## Department of Health and Human Services

## DEPARTMENTAL APPEALS BOARD

## **Appellate Division**

In the Case of:

DATE: December 17, 2009

Peter McCambridge, C.F.A.,

Civil Remedies CR1961

Petitioner,

App. Div. Dkt. No. A-09-104

Decision No. 2290

Centers for Medicare &

Medicaid Services.

# FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Peter McCambridge (Petitioner) appeals the June 16, 2009 decision by Administrative Law Judge (ALJ) Richard J. Smith, Peter McCambridge, C.F.A., DAB CR1961 (2009) (ALJ Decision). The ALJ upheld a determination by the Centers for Medicare & Medicaid Services (CMS) to deny Petitioner's application for enrollment in Part B of the Medicare program. In support of his enrollment application, Petitioner, a surgical first assistant, claims that because he provides services covered by Medicare, and because he also is a "health care provider" as defined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936, he qualifies for enrollment in Medicare Part B. As we discuss below, the federal Medicare statute and regulations, not HIPAA and its implementing regulations, govern eligibility for Medicare enrollment. Furthermore, the ALJ correctly determined that the Medicare statute and regulations do not authorize CMS to enroll Petitioner in the Medicare program as a surgical first assistant. We thus affirm the ALJ Decision.

### Legal Background

The Medicare program provides health insurance benefits to persons 65 years and older and to certain disabled persons. CMS, a component of the Department of Health and Human Services (HHS), has overall responsibility for administering Medicare. CMS delegates some of its Medicare responsibilities to private contractors (usually insurance companies).

Congress established Medicare in title XVIII (sections 1801-1898) of the Social Security Act (Act). (We refer to title XVIII as the Medicare statute.) HHS has published regulations that implement the Medicare statute; those regulations are found in title 42 of the Code of Federal Regulations.

Medicare pays for health care items or services that fall within the benefit categories specified in the Medicare statute.

Medicare has two main parts: Part A, which pays for hospital stays and other institutional services; and Part B, which pays for outpatient services provided by physicians and other practitioners (as well as other items and services not covered under Part A). See Act §§ 1811, 1831. Only Part B is relevant here.

Two conditions must be met before Part B will pay for a health care service. First, the service must be a "covered service." 42 C.F.R. § 424.5(a)(1)(i). The services covered by Part B are found in section 1832 of the Act and in 42 C.F.R. Part 410. Second, the service "must have been furnished by a provider... or supplier that was, at the time it furnished the services, qualified to have payment made to them." Id. § 424.5(a)(2) (emphasis added). The term "supplier" is defined in the Medicare statute to mean "a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title." Act

The Act can be found at www.ssa.gov/OP\_Home/ssact/compssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section.

Title 42 C.F.R. § 410.1(b) states that "[t]his part [namely, part 410] sets forth the benefits available under Medicare Part B [and] the conditions for payment and the limitations on services[.]"

§ 1861(d) (emphasis added); <u>see also</u> 42 C.F.R. § 400.202 (defining a "supplier" to mean "a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare).<sup>3</sup>

In order to obtain a Medicare billing number and be eligible to receive direct payment from Medicare for covered services, a supplier must "enroll" in the Medicare program. 42 C.F.R. § 424.505.

### Case Background

The material facts of this case are undisputed. In August 2008, Petitioner, a Florida resident, submitted an application for enrollment in Medicare Part B. CMS Ex. 1. Petitioner indicated in his application that he was seeking to enroll as a "surgical first assistant." Id. at 10. Attached to Petitioner's application was a certificate issued by the National Institute of First Assisting (NIFA). Id. at 31. The certificate indicates that Petitioner completed NIFA's "First Assistant Course for Surgical Technologists."

A CMS contractor denied Petitioner's enrollment application. CMS Ex. 2. A contractor hearing officer upheld the denial, whereupon Petitioner requested a hearing before the ALJ. CMS Exs. 4-5. CMS then moved for summary judgment, contending that Petitioner's enrollment application had been properly denied because "the Medicare Part B program does [not] recognize certified first assistants as practitioners eligible for enrollment or afford coverage for their services." CMS Brief in Support of Motion for Summary Judgment at 1 (March 3, 2009). In response, Petitioner contended that he is eligible for Medicare enrollment because his services as a surgical first assistant are covered by Medicare, and because he is a "health care provider" as defined in regulations that implement HIPAA. Brief-in-Chief For Petitioner (March 24, 2009).

