

340B MANAGEMENT, LLC,	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
Appellant	:	
	:	
v.	:	
	:	
RX BLUE STAR SOLUTIONS, LLC;	:	
SACKS MEDICAL CORPORATION; SMC	:	
DIRECT LLC; PHARMBLUE LLC;	:	
PHARMBLUE HOLDINGS, LLC; MEIR	:	
SACKS a/k/a SHIM SACKS, AND	:	
YAAKOV SACKS a/k/a JAKE SACKS	:	No. 331 WDA 2017

Appeal from the Judgment entered February 15, 2017  
in the Court of Common Pleas of Allegheny County,  
Civil Division, No(s): GD 12-012001

BEFORE: MOULTON, SOLANO and MUSMANNO, JJ.

OPINION BY MUSMANNO, J.: FILED DECEMBER 19, 2017

340B Management, LLC, appeals from the Judgment entered against it and in favor of RX Blue Star Solutions, LLC ("Blue Star"), Sacks Medical Corporation, SMC Direct LLC, Pharmblue LLC, Pharmblue Holdings, LLC, Meir Sacks a/k/a Shim Sacks ("Shim"), and Yaakov Sacks a/k/a Jake Sacks ("Jake") (collectively, "Defendants"). We affirm.

The trial court aptly described the facts underlying the instant appeal as follows:

Brothers Shim [] and Jake [] owned the Evans City, Butler County[,] mail order pharmacy[,] [] Blue Star [], and

they believed the 340B Drug Pricing Program<sup>[1]</sup> presented a new potential revenue source. In April of 2009, after meeting with Ira Landsman [“Ira”], Shim and Jake engaged Ira [] to solicit health centers eligible for the 340B Drug Pricing Program to name [] Blue Star as their contract pharmacy. Ira had been successful as a certified public accountant, securities trader and a real estate developer, but he had no experience in pharmacy matters. However, he immersed himself in 340B Drug Pricing Program literature and became very knowledgeable on the subject. With Shim and Jake agreeing [that] Ira would receive fifty percent of [] Blue Star’s net profits from the 340B Program, in June of 2009[,] Ira obtained [] Blue Star’s first contract with a 340B health center. Shim and Jake then gave Ira the title of Chief Operating Officer of [] Blue Star. Ira and [] Blue Star also put their net profit[-]sharing agreement into writing [“the Agreement”], with Ira first forming 340B Management, LLC[,] to receive his fifty percent as [] Blue Star’s independent contractor.

Ira worked diligently and obtained additional health centers to sign 340B contracts with [] Blue Star, and gross revenue to [] Blue Star from the 340B Program grew dramatically to approximately \$1.7 million in 2011 and \$17.7 million in 2012. Ira’s duties involved much more than soliciting health centers eligible for the 340B Drug Pricing Program. He assisted the health centers in preparing extensive paperwork required from the health centers by the federal government, he prepared monthly reports on prescriptions filled for each customer health center[,] and he managed the relationships with all of the customer health centers.

In approximately November of 2011[,] Shim asked a healthcare merger and acquisition advisor to search for assistance selling [] Blue Star for an asking price of \$4.5 million. A potential purchaser then emerged, but the net profit sharing agreement with Ira seemed to be a deal breaker. Jake and Shim then began to perpetrate an elaborate scheme on their unsuspecting friend and business associate, Ira. Shim

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<sup>1</sup> The 340B Drug Pricing Program is a federal program that provides significant savings on outpatient drugs to qualified participants. The name is a reference to its enabling law, section 340B of the Public Health Service Act, 42 U.S.C.A. § 256b.

bombarded Ira with a series of lies about civil proceedings and potential criminal charges against [] Blue Star that Shim said could ensnare Ira, its Chief Operating Officer. Around March 29, 2012, after Shim told Ira he could avoid this impending legal crisis if he resigned, Ira[,] in fact[,] submitted his resignation as Chief Operating Officer of [] Blue Star. In April of 2012, Pharmblue purchased [] Blue Star and Pharmblue subsequently refused to honor the agreement between [] Blue Star and Ira's 340B Management.

340B Management then initiated a lawsuit against [] Blue Star, Pharmblue, Shim [] and Jake [] for, among other things, fraud and breach of contract. Ira had regularly requested an accounting of [] Blue Star's net profits to determine his fifty percent, but Jake and Shim never provided him [with] this information. Instead, [] Blue Star paid Ira's 340B Management \$18,000 in 2010, \$10,000 in 2011[] and \$65,000 in 2012[,] for a total of \$243,000. The breach of contract claim was based on the \$243,000 that [] Blue Star paid being far less than fifty percent of the net profits from the 340B Drug Pricing Program.

