Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: December 8, 2008
Cary Frounfelter and Kast Orthotics and Prosthetics, Inc.,	
Respondents,	Civil Remedies CR1808 App. Div. Docket No. A-08-119
- v. -	Decision No. 2211
Inspector General.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Cary Frounfelter and Kast Orthotics and Prosthetics, Inc. (Respondents) appeal the June 23, 2008, decision of Administrative Law Judge (ALJ) Steven T. Kessel. Cary Frounfelter and Kast Orthotics and Prosthetics, Inc., DAB No. CR1808 (2008) (ALJ Decision). The ALJ affirmed a determination by the Inspector General (I.G.) imposing on Respondents a seven-year exclusion from participation in all federally financed health care programs, a civil money penalty (CMP) of $100,000, and an assessment of $42,220 under the Civil Monetary Penalties Law (CMPL).

The ALJ found that Respondents had presented or caused to be presented for payment to the Medicare program claims that they knew or should have known were false or fraudulent or were for items or services that were not provided as claimed. Specifically, the ALJ found that the claims involved payment for orthotic devices Respondents provided to hospital inpatients prior to their discharge from the hospital. With one exception, Medicare requires hospitals to pay for such devices from the

reimbursement the hospital receives. The ALJ found that Respondents billed Medicare because the hospital refused to pay Respondents for the devices and that Respondents falsified the dates of service so that Medicare would pay. The ALJ also concluded that the remedies imposed by the I.G. were reasonable.

For the reasons discussed below, we uphold the ALJ Decision.

Relevant legal authority

The Medicare program is established by title XVIII of the Social Security Act (Act).[1] Title XVIII distinguishes between payments made under Part A and Part B. Part A pays for, among other things, the costs of a Medicare beneficiary's stay in a hospital. For purposes of Part A, the term "inpatient hospital services" generally includes "supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients" and such "other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangement with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements." Act, § 1861(b). The term "hospital" includes an institution primarily engaged in providing rehabilitation services. Act, § 1861(b). A hospital is considered a "provider of services." Act, § 1861(u).

Medicare Part B covers "medical and other health services," which generally includes "durable medical equipment" (DME) and "leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition." Act, § 1861(s). The items in the latter category are included in the definition of "prosthetic and orthotic devices" for purposes of Medicare payment. Act, § 1834(h)(4). Benefits under Medicare Part B do not, however, include payment for orthotics and prosthetics described in section 1834(h)(4) of the Act if they are furnished by a provider of services or by others under arrangements with them made by a provider of services. Act, §§ 1832(a)(2)(B) and (a)(2)(I). In general, no payment may be made under Part B for services that

[1] We reference the provisions of the Act throughout this decision. The current version of the Act can be found at www.ssa.gov/OP_Home/ssact/comp-ssa.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.

are covered under Part A. Act, §§ 1833(d); 1861(s). Thus, a supplier of orthotic devices may not lawfully claim reimbursement for an item or service under Part B if that item or service is already covered under Part A as part of hospital inpatient services.

There is an exception to the general rule that a supplier may not bill Part B for orthotics furnished to hospital inpatients. Medicare will accept a Part B claim from a supplier for an orthotic device furnished to a hospital inpatient *if* that item was supplied to the beneficiary within the two days prior to the date of the beneficiary's discharge from the hospital to the beneficiary's home and *if* that item meets other conditions, including that it was ordered for the beneficiary's post-discharge, in-home use. See, I.G. Exs. 77 (Medicare Transmittal AB-00-02); 75 (Region B Durable Medical Equipment Regional Carrier Bulletin). This exception is known informally as the "two-day" rule.

The I.G. sanctioned respondents under the CMPL, sections 1128A(a)(1)(A) and (B) of the Act. The CMPL provides, in pertinent part, that "[a]ny person (including an organization, agency, or other entity)" that "knowingly presents or causes to be presented" a claim which --

> (A) is for a medical or other item or service that the person knows or should know was not provided as claimed . . . , [or]
> (B) is for a medical or other item or service and the person knows or should know the claim is false or fraudulent,
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> * * *
>
> shall be subject . . . to a civil money penalty of no more than $10,000 for each item or service wrongly claimed . . . .

Each such person is also responsible for an assessment of up to three times the amount claimed and may be excluded from participating in federal health care programs, including Medicare and Medicaid. Id. The applicable federal regulations governing CMPL cases are at 42 C.F.R. Part 1003.

The ALJ Decision

The following facts are undisputed. Mr. Frounfelter is an orthotist who "constructs, fits, and supplies orthotic devices used in the care and rehabilitation of individuals who have suffered from orthopedic or neurological injuries." ALJ Decision at 3. Mr. Frounfelter incorporated Kast Orthotics and Prosthetics, Inc. (Kast) in 1997; he solely controlled the management and direction of Kast. Id. Kast was a successful enterprise, with about $2.5 million in annual gross sales and $400,000 in annual profits. Id., citing I.G. Ex. 42D, at 21. The 54 claims at issue are for orthotic devices that the I.G. found were delivered by Respondents to 40 inpatients at HealthSouth Rehabilitation Hospital in Largo, Florida (Largo hospital or HealthSouth). Id. The devices were delivered between December 1999 and July 2004; the claims total $20,627.34. ALJ Decision at 3, citing I.G. Exs 4-5; 25B, at 4-5.

The ALJ concluded that "the evidence in this case overwhelmingly supports the conclusion that [Respondents] systematically, fraudulently, and falsely claimed reimbursement under Part B of the Medicare program for orthotic devices which they knew or should have known were not eligible for compensation under Part B." ALJ Decision at 1. Specifically, the ALJ found that the "date of service" on each of the claim forms (item 24A on the Medicare Health Insurance Claim Form) is incorrect in that it is later than the date that Respondents actually delivered the device to the beneficiary. Id. at 4. He found that Respondents had falsified the delivery dates to convince Medicare to reimburse them directly for the services, because HealthSouth's management had "told Mr. Frounfelter that a condition for Kast being permitted by HealthSouth to provide orthotic devices to patients at the Largo hospital was that he and Kast would not bill the hospital directly for the items that Respondents provided." Id. The ALJ further found that, when Respondents billed Medicare for the orthotic devices they supplied to Largo hospital patients, "Respondents knew that Medicare would not reimburse them directly for these devices unless Respondents convinced Medicare that the devices were supplied later than the dates of their actual delivery to patients." Id. at 4. In reaching this conclusion, the ALJ relied, among other things, on Mr. Frounfelter's admission to I.G. investigators that he knew what he did was "wrong and illegal." Id. at 11, citing I.G. Ex. 42A, at 1. The ALJ rejected Respondents' arguments about why they were not liable under the CMPL, as well as their affirmative defenses. ALJ Decision at 6-14.

The ALJ also concluded that the I.G.'s remedies (exclusion of seven years, a CMP of $100,000, and an assessment of $42,220) were reasonable under section 1128A and the implementing regulations.

The ALJ held a two-day hearing in Tampa, Florida. He received into evidence I.G. Exhibits 1A thorough 105; the I.G. subsequently withdrew I.G. Exhibits 46A and 46B (Tr. at 333). The ALJ received into evidence Respondents Exhibits 2 through 21. Each party filed, as an attachment to its post-hearing brief, a summary of the documentary evidence relating to specific beneficiaries and claims. The I.G.'s summary (Summary of Documentary Evidence Demonstrating Claims are False or Fraudulent) contains information on all 54 claims and 40 beneficiaries. Respondents' summary (Medical Records Summary and Analysis) contains information on 33 beneficiaries, i.e., for seven beneficiaries, Respondents make no arguments. The ALJ did not admit the summaries as evidence, but he referred to the I.G.'s summary in discussing the parties' arguments. Below we refer to these summaries as "I.G. Summary" and "Respondents Summary."

Respondents appealed the ALJ Decision to the Board pursuant to 42 C.F.R. § 1005.21.

Standard of review

The standard of review on appeal from an ALJ decision under the CMPL on a disputed issue of fact is "whether the initial decision is supported by substantial evidence on the whole record" and on a disputed issue of law is "whether the initial decision is erroneous." 42 C.F.R. § 1005.21(h). The regulations further provide that the Board will not disturb an otherwise appropriate ruling, order or act by the ALJ for harmless error, i.e., where the substantial rights of the parties are not affected. 42 C.F.R. § 1005.23.

Analysis

A. The ALJ's determination that the claims were false is supported by substantial evidence in the record as a whole and free of legal error.

Respondents make multiple arguments to support their contention that the ALJ erred by concluding that the claims at issue were false. Below we explain why none of the arguments has merit.

1. The ALJ's determination that the HealthSouth records are reliable is supported by substantial evidence in the record as a whole.

The I.G. relied on HealthSouth records (and other evidence) in concluding that the 54 claims at issue were false. Respondents argue that "the ALJ erroneously determined that the HealthSouth records were more reliable than those of Respondents." R. Br. at 15. They assert the ALJ erred in relying on HealthSouth records because the Department of Justice "recently settled multiple lawsuits against HealthSouth for rampant fraud and abuse, including complex billing fraud schemes" and that the I.G. "had been advised during the course of its investigation that HealthSouth routinely altered its medical records, including manipulation of patient discharge dates." Id.

The evidence in the HealthSouth patient records consists of entries by doctors, nurses, physical therapists, and, in some cases, Mr. Frounfelter himself about orthotic devices Kast supplied to Medicare beneficiaries. These relevant entries reflect the date the device was ordered and delivered and the date of the beneficiary's discharge. Respondents do not actually contest the accuracy of the dates of delivery or the dates of discharge reflected in the HealthSouth records. Rather, Respondents argue that they were entitled to bill Part B for devices supplied to the majority of these beneficiaries in spite of the dates in the HealthSouth records because Respondents "switched out" the first device (shown as delivered in the HealthSouth records) with a second device after the beneficiary's discharge. R. Br. at 22-25; see also R. Summary. In other words, Respondents assert that events after a beneficiary's HealthSouth discharge made the majority of these claims legitimate, not that the dates shown in the HealthSouth records are not accurate. See Oral Argument before the Board (OA) Tr. at 34-35 (counsel asserts that the HealthSouth and Kast records can be reconciled); R. Reply at 8 (brief states that "the records can be read consistently with one another").

Moreover, the evidence in this case amply supports the reliability of the relevant aspects of the HealthSouth records, and the ALJ reasonably relied on them for the following reasons:

- As the ALJ pointed out, since the HealthSouth records show that Respondents repeatedly delivered devices to beneficiaries more than two days before they were discharged, the entries "are in fact, not in HealthSouth's interest and even support allegations of unlawful conduct by HealthSouth." ALJ Decision at 6.

Therefore, the ALJ reasonably found the HealthSouth records credible since HealthSouth had no reason to falsify the records to show, as the records did, that it should have paid Respondents for these devices out of its Medicare reimbursement.

