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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FOURTH APPELLATE DISTRICT

DIVISION THREE

GEMMEL PHARMACY GROUP, INC.,

Plaintiff and Respondent,

v.

TOBY DOUGLAS, as Director of
Department of Health Services, etc.

Defendant and Appellant.

G049322

(Super. Ct. No. CIVRS1010447)

O P I N I O N

Appeal from a judgment of the Superior Court of San Bernardino County,
Joseph R. Brisco, Judge. Affirmed.

Kamala D. Harris, Attorney General, Julie Weng-Gutierrez, Senior Assistant
Attorney General, Jennifer M. Kim and Carmen D. Snuggs, Deputy Attorneys General, for
Defendant and Appellant.

Gresham Savage Nolan & Tilden, Theodore K. Stream and Jamie E. Wrage
for Plaintiff and Respondent.

Gemmel Pharmacy Group, Inc., doing business as San Antonio Infusion Pharmacy (hereafter San Antonio), is a retail pharmacy contracted to provide pharmacy services to beneficiaries enrolled in the Medi-Cal program administered by the Department of Health Services for the State of California (the Department). From 2001 to 2004, San Antonio filled prescriptions for Medi-Cal beneficiaries for antihemophilic blood factor (AHF), an extraordinarily expensive life-sustaining product required by hemophiliacs. During the relevant time period, the Department's AHF reimbursement methodology allowed a provider to be paid its AHF "acquisition cost" plus one-percent.

In 2007, the Department conducted an audit of almost \$8 million in AHF claims submitted by San Antonio, determined it had overpaid San Antonio by over \$3 million, and demanded a refund from San Antonio. Its reasoning, affirmed by its Chief Administrative Law Judge (ALJ), was because the wholesale pharmacy (which was not a Medi-Cal contracted provider) that provided San Antonio with AHF for resale performed many functions associated with "filling" a prescription before sending it to San Antonio to be dispensed, the wholesaler was the "true provider" of AHF to Medi-Cal beneficiaries, and San Antonio was in a "de facto" partnership with the wholesale pharmacy. Thus, San Antonio's acquisition cost was limited to what the wholesale pharmacy paid manufacturers for AHF. The trial court granted San Antonio's petition for writ of administrative mandamus (Code Civ. Proc., § 1094.5), finding there was no substantial evidence to support the finding San Antonio was not the provider of AHF to Medi-Cal beneficiaries. The Department, through its director Toby Douglas, appeals contending the ALJ's decision is supported by substantial evidence, and therefore the trial court's ruling must be reversed. We reject its contentions and affirm the judgment.

FACTS & PROCEDURE

AHF

AHF is a blood clotting product used by patients with hemophilia prophylactically and on an emergency basis. In response to the outbreak of HIV/AIDS and

Hepatitis C in the 1980's, new technologies were developed to improve the safety of AHF driving the cost up dramatically. The majority of hemophilia patients receive comprehensive care through hemophilia treatment centers (usually hospital based), but because of the high expense involved in handling and storage of AHF, patients usually receive their AHF from home care companies (usually pharmacy based).

AHF Reimbursement Methodology

At the relevant times, the administrative regulation governing Medi-Cal reimbursement for AHF, California Code of Regulations, title 22, section 51525, provided, "Payment will be made for *reasonable costs* subject to maximums which may be established by the Director [of the Department]." (Italics added.) In the mid 1980's, the Director established a reimbursement formula that allowed AHF providers to be paid either a fixed .20 cents per AHF unit dispensed or the provider's AHF per unit acquisition cost plus one percent. By January 2001, the Department stopped using the .20 per unit formula, allowing reimbursement only based on the acquisition cost. When billing Medi-Cal, the provider had to provide an invoice that included the manufacturer's name and identified the product, and a certification stating the per unit acquisition cost.

But even the acquisition cost plus one percent formula was a significant disincentive to Medi-Cal providers. Most other states and Medicare had a billing formula based on a published average wholesale price. In the mid 1990's, a company called Quantum Health Resources (Quantum) that had been one of the major providers of AHF to Medi-Cal patients was audited by the Department and litigation ensued. Quantum had been receiving discounts from AHF manufacturers and did not account for those discounts in billing the Department based on per unit acquisition costs. The litigation between the Department and Quantum settled in October 1995, with Quantum agreeing to reimburse the

Department for the unreported discounts, and the Department agreeing to reassess its reimbursement methodology.¹

Nonetheless, in December 1995, Quantum's general counsel wrote to John Rodriguez, the Department's Deputy Director for Medical Services, confirming Quantum could no longer afford to be a retail provider of AHF to Medi-Cal and the other state funded programs under the Department's reimbursement methodology. He explained the other two major providers of AHF (Caremark and Coram) had also indicated they would no longer accept referrals of AHF patients covered by the state programs. To avoid disruption of AHF supplies to state program patients, Quantum proposed it would instead become a wholesale supplier of AHF. Quantum would sell AHF to the retail provider (pharmacy) at a mark up from the price it paid the manufacturer and the retail pharmacy would dispense the AHF to patients and bill Medi-Cal at its acquisition cost from Quantum, plus one percent. Quantum would provide support services to the patient such as coordinate AHF prescriptions with physicians, provide continuing education to patients on AHF use and benefits, and maintain 24-hour patient emergency hotlines. It would provide services to the retail provider including maintaining adequate supplies of AHF to service the provider's patients, deliver the AHF to the provider with appropriate packaging and shipping to deliver to patients and have ability to make emergency deliveries, assist with reimbursement processing, and record keeping.

