

**FOR PUBLICATION**  
**UNITED STATES COURT OF APPEALS**  
**FOR THE NINTH CIRCUIT**

CHRISTOPHER T. ERRINGER;  
LAWRENCE CORCORAN; ETHEL W.  
VESTAL, by her husband and next  
friend, WILLIAM A. VESTAL;  
VALERIE LAVAQUE, JAMES  
ROBERTSON, and LILLIAN LEGIER, on  
behalf of themselves and a class  
of persons similarly situated,  
*Plaintiffs-Appellants,*  
v.  
TOMMY THOMPSON, Secretary of  
Health and Human Services,  
*Defendant-Appellee.*

No. 03-16408  
D.C. No.  
CV-01-00112-BPV  
OPINION

Appeal from the United States District Court  
for the District of Arizona  
Bernardo P. Velasco, Magistrate Judge, Presiding\*

Argued and Submitted  
May 10, 2004—San Francisco, California

Filed June 10, 2004

Before: Diarmuid F. O'Scannlain, Eugene E. Siler, Jr.,\*\* and  
Michael Daly Hawkins, Circuit Judges.

Opinion by Judge Hawkins

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\*Tried by consent before a United States Magistrate Judge pursuant to 28 U.S.C. § 636(c)(1).

\*\*The Honorable Eugene E. Siler, Jr., Senior United States Circuit Judge for the Sixth Circuit, sitting by designation.

**COUNSEL**

Sally Hart, Arizona Center for Disability Law, Tucson, Arizona, for the plaintiffs-appellants.

Ori Lev, Civil Division, Department of Justice, Washington, D.C., for the defendant-appellee.

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**OPINION**

HAWKINS, Circuit Judge:

A class of Medicare beneficiaries (“the Beneficiaries”), whose claims for coverage of their health care services were denied based on Local Coverage Determinations (“LCDs”),<sup>1</sup>

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<sup>1</sup>In the district court proceedings, there was some issue as to whether the correct term for the local coverage rules was Local Medical Review

challenge rules issued by the Secretary of Health and Human Services (the “Secretary”) which give criteria to contractors for adopting LCDs. The Beneficiaries contend that the criteria governing the LCDs are substantive rules required to be promulgated under either the notice and comment requirements of the Administrative Procedures Act (“APA”), 5 U.S.C. § 553(b) and (c), or the promulgation requirements of the Medicare Act, 42 U.S.C. § 1395hh. The district court held that the unpublished criteria are not subject to the formal rule-making requirements of the APA and the Medicare Act because they are interpretive rules. We have jurisdiction under 28 U.S.C. § 1291, and we affirm.

## I. Factual and Procedural Background

### A. The Medicare Act and LCDs

The Medicare Act creates a health insurance program providing benefits to eligible elderly and disabled individuals. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh. Parts A and B provide coverage for various items and services, but exclude payment for items and services that “are not *reasonable and necessary* for the diagnosis or treatment of illness or injury . . . .” 42 U.S.C. § 1395y(a)(1)(A) (emphasis added).

Medicare is administered nationally by the Center for Medicare and Medicaid Services (“CMS”). CMS contracts with private insurance companies, who together with local peer review organizations (collectively “contractors” or “Medicare contractors”) process claims for Medicare beneficiaries. Essentially, a Medicare claim submitted for payment is approved or denied by a Medicare contractor.<sup>2</sup> In making cov-

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Policies or Local Coverage Determinations. Both parties accept the district court’s resolution of this debate; therefore we use the term LCD throughout.

