

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:)	DATE: October 31, 2008
)	
Bluegrass Orthopaedics)	
Surgical Division, LLC)	
)	
Petitioner,)	Civil Remedies CR1766
)	App. Div. Docket No. A-08-99
)	
)	Decision No. 2206
)	
- v. -)	
)	
Centers for Medicare &)	
Medicaid Services.)	

FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION

Bluegrass Orthopaedics Surgical Division, LLC (BOSD), an entity created and wholly-owned by a group of Kentucky physicians, appealed the March 25, 2008 decision by Administrative Law Judge (ALJ) Carolyn Cozad Hughes, DAB CR1766 (2008) (ALJ Decision). In that decision the ALJ granted summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS), sustaining CMS's determination that BOSD did not qualify for Medicare certification as an ambulatory surgical center (ASC) because BOSD did not have a license as required by federal regulations and Kentucky state law. For the reasons discussed below, we affirm the ALJ Decision.

Legal Background

The applicable legal authority is set out in the ALJ Decision at 1-2 and in the analysis section of our decision.

Case Background

The following undisputed facts are drawn from the ALJ Decision and the record below.

On October 5, 1992, Burke & Lockstadt, P.S.C. (B&L) was organized under Kentucky Law as a professional services corporation to provide health care services. BOSD Ex. 1, at 2. B&L is wholly owned by seven physicians who are licensed to practice medicine in the Commonwealth of Kentucky. Id. BOSD describes its organizational structure as follows:

BOSD, the applicant, is a Kentucky limited liability company owned entirely by Bluegrass Orthopaedics. Bluegrass Orthopaedics is the assumed name of the private physicians' office of Burke & Lockstadt, P.S.C., a Kentucky professional service corporation (the "Practice"). The Practice primarily provides physician services, i.e., evaluation and management CPT codes, to all of its patients.

CMS Ex. 2. at 2. BOSD also describes its corporate relationship with B&L as follows:

The physician offices of "Burke & Lockstadt, P.S.C., d/b/a Bluegrass Orthopaedics" is organized as a professional services corporation and operates a wholly-owned subsidiary - Bluegrass Orthopaedics Surgical Division, LLC. (BOSD) is organized as a limited liability company separate and distinct from its parent (i.e., the physician office of Burke & Lockstadt, P.S.C.).

CMS Ex. 3, at 3. BOSD does not have a license from the Commonwealth of Kentucky to operate as an ASC.

BOSD applied for enrollment as a Medicare Health Care Provider/Supplier to enable it to receive reimbursement as an ASC for ambulatory care services rendered to Medicare beneficiaries. BOSD Ex. 1 at 4. BOSD's application was denied by the Medicare Part B carrier and later by CMS "because the Commonwealth of Kentucky requires certificate of need approval and state licensure to establish an ambulatory surgical center for [sic] which [BOSD] has not obtained." BOSD Ex. 10; see also CMS Ex. 1, at 1.

BOSD filed a request for hearing before an ALJ challenging CMS's decision to deny its application to participate in the Medicare program as an ASC. CMS Ex. 3. The ALJ rendered a written

decision granting CMS's motion for summary judgment thereby sustaining CMS's decision not to certify BOSD as an ASC.¹

Standard of Review

The standard of review on a disputed issue of law is whether the ALJ decision is erroneous. Green Hills Enterprises, LLC, DAB No. 2199 (September 18, 2008).

Analysis

BOSD contends that the ALJ Decision is clearly erroneous because BOSD "is exempt from - and therefore in compliance with - all state licensure requirements." P. Br. at 1. Since it is undisputed that BOSD does not have a state license to operate as an ASC, the only issue in this case is whether BOSD is required to be licensed under Kentucky state law or whether it is exempt from that licensure requirement under Kentucky's "physician's office exemption." If licensure is required by Kentucky, then BOSD is not eligible for Medicare certification. For the reasons discussed below, we find no error in the ALJ's conclusion that in order for BOSD to be Medicare certified as an ASC, BOSD must first be licensed under Kentucky State law.²

1. *The ALJ Decision that Kentucky law requires an ASC to be licensed is not erroneous.*

In states where licensure is required for an ASC providing ambulatory surgical services, the federal regulations require the ASC to comply with the licensure requirement in order to be certified to participate in Medicare as an ASC. 42 C.F.R. § 416.40; see also 42 C.F.R. § 416.26(a)(2). Thus, the initial question in this case is whether Kentucky requires an ASC to be licensed. Kentucky law provides that "no person shall operate any **health facility** in this Commonwealth without first obtaining a license" KRS § 216B.105(1) (emphasis added). In defining the term "health facility," Kentucky law explicitly includes "ambulatory surgical centers." KRS § 216B.015(12). The ALJ concluded that under the plain language of these two Kentucky statutes, a "health facility" such as BOSD is clearly required to

¹ The parties agreed that the only issue in dispute was legal and filed cross-motions for summary judgment based on the written record. ALJ Decision at 1.