- The HealthSouth patient records at issue are sequential and often contain signed handwritten notes by different individuals on different days about the beneficiary's care, which makes them less likely to have been fabricated compared to typewritten notes signed by only one or two individuals.

- Contrary to Respondents' assertion (R. Br. at 15), the I.G. submitted evidence that supports the ALJ's finding about the accuracy of the records. See I.G. Exs. 48A, at ¶ 2 (testimony of custodian of the records stating entries in patient records were "true and accurate"); 47A, at ¶ 3 (testimony of Dr. Richard Liles, HealthSouth Medical Director); 48A, at ¶ 2 (testimony of Elaine Ebaugh, HealthSouth Administrator); 50, at ¶ 3 (testimony of Dr. Christine Weot); and 51 at ¶ 3 (testimony of Dr. Michael Yu).

Respondents also complain that "[p]erhaps most egregiously, Respondents requested but were denied discovery relating to the OIG's investigation of HealthSouth, which would have allowed Respondents to address [the issue of record reliability]." R. Br. at 17. This argument is without merit. Respondents represented to the ALJ that they needed the investigation documents (large quantities of which they received) to support their selective prosecution, investigatory misconduct, and equitable estoppel defenses (discussed below) and said nothing about the documents' relevance to the integrity of the HealthSouth records. R. Response in Opposition to Petitioner's Motion for Protective Order, at 9-12. Thus, Respondents did not seek discovery for the purpose of challenging the integrity of the HealthSouth records, contrary to what they suggest. Their failure to seek discovery for this purpose is consistent with the fact that Respondents do not actually dispute the material dates in the HealthSouth records.

Finally, Respondents complain that the I.G.'s exhibits "only contain a select portion of HealthSouth records" (R. Br. at 15) and that the ALJ relied on them despite lack of testimony as to their "completeness" (id. at 17). Again, this argument is baseless. In discovery, the I.G. represented that it had provided Respondents with "PDF files of the complete HealthSouth

Corporation ('HealthSouth') patient file for the 41 beneficiaries identified in Attachment A of the OIG's notice of proposed determination dated June 5, 2007." I.G. Response to Respondent's Request for Production of Documents. Respondents do not dispute that they received such records and were free to submit any record documents they thought relevant.

Therefore, we conclude that substantial evidence in the record as a whole supports the ALJ's reliance on the HealthSouth records.

2. The ALJ's findings that the Kast patient records were unreliable and, therefore, failed to support Respondents' switch-out defense is supported by substantial evidence in the record as a whole.

Respondents argue that the majority of the 54 claims at issue were not fraudulent because Respondents first delivered a "stock" device to the beneficiary in the hospital for which they did not bill Part B and that, after discharge (or within two days of discharge), they delivered a second "custom fit" device to the beneficiary for which they billed Part B. R. Br. at 22. Respondents refer to this as their "switch-out defense." Id. Respondents rely on Kast records to prove that these switch-outs occurred; they cite Kast records for 29 beneficiaries, most of which contain entries stating that "stock" devices were delivered in the hospital and replaced by "custom" devices within two days of or after the beneficiaries' discharges. See R. Summary. The ALJ rejected Respondents' switch-out defense because he found that the Kast records documenting these alleged switch-outs were not credible. This finding is fully supported by the record.

First, the ALJ relied on testimony from a beneficiary and relatives of beneficiaries that the beneficiaries did not receive a replacement device from Respondents in conjunction with their HealthSouth hospitalization. ALJ Decision at 7. This testimony directly contradicted Kast records purporting to document that Kast replaced or switched out an original device with a second device. The ALJ stated that he found this testimony credible. Id. For example, the ALJ cited the testimony of "G.J." and related records, which show the following:

- G.J.'s HealthSouth records indicate that G.J. received a hip abduction brace by February 23, 2003. I.G. Ex. 8D, at 9.

- The Kast records confirm that the brace was provided in the hospital but also state that, on March 10, after his discharge, Respondents "replac[ed] hip abduction brace

per Dr. Near, due to terrible infection that the existing hip brace caused. Will also order additional inner liners for new H/O." In billing Medicare Part B, Respondents represented that the hip abduction brace was delivered on March 12, 2003. I.G. Ex. 8E, at 4.

- However, the ALJ found that G.J. "testified credibly that Respondents had not provided him with a second device after his discharge from the hospital." ALJ Decision at 7, citing I.G. Ex. 8A, at 2-3, Tr. at 327-329.

- Not only did the ALJ observe G.J., but the specificity of G.J.'s testimony supports the ALJ's credibility finding. G.J. testified that he received his hip brace at HealthSouth "approximately one day after being measured by the orthotist"; that it was "the only brace that I have ever received for my hip after my hip surgery"; that in March 2003 "approximately one week after being discharged home,[2] the orthotist who measured me for my hip brace during my hospitalization at HealthSouth came to my home and provided me with a set of replacement pads for the hip brace"; and that approximately one week later he went to the same orthotist who repaired but did not replace the hip brace. I.G. Ex. 8A, at 2-3; I.G. Ex. 8B, at 3.

- The Kast records stating that G.J. got a new brace in early March "per Dr. Near" because he had a "terrible infection" were disputed by G.J. G.J. testified that he received a second set of "pads" to help with a "rash" under the brace. Tr. at 328. G.J.'s wife explained to the I.G. investigator that the second set of pads allowed him to wear a set and wash a set "to improve sanitation and reduce skin irritation caused by the brace." I.G. Ex. 8B, at 4. This testimony is consistent with Dr. Near's summary of G.J.'s April 3 visit, which refers to brace-related "dermatitis" on G.J.'s "last visit." I.G. Ex. 8E, at 9.

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[2] G.J. was discharged home on March 7, 2003. He was not discharged from HealthSouth to his home because, on February 26, while at HealthSouth, he dislocated his hip and was sent to a different hospital to have the hip reset. He then continued his rehabilitation at Suncoast Medical because HealthSouth was full and could not accept him. I.G. Ex. 8B, at 3.

Additionally, the ALJ relied on in-person testimony of four relatives of deceased or relocated beneficiaries who testified that the beneficiaries (J.J., A.M., R.M., J.W.) did not receive second orthotic devices. ALJ Decision at 7. As with G.J., the Kast records for these beneficiaries state that they did all receive devices after discharge. See, I.G. Exs. 10E (J.J.), 20D (A.M.), 6D (R.M.), 16D (J.W.). On appeal, Respondents object to the ALJ's reliance on this testimony because the witnesses admitted they were not with the beneficiaries 24 hours a day. R. Br. at 24. Since each of the witnesses gave reasons why they believed they would have known if Respondents had replaced the devices at issue (see Tr. 147, 253, 356, 364), and the ALJ had the opportunity to assess the credibility of the witnesses, he could reasonably rely on this testimony for his finding that the Kast records allegedly documenting these "switch-outs" were false.[3]

In addition to the preceding testimony, the ALJ relied on testimony by a former Kast employee, James Barnes, as showing that the Kast records were not reliable. The ALJ found that the employee, who was cross examined at the hearing, "averred credibly that he had never used, nor had ever seen Mr. Frounfelter use, a stock or off the shelf ankle foot orthotic [AFO] device." ALJ Decision at 7-8, citing I.G. Ex. 54A, at 2. Most of the switch-outs allegedly documented in the Kast records involve "stock" and "custom" AFOs. See R. Summary. While the

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[3] Respondents seek to impeach the testimony of J.J.'s daughter by citing her testimony at the hearing in which she answered "No" to the question "Were you aware that during the [I.G. investigator's interview of December 2005], your mother actually informed the [I.G.] that she had, in fact, received a second leg brace in connection with her hospitalization at the HealthSouth facility?" R. Br. at 24, citing Tr. 147. This question, however, mischaracterizes the mother's statement to the investigator and is contrary to Kast's own records. The mother told the investigator that after her discharge she received a second leg brace but "could not remember the source of her second leg brace." I.G. Ex. 10B, at 3. Moreover, the daughter told the I.G. investigator in December 2005 that the second leg brace came from a different orthotic supply company, not Kast. I.G. Ex. 10C, at 3. Finally, Kast's records do not document a switch-out of a leg brace. I.G. Ex. 10E; see also R. Summary at 4-5 ("the device was not switched out"). The Kast records represent that a single device was delivered after J.J.'s discharge (I.G. Ex. 10E, at 3), which is contrary to J.J.'s statement that the Kast device was delivered early in her hospital stay (I.G. Ex. 10B, at 2).

employee admitted on cross examination that he was not with Mr. Frounfelter every time Mr. Frounfelter went to HealthSouth (Tr. at 202), he also explained why stock AFOs were not used by Kast at HealthSouth and stated that prompt delivery of the custom item was important so that "the item could be used by the patient for rehabilitation" and "there was sufficient time before discharge to ensure proper fit." I.G. Ex. 54A at 2. He stated that "Kast had a policy that clinical practitioners were to measure, fabricate and fit the patient with the O&P item . . . within 24 hours of the referral." I.G. Ex. 54B, at 1. This evidence also tends to show that the Kast records documenting switch-outs of stock AFOs were not reliable.

Finally, as the ALJ noted, in their pre-hearing brief, Respondents' relied on the declaration of Mr. Frounfelter as support for the switch-out defense. ALJ Decision at 7. However, at the hearing, Respondents did not offer this declaration into evidence, and Mr. Frounfelter did not testify at the hearing about anything, much less the switch-out defense and the Kast records.[4] Despite the absence of in-person testimony by Mr. Frounfelter, the record does contain evidence of statements he made about these claims that support the ALJ's finding that the Kast records were unreliable.

- The I.G. investigator in charge of the HealthSouth investigation, Agent Jurs, interviewed Mr. Frounfelter on May 20, 2004.[5] I.G. Ex. 42A. Agent Jurs stated in the interview report (and affirmed at the hearing (I.G.

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[4] On appeal, Respondents' counsel asserts that Mr. Frounfelter did not testify "because he was prohibited (via operation of ALJ Kessel's pre-hearing orders . . .) from presenting equitable and factual defenses critical to his defense." R. Br. at 24. Leaving aside the accuracy of this statement, it does not explain why Mr. Frounfelter would choose not to testify in support of the integrity of Kast records, particularly after the I.G. submitted repeated exhibits and testimony tending to show that they were unreliable.

[5] The ALJ recognized that "Respondents have averred at times that the I.G. agents who participated in this initial interview of Mr. Frounfelter are not credible and that their report of the interview is false." ALJ Decision at 11, n.7. The ALJ explained why he found no evidence to support this assertion. On appeal, Respondents offered no credible grounds for disturbing the ALJ's assessment of the agents' conduct or reports of their interviews.

> Ex. 58, at ¶¶ 6, 7)) that Mr. Frounfelter told him that "he realized that any . . . orthotics provided to Medicare patients in an inpatient acute care setting were not separately billable to Medicare, . . . that he was supposed to secure a purchase order from the inpatient facility and bill them directly, . . . [and] that the manner in which the billing was being performed was wrong and illegal." Id. at 1; see also I.G. Ex. 58, at ¶¶ 6, 7.[6] In this interview, Mr. Frounfelter did not mention switching out devices.

