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IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION ONE

JOSEPH PALESKI, Plaintiff and Appellant, v. STATE DEPARTMENT OF HEALTH SERVICES et al., Defendants and Respondents.	B186206 (Los Angeles County Super. Ct. No. BS088330)

APPEAL from a judgment of the Superior Court of Los Angeles County, David P. Yaffe, Judge. Affirmed.

Arnold & Porter, Brian K. Condon; Disability Rights Legal Center and Shawna L. Parks for Plaintiff and Appellant.

Bill Lockyer, California Attorney General, Thomas R. Yanger, Senior Assistant Attorney General, Julie Weng-Gutierrez, Supervising Deputy Attorney General, and Margarita Altamirano, Deputy Attorney General, for Defendants and Respondents.

Plaintiff, a beneficiary of the California Medical Assistance Program (Medi-Cal), has AIDS (acquired immune deficiency syndrome). He depends upon Medi-Cal for prescription drugs. Plaintiff's physician diagnosed him with wasting syndrome, a disorder related to HIV (human immunodeficiency virus) that causes the body to use lean body mass rather than fat as an energy source. Plaintiff's physician prescribed a drug specifically approved for the treatment of HIV-related wasting.

After an initial course of treatment, which proved beneficial, plaintiff's physician concluded plaintiff was still suffering from wasting syndrome and prescribed the drug for an additional period. The state Department of Health Services (Department), which administers Medi-Cal, disagreed with the physician's determination and denied the request based on its published drug criteria. Several weeks later, a second prescription request was submitted to the Department and also denied.

Plaintiff filed a petition for a writ of mandate in the trial court, challenging the Department's published drug criteria on the grounds: (1) they had not been promulgated in accordance with the Administrative Procedure Act (APA) (Gov. Code, § 11340 et seq.) or the Medi-Cal Act (Welf. & Inst. Code, § 14105.395); and (2) they did not accord proper deference to a treating physician's determination of medical necessity, thereby violating state and federal law. The trial court denied the petition.

We conclude that state law exempts the Department's published drug criteria from the APA (see Welf. & Inst. Code, § 14105.395, subds. (a), (c)) but requires compliance with the Medi-Cal Act's notice and comment provisions (*id.*, subds. (b), (c)). Plaintiff has not demonstrated that the Department failed in that respect. Further, neither state nor federal law requires the Department to defer to a treating physician's determination of medical necessity when the Department's published drug criteria dictate a contrary conclusion, but the physician's determination is a factor that must be considered.

I

BACKGROUND

Plaintiff has been living with AIDS since 1984. Eventually, his physician diagnosed him with HIV-related wasting, a chronic, progressive syndrome that, if left

untreated, may be debilitating and potentially life-threatening, causing muscle weakness and an increase in disease complications. Wasting syndrome typically consists of weight loss throughout the body and a decrease in lean body mass.

A human growth hormone, somatropin, sold under the trade name Serostim, has been approved by the federal Food and Drug Administration (FDA) to treat HIV-related wasting syndrome. Serostim increases lean body mass, body weight, and protein synthesis. FDA approval was based on an analysis of patients' body weight and lean body mass in studies lasting up to 12 weeks. Anabolic steroids, which promote weight gain, have also been used to treat wasting syndrome.

There is no single, optimal treatment for wasting syndrome. Treatment must be individualized. A physician needs to manage a patient's condition on an individual basis. AIDS patients taking antiretroviral drugs may experience changes in body mass and fat distribution that mask wasting syndrome. Similarly, several factors can cause weight loss in patients with HIV, making it necessary to treat those underlying causes before determining whether Serostim is appropriate.

Under the auspices of the federal Medicaid program, Medi-Cal provides low-income individuals with health care benefits that are medically necessary. (See 42 U.S.C. § 1396 et seq.; Welf. & Inst. Code, §§ 14000, 14001.1, 14132, 14133.3; *Morris v. Williams* (1967) 67 Cal.2d 733, 738–741.) As permitted by federal law, the Department "may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." (42 C.F.R. § 440.230(d) (2005).) In turn, state law authorizes the "[p]urchase of prescribed drugs . . . subject to the Medi-Cal List of Contract Drugs and utilization controls." (Welf. & Inst. Code, § 14132, subd. (d).)

When Serostim was approved by the FDA in 1996, it was added by operation of law to the Medi-Cal List of Contract Drugs for the treatment of certain AIDS conditions. (Welf. & Inst. Code, § 14105.43, subds. (a), (b).) Its use by individual patients — if "used under the conditions specified on the Medi-Cal List of Contract Drugs" (Cal. Code Regs., tit. 22, § 51313.3, subd. (b)) — was not subject to "utilization controls," namely, "prior authorization, which is approval by a department consultant, of a specified [drug]

in advance of the [use] of that [drug] based upon a determination of medical necessity" (Welf. & Inst. Code, § 14133, subd. (a)).

Thus, at first, the Department did not require prior authorization — there were no utilization controls — if Serostim was prescribed for the treatment of AIDS wasting or cachexia associated with AIDS.[1] Then, in 2001, the Department adopted more restrictive utilization controls and started to require prior authorization if a patient sought to take Serostim for more than 12 weeks. This change in utilization controls was announced beforehand in Pharmacy Bulletins 505 and 515, dated February 2001 and July 2001, respectively, and the Department issued updated replacement pages for insertion into pharmacies' provider manuals. The Department also developed prior authorization criteria to implement the change but did not make them available to providers.

