Civil Rights

Colwell v. United States Department of Health and Human Services: Feds Order Physicians and Health Care Providers to Provide Free Language Translation Services to Limited English Proficient Patients

*By Sharon L. Browne**

> *"I will follow that system of regimen which,according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous."*
> *The Oath and Law of Hippocrates.*[1]

For 2,400 years, society has been confident that properly trained, competent, and compassionate physicians will not abuse such power. Not so, says the federal government. The patient-physician relationship came under attack by the United States Department of Health and Human Services (HHS) when it adopted a language policy controlling the manner in which physicians must communicate with their limited English proficient (LEP) patients.[2] Physicians are fighting back.

On August 30, 2004, three physicians, ProEnglish,[3] and The Association of American Physicians & Surgeons[4] filed a complaint for declaratory and injunctive relief in the United States District Court for the Southern District of California.[5] *Colwell v. United States Department of Health and Human Services* is a facial challenge to HHS's unprecedented expansion of Title VI of the Civil Rights Act of 1964,[6] (Title VI) when the Department adopted its *Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons* (Policy Guidance Rule).[7] Title VI prohibits "discrimination under any program or activity receiving Federal financial assistance" against any person in the United States "on the ground of race, color, or national origin." Although neither language nor LEP status are protected classifications under Title VI,[8] the Policy Guidance Rule requires physicians who receive funding from HHS to provide free oral and written translation services to LEP patients, without reimbursement, to avoid possible prosecution for national origin discrimination under Title VI.

I. Background of the Policy Guidance Rule

People from all over the world immigrate to the United States. They come with different cultures, ways of thinking, languages, and social and economic backgrounds.[9] The United States has an increasingly diverse population of which "47 million people over the age of 5-years old, out of a total of 262.4 million, speak a primary language other than English."[10] Besides English, there were almost "500 different languages spoken in the United States in 2000, up from 400 in 1990."[11] Approximately 14 million people lack English proficiency and are designated LEP persons.[12]

Shortly before President Clinton left office on August 11, 2000, he signed Executive Order 13,166, *Improving Access to Services for Persons with Limited English Proficiency*.[13] It directs all federal agencies to adopt a plan to "improve access" to federally funded programs for persons who do not speak English.[14] The order states that each Federal agency must develop plans and implement systems consistent with the "general guidance document" issued by the Department of Justice.[15] This document was to set forth "the compliance standards that recipients must follow to ensure that the programs and activities they normally provide in English are accessible to LEP persons and thus do not discriminate on the basis of national origin in violation of Title VI of the Civil Rights Act of 1964, as amended, and its implementing regulations."[16] As this passage indicates, the executive order almost casually blurs the important distinction between language and national origin.[17] In doing so, it ignores three decades of judicial rejection of the notion of equating language with national origin under Titles VI and VII of the Civil Rights Act.[18]

II. The Policy Guidance Rule

On August 8, 2003, HHS published its third version of the Policy Guidance Rule.[19] Despite constituting a significant change in policy to the detriment of physicians nationwide, this rule took effect without complying with the notice and comment rulemaking requirements of the Administrative Procedures Act (APA).[20] Like the earlier versions, HHS announced that the Policy Guidance Rule was effective immediately.[21] It is a sweeping new policy that requires all physicians who receive any federal funding from HHS, including Medicare or Medicaid, to provide free oral and written translations for any patient who has limited English speaking skills and to ensure the quality and accuracy of the translation—or face possible prosecution for national origin discrimination.[22]

The rule covers all HHS funded recipients, including those that receive federal funds directly or indirectly from HHS, as well as public or private organizations operating health and social service programs.[23] It expressly identifies hospitals, physicians in private practice, nursing homes, welfare agencies, contractors, subcontractors, vendors, and other health care providers.[24] This means physicians who receive financial reimbursement or payments under the Medicaid and/or Medicare programs, or work in hospitals that receive federal funds, must comply with the rule's new standards to provide free language assistance in the form of interpreters and translated documents to all LEP patients.[25]

