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CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION TWO

CALIFORNIA ASSOCIATION OF MEDICAL PRODUCTS SUPPLIERS, Plaintiff and Appellant, v. DAVID MAXWELL-JOLLY, as Director, etc., et al. Defendants and Respondents.	A126749 (Alameda County Super Ct. No. RG09438893)

Appellant California Association of Medical Products Suppliers (CAMPS) appeals from the trial court's denial of its petition for a writ of mandate and complaint for declaratory and injunctive relief. CAMPS argues the trial court should have granted its petition, in which it sought the invalidation of regulations adopted in 2004 by respondent California Department of Health Care Services (Department). The regulations set upper billing limits for providers of durable medical equipment and certain medical supplies to Medi-Cal recipients.

According to the Department, these upper billing limit regulations (UBL) close a loophole in Medi-Cal regulations, under which some providers were purchasing discounted products, or obtaining them at no cost, and billing Medi-Cal for reimbursement without taking into account the actual product purchase prices. As a result, they were able to obtain significant profits at taxpayer expense. The UBL closes this loophole by requiring providers to bill Medi-Cal based on the lesser of the usual charges made to the general public or, alternatively, the net purchase prices of the products as documented in the providers' books and records plus no more than a 100 percent markup.

CAMPS argues the Department's adoption of the UBL was outside the Department's statutory authority and violated the Administrative Procedures Act (APA) for several reasons. We conclude the Department acted within its authority and pursuant to the APA, and affirm the judgment in its entirety.

BACKGROUND

Before the UBL

The UBL as finally adopted in 2004 targeted dispensed medical supplies, incontinence medical supplies, and durable medical equipment. At the time of its adoption, each category was governed by a different reimbursement methodology.

For dispensed medical supplies (by assistive device and sickroom supply dealers and pharmacies), reimbursement was not to exceed 23 percent of the cost of the item dispensed, as defined by the Department. (Former Welf. & Inst. Code, § 14105.2, subd. (a), Stats. 2002, ch. 1161, § 53.5.)[1]

For incontinence medical supplies, reimbursement was "the weighted average of the negotiated contract prices within each product category, plus a markup fee equal to 38 percent of the resulting adjusted contract price." (Former § 14125; Stats. 2002, ch. 1161, § 81.)

For durable medical equipment rentals or purchases, reimbursements were to "be the usual charges made to the general public not to exceed . . . [t]he maximum reimbursements" listed, reasonable maximums for equipment reimbursed "By Report," or the lowest charge levels established pursuant to federal regulation. (Cal. Code Regs., tit. 22, § 51521.) Certain repair and services were also reimbursable. (*Ibid*.) According to the Department when it adopted the UBL, "[t]here [were] no specific statutory or regulatory percentage reimbursement markups for durable medical equipment; however, the maximum reimbursement rates established in regulations under [California Code of Regulations, title 22,] section 51521 for these products [were] based on their estimated acquisition cost plus no more than a 100 percent reimbursement markup."

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[1] All further unspecified section references are to the Welfare and Institutions Code.

The Department's Findings and Adoption of the UBL

In February 2003, the Department issued a notice of emergency rulemaking that it was adopting the UBL on an emergency basis pursuant to section 14043.75, and also invited public comments pursuant to the APA. Section 14043.75, enacted in 1999, allowed the Department's director to adopt emergency regulations to "prevent or curtail fraud and abuse." (Former § 14043.75; Stats. 1999, ch. 322, § 25; Stats. 1999, ch. 146, § 37) The Department also stated it was acting pursuant to section 14105.

This initial version of the UBL mandated that providers' billings to Medi-Cal for defined durable medical equipment, prosthetic and orthotic appliances, medical supplies, and incontinence medical supplies "shall not exceed an amount that is the lesser of" either "[t]he usual charges made to the general public," or "[t]he net purchase price of the item, which shall be documented in the provider's books and records, plus no more than a 100 percent markup. Documentation shall include, but not be limited to, evidence of purchase such as invoices or receipts." Providers were not to submit bills for items obtained at no cost.

The Department stated it was changing the reimbursement methodology because the previous methodology "was established under the assumption that providers operate under market conditions; i.e., they acquire retail products from legitimate distribution channels in the open market. The same assumption applies to Medi-Cal payment of the weighted average of the negotiated contract price plus a 38% markup for incontinence medical supplies. However, . . . enforcement efforts by the Department have revealed this assumption to be invalid. Certain providers have billed the Medi-Cal program at the maximum reimbursement rates for products that they obtained at substantially below the estimated acquisition cost or the weighted average of the negotiated contract price."

According to the Department, "providers' methods of billing for the acquired products end up costing the State of California more in payments than would be paid if they instead billed within the assumptions the Department used in creating the reimbursement methodology, i.e., they acquired the retail products they are billing for from legitimate distribution channels in the open market. It is the prevention of such

conduct that the Department seeks to address with this regulatory proposal. [¶] In [the] proposed [California Code of Regulations, title 22,] section 51008.1, the Department adopts in regulation the requirement that billings by providers . . . must ultimately be based on the net purchase price of these products, not the estimated acquisition cost for the weighted average of the negotiated contract price which both presume operation of market conditions."

The Department stated it was "not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the emergency action." It made an "initial determination that the regulations would not have a significant statewide adverse economic impact directly affecting business," and "determined that the regulations would not significantly affect" the creation or elimination of jobs, the creation of new businesses or elimination of existing businesses, or the expansion of businesses currently doing business within the State of California. The Department "determined that the regulations would affect small business."

In February 2003, the Department prepared other documents that contained additional relevant information. In its "Finding of Emergency," the Department stated that its investigations "reveal exploitation of the Medi-Cal reimbursement system by providers who employ non-market practices to obtain [supplies and appliances] at substantially below cost and then bill Medi-Cal at the maximum reimbursement rates. In order to protect the fiscal integrity of the Medi-Cal program against such potentially fraudulent practices, immediate action is needed to establish in regulations that the amount providers may bill and be reimbursed by Medi-Cal is tied to the net purchase price of the products."

In its "Initial Statement of Reasons," the Department stated the UBL was necessary to combat fraud and abuse, which occurred "when providers bill the Medi-Cal program for items they did not actually purchase or purchased at significantly below market rates, or bill in amounts that represent more than a 100 percent markup over their net purchase for the products, irrespective of their usual charges to the general public. The Department believes such billings can result in unnecessary costs to the Medi-Cal

program and are outside sound fiscal or business practices." It was "the prevention of such abusive billing conduct, outside the assumptions, that the Department seeks to address with this regulatory proposal." By linking billings to the actual net purchase price and allowing up to a 100 percent markup, "a provider who acquires a product for nothing, usually under non-market conditions, will receive no reimbursement from Medi-Cal. For the majority of providers who are within the market-place assumptions, however, Medi-Cal reimbursement will not change, as their net purchase price equals or exceeds the estimated acquisition cost or the weighted average of the negotiated contract price."

The Department did not expect the UBL to affect many providers. The UBL's 100 percent markup was "intended to be at a level that will not impact the reimbursement markup, as no currently established reimbursement markup exceeds 100 percent. For example, the allowable reimbursement markup for medical supplies is 23 percent [citation]. For incontinence medical supplies, it is the weighted average of the negotiated contract price plus 38 percent [citation]. There are no specific statutory or regulatory percentage reimbursement markups for durable medical equipment . . . however, the maximum reimbursement rates established in regulations ([Cal. Code Regs., tit. 22,] § 51521) for these products are based on their estimated acquisition cost plus no more than a 100 percent reimbursement markup. Thus, in regulations, there are established maximum Medi-Cal reimbursement markups for all these product types."

The Department's "Economic and Fiscal Impact Statement" made summary statements and did not estimate whether the UBL would have an economic impact on the private sector. It stated, "Medi-Cal is a voluntary program for both providers and beneficiaries," and indicated the change had no fiscal effect on the state government or federal funding of state programs.

Comments at the Public Hearing and in Writing

The Department held a public hearing regarding the UBL pursuant to the APA in April 2003. A number of statements made at the hearing were representative of the issues raised about the UBL.