Because the provider manuals were used by pharmacies, the change in utilization controls soon became common knowledge. But, lacking the implementing criteria, providers did not know how the Department would determine prior authorization. To obtain prior authorization for a prescription, typically a pharmacy submitted a treatment authorization request (TAR), setting forth various medical information about the patient. (See Cal. Code Regs., tit. 22, §§ 51456, 51003; see also Welf. & Inst. Code, § 14133.01, eff. Aug. 16, 2004.) The TAR had to show that the use of the prescribed drug was medically necessary. (See Cal. Code Regs., tit. 22, § 51003, subd. (e).)

The Department never published its 2001 prior authorization criteria for Serostim, informing its field staff via e-mail that the "Serostim Prior Authorization Guidelines" were "FOR INTERNAL USE ONLY," were "NOT, repeat NOT a public document," and "may NOT be given to providers, prescribers, etc." The criteria relied on an analysis of changes in (1) body weight, (2) body mass index (BMI), and (3) body cell mass (BCM)

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[1] Cachexia is defined as "[w]eight loss, wasting of muscle, loss of appetite, and general debility that can occur during a chronic disease." (American Heritage Stedman's Medical Dict. (2002 ed.) <http://www.answers.com/topic/cachexia> [as of Nov. 6, 2006].)

to determine whether prior authorization would be granted.[2] The e-mail acknowledged that 98 percent of the TAR's requesting continuation of Serostim beyond the first 12 weeks would be denied under the unpublished criteria. As it turned out, pharmacies often submitted TAR's with clinical information and laboratory data that the Department deemed insufficient, resulting in processing delays or outright denials.

To improve the TAR process, the Department eventually decided to develop more objective prior authorization criteria for Serostim and to make them public. In 2001–2002, the Department's policy division consulted with Serostim's manufacturer, medical practitioners who specialized in HIV and AIDS treatment, and patient advocates. The policy division attended two meetings with the Department's AIDS Drug Assistance Program advisory committee, which consisted of eight physicians, one psychiatrist, three pharmacists, one county AIDS administrator, one AIDS advocacy organization representative, and three community members affected by HIV or AIDS. The Department also reviewed medical literature and published studies.

In May 2002, the package insert for Serostim stated that (1) studies of up to 12 weeks in duration showed the drug to be effective in treating AIDS-related wasting; (2) "no significant additional efficacy was observed beyond 12 weeks"; and (3) "[t]here are no data available from controlled studies for patients that start, stop, and re-start

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[2] BMI is an indicator of total body fat content. In the metric system, the formula for BMI is weight (in kilograms) divided by height (in meters squared). In the English system, BMI is calculated by dividing weight (in pounds) by height (in inches squared), then multiplying by a conversion factor of 703. A BMI of 18.5 to 24.9 is normal; 25 to 29.9 is overweight. (See U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, *BMI — Body Mass Index: About BMI for Adults* <http://www.cdc.gov/nccdphp/dnpa/bmi/adult_BMI/about_adult_BMI.htm> [as of Nov. 6, 2006].)

BCM measures the total mass of the metabolically active tissue in the body, primarily muscle tissue, organ tissue, red cells, and tissue cells. It is usually expressed as a percentage of total body weight. Under Medi-Cal, HIV-related wasting is currently associated with a BCM of less than 35 to 40 percent in men and less than 23 to 28 percent in women. (See Cal. Dept. of Health Services, Medi-Cal Update, Billing and Policy, Pharmacy Bulletin 560 (June 2003) pp. 7–9.)

treatment." A year later, the package insert indicated there were no significant changes when treatment went beyond 12 weeks. The manufacturer did note, however, that patients receiving an *additional* 12 weeks of therapy were able to *maintain* their earlier gains of lean body mass and weight.

In drafting the new prior authorization criteria, the Department considered whether to include the following provision: "In cases where the recipient's BMI, BCM, or unintentional weight loss fall outside of the listed parameters, or cannot be assessed, a clinical statement from the treating physician may be used as a basis for Serostim® approval. Such a statement would need to specify exactly why Serostim® is medically necessary and why the normal criteria, used to document AIDS wasting, [are] not applicable for this recipient." As explained by an internal Department e-mail: "Although strictly from a Policy standpoint [the foregoing provision] may not seem necessary, the reality in the field office setting is that such a statement is necessary. There are personality types, currently working in the Pharmacy Units, which see [the prior authorization criteria] as something out of the ordinary and thus will not deviate from anything included, or not included, in the [criteria]. It is the impression of the administration of these units that the above [provision] will 'relax' the perceived rigidity of the [criteria] and allow the consultant[s] to exercise their professional judgment in a more productive manner. [¶] This [provision] will also appeal to any physicians, who happen to obtain the Medi-Cal guidelines . . . . It impresses upon them that their clinical judgment is a factor in Serostim TAR adjudication."

In late 2002, the Department publicly announced new prior authorization criteria for using Serostim *after* an initial 12-week period, publishing them for physicians (Outpatient Service Bulletin 337 (Nov. 2002)) and pharmacies (Pharmacy Bulletin 548 (Dec. 2002)). The criteria were based primarily upon changes in body weight, BMI, and BCM. They did not include the proposed provision concerning a treating physician's determination of medical necessity.

According to the Department's chief of the pharmacy policy unit, "[i]n the case of Serostim, [the Department] issued the notice of *change* to Serostim *criteria* at least 30

days prior to changes in utilization control. [¶] . . . Notice to the public was also achieved by publication of bulletin articles or notices on the Medi-Cal website at www.medi-cal.ca.gov." (Italics added.)