According to the Policy Guidance Rule, physicians must notify LEP patients of their right to free language assistance services.[26] Physicians have a responsibility to ensure that their policies and procedures do not deny LEP patients access to heath care services because of a language barrier.[27] The rule requires physicians to ensure the competency and effectiveness of the free language assistance services provided to their LEP patients.[28] "[R]ecipients *are required*" to perform "an *individualized assessment*" of four factors to determine the extent of the free translation services to LEP patients.[29] The more important the service—such as serious or life-threatening implications that affect a LEP patient's health—the more likely that translation services are required.[30] The rule

encourages physicians to selectively provide language assistance to certain groups and not others based on the size of the LEP population served.[31] The rule eliminates the use of family members or friends as interpreters unless the physician has notified the LEP patient of the free language assistance and the patient has refused.[32]

Failure to follow these requirements may result in prosecution for illegal national origin discrimination.[33] If an LEP patient is dissatisfied with the level of language assistance, he or she may file a complaint, report, or other information with HHS' Office of Civil Rights (OCR).[34] OCR is required to investigate all complaints.[35] OCR may terminate a physician's funding or refer the matter to the DOJ to seek injunctive relief or pursue other enforcement proceedings against the physician.[36]

The Policy Guidance Rule places the burden on the physicians being investigated to prove that they are not intentionally discriminating on the basis of national origin.[37] To provide evidence of compliance, the rule encourages physicians to adopt an effective LEP Plan.[38] A physician under investigation can also provide "strong evidence" of compliance by meeting the "safe harbor "provision for written translations.[39]

III. The Lawsuit

In *Colwell v. USHHS*, plaintiffs make three claims that the Policy Guidance Rule is invalid and unconstitutional. First, although the Policy Guidance Rule is a legislative rule creating new obligations for physicians, HHS gave no prior notice of the policy change in violation of the notice and comment rulemaking requirements set forth in section 553 of the APA.[40] Second, the rule is ultra vires and is in violation of section 706 of the APA[41] because nothing in Title VI or its legislative history supports HHS' claim equating language with national origin. Third, the rule is overbroad and is unconstitutionally vague in violation of the First Amendment. While Plaintiffs' motion for preliminary injunction was pending, HHS filed a motion to dismiss for lack of subject matter jurisdiction and failure to state a claim. On March 7, 2005, the district court issued an order granting HHS' motion and denied the physicians' motion as moot. The case is now on appeal on the issues of standing and ripeness.[42] Because the issues in this lawsuit require no further factual development, the plaintiffs are asking the Ninth Circuit to decide the merits as well.

A. HHS' Policy Guidance Rule was Issued in Violation of the APA

The APA requires agencies to advise the public through a notice in the Federal Register of the terms or substance of a proposed substantive rule, allowing the public a period to comment.[43] The "notice and comment" requirement is "designed to give interested persons, through written submissions and oral presentations, an opportunity to participate in the rulemaking process."[44] Generally, "[t]he procedural safeguards of the APA help ensure that government agencies are accountable and their decisions are reasoned."[45]

The notice and comment requirement can be waived only for "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice."[46] In contrast, the Policy Guidance Rule should be deemed *legislative*.[47] As explained above, it creates and imposes new substantive rights and obligations without any independent legislative basis, thereby triggering the APA's notice and comment requirements.[48]

HHS maintains that the rule is merely an interpretive measure setting out compliance standards for Title VI.[49] But, regardless of HHS' claim, "if there is no legislative basis for enforcement action on third parties without the rule, then the rule necessarily creates new rights and imposes new obligations. This makes it legislative."[50] The Ninth Circuit Court of Appeals also recognizes that "when an agency does not hold out a rule as having the force of law, it may still be legislative if it is inconsistent with a prior rule having the force of law."[51]

In this case, prior to implementation of the Policy Guidance Rule, physicians were able to manage their LEP patients based upon their best professional judgment. Now, physicians are required to provide free oral and written translation services to LEP patients or face the threat of prosecution for national origin discrimination. The rule adds substantive requirements to Title VI based on lack of proficiency in the English language.

