Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: September 14, 2006
Timothy Wayne Hensley,	
Petitioner,	Civil Remedies CR1415 App. Div. Docket No. A-06-67
- v. -	Decision No. 2044
Inspector General.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Timothy Wayne Hensley (Hensley or Petitioner) appealed the February 24, 2006 decision of Administrative Law Judge (ALJ) Anne E. Blair. Timothy Wayne Hensley, DAB CR1415 (2006) (ALJ Decision). The ALJ Decision upheld a determination by the Inspector General (I.G.) excluding Hensley from participation in any federal health care program for five years. The I.G. excluded Hensley pursuant to section 1128(a)(1) of the Social Security Act (the Act) on the ground that he had been convicted of a criminal offense related to the delivery of an item or service under Medicare or a state health care program.[1]

[1] The current version of the Social Security 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.

For the reasons discussed below, we uphold the ALJ's determination that the I.G. properly excluded Hensley from participation in federal health care programs for five years. Further, we reject Hensley's argument that the ALJ erred in granting summary judgment in favor of the I.G. Our decision is based on the record before the ALJ, the parties' submissions on appeal, and the transcript of an oral argument before the Board.

Standard of Review

Our standard of review of an ALJ decision involving the I.G.'s determination to impose an exclusion is set by regulation. We review to determine whether the decision is erroneous as to a disputed issue of law and, if there are disputed issues of fact, whether the findings on those issues are supported by substantial evidence in the record as a whole. 42 C.F.R. § 1005.21(h).

An ALJ may "[u]pon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact . . . ." 42 C.F.R. § 1005.4(b)(12). A requirement affording the opportunity for an oral hearing is not contravened by a summary judgment if there are no genuine issues of material fact. Travers v. Shalala, 20 F.3d 993, 998 (9th Cir. 1994). Thus, summary judgment is appropriate if the affected party either had conceded all of the material facts or proffered testimonial evidence only on facts which, even if proved, clearly would not make any substantive difference in the result. Big Bend Hospital Corp., DAB No. 1814 (2002), aff'd, Big Bend Hospital Corp. v. Thompson, No. P-02-CA-030 (W.D. Tex. Jan. 2, 2003).

Whether summary judgment is appropriate is a legal issue that we address *de novo*, viewing the proffered evidence in the light most favorable to the non-moving party. See, e.g., Crestview Parke Care Center, DAB No. 1836 (2002), aff'd in part, Crestview Parke Ctr. v. Thompson, 373 F.3d 743 (6th Cir. 2004). Although the Federal Rules of Civil Procedure (FRCP) are inapplicable in this administrative proceeding, we are guided by those rules and by judicial decisions on summary judgment in determining whether the ALJ properly granted summary judgment. See Thelma Walley, DAB No. 1367 (1992).[2]

[2] The ALJ here advised the parties that FRCP 56 would be "referred to for guidance in ruling upon a motion or cross-motions for summary judgment." ALJ Order of Aug. 17, 2005, ¶ 6.

Applicable Authority

The I.G. excluded Hensley for five years pursuant to section 1128(a)(1) of the Act, which provides:

> (a) The Secretary shall exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1128B(f)):
>
> > (1) Conviction of program-related crimes.––An individual . . . that has been convicted of a criminal offense related to the delivery of an item or service under title XVIII [Medicare] or under any State health care program.

Section 1128(c)(3)(B) provides that an exclusion pursuant to section 1128(a) must be for a minimum period of five years.

A section 1128(a)(1) exclusion is a derivative exclusion based on a conviction. "The basis for the underlying [conviction] is not reviewable and the individual may not collaterally attack the underlying determination, either on substantive or procedural grounds . . . ." 42 C.F.R. § 1001.2007(d). Thus, Hensley may not deny, in this proceeding, a necessary element of the offense for which he was convicted. Frank R. Pennington, DAB No. 1786 (2001).

Background

Hensley pled guilty to an offense under section 1128B(a)(2) of the Act. ALJ Decision at 5. The misdemeanor provision of section 1128B(a)(2) states that whoever "at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to . . . payment [under a Federal health care program] shall (ii) in the case of such a statement, [or] representation . . . by any other person be guilty of a misdemeanor."

The Information to which Hensley pled guilty provided:

> On or about August 16, 2000 . . . [Hensley] did knowingly and willfully withhold from Southern Medical Distributors [SMD] a material fact for use in determining rights to . . . payments under . . . the Medicare program, in violation of 42 U.S.C. Section 1320a-7b(a)(2) [section 1128B(a)(2)] and 18 U.S.C. § 2.

I.G. Ex. 3.

