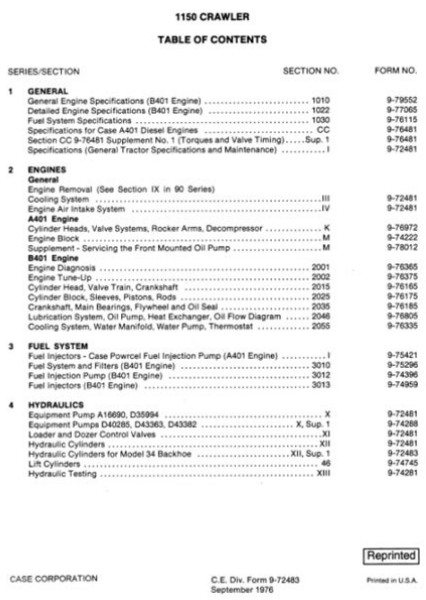
bowen technical manual no. 1150



1150 CRAWLER

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CASE CORPORATION C.E. Div. Form 9-72483 September 1976 Printed in U.S.A.

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In 1982, Congress amended the Medicare Act to provide for a new method of reviewing the quality and appropriateness of the health care provided by these medical providers to Medicare beneficiaries. On this contractual term, as on others, the goal of HHS flexibility is to encourage PROs to be responsive to distinctive community needs and practices, apparently a shortcoming in the system of review preceding the PRO system. Under the 1982 amendments, hospitals, in turn, must enter into contracts with the HHSdesignated PRO in their area in order to participate in the Medicare program and thus be eligible for reimbursements. Congress required hospitals to enter into such agreements by November 15, 1984. The initial flurry of regulations promulgated by HHS filled in a variety of these details regarding PRO procedures. See 42 C.F.R. Secs. 412.42; 412.44; 412.46; 412.48; 412.82; 462.100 et seq. Many of these procedures were aimed at harmonizing the PRO concept with the new system of reimbursing Medicare providers prospectively. The procedures detailed in these regulations included basic PRO review functions, reporting hospitals misrepresentations, DRG validation, review of hospital determinations of noncoverage, and payment for coverage exceeding the standard amount allotted for each diagnostic group. In addition to these regulations, HHS issued a series of directives and transmittals governing the PRO program that are the subject of this lawsuit. These communications include PSRO Transmittals Nos. 107 and 108, Medicare Hospital Manual Transmittal No. 367 and Medicare Intermediary Transmittal No. 1079, Medicare Intermediary Transmittal No. 1102, and PRO Program Directive No. 2. These transmittals contain a wide variety of instructions, guidelines and procedures covering aspects of the PRO

program. The RFP, among other things, told wouldbe PROs what review procedures their proposals must address, and what provisions their bids must contain.http://alterconseil.fr/alterconseil/images/design-manual-for-retrofitting-flood-prone-residential-structures.xml

The contracts entered into between HHS and the PROs contain the provisions required by the RFP. The facts of its dispute with HHS leading to this lawsuit are essentially as recounted by the district court. On December 14, 1984, the thenSecretary of HHS, Margaret Heckler, wrote a letter to AHAs general counsel stating that her staff was preparing a response, but would be unable to meet the 60day deadline requested by AHA. AHA sent another letter on January 8, 1985, requesting a date for HHS response. No response to this letter was ever received. On January 29, 1985, AHA brought suit against HHS in the District Court for the District of Columbia. Its complaint argued that HHS had circumvented the notice and comment requirements of Sec. 553 of the APA, and asked that the court declare the transmittals and directives, as well as the RFPs and the contracts entered into by HHS and the PROs, invalid for failure to comply with Sec. 553. It also asked the court to order HHS to promulgate all regulations implementing the PRO program in accordance with notice and comment procedures. While this lawsuit was pending, Secretary Heckler stepped down and was succeeded by Otis R. Bowen, who is now the principal named defendant. The district court, on crossmotions for summary judgment and on HHS motion to dismiss, held that virtually all of HHS communications, with the exception of Medicare Hospital Manual Transmittal No. 367 and Medicare Intermediary Manual Transmittal No. 1079, Sec. 3789c, were invalid for failure to comply with the APAs notice and comment requirements. The courts May 30, 1986 order also invalidated the RFPs and the contracts entered into thereunder as violative of Sec. 553.