Jeffrey Galvin, counsel for Shield Healthcare (Shield), argued the UBL improperly conflicted with the statutory provisions regarding reimbursement for incontinence and dispensed medical supplies. Also, he said, there was no substantial evidence that the UBL was reasonably necessary to effectuate the purpose of Welfare and Institutions Code section 14043.75. The Department had offered only "very vague references" to abuses found in unspecified enforcement efforts that did not "justify major changes to the reimbursement rules," and had not produced any documents supporting the proposed rules in response to a Public Records Act request, leaving unanswered questions about the extent of the problem and the need for such "sweeping change."

Furthermore, Galvin contended, the 100 percent markup rate was "arbitrary and capricious," made without any sort of study or analysis, and "might be entirely inappropriate for very inexpensive medical supplies . . . that might have a very low net purchase price." The definition of "net purchase price" was too ambiguous to apply consistently.

Galvin also disagreed with the Department's determination that there would not be a significant statewide economic impact resulting from the UBL. He said Medi-Cal reimbursements to large providers "may" decrease under the UBL "because, for example, with respect to medical supplies, a 100 percent markup on net purchase price may be less than the 23 percent markup of cost that is currently set forth in the statute." Since net purchase price excluded inventory costs, "larger providers, such as Shield, will cease warehousing product and shift those costs to out-of-state manufacturers or distributors," resulting in a loss of jobs in California. Providers would incur "major" costs "developing inventory tracking systems, accounting methods, and software to track net purchase price," for which there was no ready-made software for the task.

Galvin contended there could be other more reasonable alternatives to the Department's vaguely defined problem. For example, "[i]f the Department is really concerned about the underground economy in medical supplies and medical equipment, it might require certification with claims submission that product was acquired through legitimate channels in the open market."

Laura McIlvaine, also representing Shield, said the definition of "net purchase price" was ambiguous, and emphasized providers' possible shift of the costs of things such as warehousing back to the manufacturers so they would become a reimbursable part of the net purchase price, which could have an adverse effect on California business by eliminating warehouse related jobs in California.

McIlvaine also said large volume providers like Shield "often purchase at lower rates than other providers. The savings are offset by other costs related to inventory management, which do not show on the invoice, and they certainly do not appear to be accounted for in the regulation." McIlvaine submitted several photographs of Shield's Valencia, California, warehouse and invoices to show the substantial inventory affected by the UBL.

Patricia Steck of Apria Healthcare said the proposed UBL would penalize providers who purchase through legitimate channels, and require providers create a unique business operation to cost inventory. She questioned why the Department should benefit from discounts obtained by providers as the result of volume purchases or prompt payments, which were "a result of good business practices."

Jan Sterling of Sterling Medical Marketing, Inc. characterized the UBL as a "radical change from what is currently applied in health care reimbursement in general," because providers were reimbursed "on a usual and customary charge less some sort of negotiated discount." He said the UBL could affect his company's private sector pricing, and also impact a beneficiary's access to product because reduced margins would result in less products being available.

Finally, John Wright of InvaCare Corporation, a manufacturer, urged the Department to look at the "labor intensity involved in the delivery process of these goods and services to the beneficiaries." He said that "[b]ecause of the variety of convoluted contracts, which include such things as base, incentive, and prompt pay discounts, finance charges . . . , and extended payment terms," it was "extremely convoluted" to try to establish net price for products. He had received "several" calls from providers asking

him to modify or take them off contracts, and to "increase their costs in order to have a higher net so that they can make more money in the transaction" under the UBL.

The record also contains 12 pieces of correspondence received by the Department during the 45-day comment period regarding the proposed UBL. The concerns expressed were consistent with those stated at the hearing.

The Department's Proposed Amendments to the UBL

In February 2004, the Department issued a notice of its consideration of amendments to the UBL. The proposed amendments excluded rented durable medical equipment and prosthetic and orthotic appliances, defined a "custom wheelchair," and further defined "net purchase price."[2]

The Department received four comments on these amendments during the 15-day comment period. They criticized the definition of "net purchase price" as unclear regarding what constituted "price reductions guaranteed by any contract," and argued

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[2] The Department proposed a definition for net purchase price:

"(A) Net purchase price is defined as the actual cost to the provider to purchase the item from the seller, including any rebates, refunds, discounts or any other price reducing allowances, known by the provider at the time of billing the Medi-Cal program for the item, that reduce the item's invoice amount.

"(B) The net purchase price shall reflect price reductions guaranteed by any contract to be applied to the item(s) billed to the Medi-Cal program.

"(C) The net purchase price shall not include provider costs associated with late payment penalties, interest, inventory costs, taxes, or labor.

"(D) Where a custom wheelchair as defined in (d) is subject to the provisions of this regulation, the provider may bill the provider's cost of labor to assemble the custom wheelchair which is above the 100 percent markup, only when the inclusion of the actual labor cost would result in a bill that exceeds the net purchase price of the entire custom wheelchair plus a 100 percent markup. . . . [T]he provider shall be allowed to add to the bill submitted . . . the actual cost of labor that exceeds the 100 percent markup to the claim line that would otherwise have been used to bill only the custom wheelchair's base or frame.

"(E) If the provider's actual cost of labor is included in the bill, the actual time spent assembling the entire custom wheelchair shall be itemized by hours or fractions thereof and the per hour cost of labor, and each shall be documented in the provider's books and records."

labor costs should be included and after-the-fact discounts excluded; and criticized the UBL's application to custom wheelchairs.

The Department's Responses to Comments and Final Adoption of the UBL

In March 2004, the Department issued a "Final Statement of Reasons," including two addendums addressing the comments received, and a "Statement of Determinations."

The Department's final statement of reasons repeated much of its initial statement of reasons. It also clarified the definition of "net purchase price" and further specified the costs that were not allowed to be included in its calculation, allowed the inclusion of labor costs for assembly of custom wheelchairs in certain circumstances, and excluded rented durable medical equipment.

The First Addendum

The Department's first addendum addressed comments received during the initial 45-day comment period. The Department asserted the UBL did not contradict statutory reimbursement rates for incontinence medical supplies and dispensed medical supplies, and did not exceed the Department's statutory authority because Welfare and Institutions Code section 14043.75 authorized its director to, "adopt . . . or amend additional measures to prevent or curtail fraud or abuse." The Department also asserted that California Code of Regulations, title 22, section 51520, subdivision (b) harmonized any differences between Welfare and Institutions Code sections 14043.75 and 14125 (regarding reimbursement for incontinence supplies) specifically by providing that "reimbursement for incontinence medical supplies shall be the amount billed in accordance with [California Code of Regulations, title 22,] section 51008.1, not to exceed the amount provided in . . . section 14125."

Regarding comments that it did not comply with the APA by its vague references to fraud and abuse, the Department stated it "routinely reviews the billing practices of Medi-Cal providers" and "conducts audits of providers' accounting and billing practices," that the UBL was "based on the findings of those reviews and audits," and that it "must prevent and address fraudulent and abusive billings of providers." The Department did not "believe" implementation of the UBL would reduce services to

beneficiaries. Regarding contentions that the UBL would cause providers administrative nightmares tracking actual purchase prices, the Department stated that "[s]ound business practices, as well as existing regulations ([Cal. Code Regs., tit. 22,] § 51476) requires providers to retain documentation of purchases."

Regarding comments that the 100 percent markup limit was unsupported by evidence of reasonable necessity, and was arbitrary and capricious, the Department stated that the markup was well in excess of the markups for medical supplies, and the Department "believed" it was fair and equitable to providers.

Regarding comments that it should consider alternatives like a method of purchase certification, the Department stated that it considered alternatives and determined the UBL was necessary to achieve specific anti-fraud and abuse objectives. The Department' system did not allow for certification, and it did not "believe" certification would achieve its objectives.

Regarding comments that the UBL would cause such business changes as the passing of costs back to the manufacturer and the loss of jobs, the Department stated that it could not afford to allow fraudulent and abusive billings to continue, that participation in the Medi-Cal program was voluntary, and that it "believed" providers would be able to adapt to the new billing regulation without drastic effects.

Regarding the comment that the UBL would not necessarily affect those purchasing products outside legitimate channels while potentially hurting those making purchases within those channels, the Department stated that purchases outside legitimate channels were bought "at little or no cost" in transactions that "defied wholesale market prices known to the Department." Those not selling to the public received reimbursements for excessive markups. The UBL did "not affect the ability of providers to bill the amount reimbursable under existing law."

Regarding the comment that the Department needed to further define legitimate distribution channels, the Department stated that "[f]raudulent providers claimed millions on a few dollars in purchases, claiming they got 'really good deals,' " and were able to do

so because of the loophole in State law that "did not effectively link reimbursement to the provider's purchase cost."