HHS contends that the Policy Guidance Rule is exempt from the notice and comment procedures of the APA because it does not establish a binding norm that is used to determine the rights of physicians. Yet, the express requirements of the rule show the binding effect on physicians receiving federal funds. For example, the rule requires physicians, without exception, to perform the four-factor analysis described above.[52] Then HHS uses this analysis to determine compliance with Title VI and Title VI regulations.[53] The binding effect of the rule is further established by its "safe harbor" provision for written translations.[54] Physicians can use the "safe harbor" as "strong evidence of compliance with the recipient's written-translation obligations."[55] Similarly, the rule strongly encourages physicians to develop and maintain an LEP plan because the existence of an LEP Plan can be used as a "means of documenting compliance with Title VI."[56]

The express language of the Policy Guidance Rule shows that it is a substantive rule and alters an existing regulatory scheme. It establishes a fixed standard for compliance. It binds the regulated community of physicians to a new standard of conduct. This is the kind of rule that must be issued legislatively, following the notice and comment procedures set out in section 553 of the APA. Because HHS did not follow the notice and comment procedures but declared the Policy Guidance Rule to take effect immediately, the Ninth Circuit should find HHS' action "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "without observance of procedure required by law."[57]

B. HHS' Policy Guidance Rule Exceeds HHS' Authority under Title VI

The appellate court should determine, as a matter of law, that HHS exceeded its authority under Title VI when it adopted the Policy Guidance Rule. In promulgating the rule, HHS adopted a new interpretation of Title VI equating language with national origin. No congressional policy under Title VI has ever supported such an equation of language with national origin.[58]

1. The Policy Guidance Rule Creates New Law Not Authorized by Title VI

Title VI prohibits "discrimination under any program or activity receiving Federal financial assistance" against any person in the United States "on the ground of race, color, or national origin."[59] On its face, Title VI prohibits national origin discrimination. However, neither language nor LEP status are mentioned. The legislative history of Title VI is silent as to these classifications.[60] Similarly, HHS' regulation adopted pursuant to Title VI prohibits national origin discrimination and is silent on the question of language.[61]

HHS maintains that the Policy Guidance Rule is consistent with its Title VI regulation and turns to *Lau v. Nichols*[62] to support its claim.[63] Yet, *Lau* cannot bear the weight HHS puts on it. In *Lau*, the Supreme Court held that students of Chinese ancestry who did not speak English were entitled to equal education opportunities but the Court made it clear that "[n]o specific remedy is urged upon us. Teaching English to the students of Chinese ancestry who do not speak the language is one choice. Giving instructions to this group in Chinese is another."[64] In *Lau*, there was no discussion of any regulation's validity and *Lau* was decided before the United States Supreme Court's determination that Title VI bans only disparate treatment, not disparate effects on a particular group.

In *Alexander v. Sandoval,* the Supreme Court reaffirmed that "Title VI proscribe[s] only those racial classifications that would violate the Equal Protection Clause or the Fifth Amendment."[65] Language is not an included classification. In discussing *Lau*, the Court said that "we have since rejected *Lau's* interpretation of § 601 as reaching beyond intentional discrimination."[66] In this case, the Policy Guidance Rule does not seek to prohibit intentional discrimination against LEP patients on the basis of race, color, or national origin. Instead, it provides an administrative remedy to LEP patients based on language.[67]

If Congress had intended Title VI to include language as a protected classification, it had the ability to amend Title VI. By its inaction, Congress has not considered language discrimination to be encompassed in Title VI.[68] There is no doubt HHS exceeded its congressionally delegated authority under Title VI when it adopted the Policy Guidance Rule commanding physicians to provide language assistance to non-English speakers or face the threat of prosecution for national origin discrimination under Title VI.

2. Language Is Not a Proxy for National Origin Under Title VI

In adopting the Policy Guidance Rule, HHS makes the unfounded assumption that language can be used as a proxy for national origin under Title VI. There simply is no congressional policy under Title VI that equates language with national origin. The ability to speak English and national origin are distinct qualities.

Courts have held that governmental bodies are allowed to communicate in English to the public. In *Toure v. United States*, for example, the Second Circuit rejected the contention that the federal government was obligated to furnish notices of seizure in French to a native of Togo. Toure argued that furnishing the notices in English violated his right to procedural due process because his native language was French and his ability to speak English was limited. The Second Circuit disagreed, explaining: "A requirement that the government ascertain, and provide notice in, the 'preferred' language of prison inmates or detainees would impose a patently unreasonable burden upon the government."[69]

