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OPINION	:	No. 83-909
	:	
of	:	<u>FEBRUARY 16, 1984</u>
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THE HONORABLE PETER RANK, DIRECTOR, DEPARTMENT OF HEALTH SERVICES, has requested an opinion on the following question:

Must the adjustment of drug product prices pursuant to Welfare and Institutions Code section 14105.7 be accomplished by adopting and amending formal regulations under the provisions of the Administrative Procedure Act?

CONCLUSION

The adjustment of drug product prices pursuant to Welfare and Institutions Code section 14105.7 may be accomplished by means other than adopting and amending formal regulations under the provisions of the Administrative Procedure Act.

ANALYSIS

Welfare and Institutions Code section 14105.7, subdivision (a),¹ provides:

"In order to fairly reimburse pharmacies for the furnishing of prescription drugs to Medi-Cal beneficiaries, the director shall update allowable drug product prices no less often than every 60 days. The update shall include any prior change received notice. Notice to the director shall include, but not be limited to, publication of the price change in the supplier's catalog or supplement or in nationally distributed drug price reference guides."

The question presented for analysis is whether the director of the Department of Health Services ("Department") may perform his statutory duties of adjusting drug product prices without adopting and amending formal regulations under the provisions of the Administrative Procedure Act (Gov. Code, §§ 11340-11528; hereafter "APA"). We conclude that he may.

The Department administers the Medi-Cal Act (§§ 14000-14199), enacted by the Legislature to provide "health care and related remedial or preventive services to recipients of public assistance and to medically indigent aged and other persons." (§ 14000; see *Roberts v. Brian* (1971) 6 Cal.3d 1, 4; *Morris v. Williams* (1967) 67 Cal.2d 733, 738-744; *California Medical Assn. v. Brian* (1973) 30 Cal.App.3d 637, 642.)

Services provided as benefits under the program include the purchase of prescription drugs "subject to the Medi-Cal Drug Formulary and Utilization Control." (§ 14132, subd. (d); see § 14053.)

The Department has previously issued detailed regulations which specify by name a select few prescription drugs (Cal. Admin. Code, tit. 22, §§ 51513-51513.6) and which are amended from time to time to reflect the price changes made under section 14105.7. The Department believes that such formal administrative action is burdensome, unnecessary, and in conflict with the language and intent of section 14105.7.

The Office of Administrative Law (hereafter "OAL") believes otherwise. It is responsible for reviewing administrative regulations under the APA to insure, in part, that they are "in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law." (Gov. Code, § 11349, subd. (d); see Gov.

¹ All references to the Welfare and Institutions Code prior to footnote 3 are by section number only.

Code, §§ 11342, 11349.1.) OAL believes that formal regulations must be adopted and amended to specify all drug product price changes made under section 14105.7 and that the matter is controlled by section 14105, subdivision (a):

"The director shall prescribe the policies to be followed in the administration of this chapter, may limit the rates of payment for health care services, and shall adopt such rules and regulations as are necessary for carrying out, not inconsistent with, the provisions thereof.

"Such policies and regulations shall include rates for payment for services not rendered under a contract pursuant to Chapter 8 (commencing with Section 14200) of this part. In order to implement expeditiously the budgeting decisions of the Legislature, the director shall, to the extent permitted by federal law, adopt regulations setting rates which reflect such decisions 30 days after the enactment of the Budget Act and of any other appropriation which changes the level of funding for Medi-Cal services. The proposed regulations shall be submitted to the Department of Finance five days prior to the date of adoption. With the written approval of the Department of Finance, the director shall adopt such regulations as emergency regulations in accordance with the provisions of the Administrative Procedure Act (Chapter 4.5 (commencing with Section 11371), Part 1, Division 3, Title 2 of the Government Code). For purposes of such act, the adoption of such regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, and safety or general welfare."²

Normally, to amend a regulation under the APA, the administrative agency prepares a statement of the reasons for its adoption (Gov. Code, § 11346.7),³ prepares and issues a public notice of proposed action at least 45 days prior to the hearing on the proposed amendment (§§ 11346.4, 11346.5), conducts a hearing on the proposed amendment (§ 11346.8), updates the previously prepared statement of purpose (§ 11346.7), adopts the amendment (§§ 11343, 11346.8), submits the amendment for review to OAL (§ 11343), which, after review, transmits the amendment within 30 days to the Secretary of State for filing (§§ 11343.2, 11349.1, 11349.3), with the amendment becoming effective 30 days after such filing (§ 11346.2). (See 63 Ops.Cal.Atty.Gen. 326, 328-329 (1980).)

² "Chapter 8" refers to the Waxman-Duffy Prepaid Health Plan Act (§§ 14200-14499.5) in which the Legislature has authorized persons eligible for Medi-Cal assistance to enroll in prepaid health plans.

³ All references hereafter to the Government Code are by section number only.

Welfare and Institutions Code section 14105, on the other hand, authorizes the adoption of "emergency regulations" in certain cases if given "the written approval of the Department of Finance." Such regulations would have five days of review by the Department of Finance before adoption as specified in the enabling statute.