In response to Quantum's letter, by a letter dated December 27, 1995, Rodriguez wrote Quantum the Department approved its proposal so as to avoid interruption of patient access to AHF (the Rodriguez letter). The Department's conditions were the prices Quantum charged the retail pharmacy must be "reasonable"; Quantum could not

¹ Eventually, legislation was enacted in August 2003, establishing a new reimbursement formula allowing providers to be reimbursed 120 percent of the "average sales price" charged by AHF manufacturers. (Welf. & Inst. Code, § 14105.86.) The audit at issue here concerns San Antonio's AHF billings to Medi-Cal before the new reimbursement methodology went into effect.

serve as both the wholesale supplier and retail provider of AHF; and the retail “billing provider” could not be under the control or ownership of Quantum. Moreover, the Department cautioned this was only an interim solution to the AHF reimbursement problem, until the Department concluded its studies on the reimbursement methodology.

The Pharmacy Agreement

In April 2001, National Cooperative Healthcare Services, Inc. (National), entered into a pharmacy agreement with San Antonio (the Pharmacy Agreement). National was primarily a wholesale pharmacy (although for a brief period of time it also had a retail division). It was not a licensed Medi-Cal provider. Its Medi-Cal application was denied because it did not meet the requirements for an established place of business adequate for Medi-Cal licensing (such as no on-site pharmacist in charge, not regularly dispensing medications directly to patients, no cash register to accept payments from patients, no documentation it had ability to bill insurance). San Antonio, a licensed retail pharmacy, was an enrolled Medi-Cal provider. There was no common ownership or control between National and San Antonio.

The Pharmacy Agreement provided National was in the business of marketing and selling AHF and other plasma derived therapeutic agents. National appointed San Antonio as a “non-exclusive distributor” of those products. National would deliver to San Antonio the AHF necessary to fill a patient’s prescription with an invoice and upon receipt of patient’s payment for the AHF, San Antonio would remit the invoice amount less 1.2 percent (called the pharmacy fee) to National. National would perform all the insurance billing and collection services for San Antonio. San Antonio would be solely responsible for dispensing and labeling the AHF for delivery to patients in accordance with the patient’s prescription. The Pharmacy Agreement contained a no solicitation clause prohibiting San Antonio from soliciting those patients who purchased AHF from San Antonio after expiration of the Pharmacy Agreement for seven years.

Thereafter, San Antonio began dispensing and providing AHF supplied to it by National to hemophilia patients. The interactions between National and San Antonio will be discussed in more detail anon. In general, the AHF prescription would initially be received by National from the patient or the relevant hemophilia treatment center and National's director of pharmacy, Richard Aguilar, would transfer the prescription to San Antonio. National's non-pharmacist staff would pull the necessary quantities of AHF from its inventory to fill the prescription, and ship the AHF to San Antonio in appropriate packaging and usually with other necessary infusion supplies (such as sterile water and syringes). San Antonio's pharmacist would dispense the AHF to the patient by confirming the quantities prescribed and labeling the vials of AHF for patient use and shipping the AHF out to the patient. National would prepare San Antonio's Medi-Cal billing using the amount National invoiced San Antonio for the AHF as the acquisition cost and when San Antonio received Medi-Cal payment it would remit the invoice amount back to National less the pharmacy fee.

National's pharmacist Aguilar was highly experienced in handling AHF and dealing with hemophilia patients. Many of the patients National referred to San Antonio, had followed Aguilar from the pharmacy he worked at before National. Sometime after the audit period involved in this case (and after the new regulations governing reimbursement rates for AHF were adopted) Aguilar and his wife (also a pharmacist on contract at National) started their own retail pharmacy, Aero Apothecary (Aero), which was approved as a Medi-Cal provider. Most of the patients who had been getting their AHF from San Antonio eventually followed Aguilar to Aero.

The Audit

In 2007, the Department conducted an audit of San Antonio's AHF billings to Medi-Cal from June 6, 2002, through May 24, 2004. The audit covered the billings for 10 patients during the two-year audit period (San Antonio's entire AHF billings). During that time, Medi-Cal paid \$7,759,987 on San Antonio's claims. The auditor, Ace Bautista

determined San Antonio had “falsely represented” it provided the billed services because he determined National was “the actual provider” of the AHF to Medi-Cal beneficiaries. Based on National’s costs associated with acquiring the AHF from manufacturers, the Department determined San Antonio had been overpaid by more than \$3 million.