We recount the district courts particular analysis in greater detail in the following section of our opinion, but in capsule form, the district court reasoned that the communications it invalidated were not mere interpretive rules exempt from the APAs notice and comment requirements, but rather, substantive legislative rules requiring HHS adherence to Sec. 553s strictures. HHS appealed, and on September 29, 1986, the agency was granted a stay pending the decision of this court. We heard argument on September 11, 1987, and now reverse. Section 553 of the Administrative Procedure Act requires agencies to afford notice of a proposed rulemaking and an opportunity for public comment prior to a rules promulgation, amendment, modification, or repeal. Congress, however, crafted several exceptions to these notice and comment requirements, determining that they should not apply A to interpretative rules, general statements of policy, or rules of agency organization, practice or procedure; or B when the agency for good cause finds and incorporates the finding and a brief statement of reasons therefor in the rules issued that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest. Section 553b. The issue in this case is whether the various pronouncements made by HHS in the course of its implementation of the peer review program fall within the first class of exceptions those for interpretive rules, procedural rules, or general statements of policy. We begin our analysis by noting that Congress intended the exceptions to Sec. 553s notice and comment requirements to be narrow ones. They express the agencys intended course of action, its tentative view of the meaning of a particular statutory term, or internal housekeeping measures organizing agency activities. They do not, however, foreclose alternate courses of action or conclusively affect rights of private parties.

Although an agency empowered to enact legislative rules may choose to issue nonlegislative statements, an agency without legislative rulemaking authority may issue only nonbinding statements. Unlike legislative rules, nonbinding policy statements carry no more weight on judicial review than their inherent persuasiveness commands. Batterton, 648 F.2d at 702 footnotes omitted. As in the area of federal preemption jurisprudence, analogizing to prior cases is often of limited utility in light of the exceptional degree to which decisions in this doctrinal area turn on their

precise facts. Nevertheless, recent cases shed some light on the scope of the Sec. 553 interpretive rules exemption. In Cabais v. Egger, 690 F.2d 234 D.C. Cir. 1982, we upheld as interpretive of the Federal Unemployment Tax Act directives from the Secretary of Agriculture recommending to state agencies that they pass legislation conforming their unemployment income plans to a federal scheme as they were required to do under a federal statute. Cabais thus stands for the important proposition that where an agency activity merely reminds parties of existing duties, id.Likewise, in American Postal Workers Union v. United States Postal Service, 707 F.2d 548 D.C. Cir. 1983, cert. denied, 465 U.S. 1100, 104 S. Ct. 1594, 80 L. Ed. 2d 126 1984, we held that the postal services new method of calculating the civil service retirement benefits of parttime postal workers constituted an interpretive rule. The agency cannot apply or rely upon a general statement of policy as law because a general statement of policy only announces what the agency seeks to establish as policy. Nevertheless, our prior cases, in seeking to discern the line between these two types of agency pronouncements, have provided considerable guidance. The second criterion is whether a purported policy statement genuinely leaves the agency and its decisionmakers free to exercise discretion. 627 F.2d 525, 529 D.C. Cir.

1980 citations and footnote omitted quoting Texaco v. FPC, 412 F.2d 740, 744 3d Cir. 1969. In applying these two criteria, we have observed that an agencys characterization of its own action, while not decisive, is a factor that we do consider. See Telecommunications Research and Action Committee TRAC v. FCC, 800 F.2d 1181, 1186 D.C. Cir. 1986; Pacific Gas, 506 F.2d at 39. Cases interpreting the Sec. 553 exemption for general statements of policy, like those applying the interpretive rule exemption, also tend to turn on the distinctive facts of the case and thus are not susceptible to easy generalization. We offer here several telling examples of cases upholding agency pronouncements as constituting mere statements of policy, not subject to notice and comment requirements. In TRAC, we held that an FCC order eliminating six broadcast regulatory policies that had not been established in rulemaking was a nonbinding general statement of policy, because the Commission had conceded both that it was not bound by its statement of repeal, see 800 F.2d at 1186, and that under certain circumstances it might still consider the application of the supposedly defunct regulations. Likewise, in Pacific Gas, we held that a Federal Power Commission order setting forth the Commissions view of the proper priority schedule to be followed in curtailing supplies of natural gas to certain customers in the hypothetical event of a natural gas shortage was nonbinding and hence a mere policy statement. The gradual move away from looking solely into the substantiality of the impact reflects a candid recognition that even unambiguously procedural measures affect parties to some degree. While the range of cases applying this exemption may appear idiosyncratic, a few recent decisions of this and other circuits illustrate the scope and limits of the procedural exemption.And in United States Department of Labor v. Kast Metals Corp., 744 F.2d 1145 5th Cir.