- Agent Jurs interviewed Mr. Frounfelter again in November 2004, at which time Mr. Frounfelter was represented by counsel. I.G. Ex. 42B. Agent Jurs stated in the interview report (and affirmed at the hearing) that Mr. Frounfelter now said that he thought HealthSouth's "arrangement [with orthotists] was legal." Id. at 2. Mr. Frounfelter also stated, however, that the HealthSouth controller told him "his records at Kast should be documented in such a way as to reflect a date

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[6] At oral argument before the Board, Respondents' counsel tried to characterize Mr. Frounfelter's admissions as follows:

> All Mr. Frounfelter did was when the agent came to him and said, do you know the regulations say you have to do it this way? And Cary said, well, I didn't do it that way, I did it the other way because that's what HealthSouth told me to do. And then and only then did Mr. Frounfelter agree that, well, if I did that, I guess my claims were false.

OA Tr. at 72. Counsel's characterization is not supported by any evidence in the record, nor is it a reasonable characterization of the interview report. For example, the report states:

> When asked if he [Mr. Frounfelter] discussed the arrangement between Kast and HealthSouth with anyone else, he related that it was considered a "hush" subject. He knew that the manner in which the billing was being performed was wrong and illegal, and stated that HealthSouth also knew it was wrong and illegal, and therefore neither side liked to talk about it, even with each other.

I.G. Ex. 42A, at 1.

> of delivery that is after the patient was discharged from the facility. As such the billing done under Kast used a date of delivery for the first appointment the patient had after their inpatient discharge." Id. at 3.

Mr. Frounfelter's May 2004 statement shows that Mr. Frounfelter knew his billing arrangement with HealthSouth was "wrong and illegal." Mr. Frounfelter's November 2004 statement shows that he was aware that, in order to further this arrangement, Kast records needed to document some basis for billing Part B. Thus, these statements (which as statements of a party-opponent are not hearsay) show both awareness of the falsity of the billing practice and the need to cover up that falsity through Kast records. They support the ALJ's finding that the Kast records are unreliable.

From this evidence, the ALJ reasonably inferred that Respondents "fabricated patient records in order to justify their Part B reimbursement claims and to make it look as if they had switched out devices after patients were discharged from the Largo hospital." Id. He properly treated as not credible the "switch-outs" allegedly documented by the records.

On appeal, Respondents argue that the evidence shows that "switch-outs can be medically necessary and proper." R. Br. at 23, citing Tr. at 135 (Dr. Liles); at 153 (Dr. Yu); at 265 (former Kast employee); at 202 (former Kast employee). While this testimony establishes that switch-outs can be medically necessary and proper (for example, after a reduction in swelling), none of these witnesses testified that a switch-out had been necessary or occurred in any of the claims at issue. Moreover, the following testimony of these witnesses tends to show that routine switch-outs of orthotic devices did not occur as Respondents claim:

- Dr. Liles, the Medical Director of HealthSouth, stated that he ordered custom made orthotic devices for his patients' use during their treatment at the hospital; that when he ordered a customized device he "did not expect the patient to be fitted with a prefabricated device and then have it subsequently replaced with a customized device"; that Respondents "turned around custom-made orthotic devices very fast compared to other vendors, [usually] within 24 hours after it was ordered"; that these devices were "intended to be used as part of the patient's rehabilitative treatment or physical therapy during the patient's hospital stay at HealthSouth." Finally, he stated that he was "not aware

that [Respondents] have 'switched out' any prefabricated devices provided to inpatients at HealthSouth with a customized device." I.G. Ex. 47A, at 4-5. Dr. Yu's testimony was similar. See I.G. Ex. 51A, at 3-5.

- Former Kast employee James Barnes testified that while he worked at Kast he never used a prefabricated AFO because it "generally requires a lot of adjustment and it is difficult to adjust one properly to fit the patient." I.G. Ex. 54A, at ¶ 4. He also testified that he never saw Mr. Frounfelter use one at HealthSouth. Id.

- John Clarke, who also worked for Kast, testified that he could not recall ever making a switch-out from a stock device to a custom device when he worked at Kast. Tr. at 264. On cross-examination, he admitted that, while he could not say with certainty that Mr. Frounfelter never made a switch-out, stock devices are not used by orthotists because such devices are "usually ill fitting," that custom devices can be and are modified to address reductions in swelling, and that if a custom device cannot be modified sufficiently, another custom device is supplied." Tr. at 265-66.

Thus, the testimony of doctors and the former employees undercuts Respondents' position, rather than supporting it.

On appeal, Respondents challenge the ALJ's analysis of J.R.'s records. R. Br. at 19-20, citing ALJ Decision at 9. It is undisputed that J.R. received a knee brace that allowed for a range of motion (a ROM K/O) while an inpatient at HealthSouth. Respondents assert that the hospital knee brace was a "prefit ROM/KO," which was switched-out for a different ROM K/O on December 16 after J.R. was discharged. I.G. Ex. 31B, at 3; see also R. Summary, at 11. Relying in part on the similarities between the entry Mr. Frounfelter made in J.R.'s HealthSouth record on November 30 and the entry he made in J.R.'s Kast record on December 16, the ALJ found the Kast record unreliable. ALJ Decision at 9-10. We agree with the ALJ that the evidence as a whole shows that the Kast records were unreliable; a comparison of Mr. Frounfelter's November 30 entries in HealthSouth and Kast records further supports this finding. In the November 30 HealthSouth record, Mr. Frounfelter wrote: "Set patient's ROM to Dr. Nears requirements to 30° Ext 60° Flex[.] Will adj if Dr. Liles requires different ROM." I.G. Ex. 31A, at 8. The Kast record has the following note, with the same date: "F/U [follow up] with patient existing K/O not causing pain but unable to set

proper ROM. Patient needs to be fit with ROM K/O ASAP." I.G. Ex. 31B, at 3. These two notes are contradictory: in the hospital note, Mr. Frounfelter reports he followed the doctor's order for setting the ROM; in the Kast note he says he could not set the proper ROM. This contradiction and other evidence suggest that the November 30 Kast entry is simply part of Mr. Frounfelter's falsification of J.R.'s Kast records in support of Mr. Frounfelter's last Kast entry stating that, on December 16, he delivered a second ROM K/O and set it to Dr. Near's specifications. Id.[7]

On appeal, Respondents point out that two I.G. investigator interviews of Kast patients "demonstrate that the . . . 'switch-out' technique was utilized by Kast." R. Br. at 22. It cites I.G. investigator interviews of L.G. and C.R. in which they state that they did receive replacement devices after discharge from HealthSouth. Id. citing R. Exs. 14, and 15. Since the I.G. did not include L.G. or C.R. on the list of beneficiaries for whom Respondents had made one of the 54 false claims at issue, these interviews do not show that any of the 54 claims at issue were not false. See I.G. Summary. Also, while Respondents submitted interviewer's notes of L.G.'s and C.R.'s interviews, they did not submit the related HealthSouth or Kast records. Therefore, we cannot tell if these claims were reported and billed similarly to the claims at issue. Even if we accept the interviews as evidence that sometimes replacement of a stock device with a custom device did occur for medical reasons, moreover, we would not accept them as sufficient to rebut the testimony from physicians and Kast employees that Respondents almost always provided a custom device within two days after it was ordered or other evidence that Respondents had a motive to and, in fact, did engage in a pattern of falsifying their records.

On appeal, Respondents allege that the ALJ misapplied the burden of proof when he stated that Respondents had "not offered

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[7] The HealthSouth record also demonstrates the fallacy of counsel's assertion that deliveries of stock devices were not documented in the HealthSouth records because "motivations for making the entries in the [HealthSouth] records are different [than in Kast records]." OA Tr. at 34. This may be true for HealthSouth employees or doctors, but if Mr. Frounfelter was actually delivering stock items to inpatients, he had both opportunity and reason to document this fact in HealthSouth as well as the Kast records. His failure to document the alleged delivery of stock items in beneficiaries' HealthSouth records supports the inference that he was not actually doing so.

probative evidence" that they provided customized orthotics for the claims at issue to any beneficiary "as an outpatient." R. Br. at 20-21, citing ALJ Decision at 7, see also R. Br. at 19 (alleging that the ALJ "ignored" that it is the I.G's burden "to prove the claim was false, not Respondent's burden to prove that it was proper"). Respondents mischaracterize the ALJ's holdings. He found "overwhelming evidence proving that Respondents" were liable under the CMPL. ALJ Decision at 3. As evidence of falsity, he relied on the evidence showing that Respondents delivered orthotics to inpatients, that Respondents presented Part B claims with supply dates later than the dates of actual delivery, and that Respondents had arranged with HealthSouth to bill Medicare directly since HealthSouth would not pay them. To rebut this evidence, Respondents allege that they actually billed Part B for switched-out custom orthotics, delivered on the claimed dates. The ALJ properly found this allegation was not supported by credible evidence. The burden on the I.G. is to show liability by a preponderance of the evidence. Finding that the rebuttal evidence submitted by Respondents deserves no weight does not improperly shift that burden. Moreover, to the extent the "switch-out" theory is an affirmative defense, Respondents have the burden of proof. 42 C.F.R. § 1005.15(a).

Finally, Respondents challenge the credibility of other witnesses whose testimony tends to support the ALJ's findings. R. Br. at 25. The ALJ did not, however, rely on this testimony, nor do we need to rely on it to uphold the ALJ's findings.

Therefore, we find that substantial evidence in the record as a whole supports the ALJ's finding that Respondents did not, as they claim, switch-out devices after discharge for 26 beneficiaries (R.S., T.S., M.S., B.S., R.M., A.S., G.J., P.H., R.M., V.C., A.T., J.W., R.K., H.A., A.M., T.P., E.K., V.K., E.S., J.R., R.L., E.H., D.M., M.L., E.H., M.S.) or two days before discharge for 3 beneficiaries (E.P., M.P, M.F.).[8]

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[8] We note here that, for claims for 11 beneficiaries, Respondents do not explicitly rely on the switch-out defense.

For seven beneficiaries (M.B., M.R., N.C., M.T., H.L., W.M., W.J.), Respondents make no argument and cite no evidence about why the related claims were not false. Compare beneficiaries listed on I.G. Summary with those listed on R. Summary.

For one beneficiary, L.C., Respondents represent that HealthSouth and Medicare reimbursed Kast for the device in 2004 and that Kast

(continued...)

3. The ALJ's determination that Respondents failed to show that any of the claims at issue were reimbursable under "the two-day" exception is supported by substantial evidence in the record as a whole.

The ALJ rejected Respondents' argument that "many of the questioned . . . services were delivered in an appropriate and legal timeframe and indeed complied with Medicare's [two-day] rule." ALJ Decision at 8, citing R. Post-hearing Br. at 12.