On June 1, 2003, the Department further restricted the utilization controls on Serostim so that "[p]rior authorization is . . . required" in all circumstances — including an *initial* use of 12 weeks or less — with the possible exception of emergencies. Notice of this change was given in Pharmacy Bulletin 557, dated April 2003, and updated replacement pages were issued for inclusion in pharmacies' provider manuals. In June 2003, the Department publicly announced new prior authorization criteria to implement the change, publishing them for physicians (Outpatient Services Bulletin 344 (June 2003)) and pharmacies (Pharmacy Bulletin 560 (June 2003)).

In adopting the more restrictive utilization controls and prior authorization criteria in 2002 and 2003, the Department reacted in large part to the misuse of Serostim. An underground market had developed for Serostim among bodybuilders, athletes, and entertainers who wanted to build muscle mass quickly. Some Medi-Cal beneficiaries were selling their Serostim prescriptions to cappers or recruiters who would resell the drug. The Department was also concerned about the cost of Serostim. In 2001, Medi-Cal paid $32 million for Serostim. In 2003, a month's prescription cost $6,707. By law, the Department may restrict the use of a drug based on its potential for misuse or its cost. (See Welf. & Inst. Code, § 14105.39, subd. (c)(1)(D), (E); Cal. Code Regs., tit. 22, § 51313.6, subd. (a)(1), (4).)

Plaintiff started taking Serostim in 2001, before the Department required prior authorization for more than 12 weeks' use. On February 17, 2003, after the effective date of the 12-week restriction, plaintiff's pharmacy submitted a TAR for Serostim. The TAR stated that plaintiff had HIV wasting syndrome, was 5 feet, 7 inches tall, and weighed 183 pounds. It listed plaintiff's BMI (28.66) and BCM (47.8 percent). Based on a standard BMI chart, plaintiff was overweight. Three days later, the Department denied the TAR, noting that plaintiff had been on Serostim for the preceding 12 weeks, his BMI

and BCM had normalized, and the submitted information failed to establish that he was still in a state of wasting.

On April 8, 2003, plaintiff's pharmacy submitted another TAR for Serostim. The TAR stated again that plaintiff was suffering from wasting syndrome. It listed his weight as 179 pounds and stated his BMI (28) but not his BCM. By standard measurements, plaintiff was still overweight. The next day, the Department denied the TAR, commenting that plaintiff was not in a state of wasting.

Plaintiff appealed the denials administratively. In support, his physician submitted letters explaining that (1) plaintiff suffered from AIDS, wasting syndrome, and multiple complications of HIV infection; (2) plaintiff needed Serostim because other treatments for wasting syndrome, such as testosterone therapy, had not been effective; (3) plaintiff had tried anabolic steroids, but they had caused a loss of kidney function; (4) after being forced to discontinue Serostim, plaintiff lost lean body mass (he weighed 165 pounds in May 2003); (5) the Department's criteria required that plaintiff redeteriorate before Serostim would be reapproved; and (6) the cycle of gaining weight while on Serostim, losing weight when the prescription was denied, and regaining weight when the drug was finally reapproved, put a strain on plaintiff's liver and kidneys and posed a threat to his life.

After conducting a hearing on the appeal, an administrative law judge sustained the denials of the TAR's because the first TAR did not show that plaintiff's weight, BMI, or BCM had deteriorated since his recent use of Serostim, and the second TAR did not indicate his BCM. Further, notwithstanding plaintiff's drop in weight (to 165 pounds), he was still above the baseline weight for his height (148 pounds).

On February 13, 2004, plaintiff filed a petition for a writ of mandate in the trial court, naming the Department and its director as defendants. Plaintiff later filed a first amended petition. (See Code Civ. Proc., §§ 1085, 1094.5.) Defendants filed an answer.

On May 9, 2005, plaintiff filed papers in support of the petition, arguing that the prior authorization criteria violated the APA, federal Medicaid laws, and the Medi-Cal Act, and did not defer to a treating physician's determination of medical necessity.

Plaintiff did not challenge the denial of his administrative appeal. He sought a writ of mandate declaring the criteria invalid. Defendants filed opposition.

By minute order, the trial court ruled that the Medi-Cal Act (see Welf. & Inst. Code, § 14105.395) exempted the Department's criteria from the APA, the criteria had been published in accordance with the Medi-Cal Act (see *ibid*.), and the Department was not bound by a treating physician's determination of medical necessity (see *Cowan v. Myers* (1986) 187 Cal.App.3d 968 (*Cowan*)). Judgment was duly entered. Plaintiff appealed. We agree with the trial court and affirm.

II

DISCUSSION

This appeal requires that we interpret state and federal statutes and regulations. The pertinent facts are not in dispute. "'A trial court's interpretation of a statute is reviewed de novo,' and 'the application of a statutory standard to undisputed facts is reviewed de novo.'" (*Emeryville Redevelopment Agency v. Harcros Pigments, Inc*. (2002) 101 Cal.App.4th 1083, 1095.)

A. Compliance with the APA

"The APA establishes the procedures by which state agencies may adopt regulations. The agency must give the public notice of its proposed regulatory action . . . ; issue a complete text of the proposed regulation with a statement of the reasons for it . . . ; give interested parties an opportunity to comment on the proposed regulation . . . ; respond in writing to public comments . . . ; and forward a file of all materials on which the agency relied in the regulatory process to the Office of Administrative Law . . . , which reviews the regulation for consistency with the law, clarity, and necessity . . . .

