Department of Health and Human Services

# DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

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| In the Case of:<br><br>Salem Gastroenterology Associates, P.A.,<br>Pinehurst Medical Clinic, Inc.,<br><br>Petitioners,<br><br>- v. -<br><br>Centers for Medicare & Medicaid Services. | Date: May 7, 2008<br><br>Docket No. C-06-519<br>Decision No. CR1785 |

## DECISION

Petitioners, Salem Gastroenterology Associates, P.A. (Salem Gastroenterology or Petitioner) and Pinehurst Medical Clinic, Inc. (Pinehurst or Petitioner) appeal the decisions of a Medicare Part B Hearing Officer who found that they do not qualify for Medicare provider numbers as Ambulatory Surgical Centers (ASCs). For the reasons discussed below, I affirm the Hearing Officer's decisions.

### I. Background

Medicare Part B Hearing Officer Virginia Gwaltney reopened the prior hearing decisions of February 24, 2006 issued to Salem Gastroenterology and Pinehurst by another hearing officer. Hearing Officer Gwaltney issued new decisions on the reopened cases which reversed the first Hearing Officer's determinations, finding that Petitioners were not eligible to participate as ASCs. Hearing Officer's Gwaltney's new determinations were contained in revised hearing decisions dated April 21, 2006 (for Salem Gastroenterology) and April 24, 2006 (for Pinehurst).[1]

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[1] Petitioner Salem Gastroenterology applied for a Medicare provider number as an ASC in March 2003. Petitioner Pinehurst applied for a Medicare provider number as an ASC in December 2004. Both were approved for enrollment in the Medicare program as ASCs and issued Medicare provider numbers. Subsequently, both Pinehurst and Salem Gastroenterology received letters from the Medicare contractor dated June 30, 2005, and

Salem Gastroenterology and Pinehurst are represented by the same legal counsel. Both Salem Gastroenterology and Pinehurst requested hearings on June 12, 2006. On July 11, 2006, I convened a prehearing telephone conference, the substance of which is memorialized in my Order dated July 14, 2006. During the conference, I granted Petitioners' motion to consolidate these two cases. The parties disagreed as to whether an in-person hearing was necessary. I directed the parties to file briefs so that they could fully argue their positions as to whether or not an in-person hearing was necessary. I advised them that, after reviewing their submissions, I would convene another telephone conference to issue an oral ruling.

On November 22, 2006, I convened another telephone conference with the parties. I ruled that I would not hold an in-person hearing because it appeared that the only issues to be decided are legal issues. I advised the parties that this case would proceed on the merits via written submissions, and I set a briefing schedule. I advised the parties further that I was not foreclosing the need for in-person testimony should the briefing identify a genuine material issue of fact in controversy that would warrant a hearing.

CMS filed a brief, accompanied by two exhibits, CMS Exs. 1 - 2. Petitioners filed a response brief, accompanied by P. Exs. A - G. CMS filed a reply, and Petitioners filed a surreply. No objections have been filed to any of the parties' exhibits, and I have admitted them into evidence in this case.

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July 22, 2005, respectively, advising them that their Medicare provider numbers were revoked. The stated reason for the revocation of Petitioners' provider numbers was that an internal review of all Medicare-enrolled ASCs revealed that Petitioners were not licensed as ASCs by the State of North Carolina as required by CMS.

Both Petitioners requested a Hearing Officer hearing. A Medicare Hearing Officer conducted the hearings concurrently on September 15, 2005, with the same participants, witnesses, and authorized representative. The appeals concerned the same issue, and the arguments presented in the appeals were identical.

Following the hearings, the Hearing Officer issued a fully favorable decision to each Petitioner dated February 24, 2006, finding that the Medicare contractor had improperly revoked Petitioners' ASC provider numbers.