Trial Court Opinion, 4/24/17, at 1-3 (footnote added).

After discovery, Defendants filed a Motion for summary judgment as to Ira's breach of contract claim. The trial court granted the Motion, concluding that the contract for payment (based upon 50% of net profits) violated the federal Anti-Kickback Statute ("the AKS"), 42 U.S.C.A. § 1320a-7b(b)(1)(B). Consequently, the trial court dismissed Ira's breach of contract claim. A jury subsequently determined that Shim had defrauded 340B Management. The jury awarded 340B Management \$35,000 in compensatory damages, and \$400,000 in punitive damages. 340B Management filed a Motion for post-trial relief, which the trial court granted in part and denied in part. The trial court entered Judgment on the jury's award of \$35,000 in compensatory damages, and \$400,000 in punitive damages to 340B Management. 340B

Management filed the instant timely appeal of the trial court's Judgment, followed by a Pa.R.A.P. 1925(b) Concise Statement of matters complained of on appeal.

340B Management presents the following claims for our review:

- I. Whether ... a new trial is required as to [340B Management's] breach of contract claim because the [t]rial [c]ourt erred in granting partial summary judgment to [Defendants] with respect to [340B Management's] breach of contract claim based on the June 1, 2009 Agreement, as amended by the March 19, 2010 Amendment, by finding that said Agreement was unenforceable based on its violation of federal law, namely, [the AKS?]
- II. Whether a new trial is required as to [340B Management's] breach of contract claim because the [t]rial [c]ourt erred in denying [340B Management's] Motion for Post-Trial Relief Pursuant to Pa.R.Civ.P. 227.1 with respect to [340B Management's] request for a new trial as to [its] breach of contract claim[?]

Brief for Appellant at 5.

340B Management challenges the entry of summary judgment against it, and in favor of Defendants.

Our scope of review of an order granting summary judgment is plenary. We apply the same standard as the trial court, reviewing all the evidence of record to determine whether there exists a genuine issue of material fact. We view the record in the light most favorable to the non-moving party, and all doubts as to the existence of a genuine issue of material fact must be resolved against the moving party. Only where there is no genuine issue as to any material fact and it is clear that the moving party is entitled to a judgment as a matter of law will summary judgment be entered.

Motions for summary judgment necessarily and directly implicate the plaintiff's proof of the elements of his cause of action. Thus, a record that supports summary judgment will either (1) show

the material facts are undisputed or (2) contain insufficient evidence of facts to make out a prima facie cause of action or defense and, therefore, there is no issue to be submitted to the fact-finder. Upon appellate review, we are not bound by the trial court's conclusions of law, but may reach our own conclusions. The appellate court may disturb the trial court's order only upon an error of law or an abuse of discretion.

DeArmitt v. N.Y. Life Ins. Co., 73 A.3d 578, 585-86 (Pa. Super. 2013) (internal citations and quotation marks omitted; some punctuation modified).

340B Management first challenges the grant of summary judgment as to its breach of contract claim against Defendants. Brief for Appellant at 25. Specifically, 340B Management disputes the trial court's conclusion that the Agreement violated the AKS as a matter of law, and was therefore unenforceable. *Id.* 340B Management asserts that the trial court improperly failed to consider the totality and operation of the Agreement, and the purpose of the AKS. *Id.* According to 340B Management, under the Agreement, 340B Management did not receive remuneration for "'arranging for or recommending purchasing or ordering any good, facility, service, or item' to patients or physicians." *Id.* at 27. 340B Management asserts that it was at least two steps removed from arranging for or recommending that patients select Blue Star as their contract pharmacy. *Id.*

The question before us is whether the Agreement violates the AKS, 42 U.S.C.A. § 1320a-7b(b)(1)(B).<sup>2</sup> As enacted in 1972, Congress made it a misdemeanor to solicit, offer, or receive “any kickback or bribe in connection with” furnishing covered goods or services or referring a patient to a provider of those services. See Social Security Amendments Act, Pub. L. No. 92-603, §§ 242(b) and 242(c), 86 Stat. 1419 (1972). In 1977, Congress expanded the statutes’ language to prohibit the solicitation or receipt of “any remuneration (including any kickback, bribe, or rebate)” in return for referrals, prohibit the offer or payment of such remuneration to induce referrals, and to make violations of the AKS statutes a felony. See Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, 91 Stat. 1175, 1181, 1182 (1977). In 1980, a “knowing and willful” requirement was added. See Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, 94 Stat. 2599, 2625 (1981).

