# DEPARTMENTAL APPEALS BOARD
## Appellate Division

HeartFlow, Inc.
Docket No. A-17-4
Decision No. 2781
April 5, 2017

## FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Petitioner HeartFlow, Inc. (HeartFlow or Petitioner) appeals the August 12, 2016 decision of an Administrative Law Judge (ALJ). *HeartFlow, Inc.*, DAB CR4678 (2016) (ALJ Decision). The ALJ upheld a determination by a contractor of the Centers for Medicare & Medicaid Services (CMS) to deny, pursuant to 42 C.F.R. § 424.530(a)(1), Petitioner's application for enrollment in the Medicare program as an independent diagnostic testing facility (IDTF). The ALJ determined that CMS, through its contractor, acted within the ambit of its discretion in determining that the service for which Petitioner proposed to bill Medicare if permitted to enroll as an IDTF was not reimbursable and that the physician employed was not qualified to supervise the IDTF. For the reasons stated below, the Board upholds the ALJ Decision.

## Legal Background

The Medicare program, established under title XVIII of the Social Security Act (Act), pays for covered health care items and services furnished to program beneficiaries by qualified "providers" and "suppliers." *See* Act §§ 1811-1812, 1832-1833, 1866[1]; 42 C.F.R. Part 424, subpart P (requirements for providers and suppliers to obtain and maintain Medicare billing privileges). CMS administers the program, delegating certain functions to private contractors. Act §§ 1816, 1842, 1874A; 42 C.F.R. § 421.5(b).

To receive Medicare payment for covered items or services, a provider or supplier must be approved by CMS for "enrollment." 42 C.F.R. §§ 424.500, 424.505. The regulations in 42 C.F.R. Part 424, subpart P (§§ 424.500-424.570) specify the requirements that a provider or supplier must meet to enroll. The term "Enroll/Enrollment" is defined as "the process that Medicare uses to establish eligibility to submit claims for Medicare-covered

[1] The current version of the Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact-toc.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

services and supplies." *Id.* § 424.502. Enrollment requirements include the submission of an appropriate enrollment application and documentation establishing the provider's or supplier's "eligibility to furnish Medicare covered items or services" to program beneficiaries. *Id.* § 424.510(d)(1), (d)(2)(iii)(B). The process includes "[v]alidation of the provider's or supplier's eligibility to provide items or services to Medicare beneficiaries" and "[g]ranting the Medicare provider or supplier Medicare billing privileges." *Id.* § 424.502 (definition of "Enroll/Enrollment").

Medicare classifies IDTFs as suppliers (as opposed to providers). *US Ultrasound*, DAB No. 2302, at 2 (2010), citing 42 C.F.R. §§ 400.202, 498.2; Act § 1861(d) (defining supplier as an "entity . . . that furnishes items or services under [Medicare]"). Neither the Act, nor 42 C.F.R. § 410.33 (which, among other things, sets out certification requirements for IDTFs), defines "independent diagnostic testing facility."[2] However, an IDTF must meet certain requirements, one of which is that it must have a supervising physician who meets the requirements of 42 C.F.R. § 410.33(b). The supervising physician must be proficient in the performance and interpretation of the type of diagnostic procedure performed by the IDTF. *Id.* § 410.33(b)(2). The proficiency may be documented by certification in specific medical specialties or subspecialties or by criteria established by the carrier for the service area in which the IDTF is located. *Id.* However, direct or personal supervision of a physician may be required for certain procedures. *Id.* §§ 410.32(b)(3)(ii), (iii).

Also, among the "certification standards" enumerated within section 410.33(g) is the requirement that an IDTF "[o]perates its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients." *Id.* § 410.33(g)(1); *see also* Medicare Program Integrity Manual (MPIM), CMS Pub. 100-08, Ch. 15 (enrollment guidelines, including those affecting IDTFs). "If an IDTF fails to meet one or more of the standards in paragraph (g) of [section 410.33] at the time of enrollment, its enrollment will be denied." 42 C.F.R. § 410.33(h); *see also* 71 Fed. Reg. 69,624, 69,699 (Dec. 1, 2006) (stating, in the preamble to the regulations adopting section 410.33(h), that "at § 410.33(h), we are stating that if an IDTF fails to meet one or more of the standards at the time of enrollment, then the enrollment application would be denied."); MPIM, Ch. 15, § 15.5.19.1 (similar provisions).

[2] As the term IDTF indicates, IDTFs provide diagnostic testing services like X-rays. 42 C.F.R. § 410.33. Entities that provide therapeutic services (e.g., radiation therapy) are not IDTFs. Medicare Claims Processing Manual (MCPM), CMS Pub. 100-04, Ch. 35, § 10.2.C. IDTFs may be a fixed location or a mobile entity, but are independent of an attending or consulting physician's office and of a hospital. *Id.* §§ 10, 10.1.

CMS also may deny a provider's or supplier's enrollment in Medicare for the reasons set out in 42 C.F.R. § 424.530(a). One reason is when the provider or supplier –

> is determined to not be in compliance with the enrollment requirements in this subpart P or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter.

42 C.F.R. § 424.530(a)(1); *see also id.* § 424.502 (defining "Deny/Denial" to mean that "the enrolling provider or supplier has been determined to be ineligible to receive Medicare billing privileges for Medicare covered items or services provided to Medicare beneficiaries").

The reconsidered determination to deny the enrollment under section 424.530, made by CMS (or a contractor, for CMS), is an "initial determination" that may be appealed through the administrative process, to the ALJ and then to the Board. 42 C.F.R. § 498.3(b)(17); *see also* Act § 1866(j)(8) (a "provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) . . . is denied may have a hearing and judicial review of such denial . . . .").

## Case Background[3]

HeartFlow has developed FDA-approved software that uses cardiac computed tomography (CT) scan data to obtain the "fractional flow reserve," which, put simply, is the measurement of the impact of clinical significance of coronary artery blockage. The service HeartFlow proposes to provide using its software is called Fractional Flow Reserve computed tomography (FFRct). *See generally* CMS Exs. 10, 11.

By initial determination dated August 20, 2015, Noridian Healthcare Solutions (Noridian), a CMS contractor, denied HeartFlow's enrollment application on the ground that "[t]he service [HeartFlow is] intending to provide using CPT code 93799 is a portion

[3] The factual information in this section, unless otherwise indicated, is drawn from the ALJ Decision and undisputed facts in the record and is presented to provide a context for the discussion of the issues raised on appeal.

of the technical component of [CPT code] 75574, and therefore inappropriate to be billed in this manner."[4] CMS Ex. 2, at 1, citing 42 C.F.R. § 424.530(a)(1). On reconsideration, Noridian upheld its initial determination, repeating the above statement and adding:

> No evidence provided 93799 is a payable code. CPT code 75574 must have direct supervision and the supervising physician must be a board certified Radiologist. [Dr. F.S.G.] is a cardiologist.
>
> DECISION: *Heartflow Inc[.] had not provided evidence to show full compliance with the standards for which [it was] denied. Therefore [Noridian] is not going to grant [HeartFlow] access to the Medicare Trust Fund (by way or issuance) of a Medicare number.*

CMS Ex. 1, at 1 (emphases in original), citing 42 C.F.R. § 424.530(a)(1).