² We have thoroughly considered all of the arguments raised by BOSD even if they are not discussed in this written decision.

obtain a license in order to operate in Kentucky as an ASC.³ ALJ Decision at 2. BOSD does not contest this portion of the ALJ Decision.

Instead, BOSD contends that, even though it is not licensed, the ALJ erred because BOSD met the regulatory definition of an ASC set forth at 42 C.F.R. § 416.2, as a "distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization." P. Br. at 6. This argument is without merit. Even if BOSD met the definition of an "ASC" under the regulation, the regulation also specifically requires that an ASC meet the conditions set forth in subparts B and C of Part 416. 42 C.F.R. § 416.2. One of the specific conditions for Medicare participation listed under subpart C is that the "ASC comply with state licensure requirements." 42 C.F.R. § 416.40. Because Kentucky law requires an ASC to be licensed, BOSD has not met all the regulatory criteria for Medicare certification as an ASC in the definition set forth at section 416.2.

BOSD also contends that it is entitled to Medicare certification by "deemed status" because it was accredited as an ASC by the Accreditation Association for Ambulatory Health Care, Inc. (AAAHC). P. Br. at 8-9; BOSD Ex. 11. This argument also has no merit. Even in the case of certification through "deemed status," the federal regulations specifically require that "where State law requires licensure, the ASC complies with State licensure requirements." ALJ Decision at 2 (quoting 42 C.F.R. § 416.26(a)(2)). The ALJ's reading is consistent with the preamble to the regulation, which provides that: "Section 416.26(a)(2) requires that facilities seeking Medicare certification as ASCs based on their accreditation by either JCAHO or AAAHC comply with State licensure requirements where applicable." 61 Fed. Reg. 67041, 67045 (Dec. 19, 1996). Because BOSD does not have the required license under Kentucky law, BOSD has not met all the regulatory criteria for Medicare certification under "deemed status."

³ The ALJ Decision is consistent with the conclusion in this case by the Kentucky Office of Inspector General (OIG) for the Kentucky Cabinet for Health and Family Services (Cabinet), which is the Kentucky State agency that administers most Kentucky health care programs. See BOSD Ex. 10 ("Please be advised that the Commonwealth of Kentucky requires certificate of need approval and state licensure to establish an ambulatory surgical center.").

In sum, we conclude that the ALJ's conclusion that Kentucky State law requires an ASC to be licensed is not erroneous.

2. *The ALJ's Decision that BOSD Is Not Entitled to the Physician's Office Exemption from Licensure under Kentucky State Law is Not Erroneous.*

BOSD next contends that the ALJ Decision should be reversed because under the physician's office exemption, it is not subject to licensure by the Commonwealth of Kentucky. P. Br. at 4-7. As discussed below, this argument is without merit.

The practice of medicine in Kentucky is regulated by the Board of Medical Licensure (Board). See KRS §§ 311.530-311.620. Because physicians and their private offices are regulated by the Board, BOSD claims that they are "insulated from competing review and regulation by the Cabinet." P. Br. at 4. According to BOSD, this "insulation" is effectuated by what is commonly referred to as the Kentucky "physician's office exemption," which is set forth at KRS 216B.020(2)(a). *Id.* This Kentucky statute exempts the "private offices and clinics of physicians" from "licensure, supervision, regulation, or control in any manner" so long as the physician's office does not exceed the adjusted statutory threshold for purchasing major medical equipment established by KRS 216B.015(4). KRS 216B.020(2)(a).

