentation identified in the “Dear Physician” letter because they are not compensated to do so by CMS. Upon information and belief, CMS and its contractors have not taken any administrative or disciplinary action against physicians who fail to provide the documentation required by the “Dear Physician” letter.

#### CMS’ Enforcement of the “Dear Physician” Letter

61. AOPA members are not permitted to submit claims for payment for artificial limbs they provide to a Medicare patient unless they have actually fitted the prosthetic device and delivered it to the patient.

62. The cost of artificial limbs can range from a few thousand dollars to many thousands of dollars, depending on the function and sophistication of the limb.

63. Because of CMS rules, AOPA members run the risk of not recovering the substantial costs they incur in providing artificial limbs should MACs or other CMS contractors later allege that physician documentation is inadequate. AOPA members further are not compensated for the time and effort spent in responding to CMS contractor audits or in appealing wrongfully denied claims.

64. The financial risk of delayed payments can be substantial. Many AOPA members are small businesses who cannot survive the cash flow drain from being deprived of payment for prosthetic devices for Medicare patients for extended time periods.

65. Denied claims are even more financially ruinous for AOPA members. If the documentation supporting the medical necessity of the prosthetic device is viewed as insufficient, CMS contractors conducting pre-payment audits deny the claim. In the case of claims that were previously paid, CMS recovery audit contractors will demand that the AOPA member refund the payment, plus interest. In the event of a claim denial, AOPA members can appeal, first by seeking a redetermination, second by appealing to a Qualified Independent Contractor, third by requesting a hearing before an administrative law judge, and finally by appealing to the Medicare Appeals Council. However, despite statutory requirements that such appeals be resolved within certain time frames, CMS is processing the appeals of AOPA members outside those time frames, thus adding to the extreme financial burden on the AOPA members.

66. Even if the patient's status as an amputee and medical condition support some form of prosthetic device for the patient, CMS contractors will not even authorize a partial payment on the claim. CMS further does not provide any mechanism for AOPA members to



submit a revised bill for the prosthetic device if they are able to secure further documentation from the physician.

67. MACs and other CMS contractors are aggressively enforcing the new standards set forth in the “Dear Physician” letter, to the detriment of all AOPA members. Since the August 2011 posting of the “Dear Physician” letter, CMS contractors have begun performing pre-payment audits of claims submitted by AOPA members for artificial limbs and denying the claims based on the allegation that physicians submitted insufficient documentation, with the result that medical necessity has not been established. In many cases, CMS contractors are ignoring prosthetist notes that establish the medical necessity for the prosthetic devices.

68. CMS recovery audit contractors (“RACs”) also are reviewing previously paid claims and demanding repayment by AOPA members based on the allegation that the medical necessity for the prosthetic was not established because the physician submitted insufficient documentation, even where the amputation of the patient’s limb made the need for a prosthesis readily apparent. Those RACs are typically paid a percentage of any amounts they claw back from AOPA members. Despite AOPA complaints that the contractors are taking unreasonable positions in their audits, CMS has taken no steps to rein in the RACs or to monitor their denials of claims.

69. CMS claims reviewers are further relying on the “Dear Physician” letter to justify overruling the medical judgment of physicians and prosthetists regarding the K-level of the Medicare patient and the appropriate prosthetic device. Claims reviewers are disallowing claims based on their view that the prosthetic device was not medically necessary without either examining the patient or discussing the case with the treating physician or prosthetist.

70. MACs and RACs are applying the new standards set forth in the “Dear Physician” letter retroactively. MACs and RACs are reviewing and reversing the payment of claims submitted by AOPA members prior to August 2011 based on an alleged failure to provide the documentation identified in the “Dear Physician” letter.

71. Physicians are refusing to provide documentation to AOPA members even after being advised that the AOPA member’s claim is being audited or denied.

72. Upon information and belief, CMS and its contractors are making no effort to secure documentation directly from physicians before denying AOPA member claims or to penalize those physicians whose allegedly inadequate documentation warrants claims denials.

73. As a consequence of the improper actions of CMS and its contractors, all AOPA members have been injured. Many AOPA members have been forced either to cease caring for Medicare patients, to drop prosthetic devices from their product lines, or to go out of business altogether.

#### AOPA’s Presentation of its Complaints to the Secretary

74. On behalf of its members, AOPA presented to the Secretary their complaints regarding the improper posting and retroactive application of the “Dear Physician” letter. AOPA first presented these complaints in late 2011. AOPA sent further protests in 2012, and counsel for AOPA sent a December 14, 2012 letter to Marilyn Tavenner, the Acting CMS Administrator and Secretary’s designee with respect to Medicare issues, explaining the legal infirmities in the posting and substance of the “Dear Physician” letter.

75. The CMS Administrator acknowledged this presentment in a January 17, 2013 response, but she did not rectify the problems in the posting, contents, or application of the “Dear

Physician” letter. Instead, she alleged that “CMS has not changed the documentation requirements.”