Hensley's plea was based on his Stipulation of Facts that provided:

> 1. [Hensley] was the National Sales Manager of Augustine Medical, Inc. ("AMI"), a Minnesota corporation that manufactured and sold Warm-Up Active Wound Therapy ("Warm-Up").
>
> 2. [Hensley] knew that claims for Warm-Up were periodically submitted by others for reimbursement to the Medicare program, a Federal health care program.
>
> 3. On or about June 27, 2000, co-defendant, Scott D. Augustine, received a letter from TriSpan Health Services [TriSpan], a fiscal intermediary of the Medicare program which had earlier approved coverage for Warm-Up. TriSpan had now determined that Warm-Up was investigational. Defendant believed that this determination was material.
>
> 4. On or about August 16, 2000, in a meeting in Atlanta, GA, [Hensley] did not disclose the June 27th letter to Southern Medical Distributors [SMD].
>
> 5. By entering into this Stipulation of Facts, [Hensley] knowingly and willfully withheld from Southern Medical Distributors a material fact for use in determining rights to benefits and payments under . . . . the Medicare program in violation of 42 U.S.C. Section 1320a-7b(a)(2) [section 1128B(a)(2)] as set forth in the Information filed herewith and is in fact guilty of that offense.

I.G. Ex. 2.[3]

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[3] On its letterhead, TriSpan identified itself as a Medicare Part A intermediary. P. Ex. 1. Part A of Medicare pays for a portion of the costs of hospital, related post-hospital, home health services, and hospice care. Section 1811 of the Act. Part B pays for, among other things, a portion of costs for physicians' services, outpatient care, and other services and supplies, such as durable medical equipment, that are medically necessary. Section 1832 of the Act.

The Medicare program is administered by the Centers for Medicare & and Medicaid Services (CMS). CMS contracts with intermediaries, such as TriSpan, "to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis (or under the Prospective Payment System for hospitals) and to

(continued...)

It is undisputed that SMD represented itself to be a durable medical equipment (DME) distributor but was actually a fictional entity set up as part of an undercover government sting operation. ALJ Decision at 5, citing P. Ex. B.

It is also undisputed that, as a result of his guilty plea, Hensley was sentenced to three years of probation and fined $100,000. ALJ Decision at 5, citing I.G. Ex. 4.

On February 28, 2005, the I.G. notified Hensley of his exclusion from participation in Medicare, Medicaid, and all federal health care programs for a mandatory five-year period pursuant to section 1128(a) of the Act. ALJ Decision 1. Hensley appealed the I.G.'s determination. The ALJ upheld the I.G.'s determination, concluding that there were no material facts at issue and that decision on the parties' cross motions for summary judgment was appropriate.[4]

ALJ Findings and Conclusions and Hensley Exceptions

The ALJ adopted 14 numbered findings of fact and conclusions of law (FFCLs). ALJ Decision at 4-5. Hensley excepts to the following FFCLs:

> 13. As discussed below, Petitioner was convicted of a criminal offense relating to the delivery of an item or service under the Medicare or a State health care program.
>
> 14. Petitioner was properly excluded for the mandatory period of five years.

Hensley asserts that he was not properly excluded for a mandatory period of five years because his offense was not related to the delivery of an item or service under Medicare or a State health care program. P. Br. at 6. In his Reply Brief, Hensley also

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(...continued)
perform other related functions." 42 C.F.R. § 421.3.

[4] The ALJ Decision was one of three involving convictions under section 1128B(a)(2) for AMI's nondisclosure to SMD of TriSpan's letter. The two other decisions are James Randall Benham, DAB CR1405 (2006), and Scott D. Augustine, DAB CR1406 (2005), decided by ALJ Alfonso J. Montano. Mr. Benham was General Counsel for AMI, and Dr. Augustine was the Chief Executive Officer for AMI. They also appealed their respective ALJ Decisions to the Board, and we issue decisions in those cases at DAB No. 2042 and DAB No. 2043.

asserted that the ALJ erred by entering summary judgment. P. Reply Br. at 3-5.

Analysis

For the following reasons, we conclude that the ALJ did not err in holding that the offense of which Hensley was convicted related to the delivery of an item or service under Medicare within the meaning of section 1128(a)(1).