1984, a case to which we shall return in greater depth later, the Fifth Circuit held that the agencys rules governing the selection of employers for workplace safety investigations was a procedural rule. By contrast, we have struck down as nonprocedural an agency rule foreclosing home health agencies from the right to deal with the Secretary of HHS in order to gain reimbursement for Medicare, see National Association of Home Health Agencies, and, as noted earlier, we have held that a parole boards selection of parole eligibility guidelines had the intent and effect of changing substantive outcomes. See Pickus. B. The Validity of HHS Actions With Regard to Peer Review Before turning to the specific directives issued by HHS implementing the peer review program, we pause first to make a point about the proper point of reference for our analysis of AHAs Sec. 553 claims. In his opinion, the district judge repeatedly suggested that it was the impact upon the peer review organizations, rather than the impact upon the hospitals whom the PROs monitor, that was dispositive. At the same time, his opinion failed to spell out what burdens the various HHS missives placed on hospitals and other medical care providers. We, on the other hand, regard hospitals and health care providers as

the only relevant points of reference from which to analyze whether HHS communications were sufficiently substantive as to require notice and comment; our perspective in that regard differs from the district courts. A peer review organization is essentially an enforcement agent of the federal government for purposes of the regulations involved here. Hired pursuant to a contract with the government, a PRO monitors the compliance with HHS strictures of the private hospitals who seek compensation from the agency. The PROs rights are contractual, stemming from its agreement with HHS.

Like an independent contractor hired to construct a government building, the PRO carries out a task for pay at the behest of the government. Should the government seek to restructure the PROs obligations after the inception of the contractual relationship, the PRO may validly claim a breach of its agreement. But short of this scenario, in situations where the PRO freely entered into a contract with the federal government, one can hardly claim that the PROor, for that matter, the independent contractorhas had substantial uninvited burdens placed upon it. Indeed, PROs have been recognized in analogous situations as agents of the federal government. Kwoun v. Southeast Missouri Professional Standards Review Organization, 811 F.2d 401 8th Cir. 1987, involved a civil rights and tort action brought by a doctor against the medical review organization that had recommended that he be excluded from eligibility for Medicare payments for 10 years. A federal district court in the Eastern District of Missouri dismissed the doctors claim on the grounds that the review organization and its officials enjoyed qualified immunity as state actors, and the Eighth Circuit affirmed. In focusing on the impact upon the PROs of various HHS directives, the district court failed to take heed of the critical difference between PROs and hospitals. It is irrelevant whether an HHS directive burdens PROs by requiring them, as a condition of entering into a contract with HHS, to channel their institutional energies towards particular hospital procedures or to focus on particular perceived abuses. To hold otherwise would be to reach the curious result that, despite Congress expressed desire that HHS utilize private review outfits, HHS cannot reach through its contracting agents the same result that it could surely reach itself by using its own employees as enforcement agents.

With that cautionary admonitionthat the ball on which we must keep our eye is the hospital, not the PROwe proceed to analyze each of the directives at issue in this case. 3 PRO Manual IM852, promulgated by HHS in March, 1985, is a 70page document that defines procedures governing many of the review functions of PROs. See Joint Appendix J.A. at 798. In our view, the district court correctly held IM852 to replicate the earlier PSRO Transmittal No. 107, the document initially challenged by AHA, and therefore we, like the district court, confine our analysis to the later document. A broadbrush description of IM852 is that it maps out an enforcement strategy for the PROs with whom HHS contracts. As the district court observed, the statutes and preexisting regulations that deal with PRO review are relatively sketchy, see 640 F. Supp. at 461, and thus IM852 makes a significant contribution towards describing the daily functions of PROs. It requires, for instance, that the PRO review at least 5% of all hospital admissions, selected at random. Finally, it includes an array of rules about notice to hospitals and parties, about the timing of PRO review, and about jurisdictional disputes between hospitals in separate PROcovered areas. The opinion of the district court, invalidating IM852, rejected the argument by appellants below that the transmittal falls within Sec. 553s exemption for interpretive rules. While we share the view of the district court that the commands of IM852 are not valid as interpretive rules, we find this conclusion beside the point. The requirements set forth in the transmittal are classic procedural rules, exempt under that distinctive prong of Sec. 553. The bulk of the regulations in the transmittal set forth an enforcement plan for HHSs agents in monitoring the quality of and necessity for various operations.