In support of its contention that it is exempt from licensure under the physician's office exemption, BOSD relies exclusively upon an opinion from the General Counsel for the Cabinet to AAAHC. CMS Ex. 8. AAAHC had sought an opinion on whether the purchase of medical equipment by "Bluegrass Orthopaedics" (i.e., B&L d/b/a Bluegrass Orthopaedics) "that would allow its physicians to perform surgical procedures within their private offices" would result in additional licensure requirements or affect Bluegrass Orthopaedics' ability to obtain Medicare certification. *Id.* In response, the General Counsel opined that given his understanding that the expenditure would not exceed the adjusted threshold under KRS 216B.015(4) and "the proposed medical equipment would be located entirely within the physicians' private offices or clinic[,] . . . the answer to both questions is 'no'." *Id.*

The ALJ found that BOSD's reliance on this opinion letter is misplaced for two reasons. First, the ALJ found that the General Counsel had qualified his opinion by emphasizing that his office had "not investigated" the ownership of Bluegrass Orthopaedics and, therefore, cannot certify that their offices and clinics are physicians' offices or clinics. ALJ Decision at 3; CMS Ex. 8.

Second, the ALJ observed that both the physician's office exemption at KRS 216B.020(2)(a) and the General Counsel's letter plainly refer to a "physicians' practice that performs surgeries, not to an ASC." ALJ Decision at 3. Thus, the ALJ concluded that "Petitioner cannot be both a physicians practice and an ASC." Id.

We find that the ALJ correctly determined that BOSD is not exempt from licensure by the Commonwealth of Kentucky under KRS 216B.020(2)(a). First, the General Counsel's statement is not relevant in resolving the licensure question involving BOSD because the letter clearly refers to "Bluegrass Orthopaedics" (which is d/b/a B&L), not BOSD, as the purchaser of medical equipment. In addition, as the ALJ noted, the General Counsel's opinion is specifically based on his "understanding" that the medical equipment was to be used in the private physician offices of B&L, not BOSD. CMS Ex. 8. It is clear from BOSD's own representation of its corporate structure that BOSD is a separate, albeit unlicensed, ASC where outpatient surgical services are performed. See CMS Ex. 3 at 3 (BOSD was organized by B&L "for the sole purpose of providing themselves with a location to perform certain ambulatory surgical services."); see also BOSD Ex. 1, at 3-4. In contrast, B&L is a "private physician office or clinic." Under Kentucky law, the definition of "office or clinic" is "the physical location at which health care services are provided." 900 KAR 6:050(12). In an opinion that was issued in 1990, the Kentucky Attorney General stated that the term "private offices and clinics" used in the physician's office exemption statute "is concerned with a specific building, room or rooms not open to the general public, which the physician uses on a regular basis to provide health services to his patients, and is not a health facility as defined in KRS 216B.015(12)." Ky. Op. Atty. Gen. 2-314, Ky. OAG 90-14, 1990 WL 512593 (Feb. 23, 1990) (emphasis added). Thus, under Kentucky law, a "private office" clearly is not a "health facility" as defined under KRS 216B.015(12). Under these circumstances, the General Counsel's opinion cannot reasonably be interpreted to mean that BOSD, as an ASC that is a different corporate entity from B&L, is entitled to exemption from licensure under the Kentucky physician's office exemption.

Second, the opinion sought from the General Counsel was also limited to addressing whether the proposed purchase of medical equipment triggered any licensing requirement. Since the amount of the purchase was below the statutory threshold set forth in KRS 216B.015(4), the General Counsel opined that under this circumstance B&L, not BOSD, did not need a license. The opinion letter contains absolutely no discussion of the crucial question

in this case - to wit - whether an ASC that is wholly-owned by physicians is entitled to the Kentucky physician's office exemption.⁴ Thus, the General Counsel's opinion does not constitute a sufficient legal basis for finding that BOSD is exempt from state licensure as an ASC.

In an attempt to show that the General Counsel's opinion is applicable here, BOSD takes a different tack and portrays BOSD and B&L as "one entity" (i.e., a composite practice group of B&L, BOSD, and the physicians) for purposes of determining whether BOSD must be licensed by the Commonwealth of Kentucky. P. Br. at 5, n.15, and 7. At the same time, however, BOSD also argues that it is a "distinct entity" (i.e., an ASC) "exclusively" providing only surgical services by virtue of its corporate structure for purposes of meeting the regulatory definition of an ASC at 42 C.F.R. § 416.2. BOSD's hybrid position is also inconsistent with the fact that the application for Medicare certification was made solely by BOSD, not the composite practice group of BOSD and B&L. P. Br. at 3, 8; CMS Ex. 2, at 2. If B&L and BOSD are essentially "one entity" for purposes of licensure, then BOSD cannot also reasonably be considered "distinct" for purposes of meeting the regulatory definition of an ASC at section 416.2. Similarly, if BOSD is exempt from licensure under the physician's office exemption as part of the same composite group practice with B&L, then BOSD cannot be "exclusively" providing surgical services within the meaning of section 416.2 because B&L "primarily provides physician services" and does not exclusively provide surgical services. CMS Ex. at 2.