In 1987, the Medicare and Medicaid statutes were combined into one statute (42 U.S.C.A. § 1320a-7b), and the Office of the Inspector General was authorized to exclude individuals and entities that violated the statutes from the Medicare and Medicaid programs. See Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat.

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<sup>2</sup> “[A] contract which violates a statute is illegal and will not be enforced.” *Robinson Coal Co. v. Goodall*, 72 A.3d 685, 690 (Pa. Super. 2013). (quoting *Rittenhouse v. Barclay White Inc.*, 625 A.2d 1208, 1211 (Pa. Super. 1993)).

680, 681-82 (1989). Subsequent amendments to the AKS are not relevant in this case.

The current AKS provides, in relevant part, as follows:

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind--

...

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$ 25,000 or imprisoned for not more than five years, or both.

42 U.S.C.A. § 1320a-7b(b)(1)(B). The United States Office of the Inspector General ("OIG") has explained that this provision of the AKS

is extremely broad. ... [P]rohibited conduct includes not only remuneration intended to induce referrals of patients, but remuneration also intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or State health care programs.

General Comments, Office of Inspector General, Notice of Final Rule, Anti-Kickback Provisions of Medicare and State Health Care Programs, 55 Fed. Reg. 35,952 (1991) (emphasis added). The AKS does not define the term "arranging." However, "[w]here Congress provides no definition for a term in a statute, the court looks to the word's ordinary meaning." *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 407 (2011). The ordinary meaning of "arrange" is "to make preparations for: plan[;] ... to

bring about an agreement or understanding concerning.” MERRIAM-WEBSTER’S COLLEGIATE DICTIONARY 64.

“Compliance with the AKS is clearly a condition of payment under Parts C and D of Medicare[.]” U.S. ex rel. Wilkins v. United Health Grp., Inc., 659 F.3d 295, 313 (3d Cir. 2011). Given the extremely broad scope of § 1320a-7b(b)(1), Congress authorized the OIG to issue advisory opinions and promulgate regulatory “safe harbors” under the AKS. 42 U.S.C.A. § 1320a-7d. Subsequently, six “safe harbor” regulations were promulgated to determine if an agreement falls outside of the class of agreements prohibited by section 1320a-7b(b)(1). In particular, we observe the fifth factor, which provides as follows:

As used in [42 U.S.C.A. § 1320a-7b(b)(1)], “remuneration” does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as the following six standards are met:

\* \* \*

(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume of value or any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare ....

42 C.F.R. § 1001.952(d)(5) (emphasis added). In an Advisory Opinion, the OIG found that compensation arrangements based on a percentage of sales “appear to be associated with an increased potential for program abuse.”



OIG Advisory Opinion No. 99-3, 1999 HHS OIG Adv. Op. LEXIS 37 (Mar. 23, 1999).

While there is no Pennsylvania case law regarding the interpretation of section 1320a-7b(b)(1)(B), several federal courts have interpreted the AKS, and are consistent with the result reached in this case. Under the marketing agreement in *Nursing Home Consultants, Inc. v. Quantum Health Servs., Inc.*, 926 F. Supp. 835 (E.D. Ark. 1996), *aff'd*, 112 F.3d 513 (8th Cir. 1997), *Quantum Health Services, Inc. ("Quantum")*, and *Nursing Home Consultants, Inc. ("NHC")*, entered into a contract ("the agreement") whereby NHC would identify Medicare recipients who needed medical supplies that Quantum could supply. *Id.* at 839. Under the agreement, all orders for medical supplies were to be made directly with Quantum, and NHC was prohibited from providing assistance to nursing home residents in connection with the placement of an order. *Id.* NHC's annual compensation under the agreement was to be determined based upon the number of units Quantum sold to those nursing home residents identified by NHC. *Id.* "In other words, the more residents [the plaintiff] referred to [the defendant], the more money [the plaintiff] made under the [] [a]greement." *Id.* at 857-58. The federal district court found that the agreement violated 42 U.S.C. 1320a-7b(b)(1):

NHC was paid for referring persons who needed Medicare-covered supplies to Quantum, who in turn sold them those supplies (via their nursing homes), and this type of relationship falls squarely within the transactions prohibited by subparagraph

A. Alternatively, NHC could be viewed as having been paid for recommending to Medicare recipients that they purchase their Medicare-reimbursable supplies from Quantum, and as such their relationship with Quantum would violate subparagraph B. No matter how you slice it, the [ ] [a]greement violates § 1320a-7b(b)(1), and accordingly the subject matter of that agreement (a referral scheme for the provision of Medicare-covered supplies) is prohibited by that statute, as is the performance of that agreement.