They essentially establish a frequency and focus of PRO review, urging its enforcement agents to concentrate their limited resources on particular areas where HHS evidently believes PRO attention

will prove most fruitful. The Fifth Circuits decision in United States Department of Labor v. Kast Metals Corp., 744 F.2d 1145 5th Cir. 1984, is particularly instructive with regard to this manual. We venture the guess that, had HHS established identical terms governing the frequency and focus of review by directly issuing orders to its own officers, the agencys enforcement plan would then appear more unambiguously as a valid use of its enforcement authority. But it is substance, not form, to which Sec. 553 looks the fact that the agency reached the identical result by operating through a private intermediary under contract with the agency hardly dictates a different result under Sec. 553. The manual imposes no new burdens on hospitals that warrant notice and comment review. This is not a case in which HHS has urged its reviewing agents to utilize a different standard of review in specified medical areas; rather, it asks only that they examine a greater share of operations in given medical areas. Were HHS to have inserted a new standard of review governing PRO scrutiny of a given procedure, or to have inserted a presumption of invalidity when reviewing certain operations, its measures would surely require notice and comment, as well as close scrutiny to insure that it was consistent with the agencys statutory mandate. See, e.g., Pickus. But that is not this case. At worst, Manual IM852 burdens hospitals by 1 making it more likely that their transgressions from Medicares standards will not go unnoticed and 2 imposing on them the incidental inconveniences of complying with an enforcement scheme. The former concern is patently illegitimate Congress very purpose in instituting peer review was to crack down on reimbursements for medical activity not covered by Medicare.

As for the second burden, case law clearly establishes that such derivative burdens hardly dictate notice and comment review. See, e.g., Neighborhood TV Co.; Kast Metals. Accordingly, we hold that PRO Manual IM852 is a procedural rule exempt from Sec. 553s notice and comment requirements. PRO IM853, issued in May, 1985, is a 22page transmittal letter that sets forth an enforcement plan for PROs to review hospital determinations that patients are no longer covered by Medicare and thus may be billed for its services. See J.A. at 868. The district court concluded that this transmittal replicates PSRO Transmittal 108, originally challenged by AHA, and therefore concentrated its attention on the later communication. We agree with that analysis, and do likewise. IM853, among other things, provides detailed procedures by which PROs are to review denial notices. It commands PROs to require hospitals to keep a monthly list of denial notices and to give it to the PRO, to scrutinize 10% of the cases from this list, and to evaluate each randomly chosen case for medical necessity and appropriateness. We review IM853 under the same principles that governed our evaluation of IM852. As in the case of IM852, the district court premised its invalidation on its determination that the transmittal letter in question was not valid as an interpretive rule, and as in the case of IM852, we regard that determination as correct yet beside the point. PRO IM853 is another procedural rule providing directions to PROs to target the frequency and focus of their enforcement efforts. It neither changes the standard of PRO review, nor imposes anything greater than incidental mechanical burdens on regulated hospitals. The selection of denial notices as an area of special enforcement focus is well within HHS discretionary enforcement authority. The notice is therefore valid under the same Kast Metals analysis under which we sustained the preceding transmittal.

These topics include the directives requirements that hospital agreements address DRG validation and admissions review. They also include the requirement that PROs review all cases involving a specific diagnostic group, DRG 468, and that they give hospitals no more than twentyfour hours notice of an upcoming onsite DRG validation. Accordingly, it held that the directive was invalid because the agency had failed to initiate notice and comment proceedings. We again disagree. As with its analysis of PRO IM852 and PRO IM853, the district court analyzed this directive only in terms of Sec. 553s interpretiverule exemption, overlooking the more relevant exemption, that for procedural rules. The obligations set forth in PRO Program Directive No. 2 merely sculpt the enforcement activity of the PROs, choosing within the vast terrain of legitimate review activity

specific pockets of hospital activity and behavior for more consistent scrutiny. In this area, the greater surely includes the lesser that is, the greater authority of an agency to review all hospital activity includes the lesser authority to train its reviewing resources on a subset of that activity likely to include a heavier dose of abuse. No doubt the searchlight of PRO scrutiny may expose as undeserving hospital claims for Medicare reimbursement in certain areas. Under this directive, for instance, readmissions of the same patient to a hospital will be reviewed with more regularity than will firsttime admissions. This policy no doubt reflects HHS determination that, under the system of prospectively compensating hospitals for admissions of patients to given diagnostic groups, hospitals have a great incentive to maximize the number of brief hospital stays and thus would be tempted to segment a given patients stay at a hospital into two stints.