The two-day rule (referred to incorrectly by Respondents as the "48-hour" rule) is an exception to the Medicare rule that orthotic devices supplied to inpatients may not be billed to Medicare by the supplier. It allows a supplier to bill Medicare Part B for an orthotic delivered to an inpatient beneficiary "no earlier than two days before the day the facility discharges the beneficiary" if the delivery meets this and eight other conditions. Three of these conditions are: "the item is medially necessary for use by the beneficiary in the beneficiary's home"; "the supplier delivers the item . . . in the facility solely for the purpose of fitting the beneficiary for the item, or training the beneficiary in the use of the item, and the item is for subsequent use in the beneficiary's home"; and "the reason the supplier furnishes the item is not for the purpose of eliminating the facility's responsibility to provide

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[8](...continued)
informed Medicare of its overpayment and refunded the Medicare reimbursement. R. Summary at 10. However, the refund to Medicare was in 2006, after Agent Jurs had interviewed Mr. Frounfelter about HealthSouth billing practices. Tab 23 to Ex. 1 attached to R. Post-hearing Br. at KAST00477-KAST00481. Thus, this does not undercut the evidence that, at the time Respondents made the claim, they knew it to be false.

As discussed previously in note 3, Respondents represent that they delivered a single device after discharge to J.J., but this representation is contradicted by credible evidence, including in-person testimony.

As discussed below, for two beneficiaries (R.C. and G.B.), Respondents rely on the two-day rule but do not allege there was a switch-out in arguing that the two-day rule applies. As discussed above, Respondents inconsistently treat G.J. as both a post-discharge switch-out case and a delivery within two days of anticipated discharge.

an item that is medically necessary for the beneficiary's use for treatment while the beneficiary is in the facility." I.G. Ex. 77.

While Respondents repeatedly refer to the two-day rule (see R. Br. at 16, 18, 22, 28-29; R. Summary), in their briefs they identify only two claims affected by it, R.C. (R. Br. at 21) and G.J. (R. Reply at 9) .

For R.C., the HealthSouth and Kast records indicate that a back brace was delivered November 17, 2003, and the HealthSouth records show that R.C. was discharged November 21. Respondents argue that, when the brace was delivered on November 17, the anticipated discharge date was November 19 so the two-day rule should apply here.[9] Even assuming that a supplier's "good faith" reliance on an anticipated discharge date matters and that Respondents had shown reliance in fact (which they did not), we would not find that the two-day rule applies here. Nothing in the records (including the Kast records) indicates that the brace was delivered to the inpatient "solely for the purpose of fitting the beneficiary for the item, or training the beneficiary in the use of the item," a condition of qualifying under the two-day rule. Rather, entries by Dr. Liles clearly show that R.C. was using the brace in the hospital to alleviate her back pain: on November 17 Dr. Liles wrote that he "instructed patient pain should continue to improve with time, utilize back brace, see if this helps"; on November 20, Dr. Liles wrote "[b]ack brace does help"; and on November 21, he wrote "tolerating brace." Id. at 7-8. Moreover, R.C. told an I.G. investigator in October 2005 that she "recalled using the brace during the course of her rehabilitation at HealthSouth." I.G. Ex. 1A, at 2.

In their Reply Brief, Respondents also argue that G.J.'s claim falls within the two-day rule. R. Reply at 9, citing R. Summary, at 4. Relying on a doctor's HealthSouth note of February 20 stating "discharge was tentatively anticipated for [February 24]" (I.G. Ex. 8D, at 9), Respondents represent that the device was delivered February 23. The doctor's February 20 note does not

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[9] Respondents rely on the testimony of a CMS employee responsible for supplier orthotic claims who testified that, as matter of "first impression," he would treat as payable an orthotic delivered in good faith anticipation of a discharge date, assuming it met the other conditions of the two-day rule. R. Br. at 21, citing Tr. at 225; see also 234. However, this testimony is irrelevant since, as discussed above, there has been no showing this claim met all conditions of the rule.

provide a basis for finding that Respondents delivered the brace in good faith anticipation of a February 24 discharge. The note discusses the fact that, on February 20, G.J. had dislocated his hip and been transferred back to an acute care hospital to relocate his hip. When G.J. returned to HealthSouth on February 21, a hip brace was ordered, which was used at HealthSouth to enable him to get out of the bed. Id. at 6. Thus, the doctor's February 20th note referred to the anticipated discharge in the past tense ("was tentatively anticipated"), since that anticipated event had been eclipsed by the dislocation which required further hospitalization. Moreover, we note that (as discussed above) the claimed date of service was March 12, and Kast records describe post-discharge events that purport to document a post-discharge switch-out. This record fabrication shows that Respondents fully understood at the time that G.J.'s device could not be billed under the two-day rule.

Respondents' Summary indicates that they are relying on the two-day rule in an additional four cases, but this reliance is misplaced, for the following reasons:

- In three of these cases Respondents do not dispute the HealthSouth records showing that they delivered devices to each of these beneficiaries more than two days prior to discharge. Rather, they rely on Kast records which reflect the delivery of a second "custom" or "new" device within two days of discharge. R. Summary at 6 (E.P.), 10 (M.P) and 14 (M.F.). Above we upheld the ALJ's determination that the Kast records are not credible. Respondents have identified no additional evidence that supports their representations as to the delivery of replacement devices two days prior to discharge.

- Respondents argue that G.B. falls within the two-day rule because they measured her for an AFO on May 8, 2001 while she was in an acute care hospital but delivered the AFO on May 10 after she transferred to HealthSouth on May 9. They conclude: "[G]iven that discharge was on 5/9/01, this claim was arguably proper under the [two-day rule]." R. Summary at 9-10. Respondents are wrong. This discharge does not meet Condition 9 of the rule, which provides that a beneficiary must be discharged to a "qualified place of service, i.e., home, custodial facility, etc., but not to another facility . . . that does not qualify as the beneficiary's home." I.G. Ex. 77, at 1.

Therefore, we conclude the ALJ did not err in determining that none of these claims were legitimate under the two-day rule.

4. The ALJ's analysis of the 54 claims was not constitutionally defective.

Respondents assert that the ALJ "analyzed only a fraction of the claims at issue and subsequently and impermissibly 'inferred' that all 54 must likewise be 'false.'" R. Br. at 18. Respondents argue that this constituted impermissible "extrapolation" based on an "[in]valid statistical sample" (OA Tr. at 32) and that, "[a]t a minimum, due process requires individualized determinations as to each of the allegedly false claims (R. Br. at 18)." Respondents also complain that the ALJ treated the I.G. Summary as evidence. R. Reply at 7-8.

Respondents mischaracterize the ALJ's analysis and then draw unwarranted conclusions. The ALJ specifically stated that he "[made] all my fact findings from the [I.G.'s] exhibits" and referred to the I.G. Summary only for the "purposes of brevity." ALJ Decision at 3, n.2. The ALJ repeatedly referred to "each" claim, indicating that he considered them individually. See, e.g., ALJ Decision at 4, 5, 6. The ALJ was not required to individually discuss all of the claims in his decision once he reached the overarching and well-supported findings that the Kast records were fabricated and that the other evidence on which Respondents relied to support their allegations was not credible. The ALJ discussed a few claims, specifically indicating he considered each an "example" that he was using to illustrate the basis for his conclusion that the Kast records were fabricated, but this does not mean that he engaged in sampling or improperly extrapolated results of an analysis of a few claims to the 54 claims at issue.

Our review of the individual claims indicates that one of the ALJ's broad statements is not entirely accurate, but that inaccuracy is not material. Specifically, the ALJ stated that "[e]ach of these [54] claims is factually incorrect in that it claims a date for supply of an orthotic device that is later than the date when Respondents actually supplied the device." ALJ Decision at 4. The claims records show (and the I.G. Summary correctly reflected), however, that the claimed dates of service for devices supplied to G.B., L.C., and M.T. did not postdate the delivery dates shown in the HealthSouth records. I.G. Summary, at 10 and exhibits cited therein. These claims were nonetheless false since each falsely represented that Part B reimbursement was due when it was not. We note that each claim uses a "POS" [Place of Service] code of "12." See, I.G. Exs. 24B, at 12, 25

(G.B); 25B, at 4, 5 (L.C.); 28B, at 7, 8 (M.T.). Mr. Frounfelter stated pursuant to the investigative subpoena that he was unsure what POS code "12" meant (I.G. Ex. 42, at 219-220). Since, however, Respondents used code "12" for the other claims at issue (see, e.g., I.G. Exs. 1C, at 4; 2D, at 3, 4; 3D, at 3, 4; 4D, at 5, 6) and CMS paid some of these claims, we infer that by using the code "12" Respondents were representing to CMS that the place of delivery was not a hospital, when it fact it was.

Given how well-supported the ALJ findings are as a whole, we conclude that the ALJ assessed the evidence in the record in all material respects. The ALJ's process did not violate Respondents' due process rights.

B. The ALJ's determination that Respondents knew the claims were false is supported by substantial evidence in the record as a whole and free of legal error.

1. Substantial evidence in the record as a whole supports the ALJ's finding that Respondents knowingly presented or caused to be presented claims for items they knew or should have known were not provided as claimed or presented claims they knew or should have known were false or fraudulent.

Respondents argue that their claims were not false because the claims were "made with a good faith belief as to their propriety and reimbursability, therefore negating intent and showing that Mr. Frounfelter did not act 'knowingly' in this case." R. Br. at 26.

Section 1003.102(e) of 42 C.F.R. defines "knowingly" as follows:

> For purposes of this section, the term knowingly is defined consistent with the definition set forth in the Civil False Claims Act (31 U.S.C. 3729(b)), that is, a person, with respect to information, has actual knowledge of information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information, and that no proof of specific intent to defraud is required.

Respondents assert that Mr. Frounfelter relied on advice of the HealthSouth Largo hospital management. R. Br. at 26. At the hearing, counsel for the I.G. agreed that Mr. Frounfelter was told that the hospital would not compensate Kast for the

orthotics delivered to inpatients and that Kast could bill Medicare Part B for these orthotics under a "final fit" policy. Tr. at 95. The Largo hospital controller testified that, under the final fit policy, "the date of service that the orthotic . . . item was supplied to the beneficiary for purposes of billing Medicare Part B was the date that the 'final adjustment' was made to the . . . device." I.G. Ex. 49A, at 4. This description is consistent with Mr. Frounfelter's description of the final fit policy to Agent Jurs in May and November of 2004 and pursuant to the investigative subpoena. I.G. Exs 42A, at 2; 42B, at 2; 42D, at 162-163. Mr. Frounfelter understood that any "final fit" was not to occur prior to the beneficiary's discharge from the Largo hospital. I.G. Exs. 42A, at 2; 42B, at 3. Mr. Frounfelter stated that his practice was to use a "post-discharge follow-up visit" as the date of delivery (i.e., date of service on the Medicare claim form). I.G. Ex. 42D at 162.