## II. Discussion

### A. Applicable Law

Section 1866(j)(1)(A) of the Act directs the Secretary to establish regulations for the enrollment in the Medicare program of providers of services and suppliers. Section 1866(j)(2) of the Act gives providers and suppliers appeal rights, for certain determinations involving enrollment, using the procedures that apply under section 1866(h)(1)(A) of the Act. Those procedures are set out at 42 C.F.R. Part 498, *et seq.* and provide for hearings by Administrative Law Judges (ALJs) and review by the Departmental Appeals Board (Board).

In provider appeals under 42 C.F.R. Part 498, the Board has determined that CMS must make a *prima facie* case that an entity has failed to comply substantially with federal requirements. *See MediSource Corporation*, DAB No. 2011 ( 2006). *"Prima facie"* means that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004); *see also Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd, Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (GEB) (D.N.J. May 13, 1999). To prevail, the entity must overcome CMS's showing by a preponderance of the evidence. *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd*, *Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (GEB) (D.N.J. May 13, 1999).

### B. Issue

The only issue in this case is whether Hearing Officer Gwaltney's revised decisions of April 21, 2006, and April 24, 2006, which concluded that Petitioners were not qualified to enroll in Medicare as ASCs, should be affirmed.

### C. Analysis

Before I examine the parties' respective arguments, it is instructive to first examine the rationale provided in Hearing Officer Gwaltney's revised decisions dated April 21, 2006 and April 24, 2006. Because the decisions contain the same rationale, I will not distinguish between them. Instead, I shall use the phrase "revised decision" to collectively refer to both of Hearing Officer Gwaltney's revised decisions.

In her revised decision, Hearing Officer Gwaltney focused on the requirement that an ASC must comply with state licensure requirements as a condition for coverage, as set forth at 42 C.F.R. § 416.40. Hearing Officer Gwaltney, moreover, pointed out the existence of N.C. Gen. Stat. § 131E-147, which explicitly prohibits a person from operating an ambulatory surgical facility without a license obtained from the [North Carolina] Department [of Health and Human Services]. Hearing Officer Gwaltney stated that the previously issued hearing decisions issued by the first Hearing Officer dated February 24, 2006, were not correct and failed to address and rule on the licensing issue.

Hearing Officer Gwaltney noted that, according to the records in the file, both Petitioners have admitted that they are not licensed as ASCs by the State of North Carolina. The Hearing Officer stated that the essence of their arguments is that the State of North Carolina does not require them to be licensed as ASCs in order to perform office endoscopies and therefore, they are compliant with North Carolina licensure laws and eligible for Medicare approval as an ASC. Hearing Officer's revised decision.

Hearing Officer Gwaltney found Petitioners' argument to be misguided and incorrect. She distinguished between performing endoscopies in physicians' offices, which does not require state licensure, and performing endoscopies as part of the operation of an ASC, which *does* require state licensure. She noted that Petitioners had applied for enrollment not as a physician's office with an endoscopy procedure room, but as ASCs performing endoscopies. As such, to operate as ASCs and bill Medicare the fees for the endoscopies, Petitioners were required to comply with the State licensure requirement contained in 42 C.F.R. § 416.40. Because the State of North Carolina requires a license to operate as an ASC (N.C. Gen. Stat. § 131E-147), Petitioners were required to be in compliance with this state licensing requirement. The Hearing Officer concluded that as long as Petitioners lacked state licenses as ASCs, they were not qualified to enroll in Medicare as ASCs.

Hearing Officer Gwaltney next addressed Petitioners' argument that their accreditation by a national accrediting agency was sufficient for Medicare certification in North Carolina. She also found this argument to be without merit.

Hearing Officer Gwaltney noted that Petitioner Pinehurst was granted accreditation in the Medicare deemed status program by the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC), effective September 23, 2004. She noted that the AAAHC website "acknowledges that being deemed to meet the Medicare conditions of coverage for ASCs through accreditation" by the AAAHC gives an ASC an option to a state agency review, but also notes that there may be other state licensing obligations that need to be fulfilled by ASCs. CMS Ex. 1, at 9; CMS Ex. 2, at 8.