> *(1) There is a common sense connection between Hensley's offense and the delivery of an item or service under Medicare.*

Section 1128(a)(1) requires merely that an offense be "related to" the delivery of an item or service under a covered program. It does not require that the offense result in a delivery and therefore does not require an actual delivery of an item or service. Based on the plain meaning of the word "related," the Board has repeatedly held that an offense is "related to" the delivery of an item or service under a covered program if there is a common sense connection or nexus between the offense and the delivery of an item or service under the program. See, e.g., Berton Siegel, D.O., DAB No. 1467 (1994); Thelma Walley, DAB No. 1367 (1992); Niranjana B. Parikh, M.D., DAB No. 1334 (1992). Therefore, the Board has determined that an offense committed by someone providing billing or accounting services was related, Jack W. Greene, DAB No. 1078 (1989), aff'd Green v. Sullivan, 731 F.Supp. 835 (E.D. Tenn. 1990); Michael Travers, M.D., DAB No. 1237 (1991), aff'd, Travers v. Sullivan, 791 F.Supp. 1471, 1481 (E.D. Wash. 1992) and Travers v. Shalala, 20 F.3d 993 (9th Cir. 1994); that no showing of harm to a protected program was necessary in order for an offense to be related, Neil R. Hirsch, M.D., DAB No. 1550 (1995), aff'd, Hirsch v. Shalala No. 96-4008 (C.D. Ill. Nov. 4, 1996); Paul R. Scollo, D.P.M., DAB No. 1498 (1994); that an offense could be related even if the services were actually provided by an entity different from the individual being excluded, Napoleon S. Maminta, M.D., DAB No. 1135, at 7 (1990); that an offense could be related even if no service or item was actually delivered, Francis Shaenboen, R.Ph., DAB No. 1249, at 4 (1991); and that an offense could be related even if it did not directly involve the delivery of items or services, Salvacion Lee, M.D., DAB No. 1850 (2002).

The undisputed facts that establish (in several different ways) that the offense for which Hensley was convicted was related to the delivery of an item under Medicare include the following:

- Prior to June 2000, claims for Warm-Up were submitted to Medicare for reimbursement, and TriSpan, a Medicare fiscal intermediary, had approved Warm-Up for Medicare coverage.

In June 2000, TriSpan modified its coverage determination by notifying AMI that Warm-Up was "investigational," and this is the fact that was withheld from SMD.[5] TriSpan had reason to notify AMI that it had altered Warm-Up's status with respect to Medicare coverage since Warm-Up had previously been delivered and claimed for Medicare payment. Thus, Hensley's offense was related to the delivery of an item under Medicare.

- Hensley pled guilty to violating section 1128B(a)(2) of the Act by knowingly and willfully withholding a fact material to determining whether Medicare would pay for Warm-Up and stipulated that the fact withheld was TriSpan's determination. Additionally, Hensley did not except to FFCL 4 in which the ALJ found "Petitioner understood that TriSpan's determination . . . was material to a purchaser's ability to claim Medicare reimbursement for Warm-Up." Hensley's offense thus consisted of withholding from SMD, a purported DME distributor, a fact material to a purchaser's ability to claim Medicare reimbursement for Warm-Up. The extent to which Warm-Up would continue to be delivered as an

[5] Before the Board, Hensley states that "'investigational' is a term commonly used by the Food and Drug Administration; however, it is not a term commonly used to indicate that a product or service is not covered by Medicare." P. Br. at 4, n.1. In his reply brief, he states that "there is no evidence in the record that the term 'investigational' was used by the fiscal intermediary to indicate that the product at issue would not be covered by Medicare." P. Reply Br. at 3. The lack of such evidence, however, does not matter since the Medicare regulations establish the significance of the term "investigational" for purposes of Medicare coverage.

Medicare regulations use Food and Drug Administration (FDA) categorizations such as "investigational" as a factor in making Medicare coverage, and thus payment, decisions for devices, specifically, whether they are "reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member" within the meaning of section 1862(a)(1) of the Act. 42 C.F.R. §§ 405.201(a); 405.203(c). Because Hensley was convicted for withholding a material fact about Medicare payment and may not collaterally attack elements of his conviction, we do not need to decide whether TriSpan's "investigational" determination meant Warm-Up was no longer covered under Medicare or meant that payment for Warm-Up was affected in some other material way. P. Br. at 4, n.1; see also 42 C.F.R. § 1001.2007(d).

item under Medicare was dependent on this material fact, so the offense is related to delivery in this way as well.

- Hensley, AMI's National Sales Manager, committed this offense as part of an attempt to sell Warm-Up to SMD for distribution. Since it is undisputed that Warm-Up had been delivered to Medicare beneficiaries as a Medicare item in the past, it is reasonable to infer that, if Hensley had succeeded in distributing Warm-Up, Warm-Up would have continued to be delivered to Medicare beneficiaries and claims would have been made for Medicare payment. Once delivered, either Medicare would pay or, if Medicare did not pay, Medicare beneficiaries or providers or suppliers would have to bear the cost. Either alternative is related to the delivery of an item under Medicare.