On April 6, 2016, HeartFlow filed (by DAB E-File) its Request for Hearing (RFH), along with two Noridian-issued reconsidered determinations, evidently identical but for the dates of issuance and the addressee information. The earlier determination, dated December 17, 2015, was addressed to HeartFlow, Inc. in "Redwood, California"; the later determination, dated March 18, 2016 (CMS Exhibit 1), was addressed to HeartFlow's attorney. In its RFH, HeartFlow, by its attorney, stated that after it filed its reconsideration request in October 2015, it repeatedly asked Noridian about the status of reconsideration review, but that it "did not receive . . . what purportedly is a reconsideration decision . . . dated December 17, 2015 . . . incorrectly addressed to 'Redwood,'" not "Redwood City," "until March 16, 2016." RFH at 2. HeartFlow also stated that, after further communication with Noridian about the delay in review and the December 17, 2015 determination, Noridian issued the March 18, 2016 determination, addressed to its attorney's prior law firm address. *Id.* HeartFlow asked the ALJ to accept the RFH as a timely appeal of the March 18, 2016 determination, or as timely based on March 16, 2016 receipt of the December 17, 2015 determination, or as untimely but

[4] Healthcare Common Procedure Coding System (HCPCS) is a compilation of definitions of services, and of codes and code modifiers for those services, used to process and pay Medicare claims. HCPCS incorporates the American Medical Association (AMA)'s Current Procedural Terminology (CPT), which provides descriptive terms and numeric codes used to report services provided by health care professionals. 42 C.F.R. §§ 414.2, 414.40; 45 C.F.R. § 162.1002. Services may include "professional" and "technical" components. *E.g.*, for an electroencephalogram (EEG), the EEG is the technical component; interpretation of the EEG is the professional component. 42 C.F.R. § 414.40(b). HCPCS/CPT code 75574 is defined "Computed tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)." CMS Ex. 5, at 1. HCPCS/CPT code 93799 designates an "unlisted cardiovascular service or procedure." CMS Ex. 4, at 1. Herein we refer to the codes as CPT codes 75574 and 93799.

excused for good cause based on delayed delivery of the December 17, 2015 determination. *Id.* at 2-3, citing 42 C.F.R. § 498.40 (ALJ may extend the 60-day appeal period for good cause). The record does not show CMS's dispute on timeliness grounds, or an affirmative ruling by the ALJ as to the timeliness of appeal.[5] The ALJ did not dismiss the appeal on timeliness grounds, and proceeded with the merits of the appeal.

The ALJ issued a decision upholding the denial[6] based on the written submittals alone, since neither CMS nor HeartFlow asked him to convene an in-person hearing and he found no reason to do so. ALJ Decision at 2. The ALJ described FFRct as an "interpretative procedure which consists of further analysis of a test known as a Cardiac Computed Tomography (CT) scan." *Id.* at 3, citing CMS Exs. 10, 11. FFRct, the ALJ said, is "not an additional test so much as it is an interpretation of a test." *Id.* HeartFlow, the ALJ said, proposed to examine the results of CT scans performed elsewhere and uploaded digitally to HeartFlow, using HeartFlow's software, and would create a personal, digital, three-dimensional model of a patient's arteries, which HeartFlow would provide to clinicians for their use. *Id.*, citing CMS Ex. 11, at 3. HeartFlow proposed to claim payment for FFRct under CPT code 93799 for unspecified tests. *Id.*

The ALJ asked the parties to submit additional briefs: (1) identifying any local coverage determination(s) (LCD(s)) that address(es) the procedure code(s) an IDTF may use to bill, including FFRct, and the credentials of the supervising physician; (2) addressing whether CMS or its contractor may exercise case-by-case discretion to determine the code(s) that may be used and the supervising physician's credentials if there is no such LCD; and (3) addressing whether any such exercise of discretion is reviewable. July 13, 2016 Order Directing Parties to Respond.

In its August 1, 2016 response, HeartFlow stated that there is no such LCD issued by any CMS contractor. It also stated that physicians are using, and insurance carriers are paying for claims submitted using, CPT code 93799 for FFRct, and that for a new, non-invasive test such as the FFRct, general supervision of the performance of such a procedure by a cardiologist would be appropriate. HeartFlow did not expressly state whether it believes CMS or its contractor may exercise discretion in determining what

[5] The operative reconsidered determination would be that dated December 17, 2015. CMS raised no dispute about HeartFlow's representation that it received notice of this determination on March 16, 2016, and nothing in the record causes us to question that representation. Assuming receipt on March 16, 2016, the request for hearing was filed timely, within 60 days after receipt of the December 17, 2015 determination, and there would be no need to consider the second, substantively identical determination dated March 18, 2016 to decide timeliness.

[6] The ALJ did not expressly state that he was upholding the denial based on the grounds cited on reconsideration, or cite section 424.530(a)(1), the regulatory basis for denial. Nevertheless, the ALJ's rationale, read in its entirety, is not inconsistent with section 424.530(a)(1). Neither party argues that the ALJ upheld the denial on a regulatory basis other than section 424.530(a)(1), or otherwise takes issue with the ALJ Decision to the extent the ALJ did not expressly state that he was upholding denial based on section 424.530(a)(1).

code to apply or what supervising physician to require. However, it contended that, to the extent CMS or its contractor has discretion, the correct or appropriate decision here would have been to permit HeartFlow to enroll as an IDTF and bill for FFRct using CPT code 93799 for unlisted cardiac procedures because doing so would have been consistent with what HeartFlow said is current prevailing practice. Lastly, HeartFlow maintained that, to the extent CMS or Noridian exercised discretion in denying enrollment, all aspects of that decision through the reconsideration level, including any discretionary policy developed or applied to deny enrollment, are subject to ALJ review.

In its August 4, 2016 response,[7] CMS informed the ALJ that Noridian has not issued any such LCD and, in any case, Part 424 regulations, not LCDs, govern a determination of whether a supplier meets the enrollment requirements. Also, according to CMS, for a procedure like FFRct for which there is no current CPT code, in the absence of an applicable national or local coverage determination, a determination as to what available code should be used for reimbursement is left to contractor discretion. CMS argued that, on appeal under Part 498 regulations, the ALJ has authority to determine whether CMS properly denied HeartFlow's enrollment pursuant to section 424.530(a)(1). CMS further stated that cardiac CTA (computed tomographic angiography) testing services performed at non-hospital locations like IDTFs must be performed by or under direct personal supervision of a radiologist or other qualified physician and that a service billed using CPT code 75574 requires a direct level of supervision.

In upholding the denial of enrollment, the ALJ first noted that the contractor (acting for CMS) determined that a board-certified radiologist must supervise HeartFlow and that the physician HeartFlow identified as its supervising physician is a cardiologist and not a radiologist. ALJ Decision at 2 (citing 42 C.F.R. § 410.33(b)), 3-4. Second, the ALJ noted the contractor's determination that HeartFlow's FFRct procedure (which it proposed to perform and claim payment for using CPT code 93799, "a code that is intended to capture unlisted cardiovascular services or procedures that are not captured under other CPT codes") is essentially a "non-reimbursable service" because the service is "considered to be an integral component of the CT scan" that Medicare may reimburse under CPT code 75574. *Id.* at 3. That is, CPT code 75574 "covered the CT scan *and* subsequent analyses, including FFRct." *Id.* at 3 (ALJ's emphasis). The ALJ then said, "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 it could not perform the

[7] CMS appended an exhibit (CMS website search results of a "physician fee schedule search" on CPT code 75574) to its August 4, 2016 response. The ALJ excluded CMS's "supplemental exhibit," stating that his "instructions . . . did not leave open the possibility that either party could supplement its evidentiary exchange." ALJ Decision at 1. Neither party disputes the ALJ's exclusion of CMS's "supplemental exhibit."

CT scan of which FFRct is an integral component." *Id.* Both grounds for denial, the ALJ emphasized, are the products of "case-by-case" discretionary decision-making since the IDTF requirements in section 410.33 do not spell out what qualifications an IDTF supervising physician must have (*id.* at 2), or how Medicare will reimburse procedures that may be "novel, rarely provided, or unusual," including those that the contractor may properly determine as payable if claimed under an "unlisted procedure" code. *Id.* at 3, citing MCPM, Ch. 13, § 120.

The ALJ wrote:

> [T]he contractor plainly acted within the ambit of discretion. As I have stated, the regulations confer on the contractor the discretion to determine the necessary qualification 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 authority to do so.