Soberal-Perez v. Heckler, on which the *Toure* court relied, is to the same effect.[70] There, the Second Circuit rejected the claims that the failure of HHS to provide notices and instructions in Spanish discriminated against Hispanics on the basis of their national origin in violation of Title VI, due process and the Equal Protection Clause. The court explained: "the Secretary's failure to provide forms and services in the Spanish language does not on its face make any classification with respect to Hispanics as an ethnic group. A classification is implicitly made, but it is on the basis of language, i.e., English-speaking versus non-English-speaking individuals, and not on the basis of race, religion or national origin. *Language, by itself, does not identify members of a suspect class*."[71]

HHS in adopting the Policy Guidance Rule conflates national origin and language. Such a position has no legal or scientific support and the Ninth Circuit should find that HHS exceeded its authority under Title VI in violation of section 706 of the APA.

C. The Policy Guidance Rule Forces Physicians to Speak in Violation of the First Amendment

The Policy Guidance Rule directly impinges on the physician-patient relationship. It controls the manner in which physicians communicate with their LEP patients, i.e. physicians must speak to LEP patients through foreign language interpreters or face the threat of prosecution for national origin discrimination. HHS maintains that control over physicians' speech by requiring the physician to communicate in a foreign language as a condition of the receipt of federal funds is necessary to avoid national origin discrimination and is not overbroad. However, the Policy Guidance Rule controls far too much speech to be constitutional. As described above, it covers the entire physician-patient relationship.

The Policy Guidance Rule is also invalid because it is facially vague. Vague laws are unconstitutional not only because they "may trap the innocent by not providing fair warning" but also because they pose a heightened risk of "arbitrary and discriminatory enforcement."[72] This risk is uniquely great under the Policy Guidance Rule. Physicians are required to use the four-factor assessment to determine the extent of their compliance obligation in order to avoid charges of national origin discrimination. The four-factor assessment is supposed to inform physicians "what reasonable steps, if any, they should take to ensure meaningful access for LEP persons."[73] Yet, the assessment fails at this task. Instead, it sets forth a series of standardless mandates, that only serve to confuse instead of clarify.

For example, "eligible service population" is not defined beyond saying that the "greater the number or proportion of these LEP persons, the more likely language services are needed."[74] Physicians are told to examine everything from "their previous experiences with LEP encounters" to "census data" but are never told how HHS defines "eligible service population."

Similarly indefinite is the requirement for physicians to examine the "frequency with which LEP individuals come in contact with the recipient's program, activity of service."[75] As an explanation, the rule only provides this broad statement: "The more frequent the

contact with a particular language group, the more likely that enhanced language services in that language are needed."[76] No standard is provided by which to judge what degree of contact triggers a given requirement of language assistance, other than the general statement "[t]he steps that are reasonable for a recipient that serves an LEP person on a one-time basis will be very different than those expected from a recipient that serves LEP persons daily."[77] Physicians who encounter LEP patients daily have "greater duties" than those servicing LEP patients on an infrequent basis, but the Policy Guidance Rule does not say how much greater, nor indicate what level or type of service HHS will consider sufficient to avoid prosecution for national origin discrimination. There are many other examples of vague standards throughout the Policy Guidance Rule. The bottom line is that the rule lacks clear and understandable guidelines. Physicians cannot establish with reasonable certainty that they have met some entirely subjective standard of compliance in an area such as language that is in constant flux. The rule places physicians in a no-win situation by forcing them to guess at its meaning at the risk of sanction whichever way they turn.

Conclusion

HHS's Policy Guidance Rule is poorly conceived and illegal. It rests on an interpretation of federal civil rights laws that has no basis in fact or law, attempts to impose new nationwide obligations without notice or opportunity for comment, and requires physicians to interpret impossibly vague standards at the risk of prosecution or loss of their livelihood.

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Footnotes

[1] Hippocrates, *The Oath and Law of Hippocrates. Vol. XXXVIII, Part 1*. The Harvard Classics (New York: P.F. Collier & Son, 1909–14)(Mar. 15, 2005), *available at* www.bartleby.com/38/1/.

[2] LEP persons are defined as "[i]ndividuals who do not speak English as their primary language and who have a limited ability to read, write, speak or understand English." 68 Fed. Reg. at 47,313.

[3] ProEnglish is a nonprofit advocacy organization that promotes English as a common language in American political and governmental life. Information on ProEnglish is available at www.proenglish.org.