Thus, we conclude that the offense was related to the delivery of an item under Medicare.

(2) The ALJ did not apply an incorrect legal standard.

Hensley argues that the ALJ "applied the incorrect legal standard and consequently reached the erroneous legal conclusion that . . . section 1128(a)(1) appl[ies] in this case." P. Br. at 7. Hensley asserts that the ALJ held that a conviction under section 1128B "need not relate to the delivery of an item or service" under Medicare or a state health care program and that this was error. Id. In characterizing the ALJ's holding, Hensley relies on the ALJ's statement that –

> because Petitioner was convicted of a violation of the Act itself, the Petitioner's conviction is inextricably related to Medicare whether or not a healthcare item was actually delivered.

Id., citing ALJ Decision at 7.

Hensley mischaracterizes the ALJ's holding. The ALJ did not hold that the offense need not relate to the delivery of an item or service under a covered program. Rather, the ALJ stated that, because Hensley was convicted of violating a part of the Act captioned "Criminal Penalties for Acts Involving Federal Health Care Programs," Hensley's conviction was related to Medicare "whether or not a healthcare item was actually delivered." ALJ Decision at 7 (emphasis added). She then went on to consider whether there was a common sense connection between this offense and delivery of an item or service under Medicare. ALJ Decision at 8-10.

(3) Case law supports the ALJ's conclusion that there was a common sense connection between this offense and the delivery of an item or service under Medicare.

Hensley argues that case law does not support the ALJ's conclusion that there is a common sense connection between his offense and delivery of an item or service under Medicare. Hensley principally relies on Greene, DAB No. 1078. Greene was a pharmacist who was convicted of falsely billing the Tennessee Medicaid program for a brand-name drug when he had actually dispensed a generic drug of lesser value. Greene argued that his offense did not fall within section 1128(a)(1) because it was "merely a financial crime, occurring after delivery . . . ." The Board and the court rejected this argument.

Hensley misconstrues Greene in two ways. First, Hensley erroneously asserts that Greene established a "bright line rule that the submission of a bill or claim for Medicaid reimbursement is the necessary step, following delivery of the item or service, to bring the item within the purview of the program." P. Br. at 8. Hensley argues that, while subsequent cases "broaden[ed] the reach of Greene," an offense cannot be related to the delivery of an item or service under a covered program unless there is the submission of a claim for reimbursement to that program or actions "related to" the submission of such a claim. Id. at 8-9.

We reject Hensley's argument. The plain language of section 1128(a)(1) does not require the submission of a claim or actions related to the submission of a claim. In Greene, the Board discussed the fact that Greene had filed claims in explaining why Greene's particular offense was related to Medicaid. The Board did not hold that filing a claim was a required element of relatedness. As subsequent cases have shown, a common sense connection between an offense and the delivery of an item or service under a covered program may or may not directly involve the submission of a claim or acts related to submission of a claim. See Lee, DAB No. 1850; Maminta, DAB No. 1135.

Second, Hensley erroneously asserts that Greene holds that only offenses that defraud a covered program fall within section 1128(a)(1), while offenses that do not defraud a covered program fall under the permissive exclusion provision at section 1128(b)(1). P. Br. at 8; Tr. at 7. Hensley relies on the following language from the district court decision:

> The language of the statute itself as well as its legislative history indicate that the dichotomy was not intended to be between financial crimes and crimes in the

> delivery of services (such as direct patient abuse) but between program-related crimes and other relevant crimes which did not defraud the program itself (such as fraud on insurance companies).

Greene v. Sullivan, 731 F. Supp. at 838.

Hensley's construction of the court's dicta is inconsistent with section 1128(a)(1) and cases applying the section. The plain language of section 1128(a)(1) requires neither fraud on a covered program nor direct contact with a covered program. Thus, while section 1128(a)(1) applies to offenses involving fraud on a covered program related to the delivery of an item or service under that program, it also encompasses other offenses as well. See Lee, DAB No. 1850; Thelma Walley, DAB No. 1367 (1992).

Hensley's construction is also inconsistent with legislative history. Section 1128(a)(1) was enacted as part of the Medicare and Medicaid Program and Patient Protection Act of 1987 (MMPPPA), Public Law No. 100-93, section 2. The Senate Report stated that the purpose of the MMPPPA was –

> to improve the ability of the Secretary and the Inspector General . . . to protect [covered programs] from fraud **and abuse**, **and to protect the beneficiaries of those programs** from incompetent practitioners and from inappropriate or inadequate care.

S.Rep. No. 109, 100th Cong., 1st Sess. 1-2 (1987), reprinted in 987 U.S.C.C.A.N. 682 (emphasis added).