"One purpose of the APA is to ensure that those persons or entities whom a regulation will affect have a voice in its creation . . . , as well as notice of the law's requirements so that they can conform their conduct accordingly . . . . The Legislature wisely perceived that the party subject to regulation is often in the best position, and has the greatest incentive, to inform the agency about possible unintended consequences of a proposed regulation. Moreover, public participation in the regulatory process directs the

attention of agency policymakers to the public they serve, thus providing some security against bureaucratic tyranny." (*Tidewater Marine Western, Inc. v. Bradshaw* (1996) 14 Cal.4th 557, 568–569, citations omitted.)

"No state agency shall issue, utilize, enforce, or attempt to enforce any guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule, which is a regulation . . . unless the guideline, criterion, bulletin, manual, instruction, order, standard of general application, or other rule has been adopted as a regulation and filed with the Secretary of State pursuant to [the APA]." (Gov. Code, § 11340.5, subd. (a).) "A regulation subject to the APA . . . has two principal identifying characteristics. . . . First, the agency must intend its rule to apply generally, rather than in a specific case. The rule need not, however, apply universally; a rule applies generally so long as it declares how a certain class of cases will be decided. . . . Second, the rule must 'implement, interpret, or make specific the law enforced or administered by [the agency], or . . . govern [the agency's] procedure.'" (*Tidewater Marine Western, Inc. v. Bradshaw*, *supra*, 14 Cal.4th at p. 571, citations omitted.)

Here, the Department's prior authorization criteria, published in late 2002 and June 2003, were not promulgated in compliance with the APA. But the question before us is whether the APA applies. (See *California Medical Assn. v. Brian* (1973) 30 Cal.App.3d 637, 655.) As we explain, the criteria are exempt from the APA.

Effective August 11, 2003, the Legislature enacted section 14105.395 of the Welfare and Institutions Code (section 14105.395), which provides:

"(a) The department may implement *utilization controls* through the establishment of guidelines, protocols, algorithms, or *criteria* for *drugs*, medical supplies, durable medical equipment, and enteral formulae. The department shall *publish* the guidelines, protocols, algorithms, or *criteria* in the pharmacy and medical *provider manuals*.

"(b) The department shall issue providers written notice of *changes* pursuant to subdivision (a) at least 30 days prior to implementation.

"(c) *Changes* made pursuant to this section are exempt from the requirements of the Administrative Procedure Act . . . , and shall not be subject to the review and

approval of the Office of Administrative Law. The department shall consult with interested parties and appropriate stakeholders in implementing this section with respect to all of the following: [¶] (1) Notifying the provider representatives of the proposed *change*. [¶] (2) Scheduling at least one meeting to discuss the *change*. [¶] (3) Allowing for written input regarding the *change*. [¶] (4) Providing advance notice on the implementation and effective date of the *change*." (Italics added.)

In construing this statute, we follow "'[t]he fundamental rule . . . that the court should ascertain the intent of the Legislature so as to effectuate the purpose of the law. . . .' . . . In determining that intent, we first examine the words of the statute itself. . . . Under the so-called 'plain meaning' rule, courts seek to give the words employed by the Legislature their usual and ordinary meaning. . . . If the language of the statute is clear and unambiguous, there is no need for construction. . . . However, the 'plain meaning' rule does not prohibit a court from determining whether the literal meaning of a statute comports with its purpose. . . . If the terms of the statute provide no definitive answer, then courts may resort to extrinsic sources, including the ostensible objects to be achieved and the legislative history. . . . '"We must select the construction that comports most closely with the apparent intent of the Legislature, with a view to promoting rather than defeating the general purpose of the statute, and avoid an interpretation that would lead to absurd consequences." . . .' . . . The legislative purpose will not be sacrificed to a literal construction of any part of the statute. . . ." (*Bodell Construction Co. v. Trustees of Cal. State University* (1998) 62 Cal.App.4th 1508, 1515–1516, citations omitted.)

Under the plain meaning rule, subdivision (a) of section 14105.395 permits the Department to effectuate drug utilization controls by adopting criteria that are published in provider manuals. In that way, the affected community learns about the criteria. The necessary effect of this subdivision is to exempt the criteria from the APA. It would make little sense to require that the criteria be published only in the provider manuals, which are of limited availability, if the broader notice requirements of the APA had to be met. (See *Alta Bates Hospital v. Lackner* (1981) 118 Cal.App.3d 614, 619–623 (*Alta*

Bates) [APA did not apply to Department's 10 percent cutback in outpatient services because Medi-Cal Act permitted Department to take steps to prevent cost overruns].)

Further, under the Medi-Cal Act, the Department may need to respond rapidly when a drug is being misused or raises cost problems. (See Welf. & Inst. Code, § 14105.39, subd. (c)(1)(D), (E); Cal. Code Regs., tit. 22, § 51313.6, subd. (a)(1), (4).) Compliance with the relatively lengthy process under the APA would frustrate that statutory purpose. (See *Alta Bates*, *supra*, 118 Cal.App.3d at pp. 621–623 & fn. 5.) Indeed, section 14105.395 itself was enacted on an urgency basis. (See Stats. 2003, ch. 230, §§ 66, 82.)

And "[t]he Administrative Procedure Act is a general law containing general provisions applicable . . . to the promulgation of regulations by administrative agencies. However, [section 14105.395] is a specific provision relating to a particular narrow subject, and, as such, under well-established principles of statutory construction, is to be treated as an exception to or as exempt from the general provisions." (*Alta Bates*, *supra*, 118 Cal.App.3d at pp. 622–623; see *State Water Resources Control Bd. v. Office of Admin. Law* (1993) 12 Cal.App.4th 697, 703–704 & fn. 6; Gov. Code, § 11346.) Similarly, subdivisions (b) and (c) of section 14105.395 require that prior authorization criteria satisfy notice and comment procedures which are less demanding than the APA.