The auditor’s findings were based on facts about Aguilar’s interaction with hemophilia patients’ care providers (e.g., doctors and hemophilia treatment centers), the actions taken by both companies in dispensing and packaging the AHF, and the way the Medi-Cal claims were billed. The hemophilia treatment centers’ records typically listed National (not San Antonio) as the patient’s chosen pharmacy, and the AHF prescriptions were typically sent by the hemophilia treatment centers directly to Aguilar at National. Staff at hemophilia treatment center’s often communicated directly with Aguilar about patients’ AHF needs. Thus, the auditor concluded Aguilar performed the pharmacist duties of receiving prescriptions and consulting with patients and doctors. Once National received a Medi-Cal patient’s prescription, the prescription was transferred to San Antonio, and National’s owner, Espinosa, and his brother pulled the precise amount of AHF required for the prescription from its inventory, and packaged it for delivery. Espinosa and his brother were not pharmacists or pharmacy technicians but licensed exemptees. The AHF was then shipped to San Antonio and often delivered to patients by San Antonio the same day. National paid the shipping costs. San Antonio did not actually store any AHF inventory at its facility. National did the Medi-Cal billing for San Antonio, and no money changed hands until San Antonio received payment from Medi-Cal. Moreover, although Espinosa and his brother pulled and packaged the Medi-Cal patients’ AHF from National’s inventory, when the prescription was for a private pay patient, Aguilar pulled the AHF from inventory, and he dispensed it to those patients directly. Thus, the auditor concluded National had the ability and licensing to fill and dispense AHF prescriptions, and were it not for the fact it was not an approved Medi-Cal provider, there would have been no reason for it to contract with San Antonio to fill Medi-Cal prescriptions. Accordingly, the auditor determined

National was the actual pharmacy rendering AHF services to the Medi-Cal beneficiaries and San Antonio's reimbursement amounts should not have exceeded National's acquisition costs.

The Administrative Hearing

San Antonio appealed the Department's audit decision and an administrative hearing was held before Administrative Law Judge (ALJ) Dwight V. Nelsen. There were three main issues litigated at the administrative hearing: (1) whether San Antonio was a provider of the billed pharmacy services; (2) whether the Department's acquisition cost plus one percent reimbursement methodology constituted an illegal "underground regulation" because it was not approved in accordance with the Administrative Procedures Act and conflicted with the only regulation, California Code of Regulations, title 22, section 51525, which requires reimbursement for "reasonable costs"; and (3) whether the Department was estopped to challenge the arrangement between National and San Antonio because it had specifically approved of such arrangements via the Rodriguez Letter in the Quantum matter.

Barry Vantinger was the owner and vice president of San Antonio. He is not a pharmacist. Vantinger testified that prior to entering into the agreement with National, San Antonio was not in the AHF business but wanted to get into it. He learned about AHF distribution practices from his sister-in-law, a pharmacist in Northern California, whose pharmacy dispensed AHF. He learned National was looking for a retail pharmacy to dispense AHF. He negotiated the Pharmacy Agreement with David Espinosa. He was not personally familiar with the reimbursement methodology set forth in the Medi-Cal providers manual (acquisition plus one percent), and relied on National for billing and pricing. Vantinger understood the National/San Antonio agreement to be the same practice his sister-in-law's pharmacy used.

Vantinger testified it was standard procedure for Medi-Cal providers to rely on contractors to do the Medi-Cal billing and to understand the applicable reimbursement rates. Vantinger thought the Pharmacy Agreement was a good low risk arrangement because

of the services National was providing as wholesaler. Under the Pharmacy Agreement, San Antonio's pharmacist was dispensing and was responsible for making sure the AHF was delivered properly. San Antonio could not have provided the services required in handling AHF (and the carrying costs of a product that cost upwards of \$35,000 per prescription) for manufacturers price plus one percent.

Aguilar was National's director of pharmacy; his wife was National's pharmacist in charge. They were contractors, not employees, and had no ownership in National, and National had no ownership interest in the retail pharmacy they later started, Aero. Aguilar had extensive experience with AHF and hemophilia patients. He explained because the patient population is small (about 2,000 in California), very few pharmacists have his level of expertise. Aguilar had worked for other pharmacies that dispensed AHF, and some of the patients followed him to National.

Aguilar testified that at National, AHF prescriptions for Medi-Cal beneficiaries were handled completely differently than for private patients and he had no role in dispensing the Medi-Cal patient prescriptions. On the few occasions that National had private pay patients, and it also had a retail pharmacy license, Aguilar was the dispensing pharmacist for those private patients.

When *dispensing* AHF to private patients, Aguilar would receive the prescription, if necessary confer with the patient's physician to make sure the prescription was correct, confirm the patient's information, pull and inspect the AHF product, label the product, perform clinical functions of confirming the particular AHF was appropriate for the patient's type of hemophilia and whether there were other drug interaction issues, oversee the packaging of all other infusion supplies to make, and oversee the private insurance billing to make sure it was correct as to the number of units dispensed and the price.

When a Medi-Cal prescription was involved, Aguilar's involvement was markedly less. He would typically receive the AHF prescription from the patient representative of hemophilia treatment centers (in particular City of Hope or Los Angeles

Children's Hospital) and immediately transferred the Medi-Cal patient prescription to San Antonio and National's wholesale division. Aguilar testified he was not the dispensing pharmacist and had no role in filling the prescription. Espinosa and his brother pulled the necessary AHF quantities for filling Medi-Cal prescriptions (and related infusion supplies) from inventory and sent the product to San Antonio to be dispensed. Because the product was so expensive, only the exact quantity specified in the prescription would be shipped. Sometimes Aguilar would take care of getting a prescription refill authorized because of his relationship with the hemophilia treatment centers professionals, and then transfer the refill prescription to San Antonio. Aguilar did not oversee Medi-Cal billing for AHF—the billing was done by Lauran Niemi, who was a National employee.