To limit section 1128(a)(1) to cases that involve only particular forms of fraud on covered programs would be contrary to the purpose of the MMPPPA, which is to enable the I.G. to protect covered programs from fraud, to protect the programs from abuse, and to protect beneficiaries.

Hensley also asserts that the I.G. may not impose a mandatory exclusion unless there is a "risk of harm" to a covered program. P. Br. at 9. Hensley argues there is no such risk "when there could be neither delivery to nor payment sought from such a program for such item or service." Id. at 10. Id.

We reject Hensley's assertion that to impose a mandatory exclusion the I.G. must find that the offense posed a risk of harm to a covered program. The plain language of section 1128(a)(1) does not require such a finding. In any event, the

undisputed facts about this offense show that Hensley's participation in covered programs would pose a risk.

Hensley argues there was no risk because SMD never agreed to purchase Warm-Up from AMI.[6] However, whether an offense evidences a risk to the programs should be evaluated from the perspective of what the excluded individual knew and/or believed when he committed the offense. Viewed from that perspective, this offense did pose a risk. The only reasonable inferences to be drawn from the undisputed facts here are that, when he committed the offense, Hensley believed that he was marketing Warm-Up to a bona fide DME distributor that would distribute the product further in a delivery chain that would result in payment being sought from Medicare. Thus, his knowing and willful withholding of a material fact about Medicare payment of Warm-Up shows that he was willing to put Medicare at risk.

Hensley argues there was no risk to Medicare because the ALJ correctly found that "no Medicare item or service could have been delivered . . . ." Tr. at 8. Hensley relies on statements by the ALJ that the "worst that can be said is that the Petitioner's failure to disclose would have caused SMD to buy products for distribution when Petitioner knew that TriSpan, the intermediary, would deny Medicare payment," that "the potential harm to Medicare . . . was entirely within Medicare's control," and that "Petitioner had no ability . . . to fool Medicare into paying claims for Warm-Up." P. Br. at 10 and Tr. at 8, citing ALJ Decision at 9. These statements by the ALJ, however, are unsupported and inconsistent with how Medicare operates. We do not adopt them, and reject Hensley's argument, for the following reasons:

- The ALJ did not provide any basis for the quoted statements, and Hensley cites to no proffered evidence or analysis to support the conclusion that Medicare would not have been at risk of paying for Warm-Up even if SMD had been a bona fide distributor.

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[6] Hensley's codefendants in the criminal case, Augustine and Benham, argued that the offense was not related because SMD was a fictional entity set up as part of a sting operation and, therefore, would not have purchased or distributed Warm-Up. We rejected that argument in the Augustine and Benham decisions. To the extent that Hensley is making a similar argument, we incorporate here our analysis in those decisions.

- Even if TriSpan had programmed its claims processing system to reject fee-for-service claims for Warm-Up as a supply item, Medicare might still have had to pay under the limitation on liability of beneficiary provision at section 1879 of the Act.

- If costs for Warm-Up were included in a cost report of an institutional provider, such as a hospital or skilled nursing facility, TriSpan might not have identified those costs as costs of Warm-Up and prevented them from being included in the provider's Medicare rate calculation.

- To suggest that a program as complex as Medicare can prevent every possibility of a payment mistake is unreasonable. Thus, Congress has seen the need to protect it by criminalizing the type of conduct to which Hensley pled.

Hensley further argues that there was no risk to Medicare because the "ALJ found that, even if SMD had been a wholesale distributor as it represented itself to be, SMD would still not be submitting bills or claims to any state or federal health care program as a result of Petitioner's failure to disclose the TriSpan letter." Tr. at 8. Hensley characterizes the offense and the underlying conduct as occurring solely between two private parties. Tr. at 9. We disagree. Merely because neither a manufacturer nor a distributor would itself have submitted claims does not mean that there would have been no risk to the program even if SMD had been a bona fide distributor. Indeed, failing to disclose a material fact about Medicare payment to a DME distributor, if a distributor distributes the product to multiple suppliers or providers, arguably could pose a greater risk to the program than if the information was withheld only from a single direct supplier of the product.

Finally, Hensley incorrectly assumes that the only risk to Medicare would be from its payment of claims. Rather, the operation of the Medicare program could have been harmed by this offense even if TriSpan did not pay subsequent third party claims. For example, providers or suppliers that purchased Warm-Up could suffer economic loss if their claims were denied, which could adversely affect access of Medicare beneficiaries to items or services. Also, withholding information relevant to whether an item is therapeutically effective could result in Medicare beneficiaries receiving less effective care and could harm their health.