Hearing Officer Gwaltney also pointed out that the AAAHC website, in the section titled "Questions and Answers Regarding Medicare Deemed Status," stated that "'organizations currently AAAHC-accredited do not automatically qualify for Medicare certification. An organization needs to apply specifically for the Accreditation Association Medicare survey and Medicare-related standards will be applied during the requested survey.'" CMS Ex. 1, at 9; CMS Ex. 2, at 8.

In examining the previous hearing decision issued on February 24, 2006, Hearing Officer Gwaltney states that the previous Hearing Officer erred in her analysis of the relevant regulation found at 42 C.F.R. § 416.26. Hearing Officer Gwaltney states that the previous Hearing Officer applied only 42 C.F.R. § 416.26(a)(1) to arrive at the incorrect conclusion that deemed compliance through AAAHC accreditation qualified Pinehurst and Salem Gastroenterology for Medicare enrollment. Hearing Officer Gwaltney points out that the previous Hearing Officer failed to apply 42 C.F.R. § 416.26(a)(2), which must be read in conjunction with subsection (a)(1) of the regulation, and that, under 42 C.F.R. § 416.26(a)(2), ASCs, even with deemed status through accreditation, must comply with state licensure requirements. CMS Ex. 1, at 11; CMS Ex. 2, at 10.

Hearing Officer Gwaltney applied the identical rationale for Salem Gastroenterology. She did note that Salem Gastroenterology was accredited by AAAHC on August 14, 2001, and that this was a general accreditation and did not provide Medicare certification. She states that Salem Gastroenterology underwent an AAAHC/Medicare deemed status survey effective June 2, 2004, which meant that, on January 27, 2004, when Salem Gastroenterology was initially approved for enrollment as an ASC, it not only lacked a state license but had not yet been deemed Medicare compliant by the accrediting association. CMS Ex. 1, at 9.

**CMS's position**

CMS argues that Petitioners have not met the definition of an ASC set forth at 42 C.F.R. § 416.2. Under the regulatory definition, an ASC must be a "distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part." CMS contends that Petitioners are not "distinct entities" separate from the physician practices. Further, CMS argues that neither Petitioner operates "exclusively" for the purpose of providing surgery because Petitioners also provide physician services. CMS Br. at 1-2.

In CMS's view, the regulatory definition of ASC requires Petitioners to create separate legal entities to perform ASC services, and that Petitioners' alleged ASCs are not separate corporations or separate partnerships, nor do they possess separate tax identification numbers. CMS asserts that Petitioners are physician practices that have been subdivided, and they are improperly seeking to operate an ASC doing endoscopies as part of the physician practices. Moreover, CMS argues that while an ASC must also be physically separated from its physician's practice, this requirement is subordinate to the requirement that the ASC must first be a distinct legal entity.

In addressing the Hearing Officer decisions of April 21 and 24, 2006, CMS notes that the Hearing Officer's rationale was "correct," but "also needlessly complex." CMS Br. at 8. CMS asserts that it agrees that Petitioners "did not meet required state law licensure requirements," but contends that "there is no need to reach that issue because they clearly do not, in any event, meet [42 C.F.R.] § 416.2." *Id.*

**Petitioner's position**

In response, Petitioners assert that CMS has "presented a new reason for rejecting" their applications, in its claim that they "are not separate legal entities from the physicians' practices which operate the [ASCs]." P. Response at 1-2. Petitioners protest CMS's new argument, contending that this issue had never been raised in the several years of litigation, and that no one from the State of North Carolina, the Medicare contractor, or CMS had ever stated or suggested that the phrase "distinct entity" contained in the regulatory definition of ASC should be interpreted as meaning a separate legal entity.