Regarding comments by providers of certain customized equipment that they operated activity based accounting practices that did not operate on strict acquisition costs, the Department stated its changes did not alter current Medi-Cal law, which provided "that the maximum reimbursement rate for durable medical equipment include[ed] reimbursement considerations for freight, delivery or transportation, installation, setup or instructions for the use of the equipment, repair, maintenance or routine servicing of rental equipment."

The Second Addendum

The Department's second addendum responded to comments received during the 15-day comment period for the Department's proposed amendments to the UBL in 2004. Regarding custom wheelchairs, the Department stated that "net purchase price" excluded discounts not known to the provider at the time of billing, that although labor cost "is never part of net purchase price," "[d]esign, delivery, beneficiary training and other labor costs should be absorbed in the 100% markup," and that, when labor costs exceed this markup, the provider could bill separately for it.

Final Adoption

In March 2004, the Department also filed a notice certifying its compliance with Government Code sections 11346.2 to 11346.9 with its final regulations, as amended. It submitted the rulemaking record to the Office of Administrative Law for review, and provided additional written responses to issues raised during the Office of Administrative Law's review. One additional response clarified the relationship of the UBL to existing reimbursement statutes:

"[California Code of Regulations, title 22,] section 51520, subdivisions (a) and (b) focus on reimbursement for medical supplies, and incontinence supplies respectively. Specifically, reimbursement for medical supplies and incontinence medical supplies shall not exceed the amount calculated from the reimbursement methodologies specified in

sections 14105.2 and 14125. There were no changes to these reimbursement methodologies.

"However, [California Code of Regulations, tit. 22,] section 51008.1 specifies the requirements for billing for medical supplies and incontinence medical supplies. Section 51008.1 now specifies [that] the upper billing limit that providers may bill the Medi-Cal program and ties the upper billing limit to the provider's net purchase price. Before the provider did not have to link the amount billed to the Medi-Cal program to their net purchase price."

The Department also responded to the comment that small business providers would be disproportionately impacted by the UBL by repeating its need to stop fraud and abuse, stated the comment was speculative, and, assuming it referred to the need to track net purchase prices, that "[i]t is believed that existing inventory tracking and accounting methods should easily accommodate these changes, and that this is within a normal range of cost to do business with the Medi-Cal program." The Department further stated that "[w]ithout additional, more specific cost information, it was unclear why small businesses would be disproportionately impacted" because, regardless of the method of purchase, the UBL still allowed businesses to bill up to a 100 percent markup over the net purchase price.

The Office of Administrative Law filed a notice approving the Department's certificate of compliance in April 2004.

The CAMPS Petition

In March 2009, a couple of years after the Department apparently increased its auditing and money recovery efforts pursuant to the UBL, CAMPS filed a petition for writ of mandate pursuant to Code of Civil Procedure section 1085 in Alameda County Superior Court. It sought to invalidate the UBL based on numerous grounds, including that the Department violated the requirements of the APA in promulgating the UBL in excess of its authority; the lack of substantial evidence that the UBL was reasonably necessary to effectuate the purpose of any statute or would not have a significant statewide adverse impact directly affecting business; and that the UBL was arbitrary and

capricious, and lacked the requisite clarity. CAMPS asked the court to issue a writ of mandate invalidating the UBL and ordering the cessation of enforcement actions, for a declaration that the UBL was illegal and null and void, and for injunctive relief.

In July 2009, the trial court issued a written order denying the petition. It stated:

"The evidence in the record is sufficient for the [Department] to have promulgated the regulations. Moreover, the premise advanced by the [Department] ([i.e.,] that in some instances medical equipment suppliers abuse the system by selling products to Medi-Cal patients with abusive markups/profit margins) is never seriously questioned by petitioner during its participation in the quasi-legislative process.

"The 100 percent markup provision is not arbitrary and capricious and has a basis for its promulgation. It is a different measure than prior limiting regulations in that a supplier's cost of doing business at any level of efficiency is factored out of the equation. It is not arbitrary or capricious for a quasi-legislative body to make such a change."

CAMPS filed a timely notice of appeal. During this appeal, we granted requests for judicial notice filed by each party.

DISCUSSION

CAMPS argues that the trial court should have granted its petition because the Department did not make an evidentiary determination that the UBL would not have a significant, statewide adverse economic impact directly affecting business. CAMPS also argues the UBL is invalid because it exceeds the Department's statutory authority, is inconsistent with the governing statutes, is not supported by substantial evidence that it is reasonably necessary to effectuate the purpose of section 14043.75, lacks the minimal level of "clarity" required by the APA, and sets an arbitrary and capricious 100 percent markup based on conjecture. We find each argument unpersuasive under our standards of review.

I. *Standard of Review*

A. *Petition for Writ of Mandate*

Code of Civil Procedure section 1085, the basis for CAMPS's petition, " 'authorizes a trial court to issue a writ of mandate to compel an act which the law

specifically requires. A petitioner . . . is required to show the existence of two elements: a clear, present and usually ministerial duty upon the part of the respondent, and a clear, present and beneficial right belonging to the petitioner in the performance of that duty.' " (*Yoo v. Shewry* (2010) 186 Cal.App.4th 131, 144 [regarding a petition about a dispute with the Department over Medi-Cal payments].)

The parties agree that the Department's adoption of the UBL regulations was a quasi-legislative act reviewable by the courts via a petition for writ of mandate. (See *20th Century Ins. Co. v. Garamendi* (1994) 8 Cal.4th 216, 275 ["an 'administration action is quasi-legislative' when the 'administrative agency is creating a new rule for future application' "]; *Pacific Legal Foundation v. California Coastal Com.* (1982) 33 Cal.3d 158, 168-169 [quasi-legislative acts reviewing only by an action for declaratory relief or for traditional mandamus].) In reviewing such a petition under Code of Civil Procedure section 1085, a trial court's role generally is to "determine whether the agency's action was arbitrary, capricious, or without evidentiary support, and/or whether it failed to conform to the law. The trial court may not substitute its judgment for that of the agency or force the agency to exercise its discretion in a certain way." (*Association of Irritated Residents v. San Joaquin Valley Unified Air Pollution Control Dist.* (2008) 168 Cal.App.4th 535, 542 (*Irritated Residents*).) In considering the validity of regulations, the courts' "function is to inquire into the legality of the regulations, not their wisdom." (*Morris v. Williams* (1967) 67 Cal.2d 733, 737 [reviewing Medi-Cal regulations].)

In reviewing the trial court's ruling, " ' "the appellate court may make its own determination when the case involves resolution of questions of law where the facts are undisputed." ' " (*Zubarau v. City of Palmdale* (2011) 192 Cal.App.4th 289, 301.) Also, "[w]hen administrative agency action is judicially reviewable under a substantial evidence standard, the rule for the reviewing trial court and appellate court is the same." (*Agricultural Labor Relations Bd. v. Exeter Packers, Inc*. (1986) 184 Cal.App.3d 483, 492 [evaluating whether substantial evidence supported the conclusion that regulations were reasonably necessary under the APA].)

B. *The Administrative Procedure Act*

CAMPS also sought a judicial declaration that the UBL was invalid pursuant to Government Code section 11350, part of the APA, Government Code section 11340, et seq. The APA is " 'intended to advance "meaningful public participation in the adoption of administrative regulations by state agencies" and create "an administrative record assuming effective judicial review." [Citation.] In order to carry out these dual objectives the APA (1) establishes "basic minimum procedural requirements for the adoption, amendment or repeal of administrative regulations" (Gov. Code, § 11346) which give "interested parties an opportunity to present statements and arguments at the time and place specified in the notice and calls upon the agency to consider all relevant matter presented to it," and (2) "provides that any interested person may obtain a judicial declaration as to the validity of any regulation by bringing an action for declaratory relief in superior court." [Citation.] The APA was born out of the Legislature's perception there existed too many regulations imposing greater than necessary burdens on the state and particularly upon small businesses.' " (*Pulaski v. Occupational Safety & Health Stds. Bd.* (1999) 75 Cal.App.4th 1315, 1327-1328 (*Pulaski*); Gov. Code, § 11350, subd. (a).)

