

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Harris Histology Services,

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-16-587

Decision No. CR4733

Date: November 10, 2016

DECISION

Petitioner, Harris Histology Services, is a slide preparation facility that does business in California. Operating as a sole proprietorship, it participated in the Medicare program for many years. When the facility reorganized itself as a limited liability company (LLC), this new legal entity applied to enroll in the Medicare program. The Centers for Medicare & Medicaid Services (CMS) denied its application, claiming that neither the Medicare statute nor any regulation allows a slide preparation facility to enroll. Petitioner appeals the denial.

The parties have filed cross-motions for summary judgment. For the reasons discussed below, I deny CMS's motion and grant Petitioner's.

Background

A "slide preparation facility" receives tissue samples from physicians, primarily dermatologists, prepares slides of those tissue samples, and returns the slides to the physician. P. Ex. 1 at 1 (Harris Decl. ¶ 4); P. Ex. 2 at 3; CMS Ex. 4 at 3-4. Such entities have apparently been serving physicians for many years. In 1976, Harris Histology began operating as a sole proprietorship, and, since 1994, it has been enrolled in the

Medicare Part B program as a supplier of services. P. Ex. 1 at 1-2 (Harris Decl. ¶¶ 5, 8). In April 2015, the business reorganized as Harris Histology Services, a limited liability company, and obtained a new taxpayer identification number. In accordance with CMS requirements, on June 8, 2015, it filed a new enrollment application (CMS Form 855B) with the Medicare contractor, Noridian Healthcare Solutions. P. Ex. 1 at 2-3 (Harris Decl. ¶¶ 11, 15); CMS Ex. 1; CMS motion and brief (CMS MSJ) at 2.

By letter dated December 2, 2015, the Medicare contractor denied Petitioner's application. CMS Ex. 3. Citing 42 C.F.R. § 424.530(a)(1), the letter asserts that no statutory or regulatory authority permits a slide preparation facility to enroll in or receive payment from the Medicare program. CMS Ex. 3 at 1.

Petitioner requested reconsideration. In a reconsidered determination, dated April 4, 2016, the contractor upheld the denial, also citing 42 C.F.R. § 424.530(a)(1), and declaring that no statutory or regulatory authority allows a slide preparation facility to enroll in or receive payment from the Medicare program. CMS Ex. 5. Petitioner timely appealed.

The parties have filed cross motions for summary judgment. With its motion and brief, CMS submitted ten exhibits (CMS Exs. 1-10). Petitioner submitted its own brief and cross-motion for summary judgment, substituting a revised version that corrected typographical errors (P. MSJ). Petitioner submitted five exhibits (P. Exs. 1-5). CMS replied to Petitioner's motion (CMS Reply).

CMS objects to four of Petitioner's exhibits – P. Ex. 1 attachments, P. Exs. 2, 4, and 5 – citing 42 C.F.R. § 498.56(e)(1), which precludes me from admitting new documentary evidence absent a showing of good cause for submitting that evidence for the first time at the Administrative Law Judge level. CMS argues that no good cause justifies my admitting this “new evidence.” These exhibits are not new documentary evidence. They are sections from manuals and other instructions from CMS to its contractors and others, i.e., these documents are sub-regulatory statements of CMS policy. As such, a party need not submit them as marked exhibits but could simply draw them to my attention, which Petitioner subsequently (and needlessly) did, re-labeling them as attachments rather than exhibits. I therefore overrule CMS's objections. For convenience, I will refer to these issuances by their exhibit numbers.

Discussion

Petitioner is entitled to summary judgment because the uncontroverted evidence establishes that, for decades, CMS has enrolled slide preparation facilities in the Medicare program and pays for the services

they provide, and no policy issuance or other directive establishes that CMS has changed this policy.¹

CMS may deny a supplier's Medicare enrollment if the supplier does not comply with enrollment requirements. 42 C.F.R. § 424.530(a)(1). From this, CMS argues that a slide preparation facility does not comply with enrollment requirements because neither the statute nor any regulation authorizes its enrollment in the Medicare program.