*Id.* at 4. The ALJ thus determined that where, as here, "the contractor acted within the ambit of its discretionary authority," he "must affirm the contractor's determination." *Id.*

HeartFlow asked the Board to review the ALJ Decision. The parties filed their briefs with the Board and, on March 9, 2017, presented oral argument before a panel of three Board Members who are signatories to this decision.

## Standard of Review and Decisional Authority

The Board's standard of review on a disputed conclusion of law is whether the ALJ's decision is erroneous. The Board's standard of review on a disputed finding of fact is whether the ALJ's finding is supported by substantial evidence in the record. *Guidelines – Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's or Supplier's Enrollment in the Medicare Program* (*Guidelines*), accessible at http://www.hhs.gov/about/agencies/dab/different-appeals-at-dab/appeals-to-board/guidelines/index.html?language=en. Applying the relevant review standards, the Board may modify or supplement an ALJ's factual findings and legal conclusions and may, as appropriate, make findings and conclusions on issues that the ALJ did not address. 42 C.F.R. § 498.88(f); *Spring Meadows Health Care Ctr.*, DAB No. 1966, at 15 n.6 (2005) (the Board may modify an ALJ decision in whole or in part).

## Analysis

In its brief in support of its request for Board review (RR), HeartFlow asserts that FFRct is a reimbursable service properly rendered by IDTFs. As we will explain, we agree with the ALJ's determination to uphold the denial of enrollment. Before we explain our reasons for upholding the denial of enrollment, we will first address HeartFlow's request for ALJ reconsideration of his decision. Lastly, we will address HeartFlow's allegations of error and/or abuse of discretion related to the ALJ's pre-hearing procedures and rulings.

### *1. HeartFlow's Request for ALJ Reconsideration of His Decision*

#### *a. HeartFlow made a timely request for ALJ reconsideration of his decision, but we do not remand the case in the interest of judicial economy.*

HeartFlow submitted, as an exhibit to its RR, "Petitioner's Request for Reconsideration" of the ALJ Decision, DAB CR4678. HeartFlow states that "[t]he ALJ declined to accept" the reconsideration request. RR at 3. Upon questioning during the March 9, 2017 oral argument before the Board, HeartFlow's attorney explained that on October 5, 2016 he inquired of the Civil Remedies Division (CRD) about requesting the ALJ to reconsider his decision. He indicated that he emailed the reconsideration request to CRD staff and to CMS counsel (the Certificate of Service appended to the reconsideration request indicates that HeartFlow's attorney sent a copy of it to CMS counsel by email). However, he was informed by CRD staff that HeartFlow could not seek reconsideration and could instead appeal the ALJ Decision to the Board. After the conclusion of oral argument, on the Board's instructions, HeartFlow's attorney submitted the October 5, 2016 emails between CRD staff and HeartFlow's attorney by uploading the emails to

DAB E-File's record for this Board appeal (Docket No. A-17-4). Those emails do indicate that HeartFlow's attorney emailed CRD staff the reconsideration request (with a copy to CMS counsel) on October 5, 2016, but was informed in an email from CRD staff that the regulations do not permit ALJs to reconsider their decisions.

HeartFlow was misinformed that it could not seek ALJ reconsideration, and CMS is incorrect in asserting (in its Response at 23 and at oral argument) that HeartFlow is not entitled to do so. The Part 498 regulations do permit an ALJ to reopen and revise his or her decision. 42 C.F.R. §§ 498.74(b)(3) (an ALJ decision is binding on parties unless, as relevant here, the decision is "revised by an ALJ") and 498.100-498.103 (providing in part, as relevant here, that an ALJ decision may be reopened within 60 days from the date of notice of the decision upon the motion of the ALJ or the Board or the petition of either party). Based on HeartFlow's representation at oral argument, as confirmed by the emails later submitted to the Board, we find that on October 5, 2016 HeartFlow made a timely request for ALJ reconsideration. Once informed that it could not seek ALJ reconsideration, two days later, on October 7, 2016, HeartFlow proceeded to timely appeal the ALJ Decision to the Board pursuant to 42 C.F.R. § 498.82. At oral argument, HeartFlow asked that, should we determine that this case could properly have been reconsidered by the ALJ based on HeartFlow's request (and we do), in the interest of judicial economy, the Board nevertheless not remand this case for ALJ reconsideration at this point. We will therefore proceed with our review.

*b. The new evidence appended to the Request for Reconsideration is not admitted.*

HeartFlow submitted additional evidence along with its request for ALJ reconsideration.[8] The evidence in question is an August 24, 2016 letter from the FDA's Director of Division of Cardiovascular Devices, Office of Device Evaluation, Center for Devices and Radiological Health, informing HeartFlow that it may market the "device" "FFRct v2.0" as a Class II "Coronary Physiologic Simulation Software Device" subject to "controls" in accordance with the applicable regulations. The FDA's letter was not before the ALJ when he issued his decision. The letter is now before us as new evidence.

[8] Also submitted with the Request for Review are the printouts of email exchanges on August 2, 2016 between the CRD staff and counsel concerning the delay in CMS's response to the ALJ's July 13, 2016 Order Directing Parties to Respond. The DAB E-File record of the ALJ proceedings (CRD docket number C-16-460) does not include these emails or the aforementioned October 5, 2016 emails concerning HeartFlow's reconsideration request. They should have been made a part of the record below. The August 2, 2016 and October 5, 2016 emails are now a part of the record of this case in DAB E-File, under the Board's docket number A-17-4.

The new evidence is not admitted. By regulation, the Board must decide this appeal based on the record as developed by the ALJ. 42 C.F.R. § 498.86(a) (excepting "provider or supplier enrollment appeals" from those appeals in which the Board may admit evidence in addition to evidence that was before the ALJ); *Guidelines*, "Development Of The Record On Appeal," ¶ (f) (citing 42 C.F.R. § 498.86(a)).[9]

### *2. The ALJ did not err in upholding CMS's denial.*

HeartFlow disagrees with the ALJ's statement that FFRct is an "'interpretive procedure'" that further analyzes a cardiac CT scan and is "'not an additional test.'" RR at 2, quoting ALJ Decision at 3. It maintains that FFRct "does not re-interpret a CT scan" and is different from a CT scan because a CT scan "merely captures images of the blockages" but FFRct evaluates functional blood flow in the coronary arteries and calculates the impact of the imaged blockages on blood flow by assessing the hemodynamic significance of stenotic lesions to assist physicians in determining whether a patient needs revascularization. RR at 3, citing CMS Exs. 10 and 11. HeartFlow also disputes the ALJ's decision (ALJ Decision at 3) to uphold the contractor's determination that a board-certified radiologist must supervise the CT scan and, consequently, its components, to include FFRct, as well. It asserts that, because FFRct and the cardiac CT scan are different tests, "a radiologist may be needed to interpret the CT images, [but] a cardiologist is also appropriate to analyze the functional blood flow values of the FFRct to determine the appropriate treatment for a patient." RR at 3.

The crux of HeartFlow's argument is that FFRct is a service separate and distinct from a cardiac CT scan and therefore should be separately reimbursable under the current Medicare claims and payment structure. As we understand HeartFlow's position, while its proprietary software uses cardiac CT scan data to derive FFRct results, FFRct does not duplicate or even "interpret" what the CT scan does; rather, it provides more specific, distinct information about a patient's coronary artery disease in the form of measured arterial blood flow that aids physicians in assessing and treating that patient. Therefore, HeartFlow's argument goes, CMS (through Noridian) erred in concluding that FFRct is a component of the CT scan (for which CMS evidently determined that existing CPT code is 75574 is appropriate for payment purposes) and is not separately billable and payable.

[9] As noted, HeartFlow asks that we proceed with our review and not remand this case for the ALJ to reconsider his decision. We understand this request to mean that it does not want an opportunity for the ALJ, on remand, to consider whether there is good cause to admit this evidence. In any case, as we address elsewhere, evidence of FDA clearance for marketing would not change the outcome for Medicare enrollment purposes.