The ALJ granted summary judgment to CMS, concluding that Petitioner's application for enrollment had been properly

The term "provider of services," which is inapplicable here, means a hospital, skilled nursing facility, or other institution or entity. Act  $\S$  1861(u).

Petitioner submitted his application on a standard form applicable to "physicians and other practitioners" (Form CMS-8551). CMS Ex. 1.

denied. Citing Medicare program regulations, the ALJ held that "[a] certified first assistant simply is not included as a category in the definition of practitioners eligible for enrollment in the Medicare program" and further noted that Petitioner's services "are not eligible for Medicare reimbursement." ALJ Decision at 5. The ALJ also found it "significant that Congress [had] declined to approve a statutory change that would have granted Certified Registered Nurse First Assistants the Medicare Part B status Petitioner now claims."

Id. Finally, the ALJ rejected Petitioner's contention that certain HIPAA regulations rendered him eligible for Medicare enrollment. Id. at 5-6.

Petitioner filed a timely request for review of the ALJ Decision. The Board held oral argument on November 12, 2009. (A tape recording of the oral argument is part of the record on appeal.)

#### Discussion

The purpose of the Medicare Part B enrollment process, the outcome of which Petitioner is appealing, is to determine a supplier's eligibility to bill and receive Medicare payment for health care services. 42 C.F.R. § 424.502 (defining the term "enrollment" to mean a process for establishing eligibility to submit payment claims to Medicare). It follows that CMS may deny Petitioner enrollment if Part B does not authorize payment for his services as a surgical first assistant. See id. § 424.505 (stating that a provider must be enrolled in the program to receive Medicare payment for "covered services"). The ALJ correctly concluded that Petitioner is ineligible for enrollment because Part B does not authorize payment for his services.

Medicare's regulations provide that Part B pays only for the "covered services" specified in 42 C.F.R. Part 410, which implements section 1832 of the Act. 42 C.F.R. §§ 424.5(a)(1)(i), 410.1(a)(1). Section 1832(a) of the Medicare statute and section 410.3 of the Medicare regulations provide that Part B covers "medical and other health services" (and other items and services not relevant to this case). The term "medical and other health services" is defined in the Medicare statute and regulations to include physician services and services performed by various types of non-physician health practitioners. Act § 1861(s); 42 C.F.R. § 410.10.

We have carefully reviewed the statutory and regulatory definitions of "medical and other health services," and they do not include services provided by a "surgical first assistant." See Act § 1861(s); 42 C.F.R. § 410.10. We note that the regulations which define the scope of covered Part B services - sections 410.1 through 410.175 - refer to services provided by various types of non-physician practitioners, including occupational therapists (§ 410.59), physical therapists (§ 410.60), speech pathologists (§ 410.62), physician assistants (§ 410.74), nurse practitioners (§ 410.75), and clinical nurse specialists (§ 410.76). Those regulations do not identify services furnished by surgical first assistants as covered services.

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In an effort to determine if there is any other basis for Petitioner to qualify for enrollment in Medicare Part B, we reviewed other potentially applicable coverage and payment provisions in the Medicare statute and regulations. However, none of those provisions mention surgical first assistants See, e.g., Act § 1832 (describing the scope of benefits covered by Part B), § 1833 (setting out rules governing the amount of, and conditions for, Part B payment for covered services). For example, a Medicare regulation entitled "To whom payment is made" contains a list of practitioners and entities that Part B may pay directly for covered services. See 42 C.F.R. § 410.150. That list includes nurse practitioners and clinical nurse specialists but not surgical first assistants. Id.  $\S 410.150(b)(2)$  to (b)(19). In addition, part 414 of the Medicare regulations contains rules governing payment for the services of various kinds of non-physician practitioners, such as physician assistants, nurse practitioners, and clinical nurse specialists. 42 C.F.R. § 414.52-.62. Again, surgical first assistants are not mentioned.