Espinosa, owner of National, testified he started National as a wholesale pharmacy. It had a retail license for a while, and during that time AHF prescriptions for private pay patients would be dispensed by Aguilar. Prescriptions for Medi-Cal patients would be faxed to National by the hemophilia treatment centers. Once National confirmed the Medi-Cal coverage, he or his brother would pull the requisite inventory, and send it to the contracting retail pharmacy (such as San Antonio) with the prescription only and no other specific patient information. Niemi in his office would prepare the Medi-Cal billing for the retail pharmacy. Espinosa testified all wholesale pharmacies mark up their price when they sell product to retail pharmacies. The invoiced wholesale amount was always the average wholesale price for AHF as published in the "Red Book" and which was the price set by Medicare and most states for reimbursement. There was no common ownership between National and San Antonio. When Aguilar started Aero, National began sending most of its Medi-Cal patients to it.

Espinosa agreed that if National had been approved as a Medi-Cal provider, it had the ability to dispense AHF directly to Medi-Cal patients. However, it would never have been able to afford to do so under the Department's acquisition cost plus one percent. He explained that given the exorbitant cost of AHF, the expense involved in maintaining,

storing, handling, and shipping inventory, and the average 70 to 90 days to receive payment from Medi-Cal, “nobody could be in the business at cost-plus-[one] percent.” That was his understanding as to why the Department had approved the Quantum approach, which was understood by everyone in the AHF community.

Shula Bernstine was San Antonio’s pharmacist in charge. Bernstine testified she dispensed the AHF to patients and performed all steps required by law of a dispensing pharmacist. Bernstine explained the single most important duty of a pharmacist in filling a prescription is the proper labeling of the product for patient use. She explained that AHF comes as a dry powder in small vials that must be reconstituted for intravenous use by the patient. The number of units in a vial can vary and one vial does not necessarily equal one dose. A doctor will prescribe a range of units per dose and a number of doses. The pharmacist must look at the range of units per dose and the number of doses to come up with the total units for the prescription, and then look at the individual vials and the number of units per vial to decide how many vials. The Medi-Cal patient prescriptions would generally be transferred to San Antonio from National, but sometimes came directly from doctors’ offices. Bernstine testified it is very common to have prescriptions transferred from other pharmacies, for retail pharmacies to buy products from wholesale pharmacies, and in the case of very expensive drugs, to only buy the exact amount needed to fill the specific prescription.

Bernstine explained that in dispensing AHF, she (or another San Antonio pharmacist performing the dispensing function) would first receive the product as shipped to her by National. It would be in the manufacturer’s box, and unlabeled just like any other drug purchased from a wholesale pharmacy. Although someone at National pulled the quantity of AHF needed to fill the prescription, the product as delivered could not legally be dispensed to the patient because it had not been checked by a pharmacist and properly labeled for patient use in accordance with the prescription. National (Aguilar) did not perform any of these functions. The AHF would be in special packaging to safely ship it to

her from National, with the unlabeled manufacturers' boxes inside on ice. The prescription would typically have been faxed over from National. Sometimes Bernstine would discuss the prescription requirements with Aguilar; she typically did not talk directly to the doctors or hemophilia treatment centers. Bernstine would check each of the vials, and confirm the number of units in each and the units per dose required by the prescription. She would enter the patient information into San Antonio's computer system and prepare pharmacy labels for the prescription. Sometimes, if the vials were from different manufacturers and different lots with different expiration dates, she had to label each vial separately. But if the vials were all from the same manufacturer, same lot, and same expiration date, in her professional judgment she could bundle them and put in one baggie with one pharmacy label. She would then repackage the AHF with ice packs and ship it to the patient or contact the patient representative or case manager to come pick it up. Bernstine agreed that if National had the proper retail license and was an approved Medi-Cal provider, it could have dispensed directly.

Bautista, the Department's auditor testified he had a degree in accounting. He concluded National was the "main player" for the hemophilia patients because once the reimbursement method changed most of the San Antonio patients followed Aguilar to his new pharmacy. In his opinion, National performed most of the patient services because it typically was where the prescription was first sent, its personnel identified the quantity of AHF called for by the prescription and they pulled only the precise amount required to ship to San Antonio. All San Antonio's pharmacist did was confirm the quantity, put a label on the package, and ship it to the patient. The San Antonio pharmacist made no changes to the quantity or packaging. In his opinion, San Antonio's pharmacist did not really do anything to dispense AHF, but he could not recall if he ever questioned Bernstine about what she did in dispensing the AHF to patients.