<sup>2</sup>A claim may be appealed after the contractor’s initial determination. The procedures differ based on which Part of the Act is applicable (A or

erage decisions, Medicare contractors rely on National Coverage Determinations (“NCDs”) and Local Coverage Determinations (“LCDs”). The Secretary adopts NCDs to exclude certain items and services from coverage on a national level that are not “reasonable and necessary” under the agency’s interpretation of the Medicare statute. *See* 42 U.S.C. § 1395ff(f)(1)(B). These determinations are binding on all Medicare contractors nationwide. When no NCD applies to a claim, Medicare contractors must still apply the “reasonable and necessary” limitation of the Medicare statute in determining whether to pay a claim and at what amount. The Secretary requires Medicare contractors to use LCDs to aid in this determination — specifically, when the contractor identifies an item or service that is never covered in certain circumstances and wishes to establish automated review or when widespread, significant risk to Medicare funds dictates. Program Integrity Manual (“PIM”) Ch.13 § 4.B. LCDs are used only on a contractor-wide basis and may differ between contractors in different regions of the country. 42 U.S.C. § 1395ff(f)(2)(B). The Secretary has issued guidelines for contractors to follow in creating LCDs. It is these guidelines, giving criteria for the creation of LCDs, that are at issue in this appeal.

The guidelines are currently contained in the Secretary’s

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B) and the amount in controversy. A Part A claim may be appealed to CMS and then to an administrative law judge (“ALJ”) only if it is for \$100 or more. 42 U.S.C. §§ 1395ff(b)(1)(A); 1395ff(b)(1)(E)(i); 42 C.F.R. § 405.710. A Part B claim may be appealed to the Medicare contractor, then a hearing officer (if \$100 or more), then finally to the ALJ. 42 C.F.R. §§ 405.810; 1395ff(b)(1)(E)(i). On the Part A side, only 0.09% of all requests for review are ultimately reviewed by an ALJ. DHHS Office of Inspector General, Pub. No. OEI-04-97-00190, “Medicare Administrative Appeals, ALJ Hearing Process” 6 (Sept. 1999). On the Part B side, it’s 1.25% of all requests. DHHS Office of Inspector General, Pub. No. OEI-04-00290, “Medicare Administrative Appeals, The Potential Impact of BIPA” 6 (Jan. 2002).

Program Integrity Manual (“PIM”).<sup>3</sup> The PIM is a compilation of guidelines which CMS issues to instruct Medicare contractors on how to conduct medical review of Medicare claims submitted by Medicare providers and suppliers for payment. Neither the PIM, nor the individual guidelines in question, are published in accordance with formal APA rule-making procedures.

### **B. The Class Action**

Beneficiaries are a nationwide class whose claims either have been denied or will be denied based on LCDs.<sup>4</sup> They brought suit in district court in 2001 challenging two particu-

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<sup>3</sup>In 1989, the Secretary published proposed regulations specifying criteria Medicare contractors would use in adopting NCDs and LCDs. 54 Fed. Reg. 4302-02 (proposed Jan. 30, 1989). The Secretary ultimately withdrew these proposed regulations in 1999. 64 Fed. Reg. 22619-01 (April 27, 1999).

In 1994, the Health Care Financing Administration (now CMS) first issued contractor manuals that mandated specific criteria for the development of LCDs. These are essentially the same criteria that the plaintiffs now challenge, although they were moved to the PIM in 2000, and the additional Least Costly Alternative policy was added at that time.

Also in 2000, the Secretary published a Notice of Intent (“NOI”), proposing the adoption of criteria for NCDs and LCDs by notice and comment rulemaking. 65 Fed. Reg. 31124-01 (proposed May 16, 2000). The Secretary is no longer pursuing the NOI.

The Secretary’s 1994 adoption of the LCD system, including the Secretary’s criteria to be used in adopting LCDs, is the subject of the class’s challenge in this lawsuit.