Hensley further argues that the ALJ misconstrued the case of Tanya A. Chuoke, R.N., DAB CR633 (1999); remanded, DAB No. 1721

(2000); DAB CR865 (2002). In Chuoke, a nurse stole pills from a Medicaid recipient in a nursing home. The ALJ stated in Chuoke that an offense was related "if the delivery of a Medicaid item or service is an element in the chain of events giving rise to the offense." Chuoke, DAB CR633, at 4. Hensley argues that Chuoke establishes that "an essential element" for the application of section 1128(a)(1) is the delivery of an item or service and there could have been no delivery here.

We reject this argument. First, the standard articulated in Chuoke was met here. Viewed from the perspective of what Hensley knew and/or believed at the time he committed the offense, the chain of events associated with this offense included: the previous delivery of Warm-Up as a Medicare item or service; the subsequent determination by a Medicare intermediary that Warm-Up was investigational, a determination material to its continued payment under Medicare; and the withholding of that material fact by Hensley, AMI's National Sales Manager, in marketing Warm-Up to a DME distributor for distribution in a chain of delivery that would likely result in future claims to Medicare.[7] Second, the statement in Chuoke, like statements in many decisions, is addressed to the specific circumstances presented by that case. It does not purport to limit the reach of section 1128(a)(1) to offenses that fall within that description.

We note that, in implementing the 1987 amendments to section 1128 of the Act, the I.G. specifically declined to adopt a definition of the phrase "related to the delivery of an item or service." The I.G. wrote:

> This term has served as the basis for exclusions from Medicare for many years and the absence of a definition has not posed any serious problems. The OIG assesses each conviction on a case-by-case basis to determine whether it falls within the ambit of the statutory language – that is, whether it is related to the delivery of an item or service under one of the programs – and each of those determinations is quite fact-specific. We believe that it will continue to

[7] However, the fact that an individual is unaware of a relationship between his/her offense and the delivery of items or services under a covered program does not necessarily make the offense unrelated. See Robert C. Greenwood, DAB No. 1423 (1993) (I.G. excluded home health aide who falsified time records that were subsequently used by his employer to bill Medicaid for services the aide had not provided to a Medicaid recipient).

> be more effective to make these determinations on a case-by-case basis than to attempt to define the phrase further.

57 Fed. Reg. 3298, 3303 (January 29, 1992). Given that one could not anticipate all of the possible factual scenarios, this approach has been a wise one, permitting application of the wording of the statute in light of its purpose.

> *(4) The absence of a decision that addressed exactly the circumstances of this case does not make the offense unrelated to the delivery of an item or service under Medicare.*

Hensley argues that "the I.G. cannot point to any existing case law where the mandatory exclusion was applied where no item or service was ever delivered, no fraudulent bill or claim or other document was submitted by anyone to a covered program, and where there was not at least some minimal contact by the excluded Petitioner with the covered program." Tr. at 7-8; see also P. Br. at 10, 13.

The mere fact that no past decisions addressed exactly the same factual scenario does not mean that the offense in question does not fall within section 1128(a)(1). Further, the premise of Hensley's basis for distinguishing this case is mistaken. The undisputed facts show that Hensley's co-defendant and employer had direct contact with Medicare. TriSpan, a fiscal intermediary of the Medicare program (which had earlier approved coverage for Warm-Up) had notified the co-defendant, the owner of AMI, that Tri-Span had made a determination about Warm-Up. In addition, it is undisputed that Hensley himself knew that claims for Medicare reimbursement (which imply delivery of Warm-Up to Medicare beneficiaries) were periodically made by others and knew that the TriSpan letter that he failed to disclose was material to determining payment under Medicare.

Finally, the fact that the elements of Hensley's offense did not include personal, direct contact between Medicare and Hensley does not take the offense out of section 1128(a)(1). Prior to the MMPPPA, section 1128(a)(1) required the I.G. to exclude individuals convicted of "a criminal offense **related to such individual's participation** in the delivery of medical care or services." (Emphasis added.) The MMPPPA broadened section 1128(a)(1) by eliminating the requirement for the individual's participation in the delivery. Hensley points to nothing in the amended language requiring that the convicted individual have had some type of personal, direct contact with a covered program. Interpreting the section to require such contact would be

inconsistent with the amended wording of the section (which requires only that the offense be "related to" the delivery of an item or service under a covered program). Moreover, such an interpretation would undercut the effectiveness of the provision by allowing untrustworthy individuals to escape its reach simply by acting through intermediaries or simply because another entity, such as a supplier or provider, actually delivers the item under Medicare. Our conclusion is supported by the court decision upholding Lyle Kai, R.Ph., DAB No. 1979 (2005), a case where the petitioner did not deny that his offense involved mislabeling pharmaceuticals and that some of these mislabeled pharmaceuticals were billed to a covered program. The court upheld an exclusion under section 1128(a)(1) "even if Plaintiff did not personally engage in the scheme or was not aware of the scheme" that resulted in the delivery of the mislabeled pharmaceuticals under the program. Kai v. Leavitt, Civ. No. 05-00514 BMK, at 12 (D. Haw. 2006).