This analysis is consistent with the purpose of the regulation as expressed in the preamble for Part 416, the regulation which governs the certification of an ASC to participate in Medicare. In explaining the purpose of Part 416, CMS stated:

Section 934 of Pub. L. 96-499 distinguished between ambulatory surgical centers and private office

⁴ The Kentucky licensing statute does not contain any exception for an ASC that is wholly-owned by physicians. BOSD has also not cited, and we are unaware of, any legal authority that demonstrates the Commonwealth of Kentucky intended the physician's office exemption to apply to physician-owned ASCs. If the Commonwealth of Kentucky had intended to permit a private physician's office to operate as an ASC, then it is reasonable to conclude that Kentucky would have explicitly provided an exception to the licensure requirement when the owners were physicians.

practices, both in terms of health and safety standards that must be met, and in terms of surgical procedures that are appropriate in each setting. The requirement that an ASC must operate "exclusively" for the purpose of providing ambulatory surgical services, will exclude private office practices that provide other health services.

* * *

While State licensure and Certificate-of-Need (CON) requirements vary a great deal from State-to-State, we believe that they will exclude many private office practices from eligibility as ASCs.

47 Fed. Reg. 34082, 34085 (Aug. 5, 1982). Thus, BOSD's attempt to be considered "one entity" for purposes of seeking exemption from state licensure is not consistent with the intent of the regulation that a physician's office that provides other health services in addition to surgical services not be certified as an ASC.⁵

Finally, BOSD argues that the ALJ "slipped" in referring to the physician's **practice** instead of physician's **office**, and that this "hints at the inherent flaw in that Decision." P. Br. at 7 (emphasis in original). BOSD argues that the "ALJ's Decision ignores Kentucky's definition of the 'practice' in the context of an applicant claiming the physician's office exemption" because the Kentucky statute defines "practice" to mean the entity that proposed to provide health care services, which includes the "owners and operators of the office." *Id.* (emphasis added). Since B&L and BOSD are owned by the same group of physicians, BOSD contends that they should be considered one "office" under Kentucky law for purposes of qualifying for the licensure exemption.

⁵ BOSD also contends that the ALJ unnecessarily interpreted an unambiguous statute by reference to irrelevant legislative history. P. Br. at 10-11 (citing ALJ Decision at 3, n.3). We need not consider this argument because the ALJ did not rely upon the legislative history of the underlying federal statute in reaching her decision. Instead, the ALJ's reference to the legislative history was merely to illustrate that Congress intended to treat ASCs differently from private physician's offices in the types of surgical services that would be reimbursed in each setting. See ALJ Decision at 3-4.

For the reasons previously addressed, we believe that the ALJ correctly characterized the nature of BOSD's inherently inconsistent position. Indeed, BOSD undercuts its own argument by also claiming that the "composite group [i.e., B&L, BOSD, and the individual physicians] constitutes the '**practice**' under Kentucky law for purposes of the physician's office exemption." Id. at 7 (emphasis added). Even if the ALJ did incorrectly "slip" in her reference to the composite group "practice" and should have instead used the term of "office" in her decision, it would be harmless error. As previously discussed, as a health facility (i.e., an ASC) under Kentucky law, BOSD cannot also be a private "physician's office or clinic" entitled to exemption from licensure. See Ky. Op. Atty. Gen. 2-314, Ky. OAG 90-14, 1990 WL 512593 (Feb. 23, 1990) (a "private office or clinic" under KRS 216B.020(2)(a) "is not a health facility as defined in KRS 216B.015(12)."). Therefore, BOSD and B&L cannot effectively be treated as "one entity" as part of a collective physician's "office" in an effort to circumvent Kentucky licensure rules and yet still maintain the charade of being "distinct" and providing "exclusive" surgical services within the meaning of section 416.2 for purposes of obtaining Medicare certification.

In sum, we conclude that the ALJ's determination that BOSD is not entitled to the physician office exemption from licensure under Kentucky State law is not erroneous.

Conclusion

For the foregoing reasons, we affirm the ALJ Decision entering summary judgment in favor of CMS.

_____/s/
Shelia Ann Hegy

_____/s/
Constance B. Tobias

_____/s/
Stephen M. Godek
Presiding Board Member