Bautista's audit decision was also based on the fact that after the AHF was dispensed, National prepared San Antonio's Medi-Cal billing based on the amount invoiced

to San Antonio, without even including the one percent mark-up. But he agreed Medi-Cal providers are permitted to use outside billing companies. Bautista detailed how he compared each of San Antonio's specific Medi-Cal billings (which were required to list the manufacturer and lot number for the AHF that was dispensed) and National's invoice to San Antonio, to the AHF manufacturer's invoices to National for the specific lots (i.e., National's acquisition cost), and there was a significant mark-up. For example, in one case, the AHF mark up was 87 percent; in another it was 92 percent. Bautista testified that if National had been an approved Medi-Cal provider, it would not have needed to involve a retail pharmacy—it could have filled the prescriptions itself. Bautista agreed he had no training in AHF, other than having read the Medi-Cal provider manual's acquisition cost plus one percent reimbursement formula. He had no knowledge of the background or controversy over AHF reimbursement, the Quantum litigation or the Rodriguez letter. He had no idea if the acquisition cost plus one percent methodology was reasonable. He agreed no statute or regulation was violated by how the claims were submitted or the billings done. His audit conclusion was based on his belief National and not San Antonio was really the entity dispensing the AHF to Medi-Cal patients.

ALJ Nelsen's Proposed Decision

In his proposed decision, ALJ Nelsen agreed with San Antonio as to the bulk of the Department's refund demand (i.e., the \$3,038,702 demanded because National, not San Antonio was the "actual provider" of the billed services).² He concluded that because National was not an authorized Medi-Cal provider, it could not provide qualifying pharmacist services to Medi-Cal beneficiaries. National was, however, a licensed wholesale pharmacy and it was perfectly legal for it to sell products to retail pharmacies. Similarly, San Antonio had to acquire AHF somewhere to dispense to Medi-Cal beneficiaries and it was perfectly legal for it to acquire AHF from National. There was no requirement that

² There was also approximately \$141,000 in audit exceptions due to inadequate documentation for the claims or duplication of claims that ALJ Nelsen did not disturb. San Antonio does not challenge those amounts.

wholesale source must be a Medi-Cal provider. There was no prohibition against a Medi-Cal pharmacy obtaining prescriptions via a transfer from another pharmacy, and National had no choice but to transfer the prescriptions because it was not a Medi-Cal provider. There was no prohibition against San Antonio contracting with an outside company to perform billing services or to deliver pharmacy products.

ALJ Nelsen concluded the only issue was whether San Antonio provided the pharmacy services required by its license. He concluded, “The uncontested professional evidence in this matter is that [San Antonio], or [its] licensed personnel, performed all of the functions as required by its pharmacist license. [It’s] licensed professional staff acted in compliance with all statutes and regulations governing their pharmacist related duties and actions. Upon receiving the packages of the AHF from [National], [it’s] professional personnel examined and verified the contents and then prepared the package for delivery to the Medi-Cal beneficiary. This is what, at a minimum, [San Antonio] was required to perform. [¶] The fact that [San Antonio] received from [National], the wholesaler, the exact amount of AHF needed to fulfill any particular prescription does not suggest that [San Antonio] was not acting in its capacity as a Medi-Cal provider nor failing to fulfill its pharmacist responsibilities and functions. [The] Department’s characterization of [San Antonio’s] involvement with the AHF as being merely ‘ministerial’ is a bit cavalier and a tremendous understatement of the legal implications of what [San Antonio] did, especially when it is [the] Department that failed to present any professional pharmacist evidence that [San Antonio] acted inconsistent with applicable pharmacist regulations or statutes. All of the professional pharmaceutical evidence in this matter supported [San Antonio]. None supported [the] Department. [San Antonio] did what it was required to do by law.” San Antonio was not only “the ‘actual’ provider, but, . . . the legal Medi-Cal provider authorized by contract with [the] Department to engage in the dispensing of pharmaceutical products to Medi-Cal beneficiaries.” ALJ Nelsen also agreed with San Antonio that the Department’s acquisition cost plus one percent reimbursement

methodology was an “underground regulation” in violation of the Administrative Procedures Act, and that the Department was estopped to challenge the reimbursement practice it had approved of in the Quantum litigation.

The Department’s Final Decision

On April 1, 2010, ALJ Nelsen’s proposed decision was rejected by the Department’s Chief ALJ Dan L. Colson, who denied San Antonio’s appeal and upheld the Department’s full audit refund demand. The Chief ALJ agreed with the argument put forward by the Department in its final briefing that National and San Antonio were in a “de facto partnership” for dispensing AHF to Medi-Cal patients and the two companies should be treated as one. Thus, the AHF acquisition cost was falsely represented to be the price National charged San Antonio but rather was the price National paid to manufacturers. The ALJ found there was no true independence between National and San Antonio because San Antonio simply accepted the invoiced amount claimed and billed by National. San Antonio was not “buying” AHF from National, but was merely dispensing it to National’s own patients. The Chief ALJ concluded National was the true provider of AHF because it “performed all of the duties that are to be performed by a patient’s pharmacist, except that it ‘farmed out’ the final rechecking and labeling of the product. [National] prepared packages of product, each package for a specific [National] patient in the correct dosages.” (Fn. omitted.) All San Antonio’s pharmacist did was “double-check the dosages and label the vials,” something National’s pharmacists could easily have done themselves. The Chief ALJ concluded that having San Antonio perform the “final steps in the process” of dispensing AHF to patients “rather than those final steps simply being performed by [National], was nothing more than a ruse to establish [San Antonio] as a ‘straw man’ retailer so that it could be asserted . . . that [National] was an independent supplier of AHF whose invoices to [San Antonio] should be used to establish the product acquisition costs for Medi-Cal claiming. [¶] In truth, [National] had no need to involve [San Antonio] in the distribution of AHF to [National’s] patients, except that [San Antonio] had a Medi-Cal

provider number and [National] did not.” (Fn. omitted.) The Chief ALJ also rejected ALJ Nelsen’s underground regulation and estoppel findings.