Equally significant is the fact that the Medicare statute authorizes payment for the <u>kind</u> of services that Petitioner provides - assisting a physician during surgery, also known as "assistant-at-surgery" services - but only when those services are performed by certain specified practitioners. In particular, the Medicare statute and regulations expressly authorize Part B payment under the physician fee schedule for

Section 410.150(b)(1) authorizes Part B to pay the "physician or other supplier" on the beneficiary's behalf for "medical and other health services." As discussed, the term "medical and other health services" does not include the services of a surgical first assistant.

assistant-at-surgery services performed by physician assistants, nurse practitioners, and clinical nurse specialists. See Act § 1833(a)(1)(0)(ii); 42 C.F.R. §§ 414.52(d), 414.56(c); 64 Fed. Reg. 39,608, 39,617 (July 22, 1999). The statute and regulations also require practitioners in each of these groups to meet certain educational, licensure, and certification requirements as a condition of their eligibility to participate in Medicare. See, e.g., Act § 1861(aa)(5); 42 C.F.R. § 410.74(c) (physician assistants), § 410.75(b) (nurse practitioners), and § 410.76(b) (clinical nurse specialists). During oral argument, Petitioner readily acknowledged that he is not licensed as a physician's assistant and does not fit into any of these other categories of practitioners eligible to receive direct payment from Part B.6

Title 42 C.F.R. § 410.10(b) states that "medical and other health services" include services "furnished incident to a physician's professional services, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills" (emphasis added). This provision also does not support Petitioner's argument because an "incident to" service is billed by the physician (or other entity or professional eligible to bill for such a service under the physician fee schedule) and not by the auxiliary practitioner who provides that service; payment for an "incident to" service is, in effect, bundled with the payment made to the physician. See 42 C.F.R. § 414.34(b) ("Services of nonphysicians that are covered as incident to a physician's service are paid as if the physician had personally furnished the service."); Medicare Claims Processing Manual (CMS Pub. 100-4), Ch. 12 § 30.6.4, and Ch. 23 § 30 (available at http://www.cms.gov/Manuals/IOM/list.asp). At oral argument Petitioner stated that he is not seeking to have payment for his services bundled with payment to a physician; rather, he is seeking to be paid independently by Medicare for his services. In any event, we have no reason to believe that Petitioner's services, which (we understand) are furnished to hospital inpatients, would even qualify for "incident to" status because they are not of the kind "commonly furnished in physicians' offices."

Nonetheless, Petitioner maintains that he does, in fact, provide "covered services," citing section 1848(i)(2) of the Act.

<sup>&</sup>lt;sup>6</sup> Petitioner further acknowledged that the state of Florida does not currently license or otherwise regulate surgical first assistants.

Request for Review (RR) at 2. However, section 1848(i)(2) is not a coverage provision. Rather, it prescribes limitations on the amount of Medicare payment for covered assistant-at-surgery services performed by physicians.

Petitioner further suggests that he is eligible for Medicare enrollment because federal and state regulations are silent about any licensure, credentialing, or certification requirements applicable to surgical first assistants. However, this view is inconsistent with the Medicare program's elaborate statutory and regulatory scheme, which creates a program of defined and limited benefits, coupled with specific practitioner qualification requirements that aim to ensure that program beneficiaries receive high quality health See Act § 1802 (stating that Medicare beneficiaries may obtain services from any institution, agency, or person "qualified to participate" in the program); Final Rule, Medicare Program; Requirements for Providers and Suppliers To Establish and Maintain Medicare Enrollment, 71 Fed. Reg. 20,754 (April 21, 2006) (noting a provider or supplier's compliance with enrollment and other statutory and regulatory participation requirements is meant to ensure that Medicare beneficiaries receive high quality care); Final Rule, Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates, 69 Fed. Reg. 48,916, 49,223 (August 11, 2004) (stating that the purpose of Medicare's participation requirements for hospitals is to ensure that participating hospitals furnish high quality care); 42 C.F.R. §§ 410.74-.77 (setting out qualification requirements for various types of practitioners, including physician assistants). Congress nor the Secretary of HHS saw fit to include surgical first assistants among the groups of practitioners eligible to receive payment for assistant-at-surgery services. The Board is required to follow the plain language of the Medicare statute and the implementing regulations, which do not authorize Medicare payment for the services of surgical first assistants.

At oral argument, Petitioner asserted that Medicare ought to pay him for his services because although he is not a physician assistant, nurse practitioner, or other licensed practitioner, he is as well-trained and experienced as those practitioners to provide assistant-at-surgery services. While it might arguably be a wise and economical policy for Medicare to pay properly trained and credentialed surgical first assistants for their services, the Board is not empowered to create or dictate such a policy. The authority to create coverage and payment policy, as embodied in the Medicare statute and regulations, rests with

Congress and CMS, not with the Board. The Board's role is to apply the Medicare laws as they exist, and we see nothing in those laws that authorizes CMS to pay for Petitioner's services as a surgical first assistant.