The problem with CMS's position is that, for more than 20 years, CMS's policies have considered that the statute and regulations authorized a slide preparation facility's program participation. Since the early 1990's, CMS and its predecessor, the Health Care Financing Administration (HCFA),² have allowed slide preparation facilities to enroll in the Medicare program as suppliers and have paid for their services "through the technical component of the surgical pathology service." CMS Ex. 4 at 5. Initially, it seems, CMS carriers³ enrolled slide preparation facilities as Independent Physiological Labs. When HCFA no longer allowed Independent Physiological Labs to enroll, some Medicare carriers converted slide preparation facilities to Independent Diagnostic Testing Facilities (IDTFs). "Due to their unique characteristics," HCFA determined that slide preparation facilities could not technically qualify as IDTFs; nevertheless, the agency recognized them as suppliers performing services that may be reimbursed under Medicare Part B. In instructions effective September 15, 1999, HCFA authorized Medicare carriers to convert slide preparation facilities to IDTFs "if that is the only way that the carrier can effect payment." HCFA indicated that "in the future" it might set standards for SPFs and "place them in a code other than an IDTF code." CMS Ex. 4 at 5.

For years thereafter, HCFA and its successor, CMS, reiterated its position that slide preparation facilities could be enrolled in the Medicare program and that Medicare would reimburse them for the services they provided:

- In a transmittal dated August 21, 2009 (Transmittal 539), CMS directed its contractors to begin a "limited provider revalidation effort," focusing on all slide preparation facilities, to ensure that CMS is "enrolling and paying [only] eligible organizations." P. Ex. 1 at 6.

¹ I make this one finding of fact/conclusion of law.

² "HCFA" was renamed "CMS" in 2001.

³ Carriers are CMS contractors that process Part B claims. Social Security Act § 1842(a).

- In a September 14, 2011 technical direction letter to its contractors, CMS advised that, in accordance with section 6401 of the Patient Protection and Affordable Care Act, existing providers “must be reevaluated under new screening guidelines by no later than March 23, 2013.” CMS Ex. 6 at 1.⁴ The memorandum exempts slide preparation facilities from revalidation “at this time.” CMS Ex. 6 at 1, 7.

CMS points to this exemption as evidence that slide preparation facilities cannot properly enroll in the Medicare program, but this does not follow. CMS Br. at 8. CMS did not explain why it exempted slide preparation facilities from its 2011 revalidation efforts, but I find it far more likely that, in the face of such a daunting task – revalidating all enrolled providers/suppliers in a relatively short time – CMS opted to exempt, for the time being, the category of suppliers whose participation it had so recently revalidated.

Moreover, CMS’s subsequent statements and instructions undercut CMS’s position.

- In letters dated January 26 and February 13, 2012, Marilyn Tavenner, CMS Acting Administrator, assured the American Association of Histology Laboratories that CMS “[is] not attempting to abolish the classification of [slide preparation facility]” and has no plans to change the “clinical laboratory improvement amendments exemption for the technical component of current procedural terminology code 88305” (i.e., the billing code for slide preparation services). She promised that Medicare would continue to pay the claims submitted for covered services “as such claims have been paid in the past,” although she cautioned that, “[a]s with any policy” CMS could revise its position. CMS Ex. 4 at 6, 8.
- Noridian’s own list of Medicare Part B specialties, updated October 15, 2013, includes Slide Preparation Facilities under its list of suppliers. CMS Ex. 4 at 10; *see also* CMS Ex. 4 at 14 (12/8/15 document listing slide preparation facilities as providing reimbursable services).
- The current version of CMS’s Medicare Claims Processing Manual provides that the services provided by slide preparation facilities are “payable through the technical component of the surgical pathology service,” and cites the payment codes. The manual repeats CMS’s long-standing position that slide preparation facilities are not IDTFs but “must enroll separately with their Medicare

⁴ CMS initially submitted a copy of this memorandum, “redacted to provide only relevant information due to confidential contents.” I have no idea why any of this should be confidential, and CMS has not explained why. But the redacted version leaves just two sentences; everything else has been obscured, which makes it impossible to determine the document’s purpose. CMS Ex. 6 at 1, 7; CMS Ex. List at 3. At my direction, CMS provided an un-redacted version, from which I could determine the purpose of the memorandum.

contractor.” Medicare Claims Processing Manual, Ch. 35 ¶ 10.2C; P. Ex. 2 at 3; *see also* P. Ex. 4 at 7 (provider/supplier taxonomy, listing slide preparation facilities under “technologists, technicians & other technical service providers/technician, other”).