Nursing Home Consultants, Inc., 926 F. Supp. at 843.

In *MedPricer.com, Inc. v. Becton, Dickinson & Co.*, 240 F. Supp. 3d 263 (D. Conn. 2017).<sup>3</sup> *MedPricer.com, Inc.* (“MedPricer”), operated a website that provided an online auction platform allowing buyers and sellers to conduct online negotiations (“Sourcing Events”), which included online requests for quotes (“RFQs”), i.e., the means to enter bids to supply services or products to health care organizations. *Id.* at 265. Medpricer did not directly participate in the Sourcing Events, but, rather, facilitated negotiations between buyers and sellers through its website. *Id.* Hospitals and healthcare service providers entered into agreements (“Service Agreements”) with MedPricer, as the exclusive provider of e-sourcing services. *Id.* Under the Service Agreements, the hospitals and healthcare service providers, not MedPricer, determined which suppliers to invite to the Sourcing Events. MedPricer then sent invitations to those suppliers. *Id.*

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<sup>3</sup> Reconsideration was granted in part, denied in part, and summary judgment entered at *MedPricer.com, Inc. v. Becton, Dixon & Co.*, 2017 U.S. Dist. LEXIS 50226 (D. Conn., filed on March 6, 2017). The federal district court did not change its legal analysis interpreting the AKS.

MedPricer provided the online forum, and offered to answer questions about the bidding process. *Id.* Under MedPricer's Service Agreements, "a fee of 1.5% of the value of the transaction shall be paid by a supplier who participates in a Sourcing Event through MedPricer and is awarded business related to a Sourcing Event." *Id.* at 266.

Analyzing the Service Agreements under section 1320a-7b(b)(1)(B), the federal district court in Connecticut explained that,

"arranging" a purchase or sale is broader than "making" a purchase or sale, and MedPricer can intend to bring about a sale even if it is not a party to the sale. In fact, MedPricer's business model is premised on making preparations for and bringing about agreements to purchase and sell between suppliers and buyers. MedPricer itself states that it is a "provider of comprehensive e-sourcing services to the healthcare sector that helps facilitate the negotiation of contracts between the healthcare sector and suppliers," and MedPricer conceded at oral argument that this means, in effect, that it "facilitates sales." It also acknowledges in its brief that its website provides "a forum where 'an agreement or understanding' may be reached between the health care facility and supplier for the possible sale of products." In addition, MedPricer makes money only if a sale occurs; the entire business model would be unsustainable if MedPricer did not intend for sales to occur....

*Id.* at 270. Consequently, the federal district court found that MedPricer "arranged" for the sale of the supplies and equipment. *Id.* "The fact that MedPricer does not choose which particular suppliers participate in the sales and which products are sold does not mean that it does not intend that a sale take place." *Id.*

The federal district court further observed that

[t]he Contract's percentage-based fee likewise points to coverage by the AKS. The OIG has found that compensation arrangements based on a percentage of sales "appear to be associated with an increased potential for program abuse." OIG Advisory Opinion No. 99-3, 1999 HHS OIG Adv. Op. LEXIS 37, 1999 WL 34984727, at \*6 (Mar. 23, 1999). These types of arrangements are subject to greater scrutiny, because their inclusion suggests that

the parties' actions under the Agreement could be motivated by their desire and ability to increase sales of ... products that might be paid for by federal or state health care programs. Regardless of which party was to be responsible for the marketing of the Zimmer products, the end result would be the same: the more products sold, the more money the parties would make.

Id. at 271 (quoting *Zimmer, Inc. v. Nu Tech Med., Inc.*, 54 F. Supp. 2d 850, 862-63 (N.D. Ind. 1999)).

In the instant case, the Agreement between 340B Management and Blue Star provided, in relevant part, as follows:

3. It shall be the obligation of [340B Management] to devote his [sic] best time and energies to the business of [Sacks Medical Corporation/Blue Star] in obtaining Centers that qualify for the 340B Program and have contracts executed with [Sacks Medical Corporation/Blue Star].

4. Once having obtained a qualified Center that is contracted with [Sacks Medical Corporation/Blue Star], it shall be [340B Management's] responsibility to review periodically its accounts and maintain the ongoing relationship with the center. [Blue Star's] responsibility is to service the center with all of the normal daily operations of a mail order pharmacy and any additional pharmacy services needed under the 340B program.

...