<sup>4</sup>There are six named plaintiffs. Because the plaintiffs do not challenge the substance of any of the LCDs in this suit — only the procedure by which the PIM guidelines relating to the LCDs were promulgated — the facts of the named plaintiffs’ cases are of little consequence. By way of example, named plaintiff Christopher Erringer has quadriplegia and suffers from pain which was successfully treated by trigger point injections. He received the injections for a number of years before the Medicare contractor who processed his claims adopted a new LCD that restricted payment for trigger point injections.

lar provisions of the PIM concerning LCDs. Section 5.1, “Coverage Provisions in [LCDs],” gives guidelines for when a service may be covered by a contractor.<sup>5</sup> PIM Ch. 13 § 5.1. Section 5.4, “Least Costly Alternative,” requires contractors to only partially pay for an item or service that substantially exceeds the cost of what is required for treatment. PIM Ch.13 § 5.4. Contractors must apply this principle when determining payment for durable medical equipment (“DME”) and *may* apply it to non-DME services, as well. *Id.*

The Medicare beneficiaries allege the Secretary violated the APA, 5 U.S.C. § 553(b) and (c), and the Medicare Act, 42 U.S.C. § 1395hh, by failing to provide notice and comment prior to promulgating the PIM provisions governing LCDs. The Beneficiaries and the Secretary filed cross-motions for summary judgment. The district court<sup>6</sup> granted the Secretary’s motion and denied the Beneficiaries’ motion, holding that

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<sup>5</sup>Section 5.1 states:

A service may be covered by a contractor if it meets all of the following conditions:

- It is one of the benefit categories described in title XVIII of the Act;
- It is not excluded by title XVIII of the Act other than 1862(a)(1); and
- It is reasonable and necessary under 1862(a)(1) of the Act.

The PIM continues that a service is “reasonable and necessary” if: the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational . . . ;
- Appropriate, including the duration and frequency that is considered appropriate for the service . . . ; and
- At least as beneficial as an existing and available medically appropriate alternative.

PIM Ch. 13 § 5.1.

<sup>6</sup>All parties consented to proceed before a magistrate judge.

Section 5.1 is both a procedural and interpretive rule, and Section 5.4 is interpretive and not binding with the force and effect of law.<sup>7</sup> Therefore, neither section was subject to the notice and comment rulemaking requirements of the APA or of the Medicare statute.

## II. Discussion

We review *de novo* the determination that an agency's rule is interpretive and not legislative as a matter of law.<sup>8</sup> *See Hemp Indus. Ass'n v. DEA* [*"Hemp Industries"*], 333 F.3d 1082, 1086 (9th Cir. 2003); *Ellison v. Robertson*, 357 F.3d 1072, 1075 (9th Cir. 2004).

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. *See* 5 U.S.C. § 553(b) and (c). This is termed the "notice and comment" requirement of the APA. "Th[e] requirement is designed to give interested persons, through written submissions and oral presentations, an opportunity to participate in the rulemaking process." *Chief Prob. Officers of California v. Shalala* [*"Probation Officers"*], 118 F.3d 1327, 1329 (9th Cir. 1997). Generally, "[t]he procedural safeguards of the APA help ensure that government agencies are accountable and their decisions are reasoned." *Sequoia Orange Co. v. Yeutter*, 973 F.2d 752, 758 (9th Cir. 1992).

[1] The notice and comment requirement, however, does not apply to "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5

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<sup>7</sup>The magistrate found that Section 5.1 "reflect[s] the agency's interpretation of the reasonable and necessary provision of the statute" and "effects no change in existing law and imposes no extra-statutory obligation." He further held that Section 5.4 is interpretive of the Medicare Act and imposes no additional restrictions on coverage.

<sup>8</sup>We use the terms "legislative" and "substantive" interchangeably.

U.S.C. § 553(b)(3)(A). The singular question we are asked to address is whether the Secretary's PIM provisions constitute substantive rules subject to formal rulemaking requirements or whether the manual provisions are interpretive and thus exempt.