In the trial court, plaintiff argued that subdivision (c) of the statute — which states that *changes* are exempt from the APA — means that *original* criteria are not exempt from the APA under subdivision (a). Plaintiff asserted that the 2002 criteria — which were applied in denying his continued use of Serostim — were original criteria and thus not exempt. We disagree.

According to the legislative history of section 14105.395, the Department "shall publish the guidelines, protocols, algorithms, or criteria in the pharmacy and medical provider manuals. In addition, [the Department] will issue pharmacy providers written notice of changes. *These actions would be exempt from requirements of the Administrative Procedures Act*." (Sen. Rules Com., Off. of Sen. Floor Analyses, 3d

reading analysis of Assem. Bill No. 1762 (2003–2004 Reg. Sess.) as amended July 27, 2003, p. 4, italics added.)

Another committee report explained: "[Section 14105.395] would allow the implementation of utilization controls through the establishment of guidelines, protocols, algorithms, or criteria for drugs, medical supplies, durable medical equipment, and enteral formulae. Utilization controls are an important piece of cost reduction. Utilization controls help ensure the appropriate use of healthcare products and services. . . . [¶] . . . [¶] [The Department] believes that it must implement new strategies to reduce or eliminate the costly, inappropriate use of drugs. . . . This new statute would allow [the Department] to *act quickly* to implement utilization controls *through policy rather than regulation* or statute. [Section 14105.395] would require [the Department] to *continue* to meet with and receive input from provider organizations and other interested parties *prior to* implementing any *new* protocols." (Cal. Health and Human Services Agency, Enrolled Bill Rep. on Assem. Bill No. 1762 (2003–2004 Reg. Sess.) Aug. 6, 2003, p. 55, italics added.)

Thus, as evidenced by legislative intent, section 14105.395 permits the Department to implement utilization controls for drugs by publishing prior authorization criteria in provider manuals. At the same time, changes in criteria, that is, *new* protocols, must comply with the statute's less stringent notice and comment requirements in subdivisions (b) and (c). Compliance with the APA is not required.

Nevertheless, the Department is not satisfied with an exemption from the APA but goes even further, arguing that the Serostim criteria did not have to comply with section 14105.395's notice and comment requirements. The Department, like plaintiff in the trial court, seeks to narrow the scope of section 14105.395 by distinguishing between *original* criteria and *changes* in criteria. Original criteria, it argues, are governed solely by subdivision (a), which stands on its own and has no applicability to changes. Under this theory, the 2002 and 2003 criteria were original and thus did not have to comply with subdivisions (b) and (c), which require 30 days' notice of changes to providers, acceptance of written comments, one meeting to discuss the changes, and advance notice

of the changes' implementation and effective date. Just as we rejected plaintiff's narrow interpretation of "changes," so we are unpersuaded by the Department's contention.

First, subdivision (b) of section 14105.395 requires that the Department give providers "notice of *changes* made *pursuant to subdivision* (*a*)" (italics added), indicating that subdivision (a) is not limited to original criteria. Subdivision (c) refers to "[c]hanges made pursuant to *this section*" (italics added) and mandates that the notice and comment requirements be satisfied "in implementing *this section*" (italics added), supporting the same conclusion.

Second, where, as here, the drug criteria implement an announced "change" in utilization controls, the criteria themselves constitute a "change" in any sense of the word. As the Department's chief of the pharmacy policy unit acknowledged, the 2002 criteria — the first published criteria — were a "change to Serostim criteria." And the 2003 criteria — setting forth the standards for the *first* 12 weeks of Serostim use — made "changes" in the 2002 criteria — which outlined the requirements for use *after* 12 weeks.

Third, the legislative history indicates that the term "changes" includes original criteria, stating that "new protocols" will "continue" to require a meeting with, and input from, provider organizations and interested persons. In other words, new criteria need not comply with the APA but will continue to be subject to a preapproval process, as established in subdivisions (b) and (c). In this case, the 2002 and 2003 criteria were "new" and thus came within the meaning of "changes."

Finally, we cannot surmise any reason why the Legislature would exempt so-called original criteria from *all* notice and comment requirements but mandate that *subsequent* changes go through such a process. The limited approval procedure mandated by subdivisions (b) and (c) — 30 days' notice, one meeting, and written input — will not interfere with the Department's need to act quickly in response to the misuse or high cost of medications.

In short, we reject the parties' narrow reading of "changes." Section 14105.395 in its entirety applies to *all* drug criteria that implement utilization controls. The statute's reference to "changes" includes new as well as original criteria. Consequently, the

Department's drug criteria — whether characterized as original, new, or modified — must be published in provider manuals and comply with the notice and comment requirements of the statute but need not comply with the APA.

In this case, plaintiff does not challenge the *substance* of the prior authorization criteria. He does not dispute that they are adequately supported by medical data. Nor does he seek an award of damages. And he does not request review of the denial of his administrative appeal. Rather, he contends that the criteria are *procedurally* infirm. In these circumstances, plaintiff's petition to declare the criteria invalid seeks *prospective* relief, that is, a judicial decision as to whether the criteria are presently valid. (See *Hartwell Corp. v. Superior Court* (2002) 27 Cal.4th 256, 277.) A statute does not operate retroactively merely because some of the facts upon which its application depends came into existence before its enactment, here, the earlier publication of the Serostim criteria. (See *Kizer v. Hanna* (1989) 48 Cal.3d 1, 7; accord, *Department of Health Services v. Fontes* (1985) 169 Cal.App.3d 301, 304.)