The regulation "may" be declared to be invalid by a court because of "a substantial failure to comply with" the APA. (*Pulaski, supra,* 75 Cal.App.4th at pp. 1327-1328.) Furthermore, an agency adopting a regulation must "assess" and "consider" the potential for adverse economic impact directly on California business. (Gov. Code, § 11346.3.) A regulation "may" be declared invalid if the agency makes an "initial determination" that an action does not have a significant, statewide adverse economic impact directly affecting business, but that determination is in conflict with substantial evidence in the record. (Gov. Code, §§ 11346.5, subd. (a)(8), 11350, subd. (b)(2)). A regulation also "may" be declared invalid for lack of substantial evidence to support an agency's determination that the regulation is reasonably necessary to effectuate the purpose of a statute. (Gov. Code, § 11350, subd. (b)(1).)

II. *Significant, Statewide Adverse Economic Impact*

CAMPS argues the trial court should have granted its petition because the Department, when it adopted the UBL in 2004, did not make an evidentiary determination that the UBL would not have a significant, statewide adverse economic impact directly affecting business, instead relying on "beliefs" that were contradicted by substantial evidence. We disagree.

As we have indicated, a regulation "may" be declared invalid by a court if the agency's declaration that it has initially determined the regulation will not have a significant, statewide adverse economic impact directly affecting business is in conflict with substantial evidence in the record. (Gov. Code, § 11350, subd. (b)(2); Gov. Code, § 11346.5, subdivision (a)(8).) Pursuant to the APA, "agencies proposing to adopt, amend, or repeat any administrative regulation shall assess the potential for adverse economic impact on California business enterprises and individuals, avoiding the imposition of unnecessary or unreasonable regulations or reporting, recordkeeping, or compliance requirements." (Gov. Code, § 11346.3, subd. (a).)

In assessing such a potential for adverse economic impact, agencies are required (to the extent not in conflict with other state or federal laws), to base their action "on adequate information concerning the need for, and consequences of," the proposed action, and must "consider the proposal's impact on business, with consideration of industries affected[.]" (Gov. Code, § 11346.3, subd. (a)(1) & (2).) These provisions are *not* intended to impose additional criteria on agencies, above that which exists in current law, in assessing "adverse economic impact on California business enterprises." (Gov. Code, § 11346.3, subd. (a).) Rather, they are "only to assure that the assessment is made early in the process of initiation and development of a proposed adoption, amendment, or repeal of a regulation." (*Id*., subd. (a)(2).)

In addition, state agencies shall assess whether and to what extent its action will affect the creation or elimination of jobs and businesses in the state, and the expansion of businesses currently doing business within the state. (Gov. Code, § 11346.3, subd. (b)(1)(A)-(C).) In declaring that it has initially determined a regulation "will not have a

significant, statewide adverse economic impact directly affecting business" (Gov. Code § 11346.5, subd. (a)(8)), an agency "shall provide in the record facts, evidence, documents, testimony, or other evidence upon which the agency relies to support its initial determination." (Gov. Code§ 11346.5, subd. (a)(8).)

A. ***The Support for an "Initial Determination" Under the APA***

CAMPS and the Department first argue over what the Department must do in making its initial determination about economic impact. CAMPS argues "an agency must make an actual, evidentiary 'determination' "and may not rely solely on its 'beliefs.' " The Department argues an agency must only "consider" a proposal's impact, a regulation is valid as long as an agency has substantially complied with the APA's requirements, and in any event it "made a formal 'determination' " that met the APA's requirements.

We agree with CAMPS that the agency must do something more than merely "consider" a proposal's impact. We also agree with the Department that it made a sufficient determination.

In interpreting the APA's provisions, we utilize the well-established canons of statutory interpretation. As this court has previously stated, " '[w]e begin with the fundamental rule that our primary task is to determine the lawmakers' intent.' " (*MacIsaac v. Waste Management Collection & Recycling, Inc.* (2005) 134 Cal.App.4th 1076, 1082 (*MacIsaac*).) In determining legislative intent, " 'a court must look first to the words of the statute themselves, giving to the language its usual, ordinary import and according significance, if possible, to every word, phrase and sentence in pursuance of the legislative purpose. . . .' " (*Quintano v. Mercury Casualty Co.* (1995) 11 Cal.4th 1049, 1055.) " 'The words . . . must be construed in context, keeping in mind the statutory purpose, and statutes or statutory sections relating to the same subject must be harmonized, both internally and with each other, to the extent possible.' " (*Id.* at p. 1055.) We give the words " 'plain and commonsense meaning' " unless the statute specifically defines the words to give them a special meaning. (*MacIsaac*, *supra*, at p. 1083.) " 'If there is no ambiguity in the language of the statute, "then the Legislature

is presumed to have meant what it said, and the plain meaning of the language governs." ' " (*Pulaski*, *supra*, 75 Cal.App.4th at pp. 1338-1339.)

We agree with CAMPS that mere speculative belief is not sufficient to support an agency declaration of its initial determination about economic impact, and that the agency must provide in the record any " 'facts, evidence, documents, testimony, or other evidence' " upon which it relies on for its initial determination. (Gov. Code, §§ 11346.5, subd. (a)(8), 11347.3, subd.(b)(4).) CAMPS urges us to consider certain legislative history, but we have no need to do so because the plain meaning of the relevant APA provisions indicates an agency should rely on more than speculative belief. An agency specifically must "assess" the potential adverse economic impact on California business and individuals of a proposed regulation (Gov. Code, § 11346.3) and declare in the notice of proposed action any "initial determination" that the action will not have a significant statewide adverse economic impact directly affecting business." (Gov. Code, § 11346.5, subd. (a)(8).) These provisions plainly call for an evaluation based on facts.

However, CAMPS's argument does not address the Department's obligation in the context of the APA as a whole. As a result, CAMPS largely ignores several important qualifications. First, a regulation is not necessarily invalid, even if it has a significant adverse economic impact on business. Government Code section 11346.3 only requires that "agencies . . . assess the potential for adverse economic impact on California business enterprises and individuals, *avoiding the imposition of unnecessary or unreasonable regulations or reporting, recordkeeping, or compliance requirements.*" (Gov. Code, § 11346.3, subd. (a), italics added.) Thus, regulations *may* have negative economic impacts if necessary or reasonable under the circumstances.

Furthermore, the APA instructs that "a regulation . . . *may* be declared invalid if . . . [t]he agency declaration . . . is in conflict with substantial evidence in the record." (Gov. Code, § 11350, subd. (b)(2).) " ' " 'It is a well established rule of statutory construction that the word "shall" connotes mandatory action and "may" connotes discretionary action.' " ' " (*In re Marriage of Fossum* (2011) 192 Cal.App.4th 336, 348.) Thus, courts are not *required* to declare a regulation invalid if an agency's declaration

regarding negative economic impact on business is in conflict with substantial evidence in the record. (See *Pulaski, supra,* 75 Cal.App.4th at pp. 1329-1330 ["Government Code section 11350, subdivision (b)(1) declares that the court *may* invalidate a regulation if it finds '[t]he agency's determination that the regulation is reasonably necessary to effectuate the purpose of the statute . . . is not supported by substantial evidence.' "]; *20th Century Ins. Co. v. Garamendi, supra,* 8 Cal.4th at p. 272 [repeating its previous statement that " 'Government Code section 11350, subdivision (b), . . . *permits* a court to declare a regulation invalid . . . ." (Italics added.)].) As we have already discussed, a trial court's duty is to "determine whether the agency's action was arbitrary, capricious, or without evidentiary support, and/or whether it failed to conform to the law." (*Irritated Residents, supra,* 168 Cal.App.4th at p. 542.)

Second, as the Department points out, Government Code section 11346.3's terms focus on an early, rather than in-depth, assessment. The Legislature specifically stated that "[i]t is *not* the intent of this section to impose additional criteria on agencies, above that which exists in current law, in assessing adverse economic impact on California business enterprises, *but only to assure that the assessment is made early in the process* of initiation and development of a proposed adoption, amendment, or repeal of a regulation." (Gov. Code, § 11346.3, subd. (a)(2), italics added.)

Third, and consistent with this second point, the reference to a "determination" in Government Code section 11346.5, subdivision (a)(8) states merely that if an agency makes an "*initial* determination that the action will not have a *significant,* statewide adverse economic impact directly affecting business . . . it shall make a declaration to that effect in the notice of proposed action." (Gov. Code, § 11346.5, subd. (a)(8), italics added.) The qualifying adjective "initial" indicates the agency's determination need not be conclusive, and the qualifying adjective "significant" indicates that the agency need not assess or declare *all* adverse economic impact anticipated.