76. In reality, CMS had changed the documentation requirements, as a comparison of the “Dear Physician” letter to the Program Integrity Manual shows. The handling of claims also demonstrates the change. Prior to the posting of the letter, almost 100% of claims for prostheses were approved. By contrast, in November 2011, a CMS contractor reported an 86.6% *denial* rate for prosthetic claims. According to the same contractor, 96% of the claims were denied on the basis that there was inadequate physician documentation.

77. AOPA further presented to the Secretary’s designees, George Mills and Marilyn Tavenner, a March 8, 2013 letter raising complaints about claims reviewers overruling the medical judgments of physicians and prosthetists. CMS responded to those complaints in an April 10, 2013 letter but refused to adjust the practices of the CMS claims reviewers.

78. AOPA also submitted to the Secretary, through an April 15, 2013 letter, AOPA’s complaints regarding the improper means by which CMS contractors were enforcing the new rules reflected in the “Dear Physician” letter.

79. Neither the Secretary nor her designees responded to the April 15 letter in writing. Since delivery of the April 15 letter, neither the Secretary nor her designees have stated any intention of withdrawing the “Dear Physician” letter or materially altering the legal standards under which CMS contractors, MACs, and RACs evaluate claims submitted by AOPA members.

80. Despite AOPA’s complaints to the Secretary and her designees, MACs and RACs continue to rely on the “Dear Physician” letter and thus have continued to deny the claims of AOPA members based on the allegation that ordering physicians have not generated sufficient medical documentation to justify the artificial limb.

81. AOPA members have challenged the denial of claims for artificial limbs in administrative appeals. AOPA members have won a significant percentage of those appeals. Despite the losses on appeal, CMS has refused to withdraw the “Dear Physician” letter, revise the rules reflected in it, or change the practices of its contractors and claims reviewers regarding prosthetic devices. Rather than viewing the adverse appeal decisions as evidence that its standards need revision, CMS is considering abolishing the role of the administrative law judges who are ruling against CMS in the AOPA member appeals.

COUNT I (VIOLATIONS OF THE RULEMAKING PROVISIONS OF THE MEDICARE ACT)

82. AOPA realleges and incorporates by reference ¶¶ 1-81.

83. Section 1871(a)(2) of the Medicare Act, 42 U.S.C. § 1395hh(a)(2), provides that no rule or requirement that establishes or changes a substantive legal standard governing the scope of benefits or the payment for services shall take effect unless it is promulgated by the Secretary by regulation.

84. The Secretary previously recognized this statutory obligation when issuing regulations that impose similar documentation requirements for the ordering of durable medical equipment. *See* 71 Fed. Reg. 17021 (April 5, 2006).

85. The Secretary failed to follow the rulemaking process specified by the Medicare Act. Even though the documentation requirement identified in the “Dear Physician” letter establishes and/or changes a substantive legal standard for the payment of claims for artificial limbs, the requirement was not set forth in any regulations for which public notice or an opportunity to provide comments was provided.

86. The “Dear Physician” letter does not meet any of the exceptions to the rulemaking requirement of 42 U.S.C. § 1395hh.

87. The Secretary's failure to follow the notice and comment requirement renders the rules set forth in the "Dear Physician" letter null and void.

88. Section 1871(e) of the Medicare Act, 42 U.S.C. § 1395hh(e), prohibits the Secretary from applying retroactively any substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability except in certain limited cases, none of which is applicable here. Contrary to this provision, the Secretary is enforcing the documentation requirement of the "Dear Physician" letter retroactively.

#### COUNT II (VIOLATION OF THE MEDICARE ACT)

89. AOPA realleges and incorporates by reference ¶¶ 1-88.

90. The Secretary has failed to take any steps to compel treating physicians to honor their duty under 42 U.S.C. § 1395u(p)(4) to provide the documentation specified in the "Dear Physician" letter. The Secretary instead has put the onus on AOPA members to secure the documentation from treating physicians.

91. The Secretary's requirement that AOPA members secure the documentation identified in the "Dear Physician" letter is contrary to 42 U.S.C. § 1395u(p)(4), which requires that physicians must supply any such documentation at the time they order artificial limbs for Medicare patients.

92. The Secretary's failure to comply with 42 U.S.C. § 1395u(p)(4) renders the "Dear Physician" letter null and void.

#### COUNT III (VIOLATION OF THE APA)

93. AOPA realleges and incorporates by reference ¶¶ 1-92.

94. The APA prohibits the Secretary from implementing the Medicare Act through actions, findings, or conclusions accomplished without observing legally-required procedures.

5 U.S.C. § 706(2)(A). Both the APA and Medicare Act require agencies to give the public notice of a proposed rulemaking and an opportunity to submit comments prior to the promulgation of regulations. 42 U.S.C. § 1395hh; 5 U.S.C. § 553.