Writ Petition and Judgment

San Antonio filed a petition for writ of administrative mandamus in the superior court, asking it to set aside the Department’s final decision as to the alleged overpayment of \$3,038,702. It asserted the reimbursement methodology was an invalid underground regulation, the Department was estopped to claim overpayment, and the Department’s finding San Antonio was not the “actual provider” of services was not supported by substantial evidence. The trial court granted the petition. There was no statement of decision. The trial court’s minute order stated it found, “there is not substantial evidence to support the conclusion in the [f]inal [d]ecision that [San Antonio] was not the ‘actual provider’ of AHF, but rather, a ‘de facto partner’ with the wholesale provider, [National]. There is no evidence that a [National] pharmacist actually dispenses AHF to the Medi-Cal beneficiaries or that [National and San Antonio] had any common ownership or control. The remaining issues . . . are moot.” The court entered a judgment granting a peremptory writ of mandate ordering the Department to set aside its final decision as to the claimed \$3,038,702 overpayment and the Department appealed.

DISCUSSION

Standard of Review

“The state Medi-Cal program effectuates the federal Medicaid program established under title XIX of the Social Security Act [citation], which authorizes the payment of federal funds to states to defray the cost of providing medical assistance to low-income persons. [Citation.]” (*Children’s Hospital & Medical Center v. Bonta* (2002) 97 Cal.App.4th 740, 747.) The Department administers the Medi-Cal program. (Welf. & Inst. Code, § 14000 et seq; Cal. Code Regs., tit. 22, § 50004.)

To provide services to Medi-Cal beneficiaries, a provider must be enrolled with the Department. (Cal. Code Regs., tit. 22, § 51000.30, subd. (a).) The relationship

between the state and Medi-Cal providers is essentially contractual in nature. (*California Medical Assn. v. Lackner* (1981) 117 Cal.App.3d 552, 561.) A pharmacy or pharmacist may be an enrolled Medi-Cal provider. (Cal. Code Regs., tit. 22, § 51051, subd. (b).)

The Department is authorized to inspect records and conduct audits of providers and recover overpayments. (Welf. & Inst. Code, §§ 14124.2, 14170; Cal. Code Regs., tit. 22, § 51458.1.) A provider aggrieved by the Department's audit findings may invoke an administrative appeal process. (Welf. & Inst. Code, § 14171.) The grievance is heard in an evidentiary hearing before an ALJ. The Department may reject the ALJ's proposed decision and issue a final decision, which is then subject to judicial review via administrative mandate under Code of Civil Procedure section 1094.5. (Welf. & Inst. Code, § 14171, subsd. (f) & (j).)

The trial court's inquiry in administrative mandamus "extend[s] to the questions whether the [agency] has proceeded without, or in excess of, jurisdiction; whether there was a fair trial; and whether there was any prejudicial abuse of discretion." (Code Civ. Proc., § 1094.5, subd. (b).) Abuse of discretion is established if the [agency] has not proceeded in the manner required by law, the order or decision is not supported by the findings, or the findings are not supported by the evidence. (Code Civ. Proc., § 1094.5, subd. (b).)" (*Kifle-Thompson v. State Bd. of Chiropractic Examiners* (2012) 208 Cal.App.4th 518, 523.)

"Where, as here, the trial court was called upon to decide whether an agency's administrative decision was supported by substantial evidence, the function of the appellate court is the same as that of the trial court, that is, to review the administrative decision to determine whether it is supported by substantial evidence. [Citation.] 'Substantial evidence has been defined as relevant evidence that a reasonable mind might accept as adequate support for a conclusion. [Citation.] A presumption exists that an administrative action was supported by substantial evidence. [Citation.]" (*Bhatt v. State Dept. of Health Services* (2005) 133 Cal.App.4th 923, 928 (*Bhatt*).)

Here, the Department contends there is sufficient evidence to support the Department's finding San Antonio was not the "actual" or "sole" provider of AHF to Medi-Cal beneficiaries but was in a de facto partnership with National, and therefore under the reimbursement formula applicable during the audit period, San Antonio's reimbursement is limited to National's AHF acquisition cost. Therefore, the Department argues the trial court erred by granting San Antonio's petition for writ of administrative mandate. We agree with the trial court there is no substantial evidence to support the Department's findings.

Substantial Evidence

San Antonio was an enrolled Medi-Cal provider authorized to dispense drugs to Medi-Cal beneficiaries. Business and Professions Code section 4024 defines "dispense" as "means the furnishing of drugs or devices upon a prescription from a physician" (See also Health & Saf. Code, § 11010 [under Controlled Substances Act, "'Dispense' means to deliver a controlled substance to an ultimate user . . . pursuant to the lawful order of a practitioner, including the prescribing, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery".])