Fourth, as the Department also points out, a court may declare the regulation invalid only for lack of "substantial failure" to comply with the act. (Gov. Code, § 11350, subd. (a).) " ' " 'Substantial compliance, as the phrase is used in the decisions,

means *actual* compliance in respect to the substance essential to every reasonable objective of the statute.' . . . Where there is compliance as to all matters of substance technical deviations are not to be given the stature of noncompliance. . . . Substance prevails over form." ' " (*Pulaski*, *supra*, 75 Cal.App.4th at p. 1328.)

Fifth, CAMPS points out the references in the APA to "substantial evidence," but it does not argue that there was a particular "burden of proof" to be met, or that the Department in its rulemaking capacity is required to follow formal rules of evidence. We are also mindful that, generally, "[o]f all the activities undertaken by an administrative agency, quasi-legislative acts are accorded the most deferential level of judicial scrutiny." (*Pulaski, supra*, 75 Cal.App.4th at p. 1331.)

Given these factors, we conclude the Department's obligation in its initial determination was to make an initial showing that there was some factual basis for the Department's decision. We review the Department's initial determination to determine that the Department has substantially complied with its obligations, and whether it is supported by some substantial evidence. (See *Pulaski, supra,* 75 Cal.App.4th at pp. 1328-1329 [evaluating whether administrative conclusions about economic impact pursuant to Government Code section 11346.3, subdivision (a) were supported by substantial evidence].) Moreover, if its initial determination is in conflict with substantial evidence in the record, this *may* be grounds for finding the UBL invalid.

B. *The Department's Initial Determination*

The Department's declaration of its initial determination met the APA's requirements, and was not in conflict with substantial evidence in the record. Therefore, we have no reason to overturn the UBL based on the Department's declaration.

" 'Substantial evidence' is evidence of ponderable legal significance, evidence that is reasonable, credible and of solid value. [Citations.] 'Substantial evidence . . . is not synonymous with "any" evidence.' Instead, it is ' " 'substantial' proof of the essentials which the law requires." ' [Citations.] The focus is on the quality, rather than the quantity, of the evidence. 'Very little solid evidence may be "substantial," while a lot of

extremely weak evidence might be "insubstantial." ' " (*Roddenberry v. Roddenberry* (1996) 44 Cal.App.4th 634, 651.)

The parties acknowledge inferences that are the product of logic and reason may be substantial evidence. "Inferences may constitute substantial evidence, but they must be the product of logic and reason. Speculation or conjecture alone is not substantial evidence." (*Roddenberry v. Roddenberry*, *supra*, 44 Cal.App.4th at p. 651.) "The ultimate test is whether it is reasonable . . . to make the ruling in question in light of the whole record." (*Id*. at p. 652.) However, logic is not supported by substantial evidence if it "is flawed, or if it is contrary to the evidence[.]" (*California Unions for Reliable Energy v. Mojave Desert Air Quality Management Dist.* (2009) 178 Cal.App.4th 1225, 1241 (*CURE*).)

The Department stated in support of its initial determination: "These emergency regulations require certain Medi-Cal providers to submit claims to the Medi-Cal program at an amount that is the lesser of their usual charges made to the general public or the amount they paid for a product plus no more than a 100 percent markup. Medi-Cal is a voluntary program for which providers enroll."

The Department also stated that it did not expect the change to the UBL to have a significant impact on the provider who had not engaged in the fraud or abuse targeted by the Department, i.e., billing at maximum reimbursement rates for products obtained at substantially below the estimated acquisition cost or weighted average of the negotiated contract price for retail products purchased from legitimate distribution channels in the open market. According to the Department, neither the change to net purchase price nor the 100 percent markup limit would affect most providers because "their net purchase price equals or exceeds the estimated acquisition cost or the weighted average of the negotiated contract price" and "no currently established reimbursement markup exceeds 100 percent."

CAMPS argues that the Department did not provide any " 'facts, evidence, documents, testimony, or other evidence' " (Gov. Code, § 11346.5, subd. (a)(8), see also Gov. Code, § 11347.3, subd. (b)(4)) to support its determination. CAMPS concludes

that, "[a]ccordingly, the Department's initial 'determination' resembles a 'belief,' more than a reasoned determination."

CAMPS's argument ignores that the Department's statements demonstrate a reliance on the facts and circumstances before it, and the logical inferences that can be drawn from them, i.e., the specific changes it was making, the existing reimbursement rates, the fact that participation in the program is voluntary, the fraud and abuse that had occurred, and the Department's market-place assumptions. The Department concluded its proposed changes were relatively insignificant for providers obtaining retail products from legitimate distribution channels in the open market. Its reasoning is supported by the specific changes it was making. It was requiring providers to bill Medi-Cal using "net purchase price," rather than such things as "estimated acquisition cost" and "weighted average of negotiated contract price," and limited the maximum markup rate at 100 percent of this net purchase price. The Department could reasonably conclude that these specific changes would not cause "significant," statewide adverse economic impact directly affecting business for providers who were not engaged in abusive billing practices. A 100 percent markup rate is more than four times higher than the 23 percent markup rate for medical supplies, almost three times higher than a 38 percent markup rate for incontinence medical supplies, and no greater than the maximum markup rate allowed for durable medical equipment. As the Department also noted, to the extent any provider was receiving a greater than 100 percent markup on what they actually paid for a product, that provider was engaging in what the Department considered to be abusive billing practices. Finally, as the Department correctly noted, providers' participation in Medi-Cal is *voluntary*; no business would be captive to the UBL, since they were free to pursue a more profitable business strategy outside of the program. Its reasoning based on the facts and circumstances before it was sufficient substantial evidence that the UBL would not have a significant, statewide adverse economic impact directly affecting business.

CAMPS also argues the Department could not rely on "mere conclusions," but instead was required to present "actual evidence." CAMPS relies on case law regarding the California Environmental Quality Act (CEQA), such as *CURE, supra,* 178

Cal.App.4th at page 1237. Under CEQA, "if the court perceives that there was substantial evidence that the project might have an adverse impact, but the agency failed to secure preparation of an EIR, the agency's action must be set aside because the agency abused its discretion by failing to follow the law." (*Dunn-Edwards Corp. v. Bay Area Air Quality Management Dist.* (1992) 9 Cal.App.4th 644, 656.)

Obviously, CEQA and the APA contain very different standards and requirements. Here, as we have indicated, the Department needed only to provide some factual basis for its initial determination, and in any event, a court "may" declare a regulation invalid if an agency's declaration "is in conflict with substantial evidence in the record." (Gov. Code, § 11350, subd. (b)(2).) These standards are very different than those found in CEQA. (See, e.g., *Dunn-Edwards Corp. v. Bay Area Air Quality Management Dist.*, *supra*, 9 Cal.App.4th at p. 656 [stating that, upon a preliminary review, "a project is only exempt from CEQA '[w]here it can be seen *with certainty that there is no possibility* that the activity in question may have a significant effect on the environment,' " italics added], disapproved on other grounds as stated in *Western States Petroleum Assn. v. Superior Court* (1995) 9 Cal.4th 559, 576, fn. 6.) Therefore, we do not find the analogy relevant.

We also conclude there is not substantial evidence that the UBL would have a "significant, statewide adverse economic impact on business." CAMPS offers seven contentions to the contrary. None of them are persuasive. Specifically, it contends that "(1) the UBL may result in an economic loss to providers because the UBL methodology may result in payments lower than established reimbursement rates or the costs of doing business; (2) providers would incur costs to develop inventory tracking systems, accounting methods and software to track net purchase price; (3) large providers may cease warehousing products and shift these costs to out-of-state manufacturers or distributors; (4) the loss of these wharehousing functions could result in a loss of jobs in California; (5) providers may stop seeking discounted pricing due to the UBL; (6) providers that could not adjust to the UBL methodology would have to exit the marketplace; and (7) providers may have to change private sector pricing at a loss."

