

UNITED STATES DISTRICT COURT  
DISTRICT OF MAINE

PINE TREE MEDICAL ASSOCIATES, )  
 )  
 Plaintiff )  
 v. ) Civ. No. 96-0005-B  
 )  
 SECRETARY OF HEALTH AND )  
 HUMAN SERVICES, ET AL, )  
 )  
 Defendant )

ORDER AND MEMORANDUM OF DECISION

BRODY, District Judge

Plaintiff, Pine Tree Medical Associates (Pine Tree), requests declaratory and injunctive relief pursuant to 5 U.S.C. § 702, arising from Defendants', Secretary of the U.S. Department of Health and Human Services and Director of the Bureau of Primary Health Care, denial of Pine Tree's application to have the low-income population of Primary Care Analysis Area 17 (Farmington PCAA) designated as a medically underserved population. Defendants filed a Motion to Dismiss for Lack of Standing on March 11, 1996. Pine Tree filed a Motion for Summary Judgment on March 25, 1996, and then again on May 3, 1996. Defendants filed a Motion for Summary Judgment on May 3, 1996.

The parties stipulated to a set of facts on May 3, 1996. The Court finds that there is no genuine issue as to any material fact, and summary judgment is appropriate.<sup>1</sup> For the reasons set

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<sup>1</sup> In Pine Tree's Memorandum of Law in Opposition to the Defendants' Motion for Summary Judgment and Plaintiff's Memorandum in Reply to Defendants' Memorandum in Opposition to Plaintiff's Motion for Summary Judgment, Pine Tree objects to certain statements of fact made by Defendants in Defendants' Opposition and Objections to Plaintiff's Motion for Summary Judgment and to specific portions of a declaration made by Evan R. Arrindell that was relied upon by Defendants in its Opposition. Because there is enough information in the

forth below, the Court grants Defendants' Motion for Summary Judgment and denies Pine Tree's Motion for Summary Judgment.<sup>2</sup>

## I. SUMMARY JUDGMENT

Summary Judgment is appropriate when there are no genuine issues as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). An issue is genuine, for summary judgment purposes, if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A material fact is one that has "the potential to affect the outcome of the suit under applicable law." Nereida-Gonzalez v. Tirado-Delgado, 990 F.2d 701, 703 (1st Cir. 1993). The Court views the record in the light most favorable to the nonmoving party. McCarthy v. Northwest Airlines, Inc., 56 F.3d 313, 315 (1st Cir. 1995).

## II. BACKGROUND

Pine Tree is a tax exempt, nonprofit corporation that provides primary health care services in Farmington, Maine. On May 18, 1995, Pine Tree submitted an application to the Division of Shortage Designation (Division), a subordinate agency of the Bureau of Primary Health Care within the U.S. Department of Health and Human Services (HHS), requesting that the low-income population of the Farmington PCAA be designated as a medically underserved population (MUP). In an area designated as a MUP, health care providers can request to be certified as Federally Qualified Health Centers (FQHCs). FQHCs are reimbursed under the

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stipulated facts to support a granting of summary judgment, Pine Tree's objections are irrelevant and the Court declines to rule on them.

<sup>2</sup> Consequently, the Court will not address Defendants' Motion to Dismiss for Lack of Standing.

Medicare and Medicaid programs, 42 C.F.R. § 405.2462, providing participants with cost-based reimbursement as an incentive to make health care accessible to the low income population, rather than on the basis of lower fee-for-service payments.

The Secretary of HHS (Secretary) has authority to designate urban or rural populations as MUPs under the Public Health Service Act (PHSA). 42 U.S.C. § 254c(b)(3). In determining whether an area qualifies as a MUP, the Secretary considers a number of criteria and variables. 42 U.S.C. § 254c(b). In particular, the PHSA directs the Secretary to consider “the ability of the residents of an area or of a population group to pay for health services . . . .” 42 U.S.C. § 254c(b)(4)(B). In 1976, regulations were published after notice and comment that elaborated on the PHSA’s directive and required the Secretary to consider “[e]conomic factors affecting the population’s access to health services, such as percentage of the population with incomes below the poverty level . . . .” 42 C.F.R. § 51c.102(e)(3). The term “population,” however, was undefined and the regulation did not specify how the percentage of the population was to be calculated.