On appeal, the questions for the Board are whether the ALJ's determination to uphold CMS's denial is legally sound and whether his fact-finding is supported by substantial evidence. We first examine the regulation cited as the ground for denial, section 424.530(a)(1), which permits denial of enrollment in the Medicare program when an applicant does not meet the enrollment requirements for the type of supplier in question. Thus, HeartFlow must meet the requirements for IDTFs in order to be permitted to enroll. Noridian denied enrollment primarily because HeartFlow did not identify a service that would be reimbursable under the existing reimbursement structure. That conclusion was based on the determination that CPT code 93799, the code HeartFlow seeks to use, may not be used for FFRct because FFRct is considered to be a technical component of CPT code 75574. Plainly, HeartFlow could not be, and indeed would have no reason to seek to be, enrolled in Medicare, as an IDTF or any type of supplier, if it could not bill and be paid by Medicare for its single service. Secondarily, enrollment was denied because Noridian determined that HeartFlow did not meet an IDTF-specific requirement concerning supervising physicians. CMS determined that a service billed under CPT code 75574 requires direct supervision under section 410.33(b), by a radiologist, not a cardiologist as proposed by HeartFlow.

Neither party alleges that any coverage determination or other authority or guidance directly addresses whether and how Medicare may pay for FFRct or the specific qualifications of the physician who will supervise an IDTF providing FFRct. The ALJ determined, and HeartFlow does not specifically dispute, that under these circumstances CMS and its contractor have discretion to determine whether, and under what code, the applicant may be reimbursed for the service it proposes to furnish if enrolled, as well as whether an applicable supplier-specific requirement has been met. HeartFlow's quarrel with the ALJ's decision is that the ALJ "essentially defer[red] to the Medicare contractor's decision[,]" "framing the issue around scope of [CMS or contractor] authority," thus "permit[ting] the ALJ to avoid rendering an independent decision that considers whether or not [HeartFlow] has proven, by a preponderance of the evidence, that the Medicare contractor's decision is factually or legally incorrect." Reply at 3; RR at 3-4 (disagreeing with the ALJ's statements in page 4 of his decision that he may not "second-guess or look behind" the contractor's determination, and asserting that the ALJ has authority to review that determination). HeartFlow essentially argues that, while CMS and its contractor may have discretion under these circumstances, the ALJ, on de novo review, still must independently review their determination to determine whether it is legally supportable. We conclude that CMS did not abuse its discretion in denying enrollment based on its determination that HeartFlow has not proposed to provide a service that is reimbursable under the existing Medicare payment structure.

On reconsideration, CMS, by Noridian, determined that CPT code 75574, under which the underlying cardiac CT scan is payable, includes FFRct as a "technical component" of CPT code 75574, and that FFRct therefore may not be unbundled from the CT scan and reimbursed separately. HeartFlow correctly points out that the description for CPT code 75574 does not expressly state that FFRct is included within that code. *See* CMS Ex. 7, at 2 (reconsideration request, stating that "nothing in the description of CPT code 75574 . . . reveals or even suggests that [FFRct] is a portion of the technical component of the service denoted by CPT code 75574"); CMS Ex. 5, at 1 (description of CPT code 75574). However, HeartFlow points to no authority or guidance that requires Medicare to pay separately for a particular service or procedure, like FFRct, merely because the procedure is not expressly named in the CPT descriptor, where the descriptor – which expressly includes 3D imaging of the heart, coronary arteries and bypass grafts (if present) for "evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed" – is broad enough to be interpreted to include it. *See* CMS Ex. 5, at 1.

HeartFlow relies on the Society of Cardiovascular Computed Tomography (SCCT)'s March 10, 2016 letter (2 pages) as support for its position. RR at 6 ("According to the professional association [SCCT] that requested and obtained CPT code 75574 from the AMA in 2010, the service denoted by that CPT code does not encompass FFRct . . . ."). In its letter SCCT distinguished a CTA (computed tomographic angiography) from FFRct as "two separate services" and indicated that FFRct is "not captured" in any of the Category I CPT codes for "cardiac CT and coronary CTA services" (including 75574) for which SCCT sought and received approval for implementation effective January 1, 2010.

SCCT's expectations as to what the code it sought might cover or capture in 2010 is not conclusive, however. As Dr. Charles Haley (Noridian's Medical Director) indicated in his email to HeartFlow on June 19, 2015, for Medicare reimbursement purposes, the contractor "expect[ed] that the facility performing the [CT] scan and the physician performing the professional interpretation to bill for the components of 75574." CMS Ex. 9, at 12; *id.* at 34-35. We understand this to mean that Noridian expects that the technical components of CPT code 75574 (including the CT scan as well as any related tests or procedures like FFRct for which Noridian determined CPT code 75574 is the appropriate code) and the professional component (all analysis and interpretation of the results) may not be separated or unbundled for billing and payment purposes.

HeartFlow, using its software, would remotely generate FFRct based on data from the CT scan performed elsewhere. HeartFlow would then provide the FFRct results to the physician who ordered or referred the CT scan data for FFRct. The referring or ordering physician then "receives and interprets the FFRct results" to make a "personalized

clinical decision for the patient's treatment." Pre-Hearing Brief of Petitioner at 2-3, 14-15. Based on HeartFlow's own description of its FFRct service, FFRct is a "technical" procedure consistent with Noridian's determination. The HeartFlow physician would not provide the "professional" services as a part of HeartFlow's FFRct service.

On reconsideration, CMS also determined that HeartFlow may not be reimbursed for FFRct under the general, unlisted procedures code, CPT code 93799, since it is already encompassed in CPT code 75574. CMS Ex. 1, at 1; *see also* MCPM, Ch. 13, § 120 (stating that the contractor will determine if the provider correctly identified a procedure as unlisted and, if the provider did not identify the procedure correctly as unlisted, the contractor will inform the provider of the correct code to assign). This determination is consistent with Dr. Haley's statement on June 30, 2015 that FFRct may not be billed using the "unlisted" code, i.e., CPT code 93799, because "it is included in another service" and "[t]o allow it separately is inappropriate unbundling." CMS Ex. 9, at 10, 47. In fact, one of the documents HeartFlow submitted to Noridian on March 11, 2016, referred to as the AMA's CPT Knowledgedatabase response, *id.* at 1, indicates that the use of an "unlisted code would not be applicable as there is no physician work being described," *id.* at 5, which we understand to mean that in order to bill under CPT code 93799, the procedure or service must include a professional component. Apparently referring to the Knowledgedatabase response, on March 18, 2016, Dr. Haley informed HeartFlow, "The note from CPT makes it clear that this service should not be billed with an unlisted service code." *Id.* at 64.

We therefore are not convinced by HeartFlow's argument to the effect that because Medicare in general may pay for some services or procedures claimed under an unlisted procedure code, Medicare must therefore permit HeartFlow to bill for FFRct using CPT code 93799. RR at 7 ("Noridian and other [contractors] do in fact accept, process, and pay claims with miscellaneous CPT codes filed by IDTFs."); CMS Ex. 7, at 1 (request for Noridian reconsideration, stating, "CMS has confirmed that [its contractors] have the authority and discretion to accept miscellaneous codes (e.g., CPT code 93799) to denote diagnostic tests performed by IDTFs. Therefore, Noridian may not deny HeartFlow's application stating that IDTFs may not perform and bill a test denoted by a miscellaneous code."). That Medicare recognizes unlisted procedure codes and may pay for some procedures billed under such codes, whether by an IDTF or other type of supplier, does not necessarily mean that Medicare must therefore permit HeartFlow to enroll as an IDTF and to bill for FFRct under CPT code 93799. Moreover, while we note HeartFlow's complaint that Noridian did not inform it that a "unique" CPT code (75574) should be used rather than an unlisted procedures code (93799) on the ground that FFRct is a part of the CT scan, Reply at 3, the evidence does not show that FFRct is <u>separately</u> payable under either code.