Petitioners assert that the definition of ASC at 42 C.F.R. § 416.2 requires only a "distinct entity," not a "distinct legal entity." Petitioners contend that the ASCs which they operate "are distinct entities from the physicians' practices by which they are owned." According to Petitioners, an entity called the Salem Endoscopy Center is owned and operated by Salem Gastroenterology (a physicians' practice) and is a free-standing endoscopy center that has its own waiting room, reception area, furniture, office equipment, personnel, and maintains patient information separately from the physicians' practice. Petitioners also state that an entity called the Pinehurst Medical Clinic Endoscopy Center is owned and operated by Pinehurst (a physicians' practice), and, though housed in the same building, is a physically separate and distinct operation adjacent to Pinehurst. The Pinehurst Endoscopy Center and the physicians' practice have their own waiting areas, separated from the other by a dividing wall. The Pinehurst Endoscopy Center has separate staff, and maintains separate patient information from the physicians' practice. According to Petitioners, physicians with Pinehurst have designated days in the practice and designated days in the endoscopy center, with no overlapping duties on a single day. Petitioners do not deny that their endoscopy centers are not separate legal entities from the physicians' practices with which they are affiliated.

Petitioners contend that there are no documents issued by CMS that suggest that an applicant to be an ASC must be a separate legal entity from the physicians' practice. Petitioners point to Appendix L of the CMS State Operations Manual, and contend that the manual's interpretive guidelines for 42 C.F.R. § 416.2 state only that there must be physical separation of space, separate recordkeeping, dedicated staff, and the ASC must use its space for ambulatory surgery exclusively. Petitioners assert that they have met these requirements. They assert further that the interpretive guidelines say nothing about a requirement that an ASC and its affiliated physicians' practice must be separate legal entities.

With respect to the state licensing issue, Petitioners continue to emphatically maintain that they do not need to be licensed by North Carolina. As support for its position, Petitioners cite to the State Operations Manual (SOM)'s interpretive guidelines for 42 C.F.R. § 416.40, which state the following: "Where a State has no applicable licensure requirements, or where ambulatory surgical services may be provided without licensure, a facility will be eligible if it meets the definition of § 416.2 and all other applicable Medicare requirements." P. Br. at 20 (emphasis in brief) (quoting from P. Ex. D, at 3 (SOM, Appendix L – Guidance to Surveyors: Ambulatory Surgical Services)).

Petitioners also contend that they are accredited by AAAHC, and that "if North Carolina does not require a license, such accreditation is sufficient to qualify them for Medicare," pursuant to 42 C.F.R. § 416.26(a)(1). P. Br. at 20. Petitioners also note that the director of the Division of Facility Services (DFS) of the North Carolina Department of Health and Human Services has stated under oath that Salem does not have to be licensed.

Furthermore, Petitioners insist they are covered by the exception contained at the end of N.C. Gen. Stat. § 131E-146(1), which states that "the performance of incidental, limited ambulatory surgical procedures which do not constitute an ambulatory surgical program . . . and which are performed in a physician or dentist's office does not make that office an ambulatory surgical facility." According to Petitioners, whether or not it is consistent with CMS's reading of the statute, DFS has long applied this quoted language in such a manner as to allow Petitioners, and other physicians' practices in North Carolina, to operate endoscopy centers without state licenses as ambulatory surgical facilities. P. Response Br. at 21; *see* CMS Ex. 1 at 47.

**Discussion**

The regulations define an ASC to mean "any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part." 42 C.F.R. § 416.2.

Petitioners applied for Medicare provider numbers as ASCs. Petitioners do not dispute that they do not possess licenses from the State of North Carolina to operate as ASCs. Petitioners maintain, however, that they qualify for Medicare certification based on their accreditation by AAAHC. In Petitioners' view, "[g]iven the confusing state of North Carolina law on licensing," CMS should allow them to qualify for Medicare based on their accreditation." P. Surreply at 5.

Before I discuss Petitioners' claims, I note that, in its brief, CMS asserted that Petitioners were not separate legal entities from the physicians' practices, and therefore, did not satisfy the "distinct entity" requirement contained in the definition of ASC under 42 C.F.R. § 416.2. CMS argued that Petitioners thus cannot be enrolled in Medicare as ASCs because, at the outset, they fail to even meet the definition of an ASC. In its response, Petitioners asserted that the only basis cited in the Hearing Officer's decisions for the revocation of their Medicare provider status had been their failure to have state licenses as ASCs. Petitioner alleged that CMS was introducing the "distinct entity" argument in litigation for the first time and attempting to justify revocation based on this new reason.