- The current version of CMS’s Medicare Program Integrity Manual lists entities that are not eligible to enroll in Medicare. I agree with CMS that the list was never meant to be exhaustive. However, if slide preparation facilities were on the list, my inquiry could stop there. The facilities are not on the list. P. Ex. 3; *see* P. Ex. 5 at 3.

Thus, without articulating the specific portions of the Act or regulations, CMS has treated slide preparation facilities as hybrids or subsets of IDTFs or labs, both of which are eligible for Medicare enrollment. *See, e.g.*, 42 C.F.R. § 410.33. CMS did not act illegally or extra-legally when it enrolled these entities, but exercised its discretionary authority to make policy. In this regard, I do not agree with Petitioner that CMS’s enrollment determinations are substantive rules that require notice-and-comment before they can be changed. CMS has the discretion to reverse its policy and may deny enrollment. It may also allow currently enrolled facilities to continue their enrollment, while denying new enrollment applications. And I would generally defer to CMS’s articulated policies.

But CMS must somewhere articulate that policy change so that I have some authority to which I can defer. Here, CMS cites no manual provision, policy transmittal, directive, or other generally accepted articulation of policy. Indeed, as noted above, current manual provisions authorize enrollment. Instead, CMS asks me to infer the policy change, based on flimsy evidence:

- I have already discussed why I reject CMS’s reliance on its September 14, 2009 technical direction letter, which exempted slide preparation facilities from revalidation.
- CMS points to changes in the application form (CMS Form 855B), which apparently eliminated “slide preparation facility” from its checklist of supplier types, although the form includes the option “other” and allows the applicant to fill in the “type of supplier.” CMS Ex. 1 at 9. There could be many reasons for this change, however. An enrollment application may reflect CMS policies, but it is not the appropriate means by which CMS should make or change its policies.
- CMS also points to December 23, 2009 changes in the Medicare Program Integrity Manual (CMS Transmittal 320), which deleted a section titled “slide preparation facilities.” CMS Ex. 7 at 4. But entire portions of the manual have been deleted, including sections covering such obviously Medicare-eligible entities as rural

health clinics, skilled nursing facilities, ambulatory surgical centers, CLIA labs, and many others. CMS Ex. 7 at 3-4. This does not establish any policy change with respect to slide preparation facilities.

- CMS provides the written declaration of Noridian Operations Manager Jesse Score, who says that the contractor’s “business analysts” determined, based on the September 14, 2011 technical direction letter, that slide preparation facilities may no longer enroll in Medicare. CMS Ex. 2 at 4 (Score Decl. ¶ 10). He also refers to the opinion of CMS’s Provider Enrollment Operations Group, but neither identifies the members of that group nor explains the basis for its opinion. CMS Ex. 2 at 4 (Score Decl. ¶ 11). Finally, he refers to the December 23, 2009 manual changes. CMS Ex. 2 at 5 (Score Decl. ¶ 12). As I have already discussed, these “authorities” are not persuasive evidence that CMS has changed its decades-old policy.

Conclusion

For more than twenty years, CMS (and its predecessor, HCFA) concluded that the Medicare statute and regulations authorize Medicare enrollment of slide preparation facilities. Because CMS points to no reliable evidence that it has changed that policy, I grant Petitioner Harris Histology’s motion for summary judgment and reverse the Medicare contractor’s reconsidered determination.

/s/
Carolyn Cozad Hughes
Administrative Law Judge