**A. Interpretive Rules Under the APA Do Not Have the Force of Law**

[2] In *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 88 (1995), the Supreme Court described an interpretive rule as one "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." The Ninth Circuit has put it this way: "In general terms, 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." *Hemp Industries*, 333 F.3d at 1087 (9th Cir. 2003) (internal citations omitted).<sup>9</sup>

[3] *Hemp Industries* cites with approval the D.C. Circuit's framework for distinguishing between interpretive and legislative rules set out in *American Mining Congress v. Mine Safety & Health Admin.* ["*American Mining*"], 995 F.2d 1106, 1109 (D.C. Cir. 1993). *Hemp Industries*, 333 F.3d at 1087. Specifically, the Ninth Circuit agreed that legislative rules have the "force of law," while interpretive rules do not, and adopted a three-part test for determining whether 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;

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<sup>9</sup>The district court relied on *Flagstaff Medical Center, Inc. v. Sullivan*, 962 F.2d 879, 886-87 (9th Cir. 1992), which put it similarly, saying that interpretive rules "merely clarify or explain existing laws or regulations" and are used for "discretionary fine tuning."

(2) when the agency has explicitly invoked its general legislative authority; or

(3) when the rule effectively amends a prior legislative rule.

*Id.* at 1088.

### 1. Adequate Legislative Basis

*Hemp Industries* says “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.” 333 F.3d at 1088. As an example, *American Mining* pointed to § 14 of the Securities Exchange Act. That provision, governing proxy authority, proscribes no specific conduct — only that “in contravention of such rules and regulations as the Commission may prescribe.” *American Mining*, 995 F.2d at 1109 (quoting 15 U.S.C. § 78n(b)). Absent the SEC’s promulgation of proxy rules, therefore, the statute would be an empty letter — it would provide no legislative basis for the enforcement of anything at all. The *American Mining* case itself provides another example where there was an inadequate legislative basis for enforcement without the rule in question. The statute in that case required an operator to maintain “such records . . . as the Secretary . . . may reasonably require . . .” *Id.*

[4] In contrast, the Medicare statute does contain a standard for approval of claims apart from the PIM provisions and the LCDs. If the PIM provisions and resulting LCDs did not exist, Medicare contractors would still have an overarching duty to deny claims for items and services that are not “reasonable and necessary” under the Medicare Act. 42 U.S.C. § 1395y(a)(1)(A). This is not a case of pure delegation of authority to the agency to determine a standard. Instead, the PIM provisions simply interpret the “reasonable and necessary” standard contained in the statute. Because the Medicare

Act provides an adequate legislative basis for enforcement, this factor weighs against the PIM provisions having the force of law. *See Probation Officers*, 118 F.3d at 1333 (holding a rule to be interpretive where “congressional edict” clear from statute and rule only advised public of agency’s construction statute).

The Medicare beneficiaries argue that even if there is a standard in the Medicare statute, we should consider the binding effect of the rule in question. Specifically, they argue that LCDs are binding in the early stages of the appeals process and, for this reason, we should determine that they have the force of law. We did note in *Hemp Industries* that if a rule has a binding effect on tribunals outside the agency, that is a factor in determining whether that rule has the force and effect of law. 333 F.3d at 1088. In this case, however, we are concerned with the PIM provisions and not the actual LCDs.<sup>10</sup> Although the PIM criteria do bind the Medicare contractors, our query is whether the rule has a binding effect “on tribunals *outside* the agency.” *Id.* To the extent that the contractors administer Medicare benefits under the supervision of CMS, they are not “tribunals outside the agency.”

## 2. Explicit Invocation of Authority

[5] The second prong requires us to look at the agency’s own treatment of the rule, which is relevant, if not dispositive. *See Probation Officers*, 118 F.3d at 1335 (noting that the rule did “not purport to have the force of law or to warrant the deference accorded a regulation that is challenged in the courts.”). For instance, if Congress had specifically delegated legislative power to the agency and the agency made it clear that it intended to use that power in promulgating the rule in question, that would militate toward the rule having the force

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<sup>10</sup>Even if the LCDs themselves were the subject of our concern, they are only binding in the initial adjudication and during the preliminary appeals stages. They do not bind ALJs or the federal courts.

of law and hence being legislative. *See American Mining*, 995 F.2d at 1109.<sup>11</sup> Here, the Medicare beneficiaries point to no relevant, explicit delegation of legislative power.