I agree with Petitioner that Hearing Officer Gwaltney addressed primarily the state licensure issue in her decisions and did not consider whether or not Petitioners met the "distinct entity" requirement of the regulatory definition. Hearing Officer Gwaltney acknowledged that the "essence" of Petitioners' argument was their claim that North Carolina did not require them to be licensed as ASCs and therefore, they were in compliance with state law and eligible for Medicare approval as ASCs. *See* CMS Ex. 1, at 6; CMS Ex. 2, at 5. She thus focused her analysis on the licensing issue and the related accreditation issue. Inasmuch as I agree with the issues as they were framed in Hearing Officer Gwaltney's decisions and Petitioners' hearing requests, it is unnecessary for me to address CMS's allegation that Petitioners do not meet the regulatory definition of an ASC.

As stated above, the only issue before me is whether Hearing Officer Gwaltney's revised decisions concluding that Petitioners were not licensed as ASCs by North Carolina, and therefore were not qualified to enroll in Medicare as ASCs, are correct and should be affirmed. I find the arguments advanced by Petitioners to be unavailing. Nothing in this record convinces me that Hearing Officer Gwaltney was incorrect in her analysis, and I affirm her decisions.

Pursuant to 42 C.F.R. § 416.40, an ASC must comply with State licensure requirements as a condition for coverage. The State of North Carolina has licensure requirements specific to an ASC. The language of N.C. Gen. Stat. § 131E-147 is plain: "No person shall operate an ambulatory surgical facility without a license obtained from the Department [of Health and Human Services.]" Thus, in order for a facility in North Carolina to enroll as an ASC with the Medicare program, it must demonstrate that it complies with the North Carolina state licensing requirements.

In their brief, Petitioners state that their endoscopy centers "are separate and distinct [ASCs], not just endoscopy rooms within a physician's office." P. Response at 16. However, Petitioners then make the contradictory argument that it is the physicians' practices that are performing the endoscopies, and therefore, the practices fall under the state law exception which permits a physician's office that performs "incidental, limited ambulatory surgical procedures which do not constitute an ambulatory surgical program" to remain unlicensed. N.C. Gen. Stat. § 131E-146; *see* P. Response at 21.[2]

In its reply brief, CMS argues that Petitioners are "trying to have it both ways." CMS Reply at 10. CMS asserts that it is impossible for a facility to be both a "distinct entity that operates exclusively for the purposes of providing surgical services" and to be performing surgery as "incidental" to a physician's practice, in a physician's office. CMS Reply at 11. I agree with CMS. Petitioners cannot have it both ways.

Petitioners applied for enrollment not as physician's offices with endoscopy procedure rooms, but as ASCs performing endoscopies. *See* CMS Ex. 1, at 7, CMS Ex. 2, at 6. As such, Petitioners do not satisfy the exemption from licensing articulated by N.C. Gen. Stat. § 131E-146. If they wish to be enrolled in Medicare, Petitioners are required to demonstrate compliance with the North Carolina licensing requirements applicable to ASCs.

Petitioners argue that "CMS has not come forward with any authority to support its view of North Carolina law that the Salem and Pinehurst endoscopy centers must have state licenses to continue to perform endoscopies." P. Surreply at 4. Petitioners' continued and stubborn persistence in arguing that North Carolina law does not require them to be licensed flies against the plain meaning of the law and regulations. I reiterate the text of

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[2] In a letter dated November 6, 2003 to a CIGNA representative, Petitioners' counsel wrote, *inter alia*, "Salem Gastroenterology is seeking Medicare certification as an [ASC] so it will qualify for a facilities fee. Salem Gastroenterology is operated as an endoscopy procedure room in a physician's practice, and it has been accredited by the Accreditation Association for Ambulatory Health Care. It is not licensed by North Carolina." CMS Ex. 1, at 56.