(5) The ALJ Decision does not make section 1128(b) superfluous.

Hensley argues that the ALJ Decision would make all convictions under section 1128B fall within section 1128(a)(1) and would render the permissive exclusion provisions of section 1128(b) superfluous. P. Br. at 15. Hensley argues this result would be contrary to the rules of statutory construction requiring a statute to be construed so as to give effect to all its parts.

This argument is baseless. As the ALJ recognized in her decision, offenses under section 1128B(a) must still be evaluated to determine whether there is a common sense connection with the delivery of an item or service under Medicare or a state health care program. If that connection is found, courts have repeatedly held that the I.G. is then required to impose a mandatory exclusion even if an individual's conduct also falls within the scope of a permissive exclusion provision. Dan Anderson, DAB CR855 (2002), aff'd, Anderson v. Thompson, 311 F. Supp. 2d 1121 (D. Kansas 2004); Travers v. Sullivan; Greene v. Sullivan. Moreover, section 1128(b) is in no danger of becoming superfluous. The I.G. regularly excludes and the Board upholds exclusions under section 1128(b) under a wide range of criminal statutes.

(6) Summary judgment in favor of the I.G. is appropriate.

An ALJ may "[u]pon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact . . . ." 42 C.F.R. § 1005.4(b)(12). The ALJ here granted summary judgment to the I.G., determining that "there are no material facts at issue" because the "background facts contained in findings 1-12 are not in dispute." ALJ Decision at 4. On appeal, Hensley does not argue that any of the numbered findings is incorrect, but argues that ALJ Finding 2 (that Hensley "knew that claims for reimbursement were periodically submitted for reimbursement to the Medicare program") should be considered in the appropriate context and that the ALJ ignored evidence in the record regarding the prior claims. P. Br. at 4. He also argues that the ALJ erred by entering summary judgment because the I.G., in his brief before the Board, "asserts and assumes facts not in the record." P. Reply Br. at 3.

As mentioned above, the issue of whether summary judgment is appropriate is an issue we review de novo. We conclude that summary judgment in the I.G.'s favor is appropriate because the ALJ did not ignore evidence in the record. Neither Hensley's affidavit nor other evidence proffered by Hensley raises a genuine dispute of material fact. With respect to Hensley's challenge to the I.G.'s assertions of fact, we conclude that the asserted facts are not material to all of the alternative grounds for the decision although they support the result. We further conclude that summary judgment is appropriate because Hensley has not raised a genuine dispute regarding those assertions and the asserted facts are reasonable inferences from the undisputed facts. Like the I.G. and the ALJ, we draw the same inferences.

First, the ALJ did not ignore relevant evidence regarding the prior claims. Hensley points to his affidavit, which states that he did not stipulate as part of his plea that the claims periodically submitted to Medicare were the "result of" withholding that letter, nor did he stipulate that these claims were "false or improper." P. Br. at 4. His attestations on these points are irrelevant, however. The claims he knew about at the time of his offense could hardly have been the "result of" withholding the TriSpan letter, and there is no allegation or finding here that those claims resulted from the letter or that those claims were false or improper, nor is there any need to make such a finding. Hensley further argues that, while he acknowledged that "there was a period of time in which TriSpan had approved Medicare coverage for Warm-Up," he had attested that "his misdemeanor conviction was not based on knowledge of other claims being submitted." It does not matter whether his

conviction was "based on" knowledge of the other claims, however, since he stipulated as part of his plea agreement that he knew that claims for Warm-Up were periodically submitted to Medicare.

Second, none of Hensley's arguments about assertions he says are assumptions not based on evidence in the record persuades us that summary judgment is not appropriate here.