In order to provide the Secretary with an objective basis for designating MUPS, HHS established in 1976 an Index of Medical Underservice (IMU) that was published in the Federal Register, without opportunity for comment, that incorporated the above-stated considerations. 41 Fed. Reg. 45,718 (1976). The IMU assigns an area seeking to be designated as a MUP with a score. The score is based on numerical weights that are derived from tables and assigned to data on certain variables, including the percentage of the population below the poverty level. *Id.* at 45,719-723. An area with an IMU score of 62.0 or below is designated a MUP. *Id.* at 45,718.

Since 1976, the Division has updated the criteria to be considered for MUP designation

periodically, without providing opportunity for notice and comment. In January 1994, the Division, without notice and comment, issued Summary Procedures for MUP Designation (1994 Procedures). The 1994 Procedures stated that in calculating the “percentage of the population with incomes below the poverty level,” as the 1976 regulations require, the population is “the population of the requested group within the area, rather than the total resident civilian population of the area . . . .” In its May 18, 1995, application for MUP designation, Pine Tree’s requested group was the low income population of the Farmington PCAA, which Pine Tree defined as the population with incomes under 200% of the federal poverty level. (Stip. ¶12). Applying the 1994 Procedures to Pine Tree’s request, the poverty score to be used in its IMU calculation was the number of people with incomes at or below 100% of the poverty level divided by the number of people in the requested group, which was in this instance those people with incomes at or below 200% of the poverty level. Using this arithmetic, Pine Tree’s application to have the Farmington PCAA designated a MUP indicated an IMU score of 57.7, therefore establishing the Farmington PCAA as a MUP.

On June 12, 1995, the Division issued revised Guidelines (the 1995 Guidelines), again without notice and comment, updating the criteria to be considered in MUP designations. The Division had not yet acted on Pine Tree’s application. Under the 1995 Guidelines, the term “population,” as it is used in calculating the poverty score for a MUP, was changed to the total population in the area, rather than the population of the requested group within the area. As a result, the poverty score under the 1995 Guidelines was calculated by dividing the number of people with incomes at or below 100% of the poverty level by the total number of people in the Farmington PCAA, rather than by the total number of people in the requested group. Using this

calculation, the IMU score for the Farmington PCAA was 74.6, making it ineligible for MUP designation. On June 22, 1995, the Division, having applied the 1995 Guidelines to Pine Tree's application, informed Pine Tree that "the population group in question does not meet the established criteria for [MUP] designations." (Stip.¶14). Accordingly, Pine Tree's request was denied.

On August 4, 1995, Pine Tree filed a timely request for reconsideration with the Bureau of Primary Health Care (Bureau). The Bureau took Pine Tree's request under advisement. On December 8, 1995, the Bureau denied Pine Tree's request for a second time. In its letter advising Pine Tree of its reasons, the Bureau stated, "The [1995 Guidelines] included a correction of analytic distortion with regard to how the poverty factor was determined in calculating the Index of Medical Underservice (IMU). The bureau regarded this distortion as so critical as to warrant immediate correction. Therefore, the corrected methodology was applied to requests that had not received final review . . . ." (Stip.¶16). As a result of the Bureau's decision, Pine Tree's request was denied.

On January 8, 1996, Pine Tree sued Defendants, seeking declaratory and injunctive relief from the Court. Specifically, Pine Tree asked the Court for the following relief: 1) Declare that the 1995 Guidelines are null and void for failing to comply with the notice and comment requirements of the Administrative Procedures Act (APA), 5 U.S.C. §§ 553(b), (c), and the PHS Act, 42 U.S.C. § 254c(b)(4)(B); 2) alternatively, declare that the 1995 Guidelines were impermissibly applied retroactively to Pine Tree's application; 3) enjoin Defendants from applying the 1995 Guidelines to Pine Tree's application; 4) direct Defendants to designate the Farmington PCAA as a MUP based upon the 1994 Procedures, the rules that were in effect at the

time Pine Tree submitted its application; and 5) grant Pine Tree such other relief as may be just and proper, including attorney fees and costs. Because the Court finds that Defendants did not violate the notice and comment provisions of the APA and PHSA, and that Defendants did not impermissibly apply the 1995 Guidelines retroactively to Pine Tree's application, Pine Tree's Motion for Summary Judgment is denied and Defendants' Motion for Summary Judgment is granted.