[4] The American Association of American Physicians and Surgeons is a national, nonprofit organization dedicated to preserving freedom in the practice of ethical medicine and opposes government interference in the one-on-one patient-physician relationship. Additional information on the association is available at www.aapsonline.org.

[5] *See* Appellants' Opening Brief, Colwell v. United States Dep't of Health and Human Servs.,(9th Cir. 2005) (No. 05-55450), on appeal from the United States District Court for the Southern District of California, Case No. 04 CV174SBTM.

[6] 42 U.S.C. § 2000d.

[7] 68 Fed. Reg. at 47,311.

[8] As stated in *Alexander v. Sandoval*, 532 U.S. 275, 280-81 (2001), Title VI "proscribe[s] only those racial classifications that would violate the Equal Protection Clause.'" (quoting Regents of University of California v. Bakke, 438 U.S. 276 (1987)(opinion of Powell, J.).

[9] Secretary Roderick R. Paige, Remarks at the American Council on the Teaching of Foreign Languages" (Nov. 21, 2003), ("A language is. ..a culture, a way of thinking, and a perspective on the world....The study of language is the study of life, literature, history, and thought. It is nothing less than the study of our world and ourselves."), *available at* http://www.ed.gov/news/speeches/2003/11/11212003.html (last visited July 15, 2005). *Cited in* Office of Civil Rights Evaluation, U.S. Commission on Civil Rights, Draft Report for Commissioners' Review, Toward Equal Access: Eliminating Language Barriers from Federal Programs (2004). This draft report addressed government efforts to reduce language obstacles to programs and services. At its September 17, 2004, meeting, the U.S. Civil Rights Commission declined to pass this report.

[10] U.S. Census Bureau, Language Use, English Ability, and Linguistic Isolation for the Population 5 Years and Over by State (2000) *available at* http://www.census.gov/population/www/socdemo/lang_use.html. (Last visited July 14, 2005). *See also* U.S. Civil Rights Commission, Towards Equal Access: Eliminating Language Barriers from Federal Programs (2004)(Draft Report).

[11] U.S. Civil Rights Commission, Towards Equal Access: Eliminating Language Barriers from Federal Programs (2004) (Draft Report) at 22.

[12] Mona T. Peterson, *The Unauthorized Protection of Language Under Title VI*, 85 Minn. Law. Rev. 1437 (2001).

[13] 65 Fed. Reg. 50121 (August 16, 2000).

[14] *Id*.

[15] *Id*.

[16] *Id*.

[17] *See supra* note 9. As pointed out by Roger Clegg, General Counsel for Center for Equal Opportunity: "Ability to speak English and ethnicity are obviously distinct qualities. Some people of a particular national origin will not be able to speak English well, but others will. Conversely, some people not of that particular national origin will not be able to speak English well." (Letter from Roger Clegg, General Counsel for Center for Equal Opportunity, to Merrily Friedlander, Dep't of Justice, Civil Rights Division, February 14, 2002), *available at* http://www.ceousa.org/vi.html (last reviewed July 13, 2005).

[18] The phrase "national origin" is identical in Titles VI and VII and some courts use the jurisprudence under each title interchangeably. Elston v. Talladega County Board of Education, 997 F. 2d 1394, 1407 (11th Cir. 1993). These cases are collected and discussed in Barnaby Zall, *English in the Workplace* (Center for Equal Opportunity, 2000). A partial list includes: *Long v. First Union Corp*., 894 F.Supp. 933, 941 (E.D. Virginia, 1995)("There is nothing in Title VII which protects or provides that an employee has a right to speak his or her native tongue while on the job"), *affirmed*, 86 F.3d 1151 (4th Cir. 1996); *Castaneda v. Pickard*, 648 F.2d 989, 1007 (5th Cir. 1981)("[W]e do not think it can seriously be asserted that [a] program [of allegedly inadequate bilingual education] was intended or designed to discriminate against Mexican-American students' in violation of Title VI."); *Vasquez v. McAllen Bag & Supply Co*., 660 F.2d 686 (5th Cir. 1981) (Title VII

