

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Heartflow, Inc.,

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-16-460

Decision No. CR4678

Date: August 12, 2016

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services' (CMS) Medicare Administrative Contractor, as affirmed upon reconsideration and ratified by CMS, to deny Medicare participation to Petitioner, Heartflow, Inc.

I. Background

Petitioner, seeking to participate in Medicare as an independent diagnostic testing facility (IDTF), requested a hearing to challenge the determination to deny its application for enrollment. CMS filed a brief in support of the denial along with 11 proposed exhibits that are identified as CMS Exhibit (Ex.) 1-CMS Ex. 11. Petitioner filed a brief along with six proposed exhibits that are identified as P. Ex. 1-P. Ex. 6. I directed the parties to file supplemental briefs addressing certain questions that I raised. The parties did so, and CMS filed an additional exhibit along with its supplemental brief. I receive CMS Ex. 1-CMS Ex. 11 into evidence. I also receive P. Ex. 1-P. Ex. 6. I do not receive CMS's supplemental exhibit. In my instructions to the parties concerning supplemental briefs, I did not leave open the possibility that either party could supplement its evidentiary exchange.

Neither CMS nor Petitioner requested that I convene a hearing in person and I find no reason to do so. I make my decision based on the parties' written exchanges.

II. Issue, Findings of Fact and Conclusions of Law

A. Issue

The issue is whether the Medicare contractor acted within its authority to deny Petitioner participation as an IDTF.

B. Findings of Fact and Conclusions of Law

An IDTF is a facility that performs certain diagnostic tests. It exists independently from a physician's office. 42 C.F.R. § 410.33(a)(1). In order to be certified to participate in Medicare an IDTF must comply with regulatory requirements. 42 C.F.R. § 410.33(b).

One of the requirements that an IDTF must comply with in order to participate is that it must perform tests under the authority of a supervising physician. 42 C.F.R. § 410.33(b)(1). The supervising physician must be proficient in the performance and interpretation of each type of test performed by the IDTF. 42 C.F.R. § 410.33(b)(2).

CMS has authority to determine, at its discretion, what qualifications a supervising physician must manifest in order to qualify to supervise an IDTF. The regulation states that proficiency may be demonstrated by certification in specific areas of testing performed by the IDTF or pursuant to criteria established by the Medicare carrier for the service area in which the IDTF is located. 42 C.F.R. § 410.33(b)(2). However, the regulation does not spell out in detail exactly what qualifications a supervising physician must have in order to qualify to supervise a given type of test. The regulatory language plainly leaves it to CMS – or to its delegate, a Medicare contractor – to determine what qualifications are needed on a case-by-case basis.

CMS and its contractors also have discretion to determine how an IDTF may claim reimbursement for the tests that it performs and also as to what tests are reimbursable by Medicare. As a general rule, section 1862(a)(1) of the Social Security Act authorizes CMS to determine which items or services may be reimbursed under Medicare. In specific instances such determination may be made by regulation, by a local coverage determination covering an area served by a Medicare contractor, or on a case-by-case basis. In the end, however, it is a matter of discretion as to what items or services are eligible for reimbursement.

I take notice that CMS has devised procedure codes (CPT codes) to describe the diagnostic tests for which it will make reimbursement. As a general rule, an IDTF

seeking reimbursement for a particular test must claim reimbursement under the specific CPT code that describes the test for which reimbursement is sought.

The contractor's discretion to make case-by-case determinations includes making determinations as to how Medicare will reimburse for novel, rarely provided, or unusual procedures and tests. In the event that an IDTF seeks reimbursement for something that falls within these categories, it must produce evidence that the procedure or test is not already covered under an existing CPT code. The contractor has the authority to decide whether or not it will allow the provider to claim reimbursement under an "unlisted procedure" CPT code. In the end, however, the contractor has the authority to inform the IDTF of the CPT code it must use to claim reimbursement. Medicare Claims Processing Manual, CMS Pub. 100-02, Ch. 13 § 120. It is within the contractor's discretionary authority to reject a request from an IDTF to claim reimbursement for a test or procedure pursuant to an unlisted CPT code.