HeartFlow also suggests that FDA clearance of FFRct has bearing on the Medicare enrollment question presented here. RR at 6; Reply at 4, 7 (referring to FDA clearance in 2014). Relying on the FDA's August 24, 2016 letter to HeartFlow (in which the FDA stated that HeartFlow may market "FFRct v2.0" as a Class II "Coronary Physiologic Simulation Device") appended to its request for ALJ reconsideration of his decision, HeartFlow asserts that "FDA has now confirmed that FFRct is a separate test." Request for Reconsideration at 2. We have explained that this evidence is not admissible at this stage of the proceeding, but we note here that, even if we considered it, we would not find that it altered the outcome. Even assuming FDA clearance meant that FDA has recognized FFRct as distinguishable from the cardiac CT scan that generates the data used to derive the FFRct (which is not at all clear on the face of the clearance letter), HeartFlow cites no authority for why any such clearance by FDA would control CMS's determination about whether the FFRct must be separately payable or may be considered bundled with the CT scan service for coding.

HeartFlow further takes issue with the ALJ's statement, "'The contractor determined . . . that a board-certified radiologist must supervise the CT scan and consequently, integral components of that scan such as FFRct.'" RR at 3, quoting ALJ Decision at 3. HeartFlow argues that Noridian led it to believe that "either a radiologist or a cardiologist was acceptable to Noridian." *Id.*, citing CMS Ex. 9, at 35. This argument was based on an email from a Noridian enrollment representative which stated, "I think that we require a board certified cardiologist or radiologist when billed by an IDTF." CMS Ex. 9, at 35. The language of the email is tentative and preliminary ("I think"), and refers to an IDTF supplying the full bundle of professionally-interpreted CT scan test results, reiterating that the contractor would not allow the component services to be unbundled and billed separately or under a generic code. *Id.* In any case, on reconsideration, CMS, through Noridian, specified that direct supervision by a radiologist is required, referring to CPT code 75574. CMS Ex. 1, at 1. HeartFlow's enrollment forms indicate that Dr. F.S.G., a cardiologist, would provide general supervision. CMS Ex. 7, at 76, 188, 212-213; CMS Ex. 8, at 73. The evidence does not address the precise basis for Noridian's determination that a radiologist "must" serve as the supervising physician, and that billing under CPT code 75574 requires a radiologist, not a cardiologist. CMS Ex. 1, at 1 ("CPT code 75574 must have direct supervision and the supervising physician must be a board certified Radiologist"). In any case, we need not resolve the question of whether the supervising physician must be a radiologist rather than a cardiologist because we conclude that HeartFlow has not shown that the single service it provides, FFRct, is separately reimbursable under any code.

Lastly, HeartFlow contends that some practitioners are using an unlisted procedure code to bill for FFRct and that some private insurance plans are paying for FFRct on that basis. RR at 7. Even if that is true, we are not aware of any authority that binds CMS to follow the practice of private insurance carriers, and HeartFlow identifies none. While CMS may at times be informed or guided by developments in the private insurance sector, HeartFlow has not articulated why it would be an abuse of discretion for CMS to decline to follow such practices in determining how Medicare covers or reimburses for FFRct.

HeartFlow does not specifically argue that the ALJ erred in determining that CMS (or its contractor) has discretion to set the appropriate billing code for FFRct and determine the required qualifications of the physician supervising an IDTF that provides FFRct services where such standards are not spelled out in the regulations or relevant guidance. We conclude that such an exercise of discretion may not be overturned at least in the absence of proof of abuse of discretion (which we have not found here). We therefore reject HeartFlow's position that the ALJ improperly deferred to CMS and its contractor. Accepting CMS's interpretation of the requirements to bill for FFRct services, the ALJ properly concluded that the enrollment standards were not met because HeartFlow does not propose to provide a service reimbursable under the current payment structure, nor does it have a qualifying supervising physician.

### *3. The ALJ did not violate HeartFlow's due process rights.*

#### *a. The pre-hearing procedures did not violate applicable regulations or Board precedent.*

HeartFlow asserts that the ALJ's pre-hearing procedures indicate the ALJ's intent to do away with a hearing improperly. RR at 4. According to HeartFlow, the ALJ "essentially robbed [it] of its appeal rights by ignoring the appeal regulations and abusing his discretion." *Id*. HeartFlow says that under 42 C.F.R. § 498.61, it has a right to cross-examine the opposing party's witnesses and a right "to directly examine its own witnesses at the hearing," and that the ALJ erred in "restricting the scheduling of a hearing for the sole purpose of cross-examination" and "by preventing a party [from] direct[ing] its witnesses." *Id.* at 4-5. HeartFlow also takes issue with the ALJ's statement, "'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.'" RR at 1, quoting ALJ Decision at 2. HeartFlow asserts that this statement is inaccurate as the parties did request an evidentiary hearing. *Id.* at 1-2.

First, we acknowledge that HeartFlow, by its "request for hearing," did ask the ALJ to convene a hearing. *Id.* at 1-2; Reply at 2. HeartFlow suggests that CMS, too, wanted a hearing and sought to cross-examine witnesses. RR at 1-2; Reply at 2, citing "CMS's Request to Cross-Examine." CMS objected to HeartFlow's witnesses, C.R. (Executive

Vice President and Chief Medical Officer of HeartFlow) and K.C. (Director of Health Economics and Reimbursement of HeartFlow), on the ground that HeartFlow had not submitted their written direct testimony consistent with the ALJ's Pre-Hearing Order. CMS's Objections at 2-4. CMS did assert that, in the event the ALJ permitted HeartFlow to call C.R. and K.C. despite the failure to first disclose their testimony in writing, the ALJ should take appropriate action to mitigate the potential for prejudice to CMS by, among other things, permitting CMS to cross-examine C.R. and K.C. *Id.* at 4-5. Thus, CMS asked the ALJ to convene a hearing only if necessary to protect its right to cross-examine Heartflow's witnesses should its objections be overruled.

Even assuming that the ALJ was inaccurate in stating that neither party had asked for an in-person hearing, we conclude that the ALJ did not err in proceeding to decision without a hearing. The ALJ expressly informed the parties that they had to affirmatively express an intent to cross-examine the opposing party's witness(es), and that an in-person hearing would be held only if a party first filed admissible, written direct testimony of a witness whom the opposing party then asked to cross-examine. Pre-Hearing Order, ¶¶ 9 and 10. Here, neither party submitted written direct testimony; therefore, the ALJ determined there was no need to convene a hearing for cross-examination and proceeded to decision based on the written submissions. HeartFlow does not now assert, and the record does not reveal, that the ALJ's action was contrary to the express terms of his Pre-Hearing Order.

HeartFlow's arguments thus raise two questions:

(1) Do an ALJ's procedures requiring the submittal of *written* direct testimony of witnesses, which could result in no oral hearing being held if neither party asks to cross-examine the opposing party's witness(es) whose direct testimony is submitted in writing, violate due process in the context of Part 498 proceedings?
(2) Does 42 C.F.R. § 498.62 entitle a party to an oral hearing before an ALJ specifically for the purpose of examining its own witness(es)?

The answer to both questions is no.

Section 498.62 states in its entirety:

> Witnesses at the hearing testify under oath or affirmation. The representative of each party is permitted to examine his or her own witnesses subject to interrogation by the representative of the other party. The ALJ may ask any questions that he or she deems necessary. The ALJ rules upon any objection made by either party as to the propriety of any question.

In *Vandalia Park*, the Board has determined that requiring a party to first submit the direct testimony of its witnesses in writing is not inconsistent with this regulation.[10] The Board said:

> Nothing in the regulation [section 498.62] prescribes that the examination must be conducted orally at the in-person phase of the hearing. The regulation's terms are met so long as the opportunity to cross-examine and hence observe demeanor where credibility is at issue is preserved. Written direct testimony is widely used both in administrative proceedings and federal court.