permits English-on-the-job rule for non-English-speaking truck drivers); *Frontera v. Sindell*, 522 F.2d 1215 (6th Cir. 1975)(Fourteenth Amendment allows English civil service exam for carpenters); *Garcia v. Rush Presbyterian St. Luke's Medical Center*, 660 F.2d 1217 (7th Cir. 1981)(upholding hiring practices requiring English proficiency); *An v. General Am. Life Ins. Co.*, 872 F.2d 426 (9th Cir. 1989)(table) (Section 1981 requires proof of intentional discrimination; "A policy involving an English requirement, without more, does not establish discrimination based on race or national origin."); *Velasquez v. Goldwater Mem. Hosp*., 88 F. Supp.2d 257, 261-62 (S.D.N.Y. 2000) ("Neither the statute nor common understanding equates national origin with the language that one chooses to speak.).

[19] 68 Fed. Reg. 47,3111. On August 30, 2000, HHS published its first "Notice of Policy Guidance." 65 Fed Reg. 52762 (August 30, 2000). The rule was republished on February 1, 2002, and similarly went into immediate effect. 67 Fed. Reg. 4,968 (Feb. 1, 2002). Prior to the rule, HHS attempted but failed to develop and adopt regulations equating language with national origin. Peterson, 85 Minn. L. Rev. at 1455; Allison Keers-Sanchez, *Mandatory Provision of Foreign Language Interpreters in Health Care Services*, 24 J. Legal Med. 557, 562 (2003)("To date, no legislative enactments contain specific protection against language discrimination.").

[20] 5 U.S.C. § 553(b)-(d).

[21] 68 Fed. Reg. at 47,311.

[22] 68 Fed. Reg. at 47,313. The rule states that failure to take the steps prescribed "may violate the prohibition under Title VI. . . and the Title VI regulations against national origin discrimination."

[23] 68 Fed. Reg. at 47,313. The rule covers the recipient's entire operation as well as "subreceipients" when "funds are passed through from one recipient to a subreceipients." *Id*.

[24] *Id*.

[25] *Id*. at 47,315.

[26] *Id*. at 47,320.

[27] *Id*. at 47,318.

[28] *Id*. at 47,316.

[29] *Id*. at 47,314 (emphasis added). The four factors are: (1) the number or proportion of LEP patients to be served or likely to be served, (2) the frequency the LEP patient comes in contact with the physician's services, (3) the nature and importance of the physician's services, and (4) physician's resources and costs. *Ibid*.

[30] *Id.* at 47,315.

[31] *Id*. at 47,314; 47,319.

[32] *Id*. at 47,323.

[33] *Id*. at 47,311.

[34] *Id*. at 47,321.

[35] *Id*.

[36] *Id*.

[37] *Id*.

[38] *Id*. at 47,319. An effective plan requires the recipient to identify: (1) how to determine the language of communication with an LEP person, (2) the way translations services will be provided; (3) the process for training staff; (4) the process to provide notice of free translation services to LEP persons; (5) the methods to monitor and update the LEP Plan. Also, the plan is to set clear goals and establish management accountability. *Id*. at 47,320-21.

[39] *Id*. at 47,319. *See also* 67 Fed Reg. 41,456, where the DOJ recognizes that certain languages that are only oral such as Hmong have only recently been converted to a written form.

[40] 5 U.S.C. § 553.

[41] 5 U.S.C. § 706.

[42] *Colwell v. United States Department of Health and Human Services*, (9th Cir.) Case No. 05-55450. Plaintiffs filed their opening brief on July 11, 2005.

[43] *See* 5 U.S.C. § 553(b) and (c).

[44] Chief Probation Officers of California v. Shalala, 118 F.3d 1327, 1329 (9th Cir. 1997).

[45] Sequoia Orange Co. v. Yeutter, 973 F.2d 752, 758 (9th Cir. 1992).

[46] 5 U.S.C. § 553(b)(3)(A).

[47] *Hemp Industries Ass'n v. Drug Enforcement Admin*, 333 F.3d 1082, 1087 (9th Cir. 2003), explains "that legislative rules, unlike interpretative rules, have the 'force of law.'" *Hemp* identified three circumstances in which a rule has the "force of law:" "(1) when, in the absence of the rule, there would not be an adequate legislative basis for enforcement action; (2) when the agency has explicitly invoked its general legislative authority; or (3) when the rule effectively amends a prior legislative rule." *Id*. at 1087.