Petitioner's chief argument in this appeal, as it was before the ALJ, is that certain HIPAA regulations make him eligible to enroll in Medicare. Petitioner points to a January 23, 2004 final rule issued by the Secretary of HHS, entitled HIPPA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers, 69 Fed. Reg. 3434 (Jan. 23, 2004) (January 2004 Final Rule). The January 2004 Final Rule implements certain "administrative simplification" provisions of HIPAA that are codified in sections 1171-1180 of the Act. One of those statutory provisions, section 1173(b)(1), requires the Secretary of HHS to establish a "standard unique health identifier for each individual, employer, health plan, and health care provider for use in the health care system." The January 2004 Final Rule implemented section 1173(b)(1) by adopting regulations which establish the National Provider Identifier, or NPI, as the standard unique health identifier for "health care providers" in the health care system. 69 Fed. Reg. These regulations - codified in 45 C.F.R. Part 162, subpart D - require "covered entities" to use the NPI in connection with certain health care-related "transactions." Id. at 3468-69; see also 45 C.F.R. Part 162, subparts A-I.

Title 45 C.F.R. § 160.103 specifies the "covered entities" subject to the NPI mandate and other HIPAA requirements. That regulation provides that covered entities include a "health plan" or a "health care provider that transmits any health information in electronic form in connection with a transaction covered by this subchapter" (emphasis added). The regulation further states that the term "health care provider"

means a provider of services (as defined in section 1861(u) of the Act) . . ., a provider of medical or health services (as defined in section 1861(s) of the Act) . . ., and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

45 C.F.R. § 160.103 (emphasis added). In commenting on the NPI requirements, the preamble to the January 2004 Final Rule states:

An entity that meets certain Federal statutory implementation specifications and regulations is eligible to participate in the Medicare program. Our definition of "health care provider" at § 160.103 includes those eligible to participate in Medicare as described in Federal statute (that is, in § 1861(s) and § 1861(u) of the Social Security Act). These entities, according to Federal statute and regulations, must be issued their own identification numbers in order to bill and receive payments from Medicare.

69 Fed. Reg. at 3438 (emphasis added). According to Petitioner, this passage "unambiguously" indicates that <u>all</u> covered "health care providers," as defined in section 160.103, are eligible to enroll in Medicare, and that because he meets HIPAA's definition of a health care provider – being a person who "furnishes, bills, or is paid for health care in the normal course of business" – he is eligible to enroll in Medicare. RR at 1-3. Petitioner also suggested at oral argument that Medicare should pay for his services, just as he alleges private insurers do, because he is subject to, and compliant with, HIPAA's requirements for conducting "transactions" involving the transfer of electronic health information – transactions that include the submission of insurance payment claims.

While Petitioner's legal arguments are creative, his reliance on section 160.103 and the January 2004 Final Rule is misplaced. As discussed, Petitioner's eligibility to enroll in Medicare – i.e., to receive payment directly from Part B – depends in part on whether his services are eligible for payment under that program. The rules governing Medicare payment and enrollment are set out in the Medicare statute (title XVIII of the Act) and in title 42 of the Code of Federal Regulations. HIPAA and its regulations are found elsewhere – in title XI of the Act and title 45 of the Code of Federal Regulations. Furthermore, HIPAA's regulations have nothing at all to say about what services a health insurer, such as Medicare, must pay for or who it must pay for covered services. Rather, the HIPAA regulations

See, e.g., Act § 1832 (describing the scope of benefits under Part B), § 1833 (setting out rules for Part B payment), and § 1866(j) (requiring the Secretary of HHS to "establish by regulation a process for the enrollment of providers of services and suppliers under this title"); 42 C.F.R. § 424.500 et seq. (establishing requirements for Medicare enrollment).

establish industry-wide standards - applicable to health care providers and insurers (both public and private) - to facilitate electronic health transactions and to protect the security and privacy of information exchanged in those transactions. See 45 C.F.R. Part 162. Nothing in the HIPAA statute or regulations requires a health insurer to cover or pay for a service merely because a payment claim for that service is made in accordance with HIPAA protocols. See 45 C.F.R. §§ 162.410, 162.412, 162.923-.925 (requiring covered entities to perform certain transactions as "standard transactions" and prescribing standards for such transactions).