*Vandalia Park*, DAB No. 1940, at 28-29 (2004), *aff'd, Vandalia Park v. Leavitt*, 157 F. App'x 858 (6th Cir. 2005). The Board went on to note in *Vandalia Park* that it previously approved the use of written testimony:

> The use of written direct testimony is not itself prejudicial, as long as the right to effective cross-examination is preserved. The federal courts, and this Board in other types of cases where it conducts de novo hearings, have allowed, and even strongly encouraged, written direct testimony in a variety of proceedings. Since it is offered under oath, it is generally no less credible in most instances than oral testimony in the hearing room, as long as the witness is subject to cross-examination. The submission of written direct testimony, especially when not controverted, has shortened trials . . . [it] allows counsel to present direct testimony in a measured and complete manner and reduces the possibility that vital testimony will fail to be presented . . . live cross-examination and live redirect examination of witnesses have provided ample opportunity for this court to address their demeanor and credibility. When parties have chosen not to cross-examine a witness, credibility of that particular witness has not been in question. Kuntz v. Sea Eagle, 199 F.R.D. 665 (D. Haw. 2001).

*Id.* at 29, quoting *Pacific Regency Arvin*, DAB No. 1823, at 7-8 (2002); *accord Igor Mitreski, M.D.*, DAB No. 2665, at 7 (2015) (not holding an in-person hearing does not generally pose a due process concern where neither party seeks to cross-examine any witness for whom the opposing party has submitted written direct testimony).

[10] The Pre-Hearing Order, ¶ 8, states, "A witness statement must be submitted in the form of an affidavit made under oath or as a written declaration that the witness signs under penalty of perjury for false testimony." This language comports with section 498.62.

Thus, the inquiry is two-fold: first, whether a party has been given an opportunity to present testimony of its own witness(es), which may be in writing; and second, whether that party also has been afforded an opportunity to cross-examine the opposing party's witness(es). The ALJ's procedures did not abridge HeartFlow's right to do either. HeartFlow had an opportunity to present written direct testimony of its own witnesses, but did not avail itself of that opportunity. There was no violation of its right to cross-examine inasmuch as CMS did not submit the direct written testimony of any witness for HeartFlow to cross-examine.

HeartFlow initially named two individuals, C.R. and K.C., as its witnesses. It was not until later, in responding to CMS's objections, that HeartFlow specified that it wanted to call C.R. and K.C. only as "potential rebuttal witnesses to address any arguments raised by CMS' legal counsel or testimony by Dr. Haley at the evidentiary hearing." Pet.'s Response to CMS's Objections at 1.[11] But CMS did not propose to call Dr. Haley (Noridian's Medical Director, CMS Ex. 9, at 13); it did not submit Dr. Haley's written direct testimony. To the extent HeartFlow saw a need for possible rebuttal based on its review of the documentary evidence that CMS was required to and did disclose first as part of its pre-hearing exchange, HeartFlow had an opportunity to rebut by submitting its own evidence that could include written direct testimony as part of its pre-hearing exchange. Pre-Hearing Order ¶ 4. If HeartFlow had concerns about CMS's exhibits, the contents which it believed Dr. Haley could speak to and answer questions about, it could have asked the ALJ to issue a subpoena pursuant to 42 C.F.R. § 498.58 directing Dr. Haley to make himself available for examination at hearing. The record does not indicate any such request.

We therefore reject HeartFlow's arguments that the ALJ's pre-hearing procedures deprived HeartFlow of due process.

*b. We disagree with the ALJ's Evidentiary Ruling as to the exclusion of Petitioner's Exhibit 2 on the ground the ALJ relied on; however, we find no ALJ error or abuse of discretion as to the remainder of the Evidentiary Ruling.*

The ALJ Decision indicates that the ALJ admitted into the record Petitioner's Exhibits 1 through 6. ALJ Decision at 1. HeartFlow correctly points out that the ALJ Decision does not accurately restate the ALJ's earlier ruling. RR at 1. By his July 13, 2016 Ruling

[11] In any case, HeartFlow later stated that while it initially named C.R. and K.C. as witnesses because it believed their testimony would "be helpful and to facilitate a comprehensive understanding of the facts by answering any questions from CMS and/or the ALJ[,]" it would be willing to withdraw both witnesses from its witness list "if a decision can be reached . . . without a hearing . . . as [HeartFlow] acknowledges that no witness from either CMS or [HeartFlow] can offer dispositive testimony to address any question related to the CPT codes issued by the AMA." Pet.'s Response to CMS's Objections at 1-2.

Granting [CMS's] Objections to Proposed Witnesses and Exhibits (Evidentiary Ruling), the ALJ excluded Petitioner's Exhibits 2 through 6. HeartFlow asserts that in "wrongfully grant[ing]" CMS's objections to HeartFlow's exhibits and excluding certain exhibits, the ALJ "appears to have [done so] solely to avoid scheduling a hearing." RR at 4.

In general, the Board does not disturb the ALJ's evidentiary determinations unless there is compelling reason to do so. *Community Northview Care Ctr.*, DAB No. 2295, at 28 (2009) and cases cited therein. In provider/supplier enrollment appeals, a provider or supplier must show good cause to submit new documentary evidence to the ALJ. 42 C.F.R. § 498.56(e). A determination of whether good cause has been established under this regulation is a matter for the ALJ's discretion, to which we would defer in the absence of a compelling reason to do otherwise.[12] If an ALJ determines there is no good cause, however, the ALJ is then required to exclude the new evidence. Section 498.56(e)(2)(ii) provides:

> *If good cause does not exist.* If the ALJ determines that there was not good cause for submitting the evidence for the first time at the ALJ level, the ALJ must exclude the evidence from the proceeding and may not consider it in reaching a decision.

*See also Mohammad Nawaz, M.D., and Mohammad Zaim, M.D., PA*, DAB No. 2687, at 13 (2016) and *Zille Shah, M.D., and Zille Huma Zaim, M.D., PA*, DAB No. 2688, at 14 (2016) (finding no abuse of discretion or legal error by the ALJ in construing the regulation similarly and in excluding new evidence for failure to show good cause, and stating that section 498.56(e) itself provided petitioners adequate notice of the requirement to provide all documents on reconsideration).[13]

[12] Part 498 does not define "good cause," a term used in different contexts within Part 498, e.g., to determine whether there is good cause to extend the deadline for filing a request for hearing under section 498.40. The Board has not set out an "'authoritative or complete definition'" of the term. *Meridian Nursing & Rehab at Shrewsbury*, DAB No. 2504, at 8 (2013) (quoting *Hillcrest Healthcare, L.L.C.*, DAB No. 1879, at 5 (2003)), *aff'd, Meridian Nursing & Rehab at Shrewsbury v. CMS*, 555 F. App'x 177, 2014 WL 350698 (3rd Cir. 2014). The Board does, however, review an ALJ's "good cause" determination for abuse of discretion and does not substitute its judgment for that of the ALJ. *Retail LLC d/b/a Super Buy Rite*, DAB No. 2660, at 9-10 (2015); *Kids Med (Delta Medical Branch)*, DAB No. 2471, at 4 (2012).

[13] But "[t]estimonial evidence that is submitted in written form in lieu of live in-person testimony is not 'documentary evidence' within the meaning of 42 C.F.R. § 498.56(e) . . . ." *Arkady B. Stern, M.D.*, DAB No. 2329, at 4 n.4 (2010). Thus, testimonial evidence presented to the ALJ is not subject to the good cause requirement.