### III. NOTICE AND COMMENT

Pine Tree claims that the 1995 Guidelines are null and void because Defendants failed to comply with the APA's and PHSA's notice and comment provisions. The APA states that whenever an agency proposes a new rule, it must provide the public with notice and an opportunity for comment, 5 U.S.C. §§ 553(b), (c), unless the proposed rule is merely an interpretive rule rather than a substantive rule. This exception is inapplicable, however, "when notice or hearing is required by statute . . . ." *Id.* § 553(b)(3). The PHSA states that "[t]he Secretary may modify the criteria established in regulations issued under this paragraph only after affording public notice and an opportunity for comment on any such proposed modifications." 42 U.S.C. § 254c(b)(4)(B). Pine Tree argues the following: 1) Because the 1994 Procedures are regulations issued under the PHSA and because the 1995 Guidelines modify the 1994 Procedures, Defendants were required to provide notice and opportunity for comment under the PHSA; 2) even if the 1994 Procedures are not regulations issued under the PHSA, the 1995 Guidelines modify the 1976 regulations, subsequently requiring Defendants to provide notice and opportunity for comment; 3) even if the 1995 Guidelines do not modify the 1976 regulations, the 1995 Guidelines are substantive in nature and not interpretive, and Defendants were required to

comply with the APA's notice and comment provisions for substantive rules. The Court will address these arguments in turn.

#### **A. The 1994 Procedures Are Not Regulations**

It is not in dispute that the 1995 Guidelines modify the 1994 Procedures. (Stip. ¶11) Nevertheless, if the 1994 Procedures are not regulations issued under the PHSA then the Secretary may modify them without providing notice or opportunity for comment.

The 1994 Procedures are not regulations. The fact that they were never published in the *Federal Register* or the *Code of Federal Regulations* is noteworthy. Nevertheless, this alone is not determinative. The Court finds much more compelling the fact that since the 1976 regulations were promulgated, the Division has updated periodically the criteria to be considered for MUP designation without ever giving notice or opportunity for comment, and this practice was never challenged until now. In fact, the 1994 Procedures that Pine Tree seeks to enforce were themselves implemented without notice and comment. Pine Tree's acquiescence in this regard constitutes acceptance of the Division's practice, and Pine Tree cannot now object to what it has accepted continually since 1976.

#### **B. The 1995 Guidelines Do Not Modify the 1976 Regulations**

It is undisputed that the 1976 regulations are in fact regulations. Therefore, if the 1995 Guidelines modify the 1976 regulations, then Defendants were required to provide notice and opportunity for comment under the PHSA. 42 U.S.C. § 254c(b)(4)(B).

The 1995 Guidelines do not modify the 1976 regulations. Pine Tree asserts, and Defendants agree, that the definition of "modify" is "an alteration which introduces new elements into the details, or cancels some of them, but leaves the general purpose and effect of the subject

matter intact.” (Pl’s.Opp.Br. at 6, citing Black’s Law Dictionary 1004 (6th ed. 1990 West)). The 1976 regulations direct the Secretary to consider “[e]conomic factors affecting the population’s access to health services, such as percentage of the population with incomes below the poverty level.” 42 C.F.R. § 51c.102(e)(3). The regulations do not define population or describe how the percentage is to be calculated. The 1995 Guidelines define “population” as the total population in the area; moreover, the percentage is calculated as the percent of the population in the area of residence for the population group with incomes at or below 100% of the poverty level. Pine Tree contends that because these definitions were not included in the 1976 regulations, they alter the 1976 regulations by introducing new elements. The Court disagrees. Population and percentages are both elements of the relevant provision in the 1976 regulations. The 1995 Guidelines merely clarify the 1976 regulations, as did the 1994 Procedures, by defining and by giving effect to these elements. Therefore, the 1995 Guidelines do not modify the 1976 regulations, and notice and comment were not required.