CAMPS's seven contentions are speculative in nature, for example suggesting providers "might" receive lower reimbursement payments, or that providers might incur some additional administrative costs. They are not substantial evidence of "*significant*, statewide adverse economic impact directly affecting business" (Gov. Code, § 11346.5, subd. (a)(8), italics added), and not a basis for us to find the UBL was invalid. This is particularly the case when one considers that the Department determined that the UBL, and the need for providers to keep track of net purchase prices, was reasonably necessary to prevent and curtail fraud and abuse in the Medi-Cal program, a determination for which we give considerable deference (*Communities for a Better Environment v. California Resources Agency* (2002) 103 Cal.App.4th 98, 108-109; Gov. Code, § 11346.3, subd. (a) ["agencies . . . assess the potential for adverse economic impact on California business enterprises and individuals, *avoiding the imposition of unnecessary or unreasonable regulations* . . . ." (Italics added.)].)

CAMPS also contends the Department made statements that were unsupported by logic or facts. CAMPS questions how the Department could find the UBL "would affect small business" while nonetheless concluding that there is not a significant, statewide adverse economic impact. However, the Department did not state the UBL would negatively affect small business in any significant way.

CAMPS also contends that the Department could not conclude that purportedly increased administrative costs, such as for tracking inventory, would not have a significant, statewide adverse economic impact without studying the issue, and "relied on facts that demonstrated the implementation expenses described by providers would not result in a significant, statewide adverse economic impact." We disagree. Given the speculative nature of the providers' statements, the specific changes proposed by the Department, and the general nature of administrative costs, it was reasonable for the Department to reason that any added administrative costs to businesses would not constitute "significant, statewide adverse economic impact directly affecting business."

Finally, CAMPS argues that the Department improperly relied on speculative "belief," which term the Department used in some instances. This includes its statements

that it "believ[ed] that a 100 percent markup is fair and equitable," "believed that existing inventory tracking and accounting methods should easily accommodate changes," "believe[d] providers will be able to adapt to the new billing regulation without . . . drastic effects," and "believed" that the cost of implementing the UBL was "within a normal range of cost to do business with the Medi-Cal program." These references do not indicate the Department acted based on speculative belief in light of the record as a whole.

III. *The Department's Statutory Authority to Adopt the UBL*

In 2003, the Department adopted the UBL under subdivision (a) of Welfare and Institutions Code section 14043.75, which provides in relevant part that its director may "in consultation with interested parties, by regulation, adopt . . . additional measures to prevent or curtail fraud and abuse." The Department also relied for authority on section 14105, subdivision (a), and asserts to this court that it had authority under sections 14124.5 and 10725.

CAMPS argues that the UBL exceeds the Department's statutory authority and is inconsistent with the governing statutes. We reject CAMPS's arguments regarding the Department's statutory authority under section 14043.75, and do not address the Department's authority under the other statutes.

As we have already indicated, Government Code section 11342.2 states that "no regulation adopted is valid or effective unless consistent and not in conflict with the statute and reasonably necessary to effectuate the purpose of the statute." Thus, when a petition seeks to invalidate a regulation adopted pursuant to a delegation of legislative power, " ' "the judicial function is limited to determining whether the regulation (1) is 'within the scope of the authority conferred' [citation] and (2) is 'reasonably necessary to effectuate the purpose of the statute.' " ' " (*Yamaha Corp. of America v. State Bd. of Equalization* (1998) 19 Cal.4th 1, 11.) "Under the first prong of this standard, the judiciary independently reviews the administrative regulation for consistency with controlling law." (*Communities for a Better Environment v. California Resources Agency, supra,* 103 Cal.App.4th at p. 108.) " 'Consistency' means being in harmony

with, and not in conflict with or contradictory to," existing provisions of law. (Gov. Code, § 11349, subd. (d).)

"[Q]uasi-legislative rules are reviewed independently for consistency with controlling law. A court does not . . . defer to an agency's view when deciding whether a regulation lies within the scope of the authority delegated by the Legislature. The court, not the agency, has 'final responsibility for the interpretation of the law' under which the regulation was issued." (*Yamaha Corp. of America v. State Bd. of Equalization*, *supra*, 19 Cal.4th. at p. 11, fn. 4.) We employ the well-established canons of statutory interpretation that we have already discussed.

CAMPS argues the Department was not authorized by section 14043.75 to adopt the UBL because the regulation did not address any "abuse," and acted to regulate billing and reimbursement to a *class* of providers, which was outside the statute's limited scope. Neither argument is persuasive.

A. *The Abuse*

The Department contends that "[t]he abuse at issue is . . . the practice of obtaining steep discounts (whether legitimate or not) *and then turning around and billing Medi-Cal at maximum reimbursement rates*, exploiting a previously-existing loophole in the law to obtain windfall profits, at the taxpayers' expense, that would never be sustainable in a properly functioning market." We agree that providers billing for maximum reimbursement for products purchased at steep discounts qualifies as "abuse" that the Department may address by regulation pursuant to section 14043.75.

Section 14043.1 defines "abuse" as including "[p]ractices that are inconsistent with sound fiscal or business practices and result in unnecessary cost to the . . . Medi-Cal program[.]" (§ 14043.1, subd. (a)(1).) According to CAMPS, we must read " 'sound fiscal or business practices' " "from the perspective [of] the provider, rather than the perspective of the State. The other prong of the definition for 'abuse' requires that the practice 'result in unnecessary cost' to the Medi-Cal program. If inconsistency with sound fiscal or business practice were considered solely from the State's perspective, the

second prong . . . would be rendered nugatory, in violation of the rules of statutory construction."

CAMPS's interpretation of "abuse" is not supported by the statutory definition of "abuse," which does not limit sound fiscal and business practices to the perspective of the provider. " 'It is axiomatic that in the interpretation of a statute where the language is clear, its plain meaning should be followed.' " (*Security Pacific National Bank v. Wozab* (1990) 51 Cal.3d 991, 998.) Moreover, we are not empowered to insert language, such as CAMPS's proposed limitation, into the statutory definition of "abuse." "Doing so would violate the cardinal rule of statutory construction that courts must not add provisions to statutes." (*Ibid.*; see also Code Civ. Proc., § 1858 ["[i]n the construction of a statute . . . , the office of the Judge is simply to ascertain and declare what is in terms or in substance contained therein, not to insert what has been omitted"].) Also, it is patently absurd that the Legislature would authorize the Department to address only unsound fiscal and business practices *from the providers' perspective* as "abuse" without so stating, given that the purpose of section 14043.75 is to enable the Department to curtail fraud and abuse. Therefore, we reject CAMPS's argument about the limited definition of "abuse."

CAMPS also contends that a provider's practice of buying at below market rates but nonetheless billing the Department for the maximum reimbursement allowable *is* a sound fiscal practice. According to CAMPS, "some discounts are actually granted because of providers' sound fiscal or business practices, such as volume purchases or prompt payments. These discounts provide financial incentives for providers to adopt sound fiscal or business practices." However, as the Department points out, the abuse targeted is *not* these fiscal and business practices, but providers, having obtained discounts, turning around and billing Medi-Cal at maximum reimbursement rates. Therefore, CAMPS argument is not relevant to the abuse issue.

In short, CAMPS provides no reason for us to disagree with the Department that allowing providers to continue to receive unanticipated and significant profits at taxpayer expense is an unsound fiscal and business practice for the Medi-Cal program. Therefore, it qualifies as "abuse" under sections 14043.75 and 14043.1, subd. (a)(1).

B. *The Scope of Section 14043.75*

CAMPS next argues that section 14043.75 allows the Department to regulate against fraud and abuse only through the regulation of the formal relationship between providers and the Department, such as provider enrollment and disenrollment. This also is unpersuasive. The text of section 14043.75 broadly authorizes the Department to adopt regulations to prevent fraud and abuse, without limiting its application as CAMPS suggests. It would be inappropriate for this court to attach CAMPS's proposed limitation to this provision. (*MacIsaac, supra,* 134 Cal.App.4th at pp. 1082-1083; see also Code Civ. Proc., § 1858.)

CAMPS argues that the legislative history for section 14043.75 indicates the Legislature "did not grant the Department unbridled authority when enacting section 14043.75." It quotes from two summaries contained in the Department's 1999 report to the Governor regarding section 37 of Assembly Bill 107; section 37 included the original version of section 14043.75. (Stats. 1999, ch. 146, § 37.) These summaries emphasized that section 37 addressed issues other than those involved in the present case, such as the provider enrollment process.