[6] Additionally, if the agency's rule is meant to be an invocation of the agency's *general* legislative authority, separate and apart from any particular statutory provision, that would favor a finding that the rule is legislative. *See id.* at 1110 (citing *United Techs. Corp. v. EPA*, 821 F.2d 714, 719-20 (D.C. Cir. 1987)).<sup>12</sup> But in this case, there seems to be no reason to doubt that the manual provisions interpret the specific "reasonable and necessary" mandate of the statute.<sup>13</sup>

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<sup>11</sup>The Medicare beneficiaries contend that because the Secretary previously indicated an intention to proceed through notice and comment rulemaking by publishing proposed regulations, the Secretary is bound to proceed via formal rulemaking. Although they rely on *Sequoia Orange Co. v. Yeutter*, 973 F.2d 752, 758 (9th Cir. 1992), for support, *Sequoia* does not stand for such a broad proposition. In that case, we determined that the Secretary could not change a crucial decision reached *after notice and hearing* without complying with the APA.

<sup>12</sup>There is a difference between "'constru[ing]' a statutory provision and 'supplement[ing]' it." *American Mining*, 995 F.2d at 1110 (quoting *Chamber of Commerce v. OSHA*, 636 F.2d 464, 469 (D.C. Cir. 1980)). Although this distinction is murky, "an interpretation that spells out the scope of an agency's . . . pre-existing duty . . . will be interpretive, even if . . . it widens that duty . . ." *American Mining*, 995 F.2d at 1110.

<sup>13</sup>In *American Mining*, the D.C. Circuit listed as a fourth, separate criterion, whether the agency had chosen to publish the rule in the Code of Federal Regulations ("CFR"). 995 F.2d at 1109 ("[A]n agency seems likely to have intended a rule to be legislative if it has the rule published in the Code of Federal Regulations . . ."). In choosing not to include this criterion in the three-part test in *Hemp Industries*, we noted that publication in the CFR "does not necessarily mean that the rule is not interpretive." 333 F.3d at 1087 n.5. Likewise, when we have a rule that was *not* published in the CFR, it seems to weigh against an explicit invocation of legislative authority by the Secretary. Instead, the Secretary, of necessity, must rely on the statutory mandate, without which there would be no enforcement authority. In this case, the agency did not publish the rule in the CFR, and by all representations, does not expect the rule to be binding on the courts. Although lack of publication in the CFR in and of itself is insufficient to find a rule interpretive, it does weigh in the analysis.

Thus there is no indication of an explicit invocation of legislative authority.

### 3. Effectively Amends Prior Rule

Any rule that effectively amends a prior legislative rule is legislative and must be promulgated under notice and comment rulemaking. *See American Mining*, 995 F.2d at 1109. The reasoning is that “[a]n agency is not allowed to change a legislative rule retroactively through the process of disingenuous interpretation of the rule to mean something other than its original meaning.” *Hemp Industries*, 333 F.3d at 1091 (citations omitted).

The Medicare beneficiaries argue that the manual provisions amend a prior rule even though there was no prior published regulation. They contend that the notice and comment requirement applies “where one unpublished policy is replaced by a revised version of that policy that significantly affects members of the public.”

[7] But *Hemp Industries* clearly affirmed the circuit’s prior position by citing *Probation Officers*’s statement that a rule is considered legislative under the “amends a prior legislative rule” test “only if it is inconsistent with another rule having the force of law.” *Hemp Industries*, 333 F.3d at 1088 (quoting *Probation Officers*, 118 F.3d at 1337 (in turn relying on *Guernsey*, 514 U.S. at 100)). In other words, no notice and comment rulemaking is required to amend a previous *interpretive* rule. *Id.*; *see also Probation Officers*, 118 F.3d at 1335-36 (concluding that no case stands for the blanket proposition that any change in *policy* constitutes a legislative rule). The Beneficiaries did not allege that the 1994 manual provisions amended any former rule that had the force of law. Thus, this prong of the test also weighs against a determination that the manual provisions are legislative rules.<sup>14</sup>