Petitioner sought to be certified to claim reimbursement for a service known as Fractional Flow Reserve computed tomography services (FFRct). This service is an interpretive procedure which consists of further analysis of a test known as a Cardiac Computed Topography (CT) scan. CMS Ex. 10; CMS Ex. 11. The purpose of FFRct is to analyze a CT scan so as to determine whether there is coronary artery disease or other disease affecting a patient's heart. It is not an additional test so much as it is an interpretation of a test. *Id.* What Petitioner proposed was to examine results of CT scans performed elsewhere and uploaded digitally to Petitioner, using FFRct software. Petitioner proposed to use this software in conjunction with uploaded CT scan results to create a personal, digital, three-dimensional model of a patient's arteries, which it would return to clinicians for their use. CMS Ex. 11 at 3.

Petitioner proposed to claim reimbursement for FFRct under CPT code 93799, a code that is intended to capture unlisted cardiovascular services or procedures that are not captured under other CPT codes. The contractor denied Petitioner's application, essentially because it found that Petitioner sought to perform a non-reimbursable service.

After review of Petitioner's application, the contractor determined that CPT code 75574 covered the CT scan *and* subsequent analyses, including FFRct. It found that Petitioner could not claim reimbursement pursuant to CPT code 93799 because the service that Petitioner intended to seek reimbursement for, FFRct, was considered to be an integral component of the CT scan. Consequently, Petitioner could not claim reimbursement for something that was coverable under CPT code 75574 as an independent service. Nor could Petitioner claim reimbursement for FFRct under CPT code 75574 inasmuch as Petitioner would not perform the CT scan of which FFRct is an integral component.

The contractor determined also that a board-certified radiologist must supervise the CT scan and consequently, integral components of that scan such as FFRct. The supervising

physician that Petitioner intended to use to perform FFRct is not a board-certified radiologist. The contractor denied Petitioner's application for that reason, in addition to its determination that Petitioner sought to provide a non-reimbursable service.

I do not have the authority to second-guess or look behind the contractor's determinations. As I have stated, the contractor has discretion, not only to determine what services are reimbursable, but also what qualifications a supervisory physician at an IDTF must possess. I must affirm the contractor's determination so long as the contractor acted within the ambit of its discretionary authority. *Douglas Bradley, M.D.*, DAB No. 2663 at 13-14 (2015); *Abdul Razzaque Ahmed, M.D.*, DAB No. 2261 at 19 (2009), *aff'd, Ahmed v. Sebalius*, 710 F. Supp. 2d 167 (D. Mass. 2010); *Latantia Bussell, M.D.*, DAB No. 1712 (2008).

In this case the contractor plainly acted within the ambit of its discretion. As I have stated, the regulations confer on the contractor the discretion to determine the necessary qualifications of a supervisory physician at an IDTF. Here, the contractor made an evaluation and determined that a board-certified radiologist must supervise the performance of CT scans and included analyses. Moreover, CMS has delegated to the contractor the authority to determine, on a case-by-case basis, what procedure codes will apply to given items or services. That is entirely consistent with CMS's statutory authority to determine what is necessary, reasonable, and eligible for payment. The contractor's determination in this case is a reasonable discretionary determination that it will not accept reimbursement claims for FFRct analyses separately and apart from claims for the CT scans from which they are derived.

Petitioner argues at length that I should consider the merits of allowing separate reimbursement claims for FFRct analyses. It argues additionally that the physician who it relies on to supervise the performance of these analyses is qualified to do so even if he is not a board-certified radiologist. These arguments effectively demand that I second-guess the contractor's exercise of discretion. I do not have the authority to do so.

_____/s/
Steven T. Kessel
Administrative Law Judge