Petitioner misunderstands the meaning of the quoted preamble passage upon which he relies. That passage does not indicate that all "health care providers" subject to HIPAA are also eligible to enroll in Medicare. The passage says only that the definition of a covered health provider in section 160.103 "includes" persons or entities that are eligible to participate in Medicare under applicable provisions of the Medicare statute. In addition to persons and entities eligible to participate in Medicare, HIPAA's definition of "health care provider" expressly includes "any other person or organization" that provides health care services" (see 45 C.F.R. § 160.103), which means that the universe of "health care providers" under HIPAA is, by definition, larger than the universe of persons and entities eligible to participate in Medicare. Consequently, the fact that a person meets the definition of a health care provider under HIPAA does not necessarily mean that the person is also eligible to participate in Medicare.

Section 160.103, the regulation upon which Petitioner relies, merely defines the types of persons and organizations - "health care providers" - that are subject to HIPAA requirements codified elsewhere in title 45 of the Code of Federal Regulations. Section 160.103 expressly states that its definitions, including the definition of a covered health care provider, "apply to this subchapter" (referring to subchapter C of title 45 of the Code of Federal regulations) unless otherwise indicated. Nothing in section 160.103 indicates that its terminology or definitions apply to Medicare enrollment or payment decisions, which are governed by the Medicare statute and by title 42 of the Code of Federal Regulations. We note that HIPAA and the Medicare statute use different terminology to refer to a non-physician health care practitioner like the Petitioner. Medicare refers to a non-physician practitioner, such as Petitioner, as a "supplier." HIPAA, on the other hand, classifies Petitioner as a "health care provider."

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In claiming that CMS failed to follow applicable statutes and regulations, Petitioner cites Chevron U.S.A. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). In Chevron, the Supreme Court held that if a federal statute expresses Congress's clear and unambiguous intent concerning an issue, a federal agency must give effect to that intent. U.S. at 842-43. This holding does not provide the relief that Petitioner seeks because it is not relevant here. The HIPAA statute and regulations, upon which Petitioner relies, do not address the controlling issue in this case, which is Petitioner's eligibility to participate in Medicare. Here, both the Medicare statute and the implementing regulations unambiguously address those who may qualify for enrollment, and Petitioner's status as a surgical first assistant simply does not fit into any of the authorized categories. Thus, Chevron is not applicable to the facts of this case.

We note that Petitioner submitted with his request for review exhibits that were not introduced during the ALJ proceeding. Wе are not authorized to admit these additional exhibits. 9 42 C.F.R. § 498.86 (a) (precluding, in provider and supplier enrollment appeals, the Board from admitting evidence in addition to the evidence admitted at the ALJ hearing). event, these additional exhibits would not support Petitioner's claim that he is eligible to enroll in Medicare. Exhibit 2, for example, is a GAO report entitled Medicare: Payment Changes Are Needed for Assistants-at-Surgery, GAO-04-97 (January 2004). According to Petitioner, an appendix to this report contains a memorandum from an acting CMS Administrator who discussed "payment changes to include all surgical assistants." However, we see nothing in the report's appendix indicating that Congress or CMS has changed Medicare coverage and payment rules

<sup>&</sup>lt;sup>9</sup> For the same reason, we decline to admit material that Petitioner attached to his November 13, 2009 email messages to the Board.

to include practitioners like Petitioner. Moreover, the body of the report confirms our central conclusion, which is that the Medicare statute does not authorize Part B payment for assistant-at-surgery services performed by a surgical first assistant. Report at 7-8 (indicating that Part B pays for assistant-at-surgery services performed by specific groups of non-physician practitioners that are authorized to receive payment for their services under the physician fee schedule). 10

## Conclusion

Based on the foregoing, the ALJ Decision is affirmed.

\_\_\_\_\_<u>/s/</u> Sheila Ann Hegy

\_\_\_\_\_<u>/s/</u> Leslie A. Sussan

\_\_\_\_\_\_/s/\_\_\_\_\_\_Stephen M. Godek
Presiding Board Member

The lack of statutory authorization is reflected in a January 13, 2004 cover letter to the GAO report, which states that "Congress has been asked to authorize Certified Registered Nurse First Assistants (CRNFA) and other nonphysician health professional groups whose members provide assistant-at-surgery services to bill Medicare under the physician fee schedule for these services." P. Ex. 2 (emphasis added).