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<sup>14</sup>The Medicare beneficiaries argue that the PIM provisions governing LCDs are more restrictive than the Medicare statute and, for this reason,

[8] Under the APA, then, the manual provisions governing creation of LCDs by Medicare contractors do not have the force of law and therefore are interpretive<sup>15</sup> and not legislative rules.<sup>16</sup>

### **B. Medicare Act's Promulgation Requirements**

[9] The Medicare beneficiaries argue that the Medicare Act itself creates a requirement for promulgation by regulation

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must be held to be legislative. Yet at the same time, the Beneficiaries admit that the Medicare statute must be “broadly construed” and make no compelling arguments that the PIM provisions, despite being more restrictive, are an *unreasonable* interpretation of the statutory language. Thus, this argument is unavailing.

<sup>15</sup>To the extent that the adoption of the LCD system itself was in question on appeal, which is far from clear, we determine that the requirement that contractors develop LCDs when they want to establish automated review is procedural. Even if there may be some substantive impact, procedural rules apply to “technical regulation of the form of agency action and proceedings.” *S. Cal. Edison Co. v. FERC*, 770 F.2d 779, 783 (9th Cir. 1985). Also, “procedural” rules are those that are “legitimate means of structuring [the agency’s] enforcement authority.” *American Hosp. Ass’n v. Bowen*, 834 F.2d 1037, 1055 (D.C. Cir. 1987). That is exactly what the LCD system does — it does not require regional contractors to adopt any particular, substantive LCDs, it merely requires that they do so when the contractors themselves make certain substantive findings.

<sup>16</sup>The Beneficiaries also argued that the provisions significantly affect their rights to payment for health services and, for this reason, they should be considered legislative. We note that it is unclear whether any particular beneficiary would be better off without the LCDs. In Mr. Erringer’s case, for example, his treatments could presumably be determined to not be “reasonable and necessary” by a contractor if review was on a case-by-case basis and thus not covered under the statutory scheme — the same result as if the treatments were not covered under the LCD system. If anything, without LCDs, which a contractor is required to publish on its website, Mr. Erringer and his providers would have less notice of coverage. Regardless, even if the impact of the manual provisions on the beneficiaries is significant, the Ninth Circuit has said that “impact is not a basis for finding a rule not to be interpretive.” *Probation Officers*, 118 F.3d at 1335; *see also Linoz v. Heckler*, 800 F.2d 871, 877 n.8 (9th Cir. 1986).

broadier than that of the APA. The section they rely on is titled: “Authority to prescribe regulations; ineffectiveness of *substantive rules* not promulgated by regulation.” 42 U.S.C. § 1395hh(a) (emphasis added). It says that

[n]o rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

42 U.S.C. § 1395hh(a)(2).

We have yet to determine whether the Medicare Act’s language somehow draws the line between substantive and interpretive rules in a different place than the APA and decline to do so here. Just as the D.C. Circuit in *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 814 (D.C. Cir. 2001), found no reason to explore the possibility of a distinction between the Medicare Act and the APA because the rule in question in that case was not close to the interpretive/substantive line, we too determine that the manual provisions in this case “appear[ ] to have none of the indicia that would lead us to think it a legislative rule under the APA.” *Id.* Thus, even if the Medicare Act were in some way broader, there is still no indication that the manual provisions should be determined to be legislative.

### **III. Conclusion**

The class of Medicare beneficiaries failed to demonstrate that the PIM provisions governing creation of LCDs by Medicare contractors carry the force of law. Thus, the manual provisions need not have been promulgated in accordance with

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the formal rulemaking requirements of the APA. Because the provisions have none of the indicia of substantive rules under the APA, even if the Medicare Act's language creates a broader promulgation requirement, the provisions would not be considered substantive rules.

AFFIRMED.