The Department contends San Antonio did not dispense the AHF to Medi-Cal beneficiaries because National performed many of the functions required of a pharmacy or pharmacist, and were it not for the fact National was not a Medi-Cal provider, it could have dispensed the AHF itself. The Department relies on California Code of Regulations, title 16, section 1793.1, which sets forth duties that only a licensed pharmacist may perform and details how National performed many of those functions. For example, only a pharmacist may "[r]eceive a new prescription order orally from a prescriber or other person authorized by law." (Cal. Code Regs., tit. 16, § 1793.1, subd. (a).) The Department points out that National's pharmacist Aguilar received most if not all of the prescriptions directly from the physicians. Only a pharmacist may "[i]dentify, evaluate and interpret a prescription" (Cal. Code Regs., tit. 16, § 1793.1, subd. (c)), or "[s]upervise the packaging of

drugs and check the packaging procedure and product upon completion” (Cal. Code Regs., tit. 16, § 1793.1, subd. (f)). The Department argues National fulfilled both of these functions when its staff identified the appropriate quantities of AHF to pull from its inventory for the specific AHF prescription and packaged the inventory for shipment to San Antonio in packaging appropriate for subsequent delivery to the patient. The Department argues the evidence supports its conclusion that all San Antonio’s pharmacist did to “dispense” AHF was check the quantities were correct, put its own pharmacy label on the packages, and ship the AHF back out to the patient—final dispensing functions National could easily have performed as well. Moreover, the Department argues the evidence demonstrates National and San Antonio were effectively in a partnership to fill AHF prescriptions for Medi-Cal beneficiaries (and thus were one and the same company) because the AHF shipped from San Antonio to the patient on the same FedEx account and invoice number, National did the Medi-Cal billing, there is no evidence San Antonio negotiated the price National charged for the AHF, and no money changed hands until San Antonio received Medi-Cal payment for the claim.

We reject the Department’s arguments. The question is not what National did, but what San Antonio, the licensed Medi-Cal provider, did. If San Antonio performed the essential services required by a licensed pharmacy in providing AHF to Medi-Cal patients, then it was the provider. The fact National also performed some of these functions (or even that it was capable of dispensing AHF had it been approved as a Medi-Cal provider) does not make San Antonio any less the provider. The Department’s reliance on *Bhatt, supra*, 133 Cal.App.4th 923, is misplaced because in that case the non-enrolled dentist provided all the professional services but billed through an enrolled party, who provided no services. The uncontroverted evidence here showed San Antonio provided the essential professional pharmacist AHF dispensing services to the Medi-Cal beneficiaries.

The only professional testimony regarding the duties of a pharmacist or pharmacy came from San Antonio’s pharmacist in charge, Bernstine, and National’s

director of pharmacy, Aguilar. Both testified in effect that the sine qua non of a pharmacist's job filling a prescription is confirming the pharmaceutical product dispensed conforms to the quantity and dose called for by the prescription and properly labeling the product for patient use. There is no evidence in the record supporting the conclusion San Antonio did not fulfill its legal duties as a licensed pharmacy in verifying the medication called for by the prescription, confirming the quantity of medication called for by the prescription, and properly labeling it before dispensing it to the patient.

Bernstine testified as to San Antonio pharmacists' actions in dispensing AHF. Although prescriptions were initially received by Aguilar, who had unique expertise in handling AHF prescriptions, National was not a Medi-Cal provider and it could not fill or dispense them. The prescriptions were transferred to San Antonio and transferring prescriptions between pharmacies is common and perfectly legal. (See Bus. & Prof. Code, § 4052, subd. (a)(2) [pharmacist may transmit a valid prescription to another pharmacist].) Thus, even though the prescription originated with National, San Antonio fulfilled the requirement that only a pharmacist may "[r]eceive a new prescription order orally from a prescriber or other person authorized by law." (Cal. Code Regs., tit. 16, § 1793.1, subd. (a).)

Bernstine explained that when an order for AHF was made, National (a licensed wholesale pharmacy) would pull the proper AHF product from its inventory and ship it to San Antonio. She testified it was quite common for retail pharmacies to buy pharmaceuticals from wholesalers, and in the case of very expensive drugs, to only buy the exact amount needed to fill the specific prescription. The Department's auditor, Bautista, conceded National could not fill the Medi-Cal patient prescriptions and it was a licensed wholesale pharmacy. He agreed San Antonio had to get the AHF from somewhere, and there was absolutely no prohibition against it acquiring AHF from a wholesaler as opposed to directly from the manufacturer. Moreover, we note nothing in the Medi-Cal provider

manual required the provider to acquire AHF directly from the manufacturer as opposed to acquiring it from a wholesaler.

The only evidence in the record is that when National received an AHF prescription, the AHF inventory was not pulled or shipped by a National pharmacist, a National pharmacist did not interpret and fill the prescription, and the AHF product was shipped to San Antonio in the manufacturer's boxes unlabeled by any pharmacist. Aguilar testified when he received an AHF prescription for a Medi-Cal beneficiary he transferred the prescription to San Antonio and sent the order to National's wholesale division. Non-pharmacists at National (Espinosa and his brother) packaged the necessary AHF (and related infusion supplies) from inventory and sent the unlabelled product to San Antonio to be dispensed.