### **C. The 1995 Guidelines Are Interpretive**

The APA’s notice and comment requirements do not apply to “interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice . . . .” 5 U.S.C. § 553(b)(3). An interpretive rule is “‘merely a clarification or explanation of an existing statute or rule’ and is ‘issued by an agency to advise the public of the agency’s construction of the statutes and rules which it administers.’” La Casa Del Convaleciente v. Sullivan, 965 F.2d 1175, 1178 (1st Cir. 1992) (quoting Guardian Fed. Sav. & Loan Ass’n v. FSLIC, 589 F.2d 658, 664-65 (D.C. Cir. 1978)). In contrast, a substantive rule, which requires notice and comment, “creates rights, assigns duties, or imposes obligations, the basic tenor of which is not already outlined in the law

itself . . . .” La Casa Del Convaleciente, 965 F.2d at 1178. As noted above, the 1995 Guidelines merely clarify the 1976 regulations. They are, therefore, interpretive rules that are exempt from the APA’s notice and comment requirements.

#### IV. RETROACTIVITY

Pine Tree claims that even if the 1995 Guidelines were promulgated appropriately, they were impermissibly applied retroactively to Pine Tree’s application for MUP designation, which was submitted when the 1994 Procedures were still in effect. Pine Tree argues that the Division should have applied the criteria established in the 1994 Procedures to its request. It cites Landgraf v. USI Film Products, 114 S. Ct. 1483 (1994), where the Supreme Court held that, except for a few instances, a statute should not be applied retroactively; that is, a statute enacted after the events in suit should not be applied to those events. *See id.* at 1505. The Court similarly prohibited, in most instances, retroactive application of an agency rule in Bowen v. Georgetown University Hospital, 488 U.S. 204, 208 (1988). The threshold issue to be decided in this action, therefore, is whether the Division applied the 1995 Guidelines retroactively. If it did not, then Pine Tree’s claim is without merit and the Court need go no further.

The Landgraf Court held that a new statute would have a retroactive effect if it “would impair rights a party possessed when he acted, increase a party’s liability for past conduct, or impose new duties with respect to transactions already completed.” Landgraf, 114 S. Ct. at 1505. Pine Tree’s argument can be summarized as follows: 1) Its request for MUP designation constitutes a “transaction already completed;” 2) the 1995 Guidelines, which imposed new duties on applicants for MUP designation, were promulgated after Pine Tree submitted its request; 3) therefore, applying the 1995 Guidelines to Pine Tree’s request imposes new duties with respect

to a transaction already completed; and 4) under Landgraf, this constitutes retroactive application of the 1995 Guidelines. The Court rejects this argument.

Pine Tree does not cite any cases holding that the date on which an application is submitted constitutes a “transaction already completed.” Instead, it notes two instances when Defendants chose not to apply changes in agency policy to requests pending before the changes were implemented. Assuming for the moment that these examples are analogous to the present matter, it is not axiomatic that if Defendants had applied the changes to pending requests such changes would have had a retroactive effect. Pine Tree’s arguments, therefore, are irrelevant to the present issue.

Mere submission of an application does not constitute a “transaction already completed.” The Division never took final action on Pine Tree’s application until after it implemented the 1995 Guidelines. Although Pine Tree may have relied on the continuing vitality of the 1994 Procedures, it had no right to do so. An agency must be permitted to change criteria and apply them to applications that have not yet received final action.<sup>3</sup> The Division, therefore, did not apply the 1995 Guidelines retroactively to Pine Tree’s request.

## V. CONCLUSION

Defendants properly applied the 1995 Guidelines to Pine Tree’s request for MUP designation; they did not violate the notice and comment provisions of the APA and the PHSA, and they did not impermissibly apply the 1995 Guidelines retroactively to Pine Tree’s request. Accordingly, Pine Tree’s Motion for Summary Judgment is denied and Defendants’ Motion for

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<sup>3</sup> Although Pine Tree does not argue that it had a vested right in having its application granted, the Court notes that such argument would have been rejected as well.

Summary Judgment is granted.

SO ORDERED.

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MORTON A. BRODY  
United States District Judge

Dated this 21<sup>st</sup> day of October, 1996.