The criteria were published in provider manuals in late 2002 and June 2003. In fact, the applicable criteria were published before plaintiff's TAR's were denied. Under section 14105.395, subdivision (a), which became effective on August 11, 2003, the criteria were properly published.

And plaintiff has not established that the Department violated the notice and comment provisions of the statute (§ 14105.395, subds. (b), (c)). The record contains evidence from the Department as to some of the actions it took in adopting the 2002 and 2003 criteria, suggesting it may have complied with those provisions. Plaintiff simply *asserts* the Department did not take all of the necessary steps to obtain approval. But an assertion is not evidence. Thus, no violation of the notice and comment provisions has been shown. (See *California Assn. of Nursing Homes etc., Inc. v. Williams* (1970) 4 Cal.App.3d 800, 810 [plaintiff has burden of proving statutory violation].) Accordingly, writ relief is inappropriate. (See *County of San Diego v. Brown* (1993) 19 Cal.App.4th 1054, 1086–1087 & fn. 43, 1089–1090; *Galster v. Woods* (1985) 173 Cal.App.3d 529, 545–546.)

It follows that the trial court correctly denied a writ of mandate declaring the criteria invalid under the APA (Gov. Code, § 11340 et seq.) and the Medi-Cal Act (§ 14105.395).

B. Deference to Treating Physician

We agree with plaintiff's contention that the Department must *consider* a treating physician's determination as to whether the use of a particular drug is medically necessary, but we do not conclude that, in this case, the Department failed in that regard. We also reject plaintiff's argument that a treating physician's determination necessarily trumps the Department's prior authorization criteria for Serostim.

"Medicaid is a cooperative federal-state program through which the federal government reimburses states for certain medical expenses incurred on behalf of needy persons. . . . Participation by states is voluntary, but those that choose to participate must comply both with statutory requirements imposed by the Medicaid Act and with regulations promulgated by the Secretary of Health and Human Services. . . .

"To qualify for federal assistance, participating states must submit to the Secretary, and have approved, a 'plan for medical assistance' that describes the nature and scope of the state program. . . . The Medicaid Act prescribes a laundry list of requirements that this state plan 'must' satisfy . . . , and an extensive body of regulations implements these requirements. The Secretary 'shall approve' any state plan (or amendment) that fulfills these statutory and regulatory conditions . . . .

"Under normal circumstances, if the [Secretary or statutory designee] approves the state plan, the federal government reimburses the state for a fixed percentage of certain expenses that the state incurs on behalf of Medicaid-eligible individuals. This percentage, known as the Federal Medical Assistance Percentage ('FMAP'), varies from state to state. Health care providers bill the state, the state pays the providers, and the federal government reimburses the state at the FMAP rate . . . . The state is responsible for the balance. In theory, this arrangement incentivizes states to keep rates at efficient levels, because they share financial responsibility for Medicaid costs with the federal

government." (*AK, Health & Social v. Medicare & Medicaid* (9th Cir. 2005) 424 F.3d 931, 934–935, citations omitted.)

Under federal regulations, "[e]ach [medical] service must be sufficient in amount, duration, and scope to reasonably achieve its purpose." (42 C.F.R. § 440.230(b) (2005).) The purpose of prescription drugs is "the cure, mitigation, or prevention of disease, or for health maintenance." (*Id*., § 440.120(a).) But "[t]he [state] Medicaid agency must implement a statewide surveillance and utilization control program that . . . [¶] . . . [s]afeguards against *unnecessary or inappropriate use of Medicaid services* and against excess payments." (*Id.*, § 456.3(a), italics added.) Under the Medi-Cal Act, the Department must provide "medically necessary" services, namely, those "necessary to protect life, to prevent significant illness or significant disability, or to alleviate severe pain." (Welf. & Inst. Code, § 14059.5.)

In support of his position, plaintiff relies in part on the legislative history of the Medicaid Act (42 U.S.C. § 1396 et seq.). The Senate report commented: "[T]he *physician* is to be the *key figure in determining utilization of health services* — and . . . it is a physician who is to decide upon admission to a hospital, order tests, *drugs* and treatments, and determine the length of stay. For this reason the [legislation] would require that payment could be made only if a physician certifies to the medical necessity of the services furnished." (Sen.Rep. No. 404, 89th Cong., 1st Sess. (1965), reprinted in 1965 U.S. Code Cong. & Admin. News, p. 1986, italics added.)[3]

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[3] Although this language appears in the Senate report on the bill that created Medicaid (H.R. No. 6675, 89th Cong., 1st Sess. (1965); see Pub.L. No. 89–97 (July 30, 1965) 79 Stat. 286), it refers to *Medicare*, the federal program for the aged and disabled (see 42 U.S.C. §§ 1395c, 1395f(a)(2), (3), 1395n(a)(2)). Of course, a legal analogy between the two statutory schemes may be appropriate if they are otherwise similar on a particular issue. (See *Skubel v. Sullivan* (D.Conn. 1996) 925 F.Supp. 930, 940–941, affd. as mod. *sub nom. Skubel v. Fuoroli* (2d Cir. 1997) 113 F.3d 330.) Both Medicaid and Medicare rely on physicians' determinations in the utilization process. (See, e.g., 42 U.S.C. §§ 1396a(a)(44), 1396d(a)(12), 1396r-8(k)(2)(A), 1396r-8(k)(4) [Medicaid]; *id.*, §§ 1395f(a)(2), (3), 1395n(a)(2), 1395w-102(e)(1)(A), 1395w-104(g)(2) [Medicare].)