HeartFlow proposed and submitted to the ALJ six exhibits, describing them as follows:

1. Email dated January 15, 2015, from Noridian to Petitioner confirming receipt of the Medicare enrollment application January 12, 2015 (1 page)
2. Letter dated March 10, 2016, from Society of Cardiovascular Computed Tomography (2 pages)
3. Notice from Society of Cardiovascular Computed Tomography regarding new CPT codes for 2010 (2 pages)
4. van Waardhuizen, C.N. et al., "Comparative cost-effectiveness of non-invasive imaging tests in patients presenting with chronic stable chest pain with suspected coronary artery disease: a systemic review," European Heart Journal, June 8, 2016 (49 pages)
5. Cury, R.C. et al., "CAD-RADSTM Coronary Artery Disease e [sic] Reporting and Data System. An expert consensus document of the Society of Cardiovascular Computed Tomography (SCCT), the American College of Radiology (ACR) and the North American Society for Cardiovascular Imaging (NASCI). Endorsed by the American College of Cardiology," Journal of Cardiovascular Computed Tomography, June 8, 2016 (13 pages)
6. Priority Health Medical Policy Number 91614-RO dated November 11, 2015 entitled "Computerized Tomographic Angiography Coronary Arteries (CCTA)" (8 pages)

Petitioner's June 24, 2016 Lists of Proposed Exhibits and Witnesses at 1-2.

CMS objected to Exhibits 2-6, asserting that they are new evidence not previously submitted to Noridian with the reconsideration request or during the reconsideration stage, and that Heartflow therefore must show good cause to have them admitted into the record before the ALJ. CMS's Objections at 2, 5-6;[14] Pre-Hearing Order, ¶ 6 (citing 42 C.F.R. § 498.56(e)). CMS also asserted that "Exhibits 3 and 6 were in existence on or prior to [HeartFlow's] Request for [Noridian] Reconsideration[,]" but that even assuming that any proposed Petitioner's Exhibit was not available to it at time of request for reconsideration, HeartFlow's failure to submit them with its request for hearing deprived CMS of an opportunity to review them to present its case before the ALJ. CMS's Objections at 6. CMS also argued that, since HeartFlow's arguments in its request for hearing are similar to those made to Noridian on reconsideration (and HeartFlow submitted evidence with its request for contractor reconsideration, CMS Ex. 7), HeartFlow should have included any additional supporting documents earlier. *Id.* at 7.

[14] In its objections, at 8, CMS stated that it was objecting to Petitioner's Exhibits 3-6. The reference to "3" appears to be error. The Evidentiary Ruling, at 1, indicates that the ALJ understood CMS was objecting to Petitioner's Exhibits 2-6. We read the objections similarly. Also, CMS's objections, at 7, refers to "Petitioner's proposed Exhibit 9, pp. 40-41." This too appears to be error. HeartFlow submitted six exhibits.

In addition, CMS asserted that Exhibits 4, 5, and 6 are irrelevant to whether CMS lawfully denied enrollment. *Id.* at 7-8.

The ALJ excluded Exhibits 2 through 6, finding that HeartFlow submitted "none" of these exhibits earlier and, except for Exhibits 4 and 5, did not offer a "valid explanation" for not submitting them earlier. Evidentiary Ruling at 1.[15] The ALJ rejected the argument that Exhibits 4 and 5 became available only after CMS filed its initial exchange, reasoning that, while under certain circumstances that could be good cause for late submission, Exhibit 4 and 5 "do not contain relevant evidence" as they "both . . . address the efficacy of certain diagnostic tests," which is not at issue. *Id.* The ALJ said, "The issues are related to how Petitioner intends to claim reimbursement for certain aspects of a test and also the credentials required to supervise the administration of tests." *Id.* at 2. Thus, the ALJ Decision accurately states that the ALJ admitted Petitioner's Exhibit 1. But, by his earlier ruling, the ALJ excluded Petitioner's Exhibits 2-6.[16]

Before the Board, HeartFlow disagrees with the ALJ's determination to exclude its Exhibits 2 and 4-6.[17] RR at 5. According to HeartFlow, "[u]nder the preponderance-of-the-evidence standard, good cause was present to admit" these exhibits. *Id.* (also stating that the ALJ's Evidentiary Ruling is "inaccurate" and/or "inconsistent" and "not supported by substantial evidence"). HeartFlow suggests that the ALJ took an unusual action here in deciding to exclude these exhibits, abusing his discretion, as it says, "It is unconventional for an ALJ, whose primary role in the appeal process is to be the best finder of facts as possible, to reject any evidence solely because it was allegedly not previously presented to CMS, especially under the relaxed rules of evidence in these administrative proceedings as set forth in 42 C.F.R. § 498.61." *Id.*

---

[15] On July 12, 2016, the day after CMS filed its objections, HeartFlow requested permission to file a response, stating that the response has been prepared and can be filed immediately if the ALJ permits it, and that the Pre-Hearing Order does not prohibit a "reply" to objections. Later that day, HeartFlow filed its response. The record does not show a ruling or communication from CRD to the parties responsive to the request for permission to respond. On July 13, 2016, the ALJ issued the Evidentiary Ruling, in which he referenced HeartFlow's arguments about CMS's objections. Therefore, the ALJ evidently decided to accept and consider HeartFlow's response, and then issued his Evidentiary Ruling.

[16] CMS asserted that Petitioner's Exhibit 6 (dated November 11, 2015) existed on or before the date on which HeartFlow requested reconsideration. CMS's Objections at 6. HeartFlow's reconsideration request was dated October 16, 2015. CMS Ex. 7, at 1. Thus, it appears that Exhibit 6 was not in existence and could not have been submitted with the reconsideration request. In any case, under 42 C.F.R. § 498.24(a), CMS (or its contractor) is permitted to "[r]eceive[ ] written evidence and statements that are material to the matters at issue and are submitted within a reasonable time after the request for reconsideration." Thus, the regulation does not require that all supporting documents must be submitted with the reconsideration request. The exhibit therefore could have been submitted to the contractor while the reconsideration request was pending.

[17] HeartFlow now makes no argument about the exclusion of Exhibit 3. We note that Heartflow withdrew Exhibit 3 by filing made the day before the ALJ issued his Evidentiary Ruling. Pet's Response to CMS's Objections at 2 (stating that, while HeartFlow disagreed that Exhibit 3 was new evidence and was offering Exhibit 3 "to enable a full and complete understanding of the facts[,]" it was withdrawing Exhibit 3 "for sake of judicial efficiency").

As an initial matter, the references to the "preponderance-of-the-evidence standard" and "substantial evidence" are misplaced in this discussion concerning the Evidentiary Ruling. HeartFlow first appears to conflate two distinct, but related, matters concerning Part 498 proceedings before an ALJ: pre-decisional matters within an ALJ's bailiwick, which would include his or her evidentiary rulings, and the burden of proof to be borne by the non-federal party appealing to the ALJ, i.e., to show, by a preponderance of the evidence (that it is more likely than not), that it was not in violation of an applicable requirement. *Promptcare New England Respiratory LLC*, DAB No. 2673, at 7-8 (2016) (discussing, in the context of revocation of a supplier's enrollment and billing privileges, the burden of proof to be borne by the non-federal party in Part 498 proceedings to show compliance with applicable requirements once CMS makes its prima facie case). As for "substantial evidence," generally speaking, it refers to a standard appellate courts apply in reviewing the factual findings of a lower court.[18] The Board applies this standard of review in Part 498 proceedings to determine whether any disputed fact found by an ALJ is supported by substantial evidence in the record.

We agree with HeartFlow that evidentiary rules are "relaxed" in Part 498 proceedings and that the ALJ has broad discretionary authority in evidentiary matters. 42 C.F.R. § 498.61 ("Evidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure."); *Lakeport Skilled Nursing Ctr.*, DAB No. 2435, at 6 (2012) (Federal Rules of Evidence and the Federal Rules of Civil Procedure do not apply to Part 498 proceedings); *Jennifer Matthew Nursing & Rehabilitation Ctr.*, DAB No. 2192, at 51 (2008) ("Under 42 C.F.R. § 498.61, an ALJ has broad discretion to admit evidence."). Indeed, in view of that broad discretionary authority, we do not disturb an ALJ's evidentiary ruling without compelling reason to do so. We turn next to our review of the ALJ's evidentiary rulings here.