We believe that the provisions of Welfare and Institutions Code section 14105 concerning the issuance of regulations under the APA are inapplicable to the Department's duties to update prescription drug prices.

First, we note that the updating is not a reflection of "the Budget Act [or] any other appropriation which changes the level of funding for Medi-Cal services" as specified in the statute. It would appear through use of the word "such" in Welfare and Institutions Code section 14105 that authorization for emergency regulations under the APA is given only for regulations implementing "the Budget Act [or] any other appropriation which changes the level of funding for Medi-Cal services." (See Stats. 1979, ch. 256, § 2.) The statute is ambiguous as to whether all other regulations must comply with the APA review procedure.

Second, the APA itself provides an exemption from its requirements for regulations that establish rates or prices. Subdivision (a) of section 11343 states in part:

"Every state agency shall:

"(a) Transmit to the office for filing with the Secretary of State a certified copy of every regulation adopted by it except one which:

"(1) Establishes or fixes rates, prices, or tariffs."

Section 11346.1, subdivision (a), provides in turn: "The provisions of this article shall not apply to any regulation not required to be filed with the Secretary of State under this chapter" (See § 11349.1; *State Comp. Ins. Fund v. McConnell* (1956) 46 Cal.2d 330, 343; *Winzler & Kelly v. Department of Industrial Relations* (1981) 121 Cal.App.3d 120, 126-128; *Estate of Setzer* (1961) 192 Cal.App.2d 634, 639-640; 66 Ops.Cal.Atty.Gen. - (Dec. 28, 1983).)

Third, it is clear that not all regulations of the Department need conform to the requirements of the APA. In *Alta Bates Hospital v. Lackner* (1981) 118 Cal.App.3d 614, the court examined a requirement that the Department modify the amount of payment for services under certain conditions as set forth in Welfare and Institutions Code section 14120, subdivision (c). The court pointed out that any delay caused by the issuance of a formal regulation would be contrary to the enabling legislation in question:

"As a practical matter, were we to uphold the trial court's ruling that a directive such as made in this case by the director could only be made as a regulation through the procedural mechanics of the Administrative Procedure Act, we would effectively eviscerate section 14120, subdivision (c). That section is designed to allow the director, who is uniquely in possession of the factual data through possession of records and statistics, to make the necessary fiscal determinations and projections which call for action under the section. The Legislature obviously recognized this when it provided the director with the tool of section 14120, subdivision (c), and did not specify that his use of that tool was to be slowed by the relatively cumbersome and, in this case, unnecessary procedures of the Administrative Procedure Act." (*Id.*, at p. 623.)

The court rejected the use of emergency regulations to reduce the delay:

"It cannot be successfully argued that long delay could be minimized by utilization of the 'emergency regulation' procedures set forth in the Administrative Procedure Act, specifically in former Government Code section 11422 (now § 11346.2). Under that procedure, it would be necessary to draft formal regulations, prepare cost reports, submit them to the Department of Finance, have Finance review and then file and approve them in writing with the Secretary of State and the Legislature. (Welf. & Inst. Code, § 14105, subd. (a).)" (*Id.*, at p. 623, fn. 5.)

As in *Alta Bates*, the Legislature understandably did not require in Welfare and Institutions Code section 14105.7 the adoption and amendment of formal regulations with respect to the updating of prescription drug prices. It would be unreasonable to suggest that the complex and time-consuming APA review process should apply to the frequent updating of prescription drug prices for pharmacies based upon the price changes by the drug manufacturers. Hence, "under well-established principles of statutory construction," the language of said statute "is to be treated as an exception to or as exempt from the general provisions" of the APA so as to effectuate the obvious intent of the Legislature. (See *Alta Bates Hospital v. Lackner*, *supra*, 118 Cal.App.3d 614, 622-623.)

While the updating of prescription drug prices would thus constitute a "regulation" in the broad sense (see § 11342, subd. (b); Welf. & Inst. Code, § 14105; *Armistead v. State Personnel Board* (1978) 22 Cal.3d 198, 201-203; *Ligon v. State Personnel Board* (1981) 123 Cal.App.3d 583, 588), the updating is exempt from the requirements of the APA under the exclusion for the setting of rates expressly contained

therein and under the Alta Bates rationale that the provisions of Welfare and Institutions Code section 14105.7 do not lend themselves to the APA review procedure.⁴

In answer to the question presented, therefore, we conclude that the adjustment of prescription drug prices pursuant to Welfare and Institutions Code section 14105.7 may be accomplished by means other than adopting and amending formal regulations under the provisions of the APA.

⁴ *California Assn. of Nursing Homes etc., Inc. v. Williams* (1970) 4 Cal.App.3d 800, 821 is not inconsistent with our conclusion. There the court was dealing in part with a statute that has since been repealed and with regulations "much broader than the Administrative Procedure Act's narrow exemption of rates, prices or tariffs." Here the drug price updating under Welfare and Institutions Code section 14105.7 is not broader than the APA's specific exemption.