95. The Secretary failed to observe the notice and comment requirements prior to posting and enforcement of the “Dear Physician” letter.

96. The APA further prohibits the Secretary from implementing the Medicare Act in a manner not in accordance with law or via actions, findings, or conclusions that are arbitrary and capricious. 5 U.S.C. § 706(2)(A).

97. The Secretary lacks the authority under the Medicare Act (1) to refuse to accept prosthetist notes as demonstrating the medical necessity of prosthetic devices and (2) to require instead that AOPA members secure from treating physicians the documentation set forth in the “Dear Physician” letter.

98. With BIPA and the Affordable Care Act, Congress showed its intent that implementation of supplier qualifications, rather than physician documentation, be the means of deterring waste and abuse in the supplying of prosthetic devices.

99. The Secretary’s posting and enforcement of the “Dear Physician” letter against AOPA members, and its concomitant failure to enforce the letter as to physicians, violates the Medicare Act and is arbitrary and capricious. The “Dear Physician” letter thus is invalid under the APA.

#### COUNT IV (VIOLATION OF THE RFA)

100. AOPA realleges and incorporates by reference ¶¶ 1-99.

101. The RFA obligates agencies to assess the negative impact of their rules on small businesses.

102. Because the documentation requirements set forth in the “Dear Physician” letter should have been promulgated as regulations, CMS was required to conduct an impact analysis under the RFA.

103. Most of AOPA’s members are small businesses as defined by the RFA.

104. The Secretary failed to undertake any assessment of the negative impact of the “Dear Physician” letter on AOPA members before MACs posted the letter on their websites and before MAC, RACs, and other CMS contractors began denying claims based on the letter.

105. Neither AOPA nor its members have any adequate remedy at law for the Secretary’s violation of the RFA.

COUNT V (MANDAMUS)

106. AOPA realleges and incorporates by reference ¶¶ 1-105.

107. The Secretary had a plainly defined and nondiscretionary duty to promulgate regulations under Section 427 of BIPA by December 21, 2001.

108. The Secretary has failed to carry out that duty.

109. AOPA members have been irreparably injured as a result of the Secretary’s failure to carry out that duty.

110. Neither AOPA nor its members have an adequate remedy at law to redress the Secretary’s violation of Section 427 of BIPA. Although they do not have the ability to seek a determination on this issue through the submission of a claim for payment, they have presented this issue to the Secretary.

WHEREFORE, AOPA requests that the Court enter a judgment and decree:

A. Declaring that physician documentation standards set forth in the “Dear Physician” letter violate the language and purpose of the Medicare Act and the APA and thus are invalid;

B. Declaring the terms of the “Dear Physician” letter are arbitrary and capricious because (1) prosthetist records can establish the medical necessity for prosthetic devices, (2) the Secretary has failed to provide an adequate explanation for insisting with the “Dear Physician” letter that only physician documentation can establish medical necessity, and (3) the terms put the onus for compliance on AOPA members rather than on physicians as contemplated by the Medicare Act;

C. Declaring that the “Dear Physician” letter is invalid because it was not promulgated as a regulation through a formal rulemaking in compliance with the Medicare Act and APA;

D. Declaring that the Secretary improperly has applied the “Dear Physician” letter retroactively in violation of the Medicare Act and APA;

E. Declaring that the new rules set forth in the “Dear Physician” letter violate the RFA and thus are invalid because of the Secretary’s failure to evaluate their impact on small businesses;

F. Permanently enjoining the Secretary from enforcing the “Dear Physician” letter as to AOPA members;

G. Ordering the Secretary promptly to process the pending claims of AOPA members without requiring that prosthetist records be corroborated by physician records;



H. Ordering the Secretary promptly to reopen and reprocess all claims submitted by AOPA members that were denied based on an alleged failure to meet the documentation requirements set forth in the “Dear Physician” letter;

I. Compelling the Secretary to issue regulations within 60 days regarding the qualifications of suppliers of orthotics and prosthetics as directed by Section 427(b) of BIPA;

J. Awarding AOPA costs and attorneys’ fees pursuant to the Equal Access to Justice Act, 28 U.S.C. § 2412; and

K. Granting such other injunctive and monetary relief as the Court deems appropriate.

Dated: May 13, 2013

Respectfully submitted,

WINSTON & STRAWN, LLP

By: /s/ Gordon A. Coffee  
Thomas L. Mills #911495  
[tmills@winston.com](mailto:tmills@winston.com)  
Gordon A. Coffee #384613  
[gcoffee@winston.com](mailto:gcoffee@winston.com)  
Erica E. Stauffer  
[estauffer@winston.com](mailto:estauffer@winston.com)  
1700 K Street, N.W.  
Washington, D.C. 20006  
(202) 282-5000

Attorneys for Plaintiff American  
Orthotic & Prosthetic Association