Far from imposing a new substantive burden on hospitals, the agencys decision to focus its resources on such likely problem areas gives more full effect to the intent of the congressional framers of the peer review amendments. 4. The Request for Proposals and Contract Provisions The lifeblood of the peer review system is the contracts signed between the peer review organization and the agency. In its opinion, the district court concluded that several provisions of the typical contracts signed between the agency and the PROs were legislative, not interpretive, and accordingly invalidated not only the provisions in question, but also the request for proposals that called for the adoption of these procedures in the ensuing contracts. a The Request for Proposals Before examining the specific contractual provisions at issue, we turn first to analyze the role of the RFP in the process of contract formation between HHS and the PROs. The request for proposals is a document issued by HHS soliciting proposed contracts from entities seeking to become PROs. It is a mammoth sheaf full of detailed specifications, charts, and forms the RFP included in the joint appendix in this case runs 335 pages and spells out in some detail the arrangements HHS expected to see in PRO contracts. See J.A. at 294. Broadly stated, the RFP describes the technical procedures HHS expects PROs to follow, sets forth guidelines akin to those in IM852 and IM853 on the sampling strategies it wishes its enforcement agents to deploy, including special focus on particular areas of medicine and on DRGs whose average admission rates in the area exceeds the national average. Many of the terms set forth in the RFP are duplicative of the transmittals to PROs already discussed. It is surely true that in negotiations over PRO contracts, HHS is a monopolist and thus has the upper hand in bargaining.

Accordingly, we conclude that the district court wrongly invalidated those parts of the RFP it deemed legislative in character. The discussion of whether particular terms of the hospitalPRO relationship in fact were unacceptably substantive and thus required notice and comment rulemaking is better suspended until our discussion of the contracts that incorporated those terms, for it is at the stage of contract formation that those terms suggested by HHS became binding. b The PRO Contracts We now turn to the contracts themselves. A preliminary question is whether these documents are subject to the strictures of the Administrative Procedure Act at all. HHS argues, as it did below, that apart from any Sec. 553 exemption, Congress has already granted it exemption from the various requirements of the APA by conferring upon the agency plenary contractmaking authority. The Secretary may use different contracting methods with respect to different geographic areas. And it is equally apparent that, for the PRO program to have any vitality as a means by which the federal government can respond to localized medical practices, the department must be vested with much discretion to tailor PRO contracts to diverse needs. Nevertheless, it is a considerable leap from concluding that HHS has considerable contractual discretion to concluding that the agency has received a blank check from Congress to adopt any contractual provision whatsoever without undertaking notice and comment review. As the district court, reaching the same result that we do, observed HHS may not hide behind its authority to contract in order to evade the A.P.A. Otherwise it could implement the entire PRO program through contract provisions, without promulgating a single regulation or allowing for any public participation. Congress could not have intended so

extraordinary a possibility without expressly saying so. 640 F. Supp. at 467.

Accordingly, we conclude that any contract provisions that are legislative are subject to Sec. 553s notice and comment requirements, at least while HHS waiver of the APAs contractmaking exemption is still in effect. We now move on to discuss those contracts. Most aspects of the contracts between HHS and its PROs are patently unexceptionable. In substantial measure these contracts either describe the technical terms of PROhospital and PROHHS interaction or restate the provisions of the previously discussed directives and manuals that we have concluded fell within Sec. 553s exemptions to notice and comment. The particular provisions cited by the district court in its opinion likewise cause little concern. Moreover, each objective cited above is worded very generally and clearly incorporates the substantive standard for reimbursement under the Medicare statute, i.e., whether a given procedure was indeed necessary. So long as the standard of review remains unchanged, the focus and timing of review are matters for agency discretion, falling well within Sec. 553s procedural exemption. Appellees, however, urge that there is apparently no way for a PRO to meet its precise contractual objectives with certainty, and thus that the objectives are artificial figures that can only do mischief. The argument proceeds as follows. If the objective of reducing 125 avoidable deaths over a twoyear period is to have any real meaning, one must at a minimum know how many avoidable deaths took place over the preceding twoyear period. Yet at least for the period of the initial PRO contract, the one in which these objectives are embedded, that information is apparently unavailable. Moreover, at oral argument, counsel for HHS was unable to offer any alternative practical explanation of how these numerical objectives could be met during the initial twoyear period.