The ALJ throughly discussed the reasons and supporting evidence as to why he found that Respondents "had no basis for relying on [HealthSouth's] advice and, indeed, had every reason to disregard it") and why he did not believe Mr. Frounfelter had billed Medicare in good faith reliance on the HealthSouth advice. ALJ Decision at 10-11 and n.5. Specifically, the ALJ found (and we agree):

- "[N]either HealthSouth nor the Largo hospital represented Respondents' interests"; the parties had an "arms-length business relationship"; and HealthSouth's advice to Respondents was "so transparently self-serving that Respondents should have recognized its obvious lack of credibility." Id. at 11.

- "When Mr. Frounfelter completed an application for Kast to become an approved Medicare supplier on December 2, 1997, he acknowledged that he was familiar with and agreed to abide by the Medicare laws and regulations that applied to him and his business." Id. at 10, citing I.G. Ex. 69. As "independent Medicare suppliers," Respondents are "responsible for complying with Medicare reimbursement requirements and laws governing the honesty of claims" and "for acting lawfully" and "may not hide behind the advice of other providers or suppliers to excuse them from discharging that responsibility." ALJ Decision at 10-11.

- "Respondents received manuals from Medicare that specified their obligations concerning the claims they submitted" (ALJ Decision at 11, citing I.G. Ex. 42D, at

115-116); Mr. Frounfelter stated under the investigative subpoena that he had not read these manuals (id., citing I.G. Ex. 42D, at 115-116); and "[f]ailure by a supplier to read informational and advisory material supplied to him or her by Medicare is no excuse for failure to comply with the program's claims requirements" (id. at n.6).

- "Any arguments Respondents now make about not understanding their obligations or being misled to make good faith errors are belied by admissions they made previously." ALJ Decision at 11, citing Mr. Frounfelter's admissions to the I.G. investigator in May 20, 2004 at I.G. Ex. 42A, at 1. In that interview Mr. Frounfelter "stated that he knew that the manner in which billing was being performed was wrong and illegal but that he did so because all the patients were going to HealthSouth and because billing in this manner was necessary in order to feed his family." ALJ Decision at 11. Mr. Frounfelter's subsequent recanting of these statements is not credible. Id. at 12.

- The "intentional quality of Respondents' actions is underscored by their falsification of patients' records in order to support their false and fraudulent claims." Id. at 16.

On appeal, Respondents make no persuasive response to the ALJ's findings. See R. Br. at 27-28. Respondents argue that it was "reasonable" for Respondents to "rely upon the interpretation of a more sophisticated healthcare entity" because "there was almost daily uncertainty regarding the 48-hour rule." Id. at 27. In support of this assertion, they cite I.G. Exhibit 70, which is an excerpt from a November 1997 orthotics and prosthetics (O&P) trade publication, the O&P Almanac. The excerpt addresses O&P inpatient services and states that "billing Medicare Part B for [O&P] inpatient services is illegal and considered to be fraudulent activity by Medicare." I.G. Ex. 70, at 1 (emphasis added). It then goes on to address a hypothetical question: whether an O&P supplier may bill Part B if it delivers a functional prosthesis to an inpatient and then "provide[s] the cover and finishing after the patient is discharged." The answer is that "[a]lthough the prosthesis was not covered when the patient left the hospital, it was delivered as a fully functioning device while the patient was in the hospital. The date of service in this case should be the day the prosthesis was delivered in the hospital and must not be billed to Medicare part B." I.G. Ex. 70, at 1-2 (emphasis added). Thus, contrary to

what Respondents argue, this exhibit actually demonstrates that O&P suppliers had, in addition to the Medicare Manuals and other CMS guidance, ready access to information that showed that the final fit policy espoused by HealthSouth was fraudulent. See also I.G. Exs. 71-78.

Respondents now argue that their due process rights were violated because the ALJ refused to issue hearing subpoenas for other orthotists or employees of HealthSouth. OA Tr. at 11-13. Counsel assert that this denial prejudiced Respondents' ability to prove their government knowledge defense or show that the claims were filed in good faith because the final fit policy was allegedly "vetted at the highest levels of HealthSouth." Id. at 15; see also at 12-14. These arguments are baseless. As discussed below, Respondents' government knowledge defense was based on the complaints about HealthSouth's policy of not issuing purchase orders that were made by orthotists Mark Logue and Dale Peterson, both of whom testified at the hearing. Respondents presented no evidence that Respondents knew about or relied on these complaints or that they were aware of complaints made by any other of the orthotists they sought to subpoena. Similarly, the only HealthSouth employee with whom Mr. Frounfelter told the investigators he discussed the "final fit" policy was Judy Johnson, who also testified at the hearing. See I.G. Exs. 42A, at 1; 42B, at 2. Respondents do not allege (and submitted no evidence) that Mr. Frounfelter or a Kast employee discussed the alleged "final fit" policy with any of the other HealthSouth employees they sought to subpoena. In sum, Respondents did not show that the subpoenas were "reasonably necessary for the presentation" of their case, as required by 42 C.F.R. § 1005.9, nor did they show that they were prejudiced by the ALJ's denial of the subpoenas.

The ALJ's finding that Respondents did not rely in good faith on HealthSouth's advice is supported by overwhelming evidence in the record.

2. The ALJ correctly concluded that the "government knowledge defense" does not apply in this case.

Respondents rely on cases decided under the False Claims Act (FCA) that address the FCA mens rea requirement, i.e., the requirement that the claimant knew the claim to be false. The cases recognize that a claimant may be able to prove lack of mens rea by showing that, at the time of the claim, "the claimant knows that the government is aware of the falsity of the information submitted." U.S. v. Southland Mgmt. Corp., 288 F.3d 665, at 685 (5th Cir. 2002), rev'd on other grounds, 326 F.3d 669

(5th Cir. 2003). These cases look to whether the claimant and government's course of performance gave the claimant reason to believe that the claim was not false.

Respondents characterize this as the "government knowledge defense."[10] R. Br. at 11. Respondents argue this defense applies here because: (1) one orthotist (Peterson) complained to an I.G. investigator and another orthotist (Logue) complained to the CMS Durable Medical Equipment Regional Carrier (DMERC - a processor of Medicare Part B O&P claims) as early as 1990 about HealthSouth's refusal to issue purchase orders and pay orthotists, but (2) the government did not act against HealthSouth until it intervened in a qui tam action filed in 2003. Id. at 11-14, citing Tr. 204-207 and 258-260. Respondents never assert that Mr. Frounfelter was aware of the orthotists' complaints but argue that CMS's "pre-existing knowledge and apparent long-standing acquiescence in and tacit approval of the [Largo hospital] practice and continuing to reimburse the claims must serve as a bar to liability in this case." Id. at 15.

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[10] Amendments to the FCA in 1986 changed the role of "government knowledge" in FCA actions. Prior to that time, courts did not have jurisdiction over an action brought by a private party if it was based on "evidence or information in the possession of the United States or any agency, officer, or employee thereof, at the time such suit was brought." 31 U.S.C. § 232(c)(1976). See discussion of prior version of FCA and development of subsequent case law dealing with situations in which "the government's knowledge of or cooperation with a contractor's actions is so extensive that the contractor could not as matter of law possess the requisite state of mind to be liable under the FCA" in Grynberg v. Praxair, Inc., 207 F. Supp. 2d 1163, 1177-1178 (D. Colo. 2001), rev'd in part on other grounds, U.S. ex rel. Grynberg v. Praxair, Inc., 389 F.3d 1038 (10th Cir. 2004); and Southland, 228 F.3d at 685-686.

Respondents cited the second Southland decision (326 F.3d) in their prehearing brief but the first Southland decision (228 F.3d) in their post-hearing brief. On appeal, they cite only the first opinion (R. Br. at 8), which is the opinion that addresses the government knowledge defense. The ALJ discussed the second Southland opinion, which addresses the issue of falsity under the FCA. ALJ Decision at 12-14. He correctly determined that the opinion is not relevant since the court ruled that the claim was not false under the terms of the contract, i.e., "the Owners were entitled to the housing assistance payments sought and, thus they made no false claims." Southland, 326 F.3d at 675.

This argument is totally without merit. The government's "knowledge" resulting from the two orthotists' complaints is completely different from the knowledge discussed in the cases cited by Respondents. In those cases, information was provided by the claimant to the government and by the government to the claimant in the course of the parties' dealing that led to a claim.[11] It was the claimants' awareness of the government's treatment of this information that led the claimants to (allegedly) believe their claims were not false. Even if we assume that this defense would apply where the knowledge was not a product of the parties' course of performance, Respondents do not represent that they even knew about the orthotists' complaints when they presented the claims at issue, much less that they relied on the government's inaction. Thus, we affirm the ALJ's conclusion that the government knowledge defense does not apply here.

Respondents now assert that the ALJ's discovery order prevented them from discovering whether the government's alleged nonresponse to orthotists' complaints meant that CMS personnel decided that HealthSouth's practices, and, by implication, Mr. Frounfelter's practices were "reasonable." OA Tr. at 23-24.

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[11] See U.S. ex rel. Durcholz v. FKW Inc., 189 F.3d 542, 545 (7th Cir. 1999) (in which the court "declin[ed] to hold [the claimant] liable for defrauding the government by following the government's explicit instructions" to the claimant on how to structure bidding); Southland, 288 F.3d at 685-690 (in which the U.S. Department of Housing and Urban Development was aware that claimants were falsely certifying that their apartments were decent, safe, and sanitary and communicated repeatedly with claimants about those problems while paying their claims); Grynberg v. Praxair, Inc., 207 F. Supp. at 1178 (in which the methodology used by claimants to calculate gas royalties "was known to and approved by the responsible government authorities" and "openly disclosed to the government [by the claimants] and repeatedly accepted"); Shaw v. AAA Engineering & Drafting, Inc., 213 F.3d 519, 534 (10th Cir. 2000) (recognizing that "there may still be occasions when the government's knowledge of or cooperation with a contractor's actions is so extensive that the contractor could not as a matter of law posses the requisite state of mind to be liable under the FCA."); U.S. ex rel. Stone v. Rockwell Int'l Corp., 92 Fed. Appx. 708, 732 (10th Cir. 2004) (holding that it was proper to allow the jury to consider information that the claimant asserted he communicated to lower and mid-level employees about environmental, health, and safety violations at the contract site at issue).

This argument is both untimely (42 C.F.R. § 1005.21(e)) and baseless. CMS's and the DMERC's successive issuances instructing orthotists about the narrow circumstances (i.e., the two-day rule) under which they could bill Part B for devices delivered to inpatients show that CMS regarded such practices as fraudulent and acted repeatedly to educate the orthotic community about these coverage limitations. See I.G. Exs. 74-84.

C. The ALJ's conclusion that the remedies imposed by the I.G. were reasonable is supported by substantial evidence in the whole record and free of legal error.

The I.G. imposed a CMP of $100,000. The maximum amount the I.G. could have imposed was $540,000 (54 false claims x $10,000). The I.G. imposed an assessment of $42,200. The maximum amount the I.G. could have imposed was $61,882.02 (3 x $20,627.34). The I.G. excluded Respondents for seven years. There is no minimum or maximum length of an exclusion pursuant to section 1128A(a). 42 C.F.R. § 1001.901.