N.C. Gen. Stat. § 131E-147: "No person shall operate an ambulatory surgical facility without a license obtained from the Department [of Health and Human Services.]" Contrary to what Petitioners claim, CMS is not "conjecturing" as to the meaning of North Carolina's licensing law because no "conjecture" is necessary. P. Surreply at 4. Moreover, in pointing to the SOM's Interpretive Guidelines as support for its position, Petitioners conveniently ignored the first sentence of the guidelines for 42 C.F.R. § 416.40: "In States where licensure is required for a facility providing ambulatory surgical services, ask to see the facility's current license." P. Ex. D, at 3 (SOM., Appendix L – Guidance to Surveyors: Ambulatory Surgical Services).

The requirement for a license is stated in absolutely clear and unambiguous terms in the North Carolina statute. The SOM emphasizes that ASCs must have a current license in States where a license is required. No amount of interpretative contortions by Petitioners can change the plain meaning of the statute or regulations.

In her decisions issued to Salem Gastroenterology and Pinehurst, Hearing Officer Gwaltney stated as follows:

> . . . your Provider Enrollment application is not for enrollment as a physician's office, it is for enrollment as an Ambulatory Surgical Facility. To enroll as a North Carolina [ASC], and bill Medicare both the physicians' fees and the facility fees for your endoscopies, you must be licensed by the North Carolina Department of Health and Human Services, Division of Facility Services, Licensure and Certification Section, as specified above in 42 C.F.R. § 416.40 and G.S. § 131E-147(a).

CMS Ex. 1, at 7, CMS Ex. 2, at 6. Hearing Officer Gwaltney concluded that as long as Petitioners lacked North Carolina state licenses as ASCs, they were not qualified to enroll in Medicare as ASCs. I find Hearing Officer Gwaltney's reasoning to be correct under the law and regulations.

Petitioners' accreditation argument is also without merit and demonstrates a further, misguided understanding of the regulations. In Petitioners' view, not only are they not required to be licensed under North Carolina law, but they qualify for Medicare certification based on their AAAHC accreditation.

In addressing this issue in her decision, Hearing Officer Gwaltney referred to 42 C.F.R. § 416.26, and noted that subsection (a)(2) states, "[i]n the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements." Hearing Officer Gwaltney reasoned that, under subsection (a)(2), "CMS requires that, even with deemed status through accreditation, ASCs must comply with state licensure requirements." CMS Ex. 1, at 11.

Thus, contrary to what Petitioners believe, a facility's deemed status through accreditation may not, in and of itself, be sufficient for enrollment in Medicare as ASCs. The text of 42 C.F.R. § 416.26(a)(2) explicitly indicates that, where State law requires licensure, the ASC must also comply with the requirement, in addition to having its accreditation. Again, there is no doubt that, in North Carolina, an ASC must have a state license. Petitioners have AAAHC accreditations, but failed to satisfy the state licensing requirement. Accordingly, they cannot qualify for Medicare certification on the basis of their AAAHC accreditations alone, pursuant to 42 C.F.R. § 416.26(a)(2).

Finally, regardless of what the law actually requires, Petitioners assert that CMS should take note of "actual North Carolina licensing practice." P. Surreply at 4. In Petitioners' view, the fact that North Carolina has apparently allowed Petitioners and other physicians' practices to operate endoscopy centers for years without licenses is "evidence" that they do not need to be licensed and also indicates the "confusing state of North Carolina law on licensing." P. Surreply at 4, 5; P. Response at 20. Petitioners' arguments are irrelevant to the issue before me. Even if they were relevant, I am without authority to consider such claims.

## III. Conclusion

Petitioners have failed to comply with North Carolina's state licensing requirement for ASCs. Thus, under the regulations, they do not qualify for Medicare provider numbers as ASCs and therefore, cannot be enrolled as ASCs in the Medicare program. I affirm Hearing Officer Gwaltney's revised decisions of April 21, 2006, and April 24, 2006.

/s/

Alfonso J. Montano
Administrative Law Judge