CAMPS's argument quickly falls apart upon a close examination of this legislative history. First, CAMPS's quotations from the two summaries do not include their first sentences, which state words to the effect that section 37 "implements the Governor's fraud and abuse initiative," before moving on to other issues. (Stats. 1999, ch. 146, § 37.) It is obvious that the other issues referred to, such as the provider enrollment process, related to *other* statutory provisions that were also contained in section 37. (Stats. 1999, ch. 146, § 37.) Indeed, upon reviewing section 37, it appears that section 14043.75 was a catch-all section that authorized the Department to "by regulation, adopt . . . *additional* measures to prevent or curtail fraud and abuse" (*id.*, italics added) beyond that specifically addressed by the other statutory provisions. Thus, the legislative history shows that section 14043.75 was not limited as CAMPS suggests.

CAMPS also argues that the adoption of the UBL was "inconsistent" with section 14044. It authorizes the Department to temporarily limit certain billing and

reimbursement codes pursuant to which a provider may bill, or reimbursement may be made by, the Medi-Cal program if the Department determines a provider has engaged in "excessive . . . billings, or abuse[.]" (§ 14044, subd. (a)(1).) There is no inconsistency. Both parties ignore that section 14044, enacted as part of Assembly Bill 1762, became effective August 11, 2003, after the Department first adopted the UBL as an emergency regulation. (Stats. 2003, ch. 230, § 59.) The Legislature gave no indication that its authorization of such quasi-judicial action limited the Department's existing quasi-legislative authority to promulgate general regulations to prevent or curtail fraud and abuse. To the contrary, *in the same legislation*, the Legislature incorporated the UBL into section 14105.48, also effective August 11, 2003. (Stats. 2003, ch. 230, § 67.) We conclude, as suggested by the Department and based on our own research, that this indicates the Legislature thought the Department acted within its authority to adopt the regulation (see *Moore v. California State Bd. of Accountancy* (1992) 2 Cal.4th 999, 1017 [the Legislature is presumed to be aware of an administrative construction of a statute when the construction has been made known to it]; cf. *In re Marriage of Skelley* (1976) 18 Cal.3d 365, 369 [when a judicially construed statute " 'is reenacted in the same or substantially the same terms, the Legislature is presumed to be familiar with that construction and to have adopted it as part of the law' "].) CAMPS's argument is without merit.

IV. *The Reasonable Necessity of the UBL*

CAMPS also argues that the UBL is invalid because there is not substantial evidence to support the Department's determination that the UBL was reasonably necessary to effectuate the purpose of section 14043.75. We disagree.

CAMPS's emphasis on substantial evidence obscures the principle that courts are deferential of an agency's determination of reasonable necessity. While the judiciary independently reviews a regulation adopted pursuant to the APA for consistency with controlling law, "reasonable necessity[] generally does implicate the agency's expertise; therefore it receives a much more deferential standard of review. The question is whether the agency's action was arbitrary, capricious, or without reasonable or rational basis."

(*Communities for a Better Environment v. California Resources Agency*, *supra*, 103 Cal.App.4th at pp. 108-109, fns. omitted; *20th Century Ins. Co. v. Garamendi*, *supra*, 8 Cal.4th at p. 272.) That said, a regulation which interprets a statute *may* be declared invalid if the agency's determination that the regulation is reasonably necessary to effectuate the statutory purpose is not supported by substantial evidence. (Gov. Code, § 11350, subd. (b)(1).) "Necessity" means "the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record." (Gov. Code, § 11349, subd. (a).)

As we have discussed, the Department adopted the UBL pursuant to section 14043.75 because of its determination that it was "necessary to prevent and curtail provider fraud and abuse" regarding medical supplies and durable medical equipment. The Department stated: "One way this happens is when providers bill the Medi-Cal program for items they did not actually purchase or purchased at significantly below market rates, or bill in amounts that represent more than a 100 percent markup over their net purchase price for the products, irrespective of their usual charges to the general public. The Department believes [that] such billings result in unnecessary costs to the Medi-Cal program and are outside sound fiscal or business practices."

CAMPS in essence argues that the Department did not actually produce evidence showing that any of this fraud or abuse was occurring. CAMPS states: "Throughout the rulemaking record, the Department states, with no factual support, that providers had billed Medi-Cal in amounts greater than a 100 percent markup over their net purchase price for products, as a result of purchasing products illegitimately at discounted prices or obtaining the products without paying for them. In response, providers presented a multitude of evidence that many providers received bona fide discounts on [durable medical equipment] or medical supplies through the legitimate market, often tied to sound business or fiscal practices. In addition, providers cast doubt on whether the Department could substantiate the illegitimate practices that it alleged as the basis for the

UBL. In response, the Department provided no factual evidence of the practices that the UBL was ostensibly adopted to address."

CAMPS's argument is unpersuasive because the Department's determination of potential abuse was broader than CAMPS describes. As we have already discussed, the Department acted not only to prevent fraud and abuse by providers purchasing products outside legitimate distribution channels, but also to close a loophole that enabled providers to obtain unanticipated profits from the Medi-Cal program at taxpayer expense by billing the program at its maximum reimbursement rates for products purchased at unanticipated discounts—whether or not through legitimate distribution channels. As the Department argues, "[t]he necessity of this regulation to prevent abuse is self-evident." We agree, and conclude the loophole itself is substantial evidence to support the reasonable necessity for the UBL. Even if the Department had no evidence that any providers had yet to exploit this loophole, it would have been entitled to adopt the UBL to "*prevent*" abuse in the future under section 14043.75. (§ 14043.75, subd. (a).)

Furthermore, the record contains other factual bases supporting the Department's conclusion that it was reasonably necessary to implement the UBL in order to curtail and prevent fraud and abuse of the Medi-Cal program. The Department stated in both its initial and final statements of reasons for the UBL that "providers whose businesses are either 100 percent Medi-Cal, or for other reasons have not established charges to the general public, have billed the Medi-Cal program at the maximum reimbursement rates, regardless of how much they have paid for the product(s)." The Department also stated that "[c]ertain providers have billed the Medi-Cal program at the maximum reimbursement rates for products that they obtained at substantially below the estimated acquisition cost or the weighted average of the negotiated contract price." In its finding of emergency, the Department stated that its "[i]nvestigations . . . reveal exploitation of the Medi-Cal reimbursement system by providers who employ non-market practices to obtain [products] at substantially below cost and then bill Medi-Cal at the maximum reimbursement rates." The Department stated that it "routinely reviews the billing practices of Medi-Cal providers" and "conducts audits of providers' accounting and

billing practices," that the UBL was "based on the findings of those reviews and audits," and that it "must prevent and address fraudulent and abusive billings of providers."

Furthermore, in expressing their concerns and opposition to the durable medical equipment, a number of commenters acknowledged that, as the Department had indicated, providers were engaging in fraud and abuse. For example, Michael Simpson of Redding Medical Supply Inc. wrote that "[f]raud is rampant and the entire industry is concerned"; Douglas Zaer of Superior Mobility discussed "abusers" and stated that he understood that "fraud and abuse is a major concern of the Medi-Cal program"; Laura McIlvaine wrote that Shield supported "the Department's efforts to establish a fair and equitable reimbursement for durable medical equipment and supplies provided to Medi-Cal beneficiaries, combined with efforts to curb fraud and abuse"; and CAMPS Executive Director Bob Achermann wrote that CAMPS had "always attempted to assist the Department in their efforts to eradicate provider fraud and appreciate the difficulty of your task."

CAMPS contends that these statements in the record were "evidence suggesting the existence of general fraud and abuse" and do "not demonstrate any need for the adoption of the UBL." We disagree. The Department made factual statements that related directly to the concerns behind the UBL. The statements of the providers were made at the hearing on, or in comments regarding, the UBL, from which it can be reasonably inferred that they were directed at these same concerns.

CAMPS also contends that the Department failed to produce any "evidence justifying the necessity of the UBL in its responses to the Public Records Act submitted by providers during rulemaking and by counsel for CAMPS after rulemaking." However, CAMPS does not provide the request made during rulemaking, citing only to an oral statement by Galvin that such a request had been made. This is insufficient for us to evaluate the merits of CAMPS's contention. As for the request made "after rulemaking," it was in fact made in 2008, four years after the adoption of the UBL under the APA, and has no relevance to the question at hand, which relates to the rulemaking process in 2003 and 2004.

We conclude the loophole itself and the statements in the record that we discuss herein constitute "substantial evidence" of the "reasonable" necessity to implement the UBL in order to prevent and curtail fraud and abuse pursuant to section 14043.75. Also, we conclude the UBL was a rational response to the Department's efforts to prevent fraud and abuse because of the loophole the Department discovered, and was not arbitrary or capricious. We have no basis for invalidating the UBL for lack of reasonable necessity.