1. The $42,200 assessment levied on Respondents does not constitute impermissible double recovery.

HealthSouth was sued for its O&P billing practices in a qui tam action in which the Department of Justice intervened. I.G. Post-hearing Br., Att. 2. It was settled on behalf of 99 HealthSouth rehabilitation hospitals when HealthSouth agreed, among other things, to pay the government four million dollars. Id. Respondents assert that the ALJ "erroneously concluded that HealthSouth's omnibus o&p settlement agreement totaling **$4 million** does not cover the **$20,627.34** in o&p services at issue in this case." R. Br. at 3 (emphasis in original), citing ALJ Decision at 18-19. Respondents assert before us, as they did before the ALJ, that to collect an assessment from them amounts to a "double recovery" and a windfall to the Medicare program. Respondents also assert that the ALJ's "suggestion that the *assessment* should factor in the 'costs of investigating the fraud and bringing Respondents to justice' is totally without legal justification (as the assessment must be based on *loss*), and, in any event, there is ***no record evidence whatsoever*** pertaining to the OIG's costs in this matter." R. Br. at 7 (emphases in original).

These assertions lack merit. As the ALJ noted, Congress provided for an "assessment" of "not more than 3 times" the amount **claimed** for each item and service, specifying that the assessment was **in**

lieu of actual damages sustained.[12] ALJ Decision at 14, citing section 1128A(a) of the Act. The implementing regulations are at 42 C.F.R. Part 1003. Section 1003.104 basically repeats the statutory provisions on assessments, as applicable to specific time periods. Section 1003.106(b) sets out guidelines for taking into account the statutory factors in section 1128A(d) of the Act and 42 C.F.R. § 1003.106(a)(1) for determining the amount of a penalty or assessment.

Section 1003.106(f) provides:

> The amount imposed will not be less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution and administrative review of the case.

The preamble to the final rule explains this provision, as follows:

> *Comment:* Two commenters objected that the proposed regulation permitted the Secretary to make assessments which exceed any damage the government may have suffered. They suggested that the final regulation should provide that the amount of the assessment be limited to twice the amount falsely claimed, as provided in the False Claims Act, 31 U.S.C 3729.
>
> Response: The proposed regulation follows the statute, and no change is required. Under the False Claims Act . . . , the United States is entitled to recover, in addition to a forfeiture of $2,000 per false claim, "2 times the amount of damages the government sustains . . . ." and the costs of the civil action. Section 1128A(a), on the other hand, subjects the person filing a false or improper claim to "an assessment of not more than twice the amount claimed for each such item or service in lieu of damages . . . ." The amount of actual damages sustained as a result of fraud has often been difficult to prove. In enacting the latter

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[12] Although Congress originally provided for an assessment of twice the claimed amount, Congress raised this to three times the amount, with respect to an item or service wrongfully claimed on or after January 1, 1997. Pub. L. No. 104-191, § 231(c).

> provision, Congress clearly intended to obviate the need for the government to prove the amount of damages in order to make an assessment. Because the costs of investigating the false claim and of pursuing administrative sanctions are not separately recoverable, it is reasonable for Congress to have concluded that twice the amount claimed for such items or services would fully compensate the government for all losses incurred as a result of the claim.
>
> However, . . . the Secretary exercises discretion in fixing the amount of the assessment, taking into account the factors listed in section 1128A(c). Hence, in instances where the actual damages to the government may be readily calculated, perhaps as a result of evidence supplied by respondents in mitigation of a proposed penalty, the amount of actual damages suffered by the government will be a factor that justice requires be taken into account in arriving at a proper assessment.

48 Fed. Reg. 38,827, 38,830 (Aug. 26, 1983).

This regulatory approach was upheld in Chapman v. U.S., 821 F.2d 523 (10th Cir. 1987). Chapman involved a CMP and assessment for cost reports filed by nursing homes owned by Chapman containing "nineteen false line item cost entries for items and services purportedly [but not] provided by the nursing homes" totaling $118,136. As a result, Kansas made Medicaid overpayments of $21,115. Chapman was criminally convicted, fined, and repaid the State $21,115. The I.G. proposed a $2,000 penalty for each of the 19 false Medicaid claims and an assessment of $118,136. Chapman relied on the FCA in arguing that his assessment should be based on what he received ($21,115), not what he claimed ($118,136). The court wrote:

> Though the legislative history does not explain Congress's intentions regarding this aspect of the CMPL, it can be fairly reasoned that the difference in phrasing between the False Claims Act and the CMPL is indicative of congressional purpose. By authorizing assessments of twice "the amount claimed" rather than twice "the amount of damages," Congress seems to have deliberately shifted the focus away from the actual loss sustained and onto the amount claimed as a basis for assessments.

Chapman, supra, at 528. The court found reasonable the Secretary's interpretation reflected in the preamble to the CMPL

rule, noting that the amount claimed should be the basis for setting the upper limit of the assessment. Id. at 527, citing 48 Fed. Reg. 38,830.

Addressing Chapman's reliance on the fact that Kansas had recouped the $21,115, the court wrote:

> In this case, the ALJ [concluded] that the $21,115 setoff did not make up for expenses "such as the cost of investigation by the federal agency, the cost of pursuing administrative sanctions, and the cost of providing the hearing . . . ." As the ALJ explained, "The Government was not required to account for these costs in defending the assessments, but it is not unreasonable to assume that they exceeded $118,136." This interpretation and application of the statute seems to be what Congress had in mind when it passed the CMPL.

Id. at 528.

Here, Respondents misrepresent the ALJ's analysis, focusing only on his discussion of the HealthSouth settlement agreement. The ALJ concluded first, however, that assessment of the amount proposed was justified "even if the HealthSouth settlement made Medicare financially whole for all of the payments" to Respondents, because the damages to the program included substantial costs for investigation and litigation, as well as the "inchoate cost to the reputation of the program," not only the costs of the payments made to Respondents. ALJ Decision at 18-19.

We agree with the ALJ that, even assuming that the federal government recovered the amount of the false claims from HealthSouth, there is no double recovery here.[13] As in Chapman, it is reasonable to infer from the record that the damages suffered by the government go well beyond the amount of the payments to Respondents for the false claims and include

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[13] Respondents' reliance on Thomas M. Horras, DAB No. 2015 (2006), aff'd Horras v. Leavitt, 495 F.3d 894 (8th Cir. 2007) is misplaced. OA Tr. at 29. Horras addressed, among other things, joint and several liability for an assessment under 42 C.F.R. § 1003.102(d)(1). That section governs liability for assessments imposed on more than one person "in any case" under 42 C.F.R. Part 1003 and the CMPL. It does not address apportionment of CMPL assessments in relation to FCA penalties imposed on third parties.

"inchoate cost to the reputation of the Medicare program caused by Respondents' perpetration of their fraud." ALJ Decision at 18; see Mayers v. U.S. Dep't of Health and Human Servs., 806 F.2d 995, 999 (11th Cir. 1986) (discussing the "immense toll" on Medicare and Medicaid caused by fraudulent claims and the costs of investigating and prosecuting fraud).

The ALJ also went on to discuss the HealthSouth settlement agreement, finding nothing in that agreement from which one could reasonably conclude that the settlement actually made the government whole for all of the false claims activity generated by or related to HealthSouth's operations. This finding, while undercutting Respondents' assertion that the government had already recovered the full $20,627.34 from HealthSouth, was not necessary to the ALJ's decision, however.

Respondents point out that, only in response to their appeal to the Board did the I.G. submit evidence about the actual costs of investigating Respondents and bringing this administrative action against them. Respondents argue that the I.G.'s evidence is untimely and that, at the very least, the Board should remand to the ALJ to consider it. Respondents argue, moreover, that the evidence is unreliable because it appears to include time spent investigating HealthSouth.

We neither rely on the I.G.'s additional exhibits for our decision nor find it necessary to remand this case to the ALJ to consider those exhibits. As the analysis above indicates, a showing that the actual damages were in fact less than the amount assessed is not conclusive but is merely a factor to be considered where the actual damages to the government may be readily calculated. The example given in the preamble response is where the respondents submit evidence of actual damages in mitigation of a proposed penalty. Here, Respondents have provided no evidence that remotely suggests that the actual costs of investigating and bringing this administrative action are less than the $42,000 assessed.[14] See 42 C.F.R. § 1005.15(b)(1). The ALJ, on the other hand, reasonably inferred that the investigation and litigation costs were substantial enough to justify the assessment proposed from what the record shows about

[14] Indeed, while Respondents sought to discover information on which the I.G. relied in "calculating the amount of the proposed civil money penalty" and "the length of the exclusion," they did not ask for information related to the I.G.'s calculation of the assessment. Respondents' Request for Production of Documents at 2.

the length of the investigation, the pre-hearing proceedings, the length of the hearing, and the location of the hearing and witnesses. ALJ Decision at 18, n.9.[15]

2. The ALJ's determinations as to mitigating factors are supported by substantial evidence in the record as whole and free from legal error.

Respondents argue that, because the ALJ "ignored the strong presence of mitigating factors," he erred in concluding that the CMP, assessment, and exclusion imposed on them were reasonable. R. Br. at 28. Respondents bear the burden of proving mitigating factors. 42 C.F.R. § 1005.15(b)(1). Below we discuss the ALJ's treatment of the factors proposed by Respondents as mitigating.

Respondents assert that "the degree of influence and control that HealthSouth exercised over the manner in which the disputed claims were submitted to the Medicare program . . . negat[ed] the requisite mens rea . . . ." R. Br. at 29. The ALJ rejected this assertion, citing the "overwhelming" evidence in the case that Respondents "eagerly did business with HealthSouth and knowingly entered into a corrupt bargain with that entity that had as its centerpiece filing false and fraudulent claims with Medicare." ALJ Decision at 16. As discussed above, these findings are amply supported by the record.

Respondents make a number of assertions alleging that their conduct resulted in minimal detriment to Medicare and minimal benefit to themselves. They cite "the minimal loss, if any, (i.e., the alleged $20,000 over approximately 4 years) that resulted to the Medicare program" (R. Br. at 28); "the minimal profits realized by Respondents through their relationship with HealthSouth" (id. at 31); and the absence of claims that were "upcoded," "double billed" or billed for "non-rendered services" (id. at 33). For the following reasons, we conclude that the ALJ properly refused to treat these alleged facts as mitigating factors.

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[15] As Respondents point out, the ALJ mistakenly suggests that the I.G. flew a witness to the hearing from Hawaii. R. Br. at 7, n.2. Instead, the record indicates that the witness came from Oregon. I.G. Ex. 60, at 1; I.G. Response at 9, n.1. This error is harmless, however, since the ALJ could still reasonably infer that the costs of effectuating the CMP/assessment exceeded the $42,200 assessed, in the absence of any evidence that the costs were in fact less.