In 1990, Congress amended the Medicaid Act to require that states implement a plan for reviewing the use of prescription drugs, as follows: "The State . . . shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits . . . , typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or *duration of drug treatment*, drug-allergy interactions, and clinical *abuse*/*misuse*." (42 U.S.C. § 1396r-8(g)(2)(A)(i), italics added.)

The statute continued: "The [drug review] program shall provide . . . for the ongoing periodic examination of claims data and other records in order to identify patterns of *fraud*, *abuse*, gross overuse, or *inappropriate or medically unnecessary care*, among *physicians*, pharmacists and individuals receiving benefits . . . , or associated with specific drugs or groups of drugs." (42 U.S.C. § 1396r-8(g)(2)(B), italics added.)

The legislative history of the 1990 amendments noted: "Under current law, States may, at their option, offer coverage for prescribed drugs. In order to qualify for Federal matching funds, *drug products must be* (1) *prescribed by a physician* or other licensed practitioner, (2) dispensed by licensed pharmacists and licensed authorized practitioners, and (3) dispensed on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records. . . . States may . . . require *prior authorization* with respect to any of the prescription drugs which they elect to cover. [¶] . . . [¶]

"States that elect to offer prescription drug coverage under their Medicaid programs would be required to cover all of the drugs of any manufacturer entering into and complying with [a rebate] agreement with the Secretary. . . . As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to *safeguard against unnecessary utilization* and assure that payments are consistent with efficiency, economy, and quality of care. However, the Committee *does not intend* that States establish or implement *prior authorization controls that have the effect of preventing competent physicians from*

prescribing in accordance with their medical judgment. This would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements — i.e., assuring access by [Medicaid] beneficiaries to prescription drugs where medically necessary.

". . . States would be required to establish a drug use review program for covered outpatient drugs in order to assure that prescriptions written for Medicaid beneficiaries are appropriate and medically necessary. . . . Each State's drug use review program would have to include both prospective and retrospective drug review. *Prospective drug review* would involve the review of drug therapy *before a prescription is filled or delivered*, typically at the point-of-sale or point-of-distribution. *Retrospective drug use review* would involve the period[ic] examination of claims data and other records in order to identify patterns of *fraud*, *abuse*, gross overuse or underuse, or *inappropriate or medically unnecessary care*, among *physicians*, pharmacies, and patients, or associated with specific drugs or groups of drugs.

"The Committee emphasizes that the bill is framed to achieve significant Medicaid savings with the minimum possible amount of disruption of current program arrangements. The bill would not require therapeutic substitution or in any other way alter in any way the current relationships between Medicaid beneficiaries and their physicians or their pharmacists. It would not alter the relationship between physicians and pharmacists. Nor would it alter the current payment arrangements between State Medicaid programs and pharmacists. Finally, the bill would not affect any authority States have under current law to *impose prior authorization controls on prescription drugs*." (H.R.Rep. No. 101-881, 2d Sess., pp. 95, 98 (1990), reprinted in 1990 U.S. Code Cong. & Admin. News, pp. 2107, 2110, italics added.)

Thus, according to Medicaid's legislative history, state programs like Medi-Cal must strike a careful balance between the deference due a treating physician's decision to prescribe a particular drug and the implementation of utilization controls, including prior authorization criteria, which ensure that prescriptions are appropriate and medically necessary.

As one federal court has stated: "'[T]he Medicaid statute and regulatory scheme create *a presumption in favor of the medical judgment of the attending physician in determining the medical necessity of treatment*.' . . . At the same time, 'Medicaid was . . . designed . . . to provide the largest number of necessary medical services to the greatest number of needy people.' . . . The Act 'confers broad discretion on the States to adopt standards for determining the extent of medical assistance, requiring only that such standards be "reasonable" and "consistent with the objectives" of the Act.' . . . *A state* must 'specify the amount, duration, and scope of each service' that it provides and '*may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures*.' . . . A provided service, however, must 'be sufficient in amount, duration, and scope to reasonably achieve its purpose.' . . . The Act and its regulations both protect and limit the states' discretion." (*Smith v. Rasmussen* (8th Cir. 2001) 249 F.3d 755, 759, citations omitted, italics added.)

We are not the first California court to address this subject. In *Cowan*, *supra*, 187 Cal.App.3d 968, the court phrased the primary question before it as, "Who decides what Medi-Cal services qualify as 'medically necessary,' the physician or the State?" (*Id.* at p. 976.) The court answered: "We conclude plaintiffs are in error when they assert the physician is the *sole arbiter* of what constitutes a medical necessity. The [Medicaid] Act permits the states discretion to determine on the basis of need which services shall be provided as part of the Medicaid program." (*Ibid.*, italics added.)

Cowan reviewed federal case law and explained: "The trial court adopted plaintiffs' position that '[the] spirit of the Medicaid Act is that *physicians* make the decision of whether or not certain treatment is "medically necessary."' Support for this position is found in *Pinneke v. Preisser* (8th Cir. 1980) 623 F.2d 546, 550, wherein it was stated: 'The decision of whether or not certain treatment or a particular type of surgery is "medically necessary" rests with the individual recipient's physician and not with clerical personnel or government officials.' The sweep of this language is less broad than it would seem, however, when considered in the context in which it was made. . . .