V. *Clarity*

CAMPS next argues that we should invalidate the UBL because it lacks the minimal level of "clarity" required by the APA. The Department argues that this is not a basis for our invalidating the UBL, and that the UBL does not lack clarity. We agree with the Department that CAMPS's argument is not a basis for our invalidating the regulation, and do not address the merits of CAMPS's claim.

CAMPS argues the UBL's definition of "net purchase price" is not sufficiently clear because, while it includes discounts and rebates "known" to the provider at the time of billing the Medi-Cal program that reduce an item's invoice amount and price reductions "guaranteed by contract" (Cal. Code Regs., tit. 22. § 51008.1, subds. (a)(2)(A) & (B)), the UBL does not specify further when such things are "known" to a provider and "guaranteed" by a contract, leaving the calculation of net purchase price "fundamentally unclear to the provider community."

According to CAMPS, there has been confusion in the enforcement of the UBL as a result of this lack of clarity. The Department has applied a more stringent definition for net purchase price than that in its regulations without notice to providers, and administrative law judges have disagreed about the validity of the Department's interpretation.

The only legal support that CAMPS cites in its opening brief for its invalidity argument is Government Code section 11349, subdivision (c). That subdivision, however, merely defines "clarity." (Gov. Code, § 11349, subd. (c) [defining clarity as "written or displayed so that the meaning of regulations will be easily understood by

those persons directly affected by them"].) It does not provide a legal basis for our declaring the regulation invalid for lack of such clarity.

The Department argues that the issue raised by CAMPS is for the Office of Administrative Law, not this court, to review pursuant to Government Code section 11349.1, subdivision (a). Government Code section 11349.1, subdivision (a) provides that "[t]he office shall review all regulations adopted . . . and make determinations using all of the following standards: [¶] . . . [¶] (3) Clarity." (Gov. Code, § 11349.1, subd. (a)(3).) Based on this provision, the Third Appellate District in *Pulaski*, *supra*, 75 Cal.App.4th 1315, held that a trial court abused its discretion when it struck a provision in a regulation as "unnecessary surplusage and ambiguous." (*Id*. at p. 1332.) The appellate court stated that "it was not the court's function to clarify the standard" for the administrative board because "[t]he Legislature has expressly delegated to the [Office of Administrative Law] the responsibility for reviewing proposed regulations for 'clarity' . . . . (Gov. Code, § 11349.1, subd. (a).) A court may only sustain a facial challenge to a regulation when it is 'arbitrary, capricious or without rational basis.' " (*Ibid*.) Thus, it would be inappropriate for this court to invalidate the UBL based on CAMPS's "lack of clarity" claim.

In its reply brief, CAMPS argues that this court may entertain its claim because "an unclear regulation may rise to the level of an arbitrary and capricious act by an agency where the regulation violates due process by being too vague to provide adequate notice of the conduct proscribed or prescribed, or to provide sufficiently definite guidelines for enforcement. It also argues that "[a] regulation could . . . be so unclear that it rises to failure to substantially comply with the APA." These arguments are tardily presented, without explanation. We will not further consider them because they should have been included in the opening brief if they are the legal bases for CAMPS's claim. (*Campos v. Anderson* (1997) 57 Cal.App.4th 784, 794, fn. 3 ["[p]oints raised in the reply brief for the first time will not be considered, unless good reason is shown for failure to present them before"].) We note, however, that CAMPS's only support for its first argument is an unadorned citation to *People v. Superior Court (Caswell)* (1988) 46

Cal.3d 381, 389-390, in which the court considered whether a loitering statute was unconstitutionally vague, a far cry from the circumstances of the present case. CAMPS provides no legal authority for its "failure to substantially comply" argument, other than another unadorned citation to Government Code section 1350, subdivision (a). Both arguments are unpersuasive as presented.

VI. *The Reasonableness of the 100 Percent Markup Limit*

CAMPS next argues that the UBL is invalid because its 100 percent markup limit is arbitrary and capricious, since it is based on "mere conjecture." We disagree with this analysis as well.

In the course of adopting the UBL, the Department stated that "[f]or the majority of providers who are within the market-place
assumptions . . . Medi-Cal reimbursement will not change, as their net purchase price equals or exceeds the estimated acquisition cost or the weighted average of the negotiated contract price." The Department did not expect the UBL to affect reimbursements for providers who engaged in billing that was neither fraudulent or abusive. The UBL's 100 percent markup was "intended to be at a level that will not impact the reimbursement markup, as no currently established reimbursement markup exceeds 100 percent. For example, the allowable reimbursement markup for medical supplies is 23 percent [citation]. For incontinence medical supplies, it is the weighted average of the negotiated contract price plus 38 percent [citation]. There are no specific statutory or regulatory percentage reimbursement markups for durable medical equipment . . . ; however, the maximum reimbursement rates established in regulations [citations] for these products are based on their estimated acquisition cost plus no more than a 100 percent reimbursement markup. Thus, in regulations, there are established maximum Medi-Cal reimbursement markups for all these product types." The Department also indicated that it needed to change billing methodology so as to be based on net purchase price in order to curtail and prevent fraud, including by providers who paid well below market rates, or nothing, for products and turned around and billed the Department for the maximum reimbursement allowed under law for these products.

CAMPS argues that the Department's statements "offered a flimsy 'rationale' " for the 100 percent markup limit. It repeats comments that the Department "arbitrarily" assuming the markup limit was sufficient " 'with no study, background, or evaluation to justify this assumption.' " It criticizes the Department because it "basically 'eyeballed' a markup equal to the [net purchase price] and asserted that that amount would sufficiently reimburse providers."

The Department's analysis and determinations were reasonable in light of the specific changes it was making, including its setting a markup limit that was equal to or significantly above the allowable markups stated in statutes or previously specified in the regulations. The 100 percent markup is not arbitrary or capricious.

Furthermore, CAMPS contends, the Department's rationale "disintegrates under scrutiny." CAMPS points out with regard to durable medical equipment, which CAMPS contends is the largest category of items the UBL regulates, that the previous regulation, California Code of Regulations, title 22, section 51521, did not tie reimbursements to estimated acquisition cost or any markup limitation. This argument, however, ignores that in its initial and final statement of reasons the Department stated that, although "[t]here are no specific statutory or regulatory percentage reimbursement markups for durable medical equipment . . . the maximum reimbursement rates established in regulations [*under*] [California Code of Regulations, title 22,] section 51521 . . . respectively for these products are based on their estimated acquisition cost plus no more than a 100 percent reimbursement markup." CAMPS does not challenge the accuracy of the Department's statement. Therefore, this specific criticism falls short, and is unpersuasive.

CAMPS also argues that the 100 percent markup limit is arbitrary and capricious because it uses a different cost basis than the markups for medical supplies and incontinence medical supplies. At the time of the UBL's adoption there were, respectively, not to exceed "23 percent of the cost of the item dispensed, as defined by the [D]epartment" (former § 14105.2, subd. (a), Stats. 2002, ch. 1161, § 53.5) and "the weighted average of the negotiated contract prices within each product category, plus a

markup fee equal to 38 percent of the resulting adjusted contract price." (Former § 14125; Stats. 2002, ch. 1161, § 81.)

CAMPS's argument is unpersuasive because the UBL'S 100 percent markup limit is approximately three to four times larger than these markup rates, which the Department indicated was intended to take into account additional costs that are not to be included in net purchase price. CAMPS questions the Department's reasoning (speculating that the cost bases "could" be much different and result in "very different reimbursement amounts") without providing a persuasive reason why the Department's reasoning is so flawed as to result in an arbitrary and capricious regulation. We conclude that it is not flawed.

The Department also argues that the trial court erred in excluding certain evidence in the petition proceedings below. In light of our conclusions herein, we have no need to address this issue.

DISPOSITION

The judgment is affirmed. Respondent is awarded costs of appeal.

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Lambden, J.

We concur:

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Kline, P.J.

_____
Haerle, J.

California Association of Medical Product Suppliers v. David Maxwell-Jolly, et al.
(A126749)

Trial Court:	Alameda County Superior Court
Trial Judge:	Hon. Frank Roesch
Attorneys for Plaintiff and Appellant:	Hooper. Lundy & Bookman, Inc. Marke E. Reagan Felicia Y. Sze Paul A. Deeringer
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