[48] *See Hemp Indus.*, 333 F.3d at 1087 (citation omitted). (Interpretive rules "merely explain, but do not add to, the substantive law that already exists in the form of a statute or legislative rule. Legislative rules, on the other hand, create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress.").

[49] The Policy Guidance Rule states: "It has been determined that this revised HHS LEP Guidance does not constitute a regulation subject to the rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. § 553." 68 Fed. Reg. at 47,311. HHS insists that "[t]he policy guidance is not a regulation but rather a guide. Title VI and its implementing regulations require that recipients take reasonable steps to ensure meaningful access by LEP persons. This guidance provides an analytical framework that recipients may use to determine how best to comply with statutory and regulatory obligations." *Id*. at 47,313 n.2.

[50] 333 F. 3d at 1088.

[51] *Id*. (citations omitted).

[52] 68 Fed. Reg. at 47,314.

[53] 68 Fed. Reg. at 47,313.

[54] It is well established that "safe harbor" provisions for purposes of enforcement create norms that have a practical binding effect. Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, And The Like—Should Federal Agencies Use Them To Bind The Public?*, 41 DUKE L.J. 1311, 1339 (1992)("Sometimes the agency is stating a safe-harbor policy, such that private persons may know that if they observe the policy they will not be deemed in violation. and will not be prosecuted. But they will not necessarily be deemed in violation, or be prosecuted, if they do not observe the policy. Such a document can create binding norms.").

[55] 68 Fed. Reg. at 47,319.

[56] *Id*. Further indications of the binding effect of the Policy Guidance Rule includes: requiring a specific level and type of oral translation, *ibid*. at 47,317, prohibiting the physicians from using family members or friends unless insisted upon by the LEP patient, *ibid*. at 47,317-18, requiring physicians to be responsible for determining the competence and effectiveness of the language translation being provided, *ibid*. at 47,316, and commanding physicians to provide translation services in a timely manner, *ibid*.

[57] 5 U.S.C. § 706(2)(A) and (D).

[58] An agency that imposes a standard of conduct to expand a statute is creating a new law and is invalid. 5 U.S.C. § 706(2)(A) and (C).

[59] 42 U.S.C. § 2000d.

[60] *See* 1964 U.S.C.C.A.N. 2391, H. Rep. No. 914, 88th Cong., 2nd Sess.; and S. Rep. No. 872, 88th Cong., 2nd Sess. *See also* Raphael Metzger, *Hispanics, Health Care, and Title VI of the Civil Rights Act of 1964,* 3 KAN. J.L. & PUB. POL'Y 31 n.84 (1994) (neither the House or Senate legislative histories on the Civil Rights Act of 1964 references language in the context of national origin.).

[61] The regulation states that recipients of federal funding may not "utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program as respect individuals of a particular race, color, or national origin." 45 C.F.R. § 80.3(b)(2).

[62] Lau v. Nichols, 414 U.S. 563 (1974).

[63] 68 Fed. Reg. at 47,312.

[64] *Lau*, 414 U.S. at 564-65.

[65] 532 U.S. 275, 280-81 (citation omitted).

[66] *Id*. at 285. Almendares v. Palmer, 284 F. Supp. 2d 799, 804 n.4 (N.D. Ohio 2003) (recognized that because of *Alexander*, *Lau* is no longer good law).

[67] *See also* Roger Clegg, *Speak Now (In English) . . .Or Forever Hold Your Peace*, NATIONAL REVIEW ONLINE (1 February 2002), *available at* www.nationalreview.com/clegg/clegg020102.asp. (Retrieved July 15, 2005).

[68] Contrast Congress' treatment in Title VI with statutes requiring translation services in the Rehabilitation Act of 1973 (29 U.S.C. §§ 701, 772), and the Americans with Disabilities Act (42 U.S.C. §§ 12101, 12102, 12111).

[69] 24 F.3d 444, 446 (2d Cir. 1994).

[70] 717 F.2d 36 (2d Cir. 1983).

[71] *Id*. at 41(emphasis added).

[72] Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc., 455 U.S. at 498 (quoting Grayned v. City of Rockford, 408 U.S. 104, 108-09 (1972)).

[73] 68 Fed. Reg. at 47,314.

[74] *Id*.

[75] *Id*.

[76] *Id*.

[77] *Id*.