6. In consideration of the services to be rendered by [340B Management] and particularly in obtaining Centers for the 340B Program, it is agreed that the profits of that operation

derived from the Center or Centers shall be distributed fifty (50%) percent to [Blue Star] and fifty (50%) percent to [340B Management] on a quarterly basis payable within fifteen (15) days after the conclusion of each quarter.

...

8. [340B Management] shall have the continued responsibility for servicing each Center which he [sic] has developed for [Sacks Medical Corporation/Blue Star] and for so long as the relationship between [Sacks Medical Corporation/Blue Star] continues with the Center or Centers. [340B Management] shall continue to receive the consideration previously set forth.

9. In the event a Center terminates for any reason their relationship with Sacks/Blue Star, then [340 Management] shall no longer receive any distribution of profits from that facility and will receive an accounting up to the date of termination. However, any patients from terminated center that continues to use Blue Star after center terminates contract with Blue Star, [340 Management] will receive 50% of net profits.

Agreement, ¶¶ 3, 4, 6, 8, 9 (emphasis added).

Under the Agreement, 340B Management was responsible for "obtaining Centers that qualify for the 340B Program and have contracts executed with [Blue Star]." Agreement, ¶ 3. Thus, pursuant to the Agreement, 340 Management would receive remuneration "in return for arranging for or recommending" the services of Blue Star, "for which payment may be made in whole or in part under a Federal health care program[.]" 42 U.S.C.A. § 1320a-7b(b)(1)(B). Similar to the interpretation of the AKS applied by federal courts, performance under this Agreement is the type of conduct that the broad language of the AKS was enacted to prevent. The "safe harbor" provisions afford no relief, as 340B

Management's remuneration "takes into account the volume and value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare...." 42 C.F.R. § 1001.952(d)(5).

We additionally observe that, upon the termination of the relationship between a center and Blue Star, 340B Management would receive remuneration for directly arranging with the patient to purchase items from Blue Star, and its remuneration, again, would not fall within the "safe harbor" provisions, as it would take into account the value of referrals and business generated. See 42 U.S.C.A. § 1320a-7b(b)(1)(B); 42 C.F.R. § 1001.952(d)(5).

Thus, the plain language of section 42 U.S.C.A. § 1320a-7b(b)(1)(B) would bar 340B Management to receive remuneration "in return for ... arranging for purchasing" the products of Blue Star, "for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C.A. § 1320a-7b(b)(1)(B) (emphasis added). We agree with the trial court's conclusion that the Agreement is unenforceable, in that it contemplates a business arrangement that is prohibited by § 1320a-7b(b)(1)(B). Accordingly, we cannot grant 340B Management relief on this claim.

In its second claim of error, 340B Management argues that it is entitled to a new trial as to its breach of contract claim. Brief for Appellant

at 40. 340B Management argues that the trial court improperly found that the Agreement was illegal on its face, because the terms of the Agreement allow for performance without violation of the statute. *Id.* 340B directs our attention to language in the Agreement that 340B Management was to additionally review the accounts and maintain an ongoing relationship with the health care centers. *Id.* 340B Management argues that the Agreement required it to have continued responsibility for “servicing” each health care center. *Id.* at 41. According to 340B Management, “[t]hese substantial and important services” “would not be considered ‘arranging or recommending’ under the [AKS].” *Id.* at 42.

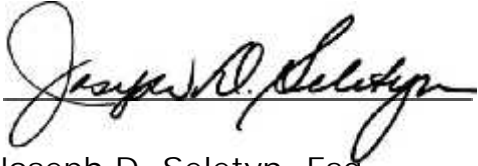
Our review of the Agreement discloses that 340B Management’s compensation was “determined in a manner that takes into account the volume of value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare[.]” 42 C.F.R. § 1001.952(d)(5). Restricting 340B Management’s obligation under the Agreement to only “servicing” the healthcare centers would restructure 340B Management’s obligations, thereby impacting the compensation which it would be owed. This Court will not reform the parties’ Agreement to nullify its illegal portions, retain its legal provisions,

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and yet retain the same compensation structure. As a result, we cannot grant 340B Management relief on this claim.<sup>4</sup>

Judgment affirmed.

Judgment Entered.

A handwritten signature in black ink, appearing to read "Joseph D. Seletyn", written over a horizontal line.

Joseph D. Seletyn, Esq.  
Prothonotary

Date: 12/19/2017

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<sup>4</sup> 340B Management's claim that Shim and Jake were aware of the Agreement's violation of the AKS affords no relief, as knowledge by either party does not change the ultimate conclusion that the Agreement is the type of transaction prohibited by 42 U.S.C.A. § 1320a-7b(b)(1)(B).