"*Pinneke* does not stand for the proposition that the physician is the sole arbiter of medical necessity. Rather, it holds that once a state plan has agreed to cover certain types of services, it may not exclude covered services for one particular *condition* where the physician determines the treatment is necessary. *Pinneke* illustrates that there are in fact two levels of medical necessity inherent in the Medicaid scheme. First, the state must decide which *services* are necessary; then, out of the covered services, the physician may determine which *treatment* is necessary for a particular condition. . . . 'We see two levels of judgment as to medical necessity in the statutory scheme. The first is the macro-decision by the legislature that only certain kinds of medical assistance are deemed sufficiently necessary to come under the coverage of its plan. The second is the micro-decision of the physician, that the condition of his patient warrants the administering of a type of medical assistance which that plan makes available.'" (*Cowan*, *supra*, 187 Cal.App.3d at pp. 977–978.)

Put another way, "the state's 'responsibility to establish standards extends at least to the shaping of a reasonable definition of medical necessity.' . . . 'This does not remove from the private physician the *primary responsibility of determining what treatment should be made available to his patients*. We hold only that the physician is required to operate within such *reasonable limitations* as the state may impose.'" (*Cowan*, *supra*, 187 Cal.App.3d at p. 979, italics added.) "The Medicaid regulations expressly permit the *State to limit services on the basis of medical necessity*. . . . We are convinced the [Medicaid] Act did not intend the physician to be the sole arbiter of medical necessity. Not only would such a rule result in inconsistent and unfair applications based on the variation between physicians . . . , but the State's requirement of reimbursement would be limited only by the imagination of physicians. Such open-ended liability was not the intent of the [federal] Act." (*Id.* at p. 980, citations omitted, italics added and omitted.)

As a practical matter, it would be unreasonable to "leav[e] the determination of medical necessity *solely* in the hands of the providers . . . . In such circumstances it is the physician who would determine whether he or she should be reimbursed for providing health care. It is not difficult to see what that determination would be in every case.

With due respect to the professionals who provide health care services under the Medi-Cal benefits program, the [Medicaid] Act never intended to grant these physicians carte blanche to charge services to the State." (*Cowan*, *supra*, 187 Cal.App.3d at p. 983, italics added.)

Cowan also approved the use of TAR's to ensure that drug prescriptions are medically necessary, stating: "[T]he [Medicaid] Act and its attendant regulations specifically allow individual states to 'place appropriate limits on a service based on . . . utilization control procedures.' . . . The TAR system is simply one type of procedure to control the utilization of Medi-Cal services. . . . The trial court's principal objection to the TAR system was its inconsistency with the perceived Medicaid mandate that the physician determine what treatment was 'medically necessary' for the needy patient. We have already determined the State's restriction on the meaning of medical necessity is proper under the [Medicaid] Act. It follows that if the State can limit services to situations where they are 'medically necessary' as defined, there must be some mechanism by which the State can enforce its definition. That prior authorization is a permissible utilization control is shown by the approval of this system by the secretary of Health and Human Services. In fact, the system of prior authorization has been in place since 1975. . . . [¶] . . . [P]rior authorization is a permissible method of ensuring that Medi-Cal services are limited to those defined as medically necessary." (*Cowan*, *supra*, 187 Cal.App.3d at pp. 984–985.) "Since the State may define which services are medically necessary, it is proper to enforce this definition *prior to* provision of the services in appropriate circumstances." (*Id.* at p. 987, italics added.)

In general, "[s]tates have considerable discretion in designing their Medicaid programs, and 'appropriate limits [may be placed] on a service based on such criteria as medical necessity or utilization control procedures.' . . . '[A] state may establish standards for individual physicians to use in determining what services are appropriate in a particular case.' . . . However, states 'may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.' . . . 'A state may place a generic

limit on Medicaid services based upon a judgment as to the degree of medical necessity of those services, so long as it does not discriminate on the basis of the specific medical condition which occasions the need.' . . . A state's definition of medically necessary services can reasonably exclude experimental treatment. . . . Although *physicians* still have the *primary responsibility* for determining what treatment should be available to their patients, they must operate within the *reasonable limitations* that the state may impose." (*Ruth v. Kizer* (1992) 8 Cal.App.4th 380, 386, citations omitted, italics added.)

Based on the foregoing authorities, we conclude that a treating physician's determination that Serostim is a medically necessary drug is a factor that the Department must consider in reviewing TAR's, although it is not controlling. The Department is also entitled to place appropriate limitations on the use of medications, but it may not ignore the physician's determination just because the prior authorization criteria do not list it as a factor. In light of the evidence in the record, there *may* be some cases where — given the medical data submitted with a TAR — the initial or continued use of Serostim may be medically necessary even though the patient's condition does not satisfy all of the Department's criteria.

But plaintiff has not challenged the denial of his administrative appeal. We therefore have no occasion to decide whether the Department properly considered his physician's determination of medical necessity. Just as HIV-related wasting syndrome is difficult to diagnosis and treat, requiring a complex assessment of each individual patient, so a court's review of the Department's decision-making process depends upon an in-depth analysis of a specific patient's administrative record — an analysis we are not called upon to perform here.

The trial court did not err in denying the petition for writ of mandate.

III

DISPOSITION

The judgment is affirmed.

CERTIFIED FOR PUBLICATION.

MALLANO, Acting P. J.

I concur:

JACKSON, J.*****

I concur in the judgment only.

VOGEL, J.

***** Judge of the Los Angeles Superior Court, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.