*Petitioner's Exhibit 2.* Petitioner's Exhibit 2 is a two-page letter from the SCCT to HeartFlow, dated March 10, 2016. In the first page of the letter SCCT acknowledges that HeartFlow plans to "pursue" a CPT code specific to FFRct, and states that in 2010 SCCT sought Category 1 CPT codes for cardiac CT and coronary CTA services and that the codes (including CPT code 75574) were "approved and implemented effective January 1, 2010." HeartFlow says that it submitted the complete letter merely because CMS submitted only page 1 of the letter (CMS Ex. 9, at 4) even though HeartFlow previously

[18] Substantial evidence means "'more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.'" *Richardson v. Perales*, 402 U.S. 389, 401 (1971), quoting *Consolidated Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938). The reviewing court considers the whole record, taking into account the evidence that favors, as well as evidence that detracts from, the weight of the evidence relied on below. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951); *Mayes v. Massanari*, 276 F.3d 453, 459 (9th Cir. 2001).

submitted the two-page letter to Noridian. RR at 5. HeartFlow says that rather than excluding Exhibit 2, the ALJ should have compelled CMS to submit page 2 of the letter, but does not state why or on what authority. *Id.* CMS has not addressed why it submitted only the first page of the letter.

The ALJ excluded Exhibit 2 for failure to show good cause for late submission. SCCT's March 10, 2016 letter could not have been submitted with the October 2015 reconsideration request or even before the issuance of the December 17, 2015 determination. Therefore, assuming the ALJ had in mind the December 2015 determination in ruling that Heartflow failed to submit the letter to Noridian, we disagree with that aspect of the ruling because HeartFlow could not have submitted it before December 17, 2015. As mentioned earlier, a second reconsidered determination was issued with the date of March 18, 2016. We also note that in the record is a March 11, 2016 email from HeartFlow to Noridian transmitting items that evidently included a "letter from the [SCCT]" "to support the reconsideration request . . . ." CMS Ex. 9, at 1. The March 11, 2016 email, considered with other emails on March 11 and 18, 2016 between HeartFlow and Dr. Haley referring to the letter (CMS Ex. 9, at 64-66), supports HeartFlow's representation that it submitted the letter to Noridian. And, it evidently did so without delay.[19] An ALJ could find that these circumstances constitute good cause. In any case, the question for us is whether the ALJ abused his discretion in not finding good cause to exclude Exhibit 2. We are not inclined to find abuse of discretion under these circumstances, though, as we explained, we disagree with the ALJ's decision to exclude Exhibit 2 on the ground the ALJ relied on to exclude it.

The salient question as to Exhibit 2 is whether its exclusion (and particularly exclusion of page 2, since the first page was admitted as CMS Ex. 9, at 4) prejudiced HeartFlow. Put differently, assuming both pages of the SCCT letter had been admitted, would the outcome for HeartFlow be different? As we explained earlier, the SCCT letter does not change the outcome.

*Petitioner's Exhibits 4 and 5*. HeartFlow's only argument about these exhibits (dated in June 2016) is that it "satisfied the good cause standard" in submitting them to the ALJ because they "first became available in June 2016." RR at 5. The ALJ acknowledged this argument as he said, "With the exception of P. Ex. 4 and P. Ex. 5 Petitioner has offered no valid explanation for its failure to" submit its exhibits to the contractor.

[19] Assuming that the record includes one reconsidered determination dated March 18, 2016, we would find that HeartFlow submitted the SCCT letter to Noridian during reconsideration based on CMS Exhibit 9, pages 1, 64-66. In that circumstance, there would be no need to determine good cause to submit the letter to the ALJ. In any case, HeartFlow's statement that it first learned on March 16, 2016 that a reconsidered determination dated December 17, 2015 had been issued is consistent with evidence indicating that only days earlier, on March 11, 2016, HeartFlow continued to supplement its application with materials in support of reconsideration review.

Evidentiary Ruling at 1. The ALJ also said that, while the fact that a document did not come into existence until a certain time "[i]n some circumstances . . . might be good cause for offering evidence not presented at reconsideration[,] . . . the exhibits do not contain relevant evidence" since they concern the "efficacy of certain diagnostic tests . . . [which] is not at issue here." *Id*. HeartFlow provides no reason for us to conclude that the ALJ abused his discretion in excluding the evidence as irrelevant. *See* 42 C.F.R. § 498.60(b)(1) (the ALJ admits into the record "relevant and material" evidence).

*Petitioner's Exhibit 6*. HeartFlow asserts that, "like the other exhibits, P. Ex. 6 did not raise any new fact or issue that would surprise CMS and is publicly available to anyone, including CMS, through the internet." RR at 5. This assertion is essentially an abbreviated restatement of HeartFlow's response to CMS's objections, at 2-3, which the ALJ rejected, finding no satisfactory explanation of good cause. Exhibit 6 is dated November 11, 2015, before Noridian issued its (first) reconsidered determination. HeartFlow did not, and still does not, directly address why it did not submit or could not have submitted this document to Noridian. It does not address why availability or accessibility of a document through the internet or the fact that the document in question does not raise a new fact or issue (even if both are true or undisputed) should constitute good cause for admitting the document initially to the ALJ where there appears to be no dispute that the document was in existence before completion of reconsideration review.

***4. HeartFlow has not shown that it has been prejudiced by the ALJ's accepting and considering CMS's response to the ALJ's July 13, 2016 Order Directing Parties to Respond filed three days after the original due date.***

As discussed earlier, by a July 13, 2016 Order, the ALJ directed the parties to submit briefs discussing coverage determination(s) addressing the FFRct, coding for FFRct, and the supervising physician's credentials; CMS discretion on these matters where they are not addressed in any coverage determination; and whether any such exercise of discretion is reviewable. HeartFlow filed its brief on August 1, 2016, as the ALJ's Order directed. CMS, however, filed its brief on August 4, 2016. HeartFlow complains that not only did CMS fail to formally request the ALJ to extend the due date, "the ALJ's office . . . reached out to CMS's legal counsel . . . [and] permitted CMS to file" late. RR at 5 (referring to aforementioned August 2, 2016 emails between CRD staff and counsel). HeartFlow asserts, moreover, that CMS counsel's reason for her inability to meet the deadline of August 1 (counsel mistakenly calendared the deadline as August 11) does not meet any definition or reasonable interpretation of good cause. *Id.* at 5-6. HeartFlow's attorney objected to the late filing in an email and asked CRD to inform him whether he must formally move to strike but received no response from CRD. *Id.* at 6; emails attached to RR.

The first email on August 2 indicates that CRD staff contacted CMS counsel at the ALJ's direction ("Petitioner has filed its response but CMS has not. [The ALJ] would like to know whether CMS intends to respond and if so, why it has not done so."). In response, CMS counsel apologized for mistakenly calendaring the deadline as August 11, expressed intent to file a response within two days, and asked whether a motion for leave to file late should be filed. Thereafter, CRD staff, evidently at the ALJ's direction, informed CMS counsel that she did not need to request leave to file late if she filed CMS's brief by August 4. The ALJ was within his authority to permit late filing of a submission which he had requested to address questions that would inform his decision. HeartFlow has shown no prejudice as a result of the three-day delay in CMS's response to the ALJ's questions. While the ultimate decision was unfavorable to HeartFlow, we see no connection between that outcome and the brief delay in the filing of CMS's response.

**Conclusion**

Based on the foregoing reasons, the Board upholds the ALJ Decision.

/s/
Christopher S. Randolph

/s/
Leslie A. Sussan

/s/
Susan S. Yim
Presiding Board Member