Hensley identifies as unsupported by the record the statement that "Medicare would not cover Warm-Up." P. Reply Br. at 3, citing I.G. Br. at 5. Hensley alleges "there is no evidence in the record that Medicare would not cover Warm-Up." P. Reply Br. at 3. Yet, we have already concluded that whether Medicare would in fact "cover" Warm-Up is not material to deciding whether Hensley was properly excluded under section 1128(a)(1). See note 5 above. Second, even if a finding about Medicare coverage of Warm-Up were material to the decision, that would not render summary judgment inappropriate here. The undisputed facts show the following. The TriSpan determination that was withheld used the term "investigational" (a factor in determining coverage), after having earlier approved Medicare coverage, and this fact was material to determining Medicare payment. From the undisputed facts, it is reasonable to infer Hensley understood that TriSpan was modifying its previous approval of coverage in a way that would affect Medicare payment, i.e., at the very least in the direction of noncoverage if not denying coverage altogether. Yet, Hensley proffered no evidence or legal argument whatsoever to show that Medicare did in fact consider Warm-Up to be a covered item.[8] Indeed, he acknowledges that Medicare

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[8] In Medicare, the term "covered" refers to "services for which the law and the regulations authorize Medicare payment." 42 C.F.R. § 409.3. Medicare will not pay for items that are not covered, nor will it pay for items for which other applicable conditions are not met.

Hensley does say on appeal that he "would testify that the meaning of the TriSpan letter was unclear because the `investigational' characterization by TriSpan was false, leading to the letter being withdrawn," but he concedes that this testimony is "not germane to this appeal and not in the record." P. Reply Br. at 9, n.3. We agree that any testimony implying that the TriSpan determination was not in fact material to determining Medicare payment or that Hensley lacked notice that the determination was material is not germane. Such testimony would constitute a collateral attack on the conviction, which is

(continued...)

approved Medicare coverage for Warm-Up only for "a period of time." P. Br. at 4. Thus, Hensley has not clearly raised a genuine dispute of fact about the issue.

Hensley also quotes the following other assertions in the I.G.'s brief as grounds for finding summary judgment improper: "the purpose of their withholding of this information was to sell Warm-Up to SMD for sale to its customers" (I.G. Br. at 6); Hensley "knew that SMD would be less likely to purchase Warm-Up from [Hensley] if its customers could not submit claims to Medicare" (I.G. Br. at 6); and "if the situation had been as Appellant believed and intended, SMD's customers ultimately would have filed claims for Warm-Up" (I.G. Br. at 6). P. Reply Br. at 3-4.

While these asserted facts support the result here, they are not necessary to the result. The exclusion here is fully supportable without any findings about the reasons for or intended effects of the offense. As we concluded above, the relationship of the offense to the delivery of an item under Medicare is established in several ways. One way the relationship is established is that Hensley's offense was for withholding a determination by a Medicare fiscal intermediary that was material to Medicare payment, after Warm-Up had been delivered and claims for Warm-Up submitted for Medicare reimbursement.

In any event, the assertions are not, as Hensley alleges, unsupported:

- The asserted facts are reasonable inferences from the undisputed facts. Hensley's offense was for knowingly and willfully withholding a fact material to payment under Medicare, and he stipulated that he knew Warm-Up had previously been claimed under Medicare. From this, it is reasonable to infer that Hensley withheld the statement from SMD because it would make SMD less likely to purchase Warm-Up for distribution if there was an issue about Medicare payment. It is also reasonable to infer that he expected, at the time, that withholding the statement would ultimately

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[8](...continued)
not permitted. 42 C.F.R. § 1001.2007(d). Further, while Hensley now says he would testify that the characterization as "investigational" was false and was withdrawn, he neither proffered such testimony to the ALJ nor proffered any evidence (even now) that would show that Warm-Up was, in fact, covered. See Hensley Affidavit of October 18, 2005.

result in SMD's customers delivering Warm-Up to Medicare beneficiaries and submitting claims for Medicare payment.

- Hensley proffered no evidence that shows, or from which it would be reasonable to infer, that his motivation in withholding this information was wholly independent of any attempt to put Warm-Up into a chain of delivery by selling it to SMD. Similarly, Hensley proffered no evidence that, at the time of the withholding, he did not believe and intend that a sale to SMD would result in delivery of Warm-Up to Medicare beneficiaries and claims for Medicare payment.

- In fact, Hensley did not proffer any evidence that would undercut these inferences and therefore might warrant a hearing. His affidavit addresses primarily what he knew "[a]t the time [he] executed the Stipulation of Facts" and states what he did not stipulate. Hensley Affidavit of October 18, 2005. Nothing in the affidavit undercuts the reasonable inferences drawn from the undisputed facts, even when the affidavit is viewed in the light most favorable to Hensley. In other words, even assuming that the facts asserted in the affidavit are true, they clearly would make no difference in the result here.

In sum, summary judgment in favor of the I.G. is proper.

Conclusion

Based on the preceding analysis, we sustain the ALJ Decision. In doing so, we affirm and adopt each of the numbered FFCLs in that decision.

/s/
Donald F. Garrett

/s/
Sheila Ann Hegy

/s/
Judith A. Ballard
Presiding Board Member