- Respondents point to no authority for their assertion that over $20,000 in false claims to Medicare should be regarded as "minimal." Exclusion regulations such as 42 C.F.R. § 1001.102(b)(1) treat "acts . . . that caused, or were intended to cause, a financial loss . . . of $5,000 or more" as an aggravating factor, showing that the Secretary does not regard claims of $20,000 to be "minimal."

- The evidence indicates that HealthSouth would have paid Kast only 70% of what Kast received by billing Medicare Part B directly. See I.G. Ex. 42B, at 4 (the HealthSouth payment rate for prefabricated orthotics was 70% of Medicare allowable reimbursement). Therefore, Respondents' arrangement with HealthSouth appears to have significantly increased the amount per device that they were reimbursed.

- Finally, contrary to Respondents' assertion (R. Br. at 31), evidence supports the ALJ's characterization of Respondents' relationship with HealthSouth as "highly lucrative" (ALJ Decision at 17). Agent Jurs testified that, based on his investigation, Kast was "the sole inpatient O/P provider at HealthSouth from [19]94 to 2004." Tr. at 96. Mark Logue (the orthotist who complained to the regional DMERC about the Largo hospital) testified that, because of business generated by amputees' initial and continuing needs, an exclusive provider relationship with a rehabilitation hospital such as HealthSouth for three or four years "would ensure that an O&P supplier business would generate" millions in annual revenue for a number of years. I.G. Ex. 53A, at ¶ 10.

Thus, the ALJ properly rejected Respondents' arguments related to the alleged minimal detriment to Medicare and minimal benefit to themselves.

Respondents posit as mitigating factors the "superior quality of [their] services" (R. Br. at 30) and the "loss to the community that would result from [their] exclusion . . . " (id. at 32). While the ALJ accepted their assertion as to the quality of their services, he declined to treat either assertion as a mitigating factor, finding that there was no reason to believe that "excluding [Respondents] from participation will have an adverse impact on Medicare beneficiaries or on the program itself" since there was no evidence "to suggest that other [orthotists] in Respondents' community are incapable of filling any gaps created

by the remedies that I impose." ALJ Decision at 17. On appeal, Respondents cite no such evidence.

Respondents assert that the exclusion penalty is "disproportionate" to the remedies imposed on the "eminently culpable HealthSouth, which was allowed to pay [four million dollars] and continue doing business with Medicare." R. Br. at 31. The ALJ properly rejected this argument, concluding that while HealthSouth's unlawful activity may have been much greater than Respondents', their "fraud is not diminished in any respect by what HealthSouth may or may not have done." ALJ Decision at 15. He concluded that Respondents' conduct demonstrated they were untrustworthy and their exclusion serves the purpose of any exclusion – "to protect [federal health care programs] and their beneficiaries and recipients from individuals and entities who have been established to be untrustworthy." Id. at 19-20.

Respondents assert that Mr. Frounfelter "cooperated and voluntarily consented to multiple interviews by [I.G.] personnel, where he fully informed them of the nature of his relationship with HealthSouth." R. Br. at 32. The ALJ reasonably declined to treat Mr. Frounfelter's interactions with the I.G. personnel as a mitigating factor. ALJ Decision at 17. Mr. Frounfelter "cooperated" only after he was contacted by an I.G. investigator about his illegal arrangement with HealthSouth. Moreover, after initially acknowledging the illegality of the arrangement, he subsequently changed his story. I.G. Exs. 42A, at 1; 42B at 2.

Respondents assert that they "have not been the subject of any other allegations of fraud or submitting false claims or any other sanction by the Medicare program. Counsel for [I.G.] stipulated to that fact." R. Br. at 32, citing Tr. at 110. The ALJ rejected this assertion, stating that Respondents "provided no proof to support this assertion and that there is evidence to the contrary in the record." ALJ Decision at 17, citing Tr. at 70-71. This is correct. I.G. counsel did not stipulate to Respondents' assertion (see Tr. at 110), and Agent Jurs testified that Respondents filed additional false claims after Agent Jurs informed Mr. Frounfelter of the illegality of the arrangement in May 2004 (Tr. at 70-71). Moreover, Mr. Frounfelter stated that he had billed Medicare Part B for orthotics supplied to inpatients at the new HealthSouth Brooksville hospital. I.G. Exs. 42A, at 2-3; 42B, at 5; see also I.G. Ex. 54B, at 2 (statement by former Kast employee that "Kast received many referrals" from the HealthSouth Brooksville area facility).

Therefore, we conclude that the ALJ properly evaluated Respondents' allegations of mitigating factors.

3. The ALJ's determinations as to the presence of aggravating factors are supported by substantial evidence in the record as whole and free from legal error.

Respondents argue that the ALJ erred by finding that there was a pattern of fraudulent claims over a lengthy period of time and that the amount of false claims was substantial. R. Br. at 33. Respondents argue that the findings "stem from [the ALJ's] unconstitutionally inadequate analysis of only a fraction of the claims at issue . . . and are clearly not supported by evidence in the record." Id. at 33-34. We reject these arguments. As we discussed above, the ALJ's analysis of the claims was sound and is supported by substantial evidence in the record as a whole.

D. ALJ did not err in rejecting Respondents' "other grounds for appeal."

1. Respondents' arguments about discovery have no merit.

Section 1005.7(a) of 42 C.F.R. provides for discovery of documents in CMPL proceedings. Section 1005.7(e)(2) allows the ALJ to restrict discovery if he finds the discovery sought "is irrelevant," "is unduly costly or burdensome," "will unduly delay the proceedings," or "seeks privileged information." Section 1005.7(e)(4) provides that the "burden of showing that discovery should be allowed is on the party seeking discovery."

Respondents make several arguments related to discovery in their briefs. At the oral argument, counsel made additional arguments, some of which had not been made before the ALJ. In this section, we discuss the general arguments made in the briefs; in other sections addressing specific defenses (such as government knowledge, misconduct), we discuss allegations made in oral argument as to these defenses. We conclude that none of Respondents' discovery arguments have merit; rather, they seek to obfuscate the overwhelming evidence showing that Respondents knowingly filed false claims.

First, Respondents argue that "the discovery allowed pursuant to 42 C.F.R. § 1005.7(e)(2) . . . is constitutionally inadequate on its face in that it impermissibly and unconstitutionally restricts the scope of allowable discovery." R. Br. at 34 (emphasis added). Respondents argue that, because of the seriousness of the matters at issue, they are constitutionally entitled to "'full due process rights' that should – at the absolute minimum – include the same level of discovery as

permitted in a criminal case regarding exculpatory information . . .", i.e., "Brady" and "Giglio" materials.[16] R. Br. at 35-36.

As the ALJ pointed out, he is bound by the Secretary's regulations and had no authority to declare the regulations unconstitutional. ALJ Rulings Denying Motion to Dismiss, at 2; see also 42 C.F.R. § 1005.4(c)(1).

Moreover, while the sanctions imposed in this case may result in "serious adverse consequences" as Respondents allege (R. Br. at 36), administrative tribunals routinely adjudicate matters that have serious adverse consequences. Respondents cite no authority for the proposition that due process requires administrative tribunals to afford litigants discovery rights equivalent to those in criminal proceedings.[17] Instead, courts have held that Brady is limited to criminal, not civil matters. See, e.g.,U.S. ex rel. (Redacted) v. (Redacted), 209 F.R.D. 475 (D. Utah 2001) (rejecting application of Brady in FCA action); Tandon v. Commissioner, 2000 WL 331926 (6th Cir. Mar. 23, 2000) (rejecting application of Brady to a civil tax case involving allegations of fraud); NLRB v. Nueva Engineering, Inc., 761 F.2d 961 (4th Cir. 1985) (rejecting application of Brady to a National Labor Relations Board proceeding); Mister Discount Stockbrokers, Inc.

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[16] Respondents describe Brady materials as "exculpatory or impeaching information that is material to the guilt or punishment of a Defendant" and Giglio materials as "material tending to impeach the character or testimony of the government's witness in a criminal trial." R. Br. at 37, n.6.

[17] We note that the I.G. did voluntarily provide Respondents Giglio-type information. Respondents sought to discover the "personnel files" of investigating agents. Respondents' Request for Production of Documents, at ¶ 1.f. In support of its motion for a protective order, the I.G. attached a declaration from "an attorney whose duties include reviewing personnel files for impeaching information." I.G.'s Brief in Support of Motion for Protective Order at 7. That attorney stated that she conducted "Giglio" reviews of the agents' personnel files for the "purpose of identifying findings or credible allegations of misconduct that go to bias or candor, and past or present criminal charges that go to bias or candor" but found no such findings, allegations, or charges. Decl. of Amitava Mazumdar. The ALJ granted the I.G.'s motion for a protective order as to these personnel files. Rulings on Parties' Motions for Protective Orders at 3.

v. SEC, 768 F.2d 875 (7th Cir. 1985) (rejecting application of Brady to a securities administrative disciplinary proceeding).

Second, Respondents cite to the preamble of the *Federal Register* notice adopting 42 C.F.R. Part 1005 in which the Secretary wrote that sanctioned providers have "full due process rights." R. Br. at 35, citing 67 Fed. Reg. 11,928 (March 18, 2002). Plainly, the Secretary was referring to the review procedures that he was adopting in that notice as constituting "full due process rights." These procedures include discovery, in-person hearings before an ALJ with opportunity for cross-examination, appellate review by the Board, and judicial review by a federal court of appeals.

Third, Respondents allege that their due process rights were violated by the ALJ's application of section 1005.7. R. Br. at 34. Pursuant to Respondents' discovery request, the I.G. produced or made available (among other documents), the non-privileged documents on which it relied in determining that Respondents violated section 1128A and in determining the amount of the CMP and other non-privileged documents from its investigation of the HealthSouth Largo hospital. I.G. Response to Respondents' Request for Production of Documents and I.G.'s Motion for Protective Order. These included the complete HealthSouth records of the beneficiaries at issue, I.G. investigator interviews (with HealthSouth personnel, former Kast employees, other orthotists who had dealings with the Largo hospital, and beneficiaries and their relatives), and a large amount (58 boxes) of other materials related to the investigation of the HealthSouth Largo hospital. Id. Respondents assert that the ALJ erred in denying their discovery request for privileged material and for information related to the I.G.'s HealthSouth investigation for hospitals other than Largo. R. Br. at 35, see also id. at 37. This argument is without merit, for the following reasons:

- As to privileged documents on which the I.G. relied in determining remedies, the ALJ properly concluded that the "I.G.'s thought processes in deciding what he is demanding as remedies in this case are irrelevant to the issue of what is or is not reasonable" since the ALJ would make a de novo ruling on the reasonableness of those remedies. Rulings on Parties Motions for Protective Order, at 2.

- As to the non-Largo hospital investigatory materials, the ALJ ruled that they were also irrelevant. Respondents had sought those documents in support of their selective

> prosecution defense (Respondents' Response in Opposition to Petitioner's Motion for Protective Order at 10), but the ALJ properly concluded he had no authority to adjudicate that defense (Rulings on Parties Motions for Protective Order at 2-3).