Bernstine testified that when the AHF was received by San Antonio, its pharmacist opened the package and examined the vials of AHF to ensure it had the correct product, the correct dosage, and the product comported with the prescription's requirements. She explained that because there are different types of AHF prescribed in different units with different units in each vial, the product had to be carefully checked by a licensed pharmacist and properly labeled before it could be sent to the patient. Thus, San Antonio's pharmacist identified, evaluated, and interpreted the prescription. (Cal. Code Regs., tit. 16, § 1793.1, subd. (c).) San Antonio's pharmacists did not simply glance at a package from the manufacturer and slap on a label. The AHF came from National with only the manufacturer's labeling—there was no pharmacist label. There are strict requirements for proper labeling prescription medications set forth in Business and Professions Code section 4076. San Antonio's pharmacist was responsible for ensuring the proper labeling was done and the Department presented no evidence its pharmacists did not do all legally required labeling. The San Antonio pharmacist performed all the proper labeling functions for the prescription. Moreover, Bernstine testified that when San Antonio received an AHF prescription, its pharmacist would enter all requisite patient information into San Antonio's

computer system before preparing a pharmacy label for the prescription, and maintain the prescription in its records for refills—again an essential function of the pharmacy dispensing AHF. (See Cal. Code Regs., tit. 16, § 1707.1 [detailing pharmacy’s legal duty to maintain medication profiles on all patients who have prescriptions filled in that pharmacy].)

The Department cannot rely upon auditor Bautista’s testimony that in his opinion San Antonio did not really do anything in the dispensing process—he agreed he had never questioned San Antonio’s pharmacists as to what they did. The Department presented no expert testimony from any pharmacist contradicting Bernstine’s and Aguilar’s testimony about what the legal duties of a pharmacist are and what each pharmacy did in fulfilling those duties. In short, the uncontroverted testimony was that the AHF arrived unlabeled from National where it was checked, labeled, repackaged, and dispensed by a San Antonio pharmacist to the Medi-Cal patient. Thus, San Antonio’s pharmacists fulfilled the duty to “[s]upervise the packaging of drugs and check the packaging procedure and product upon completion.” (Cal. Code Regs., tit. 16, § 1793.1, subd. (f).)

We turn then to the complete lack of evidence supporting the Department’s conclusion National and San Antonio had formed a partnership and thus the two companies should be treated as one. That after all was in effect its justification for its otherwise completely inconsistent conclusion San Antonio was not the provider of AHF to Medi-Cal beneficiaries, yet it should be reimbursed based on National’s acquisition cost.

“An essential element of a partnership or joint venture is the right of joint participation in the management and control of the business. [Citation.] Absent such right, the mere fact that one party is to receive benefits in consideration of services rendered . . . does not, as a matter of law, make him a partner or joint venturer. [Citations.]” (*Bank of California v. Connolly* (1973) 36 Cal.App.3d 350, 364.) There is no evidence National and San Antonio were partners, or as the Department called them “de facto partners.” The uncontroverted evidence was there was no joint ownership or control between the two companies. The two companies had a contractual arrangement whereby

San Antonio would be the retail dispensing pharmacy for AHF products which National sold. The mutual financial benefit of that contractual relationship does not make them partners.

The Department relies on the various administrative services provided by National including billing and paying for shipping, but those are not functions required to be performed by a retail provider. (Cal. Code Regs., tit. 16, § 1793.1, subds. (a)-(g)). Moreover, we are not persuaded by the Department's insistence that because the AHF was marked up in price from National to San Antonio, and San Antonio did not negotiate the wholesale price, the two companies were not operating at "arms-length" and were in effect partners in the business dispensing AHF at inflated prices. As the first ALJ observed, to dispense AHF, San Antonio had to acquire it from somewhere. There was no prohibition against it acquiring AHF from a wholesale pharmacy as opposed to directly from the manufacturer. There was no evidence that other than the fact of a mark up from what National paid manufacturers for the specific lot of AHF later dispensed by San Antonio—which in most cases was around 80 percent, but in at least one case was as high as 142 percent—that National's wholesale price did not reasonably reflect the extraordinary high costs associated with acquiring and maintaining inventory from manufacturers to keep AHF available to hemophilia patients not only on prophylactic basis but on an emergency basis, the storage and handling costs and the costs of carrying the inventory while awaiting Medi-Cal's 60 to 90-day claim processing time. The only evidence in the record is that the price National invoiced San Antonio for the AHF was the average wholesale price as published in the Red Book, which was the basis for AHF reimbursement used by Medicare and most other states. Thus, there is no support for the Departments claim National was arbitrarily setting its wholesale price for the AHF.

In sum, we agree with the trial court the Department's conclusion San Antonio was not the provider of AHF to Medi-Cal beneficiaries but was National's partner in dispensing AHF, is not supported by substantial evidence. Accordingly, we affirm the trial

court's judgment granting a peremptory writ of mandate ordering the Department to set aside its final decision as to the claimed \$3,038,702 overpayment.

DISPOSITION

The judgment is affirmed. Respondent is awarded its costs on this appeal.

O'LEARY, P. J.

WE CONCUR:

RYLAARSDAM, J.

MOORE, J.