The ALJ's conclusions are without error and do not provide grounds for finding that Respondents had a constitutional right that was violated.

2. Respondents' arguments about selective prosecution have no merit.

Respondents assert that, because the I.G. imposed sanctions (including an exclusion) on them, they "are being disciplined differently from both the main culprit (*i.e.*, HealthSouth) and other similarly situated [O&P] suppliers, and there was 'no rational basis for the difference in treatment.'" R. Br. at 50, citing Village of Willowbrook v. Olech, 528 U.S. 562, 564 (2000). They assert that this constitutes selective prosecution and violates their constitutional rights. They argue that the ALJ erred in ruling that he had no authority to review their claim of selective prosecution. Id.

Section 1005.4(c)(7) of 42 C.F.R. provides that "the ALJ does not have the authority to . . . review the exercise of discretion by the [I.G.] to impose a CMP, assessment or exclusion under part 1003 of this chapter." The ALJ, therefore, properly ruled that he did not have the authority to review the I.G.'s exercise of his enforcement discretion in imposing these remedies on Respondents and that the selective prosecution discovery sought by Respondents was not relevant to the issues before him. ALJ Ruling on Parties Motion for Protective Orders, at 2-3. As the ALJ stated, the issue before him was whether "*these Respondents* submitted or caused to be submitted claims unlawfully." Id. at 3 (emphasis in original).[18]

[18] While the ALJ's ruling foreclosed development of the record on this issue, we note that Agent Jurs testified on cross-examination that "several" individuals were "the subject of exclusion proceedings arising out of the HealthSouth investigation" including one orthotist who was also prosecuted criminally (Tr. at 49-50) and that Mr. Nico, a former HealthSouth Largo hospital Administrator, "was indicated and pleaded guilty to a felony in relation to his part in the HealthSouth fraud" (id. at 111).

Respondents also argue that they are being selectively prosecuted for an "improper motive", i.e., because they "refus[ed] to continue 'inappropriately' billing HealthSouth at Agent Jurs' request." R. Br. at 50. Respondents point to no evidence indicating Agent Jurs made such a request. Indeed, Mr. Frounfelter stated pursuant to the investigative subpoena that "he did everything [Agent Jurs] wanted." I.G. Ex. 42D, at 393.

3. Respondents' allegations as to section 1128A(c)(1) of the Act have no merit.

Section 1128A(c)(1) of the Act provides:

> The Secretary may initiate a proceeding to determine whether to impose a civil money penalty, assessment, or exclusion under subsection (a) or (b) only as authorized by the Attorney General pursuant to procedures agreed upon by them.

Respondents argue that this action should have been dismissed because the I.G. failed to comply with section 1128A(c)(1). R. Br. at 34. They argue that the ALJ erred in concluding that "regulations governing my authority to hear and decide this case at 42 C.F.R. Parts 1003 and 1005 confer no authority to look behind the I.G.'s determination and address the question of whether [the I.G. followed section 1128A(c)(1)]." Id. citing Rulings Denying Motion to Dismiss at 2. Respondents argue that issues regarding whether the I.G. met a condition precedent, like questions regarding applicable statutes of limitations, go to the I.G.'s authority to act. OA Tr. at 5-6.

Even assuming Respondents are correct regarding the scope of review, however, that would not make a difference here for the following reasons.

- Under the presumption of legitimacy or regularity, "in the absence of clear evidence to the contrary, courts presume that [Government agents] have properly discharged their official duties." United States v. Armstrong, 517 U.S. 456, 464 (1996).

- Respondents cite no basis whatsoever for their assertion that the I.G. was not authorized by the Attorney General to bring this action.

- Before us, the I.G. cites the affidavit of Agent Jurs filed in a federal court proceeding in which Respondents

made the same argument in an attempt to enjoin the ALJ proceeding. The I.G. represents that, in the affidavit, Agent Jurs explained how the I.G. "obtained the Attorney General's authorization" for this CMPL action. I.G. Response at 35, citing Frounfelter v. Leavitt, 8:08-CV-155-SCB-TBM (Declaration of Christian Jurs and attached Department of Justice declination)(Docket Entry #14, Attachment 1, at ¶ 13)(available on PACER/ECF). While Respondents filed a reply to the I.G.'s response and objected to the I.G.'s reliance on new evidence related to the amount of the assessment, they did not object to the I.G.'s citation to these documents or dispute the I.G.'s characterization of these documents as showing that the I.G. complied with section 1128A(c)(1).

- At the oral argument, counsel complained that Respondents had been denied discovery related to the I.G.'s compliance with section 1128A(c)(1). OA Tr. at 6-7. This is a new argument; it was not made in the briefs before the Board, nor do we see where such discovery was requested before the ALJ. See Respondents' Request for Production of Documents. The Board generally does not consider issues raised for the first time on appeal. 42 C.F.R. § 1005.21(e). Moreover, as discussed above, Respondents have never explained why the documents provided to them by the I.G. in the course of the federal court litigation were inadequate to demonstrate compliance with section 1128A(c)(1).

Respondents' arguments under section 1128A(c)(1) provide no basis for reversing the ALJ Decision.

4. Respondents allegations as to government misconduct have no merit.

Respondents argue that the I.G. committed "multiple instances of unconstitutional government misconduct." R. Br. at 39-40. Below we explain why none of Respondents' assertions establish unconstitutional government misconduct.

a. Alleged delay

Respondents assert that the I.G. "delayed the institution of this exclusion action against Respondents for three years following the investigatory period (*i.e.*, 1999-2004)." R. Br. at 40. Respondents argue that this "delay resulted in actual, substantial prejudice to Respondents, and it was fundamentally unfair, unreasonable, and violative of due process to permit the

action to proceed."[19] Id. Specifically, Respondents point to the death/infirmity of witnesses and the destruction of documents.

The ALJ rejected these arguments on the ground that Respondents did not allege that the I.G. failed to act within the applicable statute of limitations (section 1128A(c)(1) of the Act) or any mutually agreed-upon extensions thereof. ALJ Rulings on Motion to Dismiss at 3-4. Indeed, Respondents do not dispute the I.G.'s representations that, beginning in October 2005, the parties entered into successive "tolling agreements" of section 1128A(c)(1) while they tried to settle the dispute without litigation. I.G. Response at 39. Therefore, Respondents cannot fairly complain that the delay was unreasonable.

As to alleged prejudice resulting from beneficiaries' deaths or infirmity, Respondents list 14 beneficiaries who are now dead. R. Br. at 42. They allege that these people would have corroborated their switch-out defense. Id. This argument is not persuasive. First, many other beneficiaries (whose Kast records documented switch-outs) or their relatives told I.G. investigators that the beneficiary never received a switched-out device. Second, Respondents provided no reliable testimony from Mr. Frounfelter or any of Kasts' other orthotists to support the switch-out theory for the dead beneficiaries. Third, Respondents knew in 2004 that they were being investigated but do not allege that they sought at that time to obtain statements from any of these beneficiaries, who may still have been alive at that time.

Similarly, Respondents' arguments related to the alleged destruction of documents from the I.G.'s investigation of HealthSouth are without merit.[20] Respondents argue that such documents would have shown that the I.G. "was on notice of alleged billing improprieties" as of 1990, that the HealthSouth billing policy was "vetted, approved and promoted by

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[19] Respondents recognize that they have the burden of proof of showing that any delay caused actual prejudice. R. Br. at 41.

[20] Respondents do not cite any evidence that would establish the particular nature of the documents allegedly destroyed, who they believed destroyed them or why. Since the I.G. made available 58 boxes of material from the HealthSouth Largo hospital investigation, it is not clear why Respondents think that the destroyed documents would have had information that it believes was relevant.

HealthSouth's General Counsel," and that Respondents are the only O&P provider being sanctioned. R. Br. at 45.

We conclude that none of these potential showings are relevant in this proceeding for the following reasons.

- As discussed more fully above, Respondents provided no evidence to show that they knew about any complaints to the I.G. and relied on the I.G.'s or CMS's alleged lack of response to the complaints in deciding whether these claims were false.

- Similarly, Respondents proffered no evidence that they were told that the HealthSouth billing policy was approved by the HealthSouth General Counsel, much less that they relied on such a belief in deciding whether these claims were false.

- Respondents' selective prosecution allegation is irrelevant since (as discussed below) the ALJ had no authority to interfere with the I.G.'s discretion in bringing this enforcement action.

Therefore, we conclude that Respondents share responsibility for any lapse of time in the imposition of remedies and, also, have failed to show actual prejudice stemming from such lapse.

b. Alleged agent misconduct

In briefing, Respondents make a number of allegations about "material misrepresentations" and improper requests Agent Jurs made when he first interviewed Mr. Frounfelter in May 2004. R. Br. at 46. They assert that Mr. Frounfelter relied on these misrepresentations in "consenting to an interview that purportedly included substantial admissions by [Mr. Frounfelter]" and, therefore, the I.G. should be "equitably estopped from pursuing this action." Id. at 46.

We do not need to discuss the doctrine of equitable estoppel because Respondents point to no credible evidence tending to show that Agent Jurs made material misrepresentations or improper requests or that Mr. Frounfelter relied on them. In fact, as the ALJ pointed out, Mr. Frounfelter did not testify as to alleged agent misrepresentations or reliance (and therefore was not subject to cross-examination about statements he made pursuant to the investigative subpoena about Agent Jurs (I.G. Ex. 42D, at 393)); nothing in Agent Jurs' testimony supports Respondents' allegations of misconduct; and Respondents elected not to cross-

examine the other I.G. investigator present at the May 2004 interview at which Mr. Frounfelter admitted his billing system was illegal. ALJ Decision at 11, n.7.

At the oral argument, counsel asserted that the absence of estoppel evidence was due to the ALJ's discovery rulings. See OA Tr. at 8, 19. This assertion is without merit. First, Respondents failed to submit critical evidence exclusively within their control, i.e., any attestation of reliance from Mr. Frounfelter. Second, in discovery, the I.G. provided Respondents with the interviews that I.G. agents conducted with other orthotists, former Kast employees, and HealthSouth personnel during the investigations` of HealthSouth Largo hospital and Respondents. See I.G. Response to Respondents' Request for Productions of Documents. Yet, Respondents proffered no testimony (or representations as to attempts to obtain testimony) from such individuals that would corroborate counsel's allegations of agent misrepresentations or Mr. Frounfelter's reliance. Moreover, several of these people testified at the hearing, but Respondents posed no questions concerning agent misconduct. Respondents' argument is simply another attempt to deflect attention from the fact that the record overwhelmingly supports the ALJ's conclusion that Respondents knowingly filed false claims.

Conclusion

For the reasons explained above, we affirm the ALJ Decision.

/s/
Sheila Ann Hegy

/s/
Constance B. Tobias

/s/
Judith A. Ballard
Presiding Board Member