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OPACITY AND COST EFFECTIVENESS ANALYSIS IN MEDICARE COVERAGE DECISIONS: HEALTH POLICY ENCOUNTERS ADMINISTRATIVE LAW

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Medicare is the public health insurance program for elderly and disabled Americans. Established in 1965, today it is the primary health insurer for 46 million people.¹ Like all insurance programs, Medicare must determine what benefits to cover. In the Medicare statute, Congress established coverage for broad categories of care--hospitalization, office visits and prescription drugs--and broad categories that were excluded, such as vision and dental care.² Beyond these broad categories, Congress left the agency administering Medicare--now known as the Center for Medicare and Medicaid Services (CMS)³--to determine whether certain treatments are “reasonable and necessary” and thus eligible for Medicare coverage.⁴

Two “facts” about Medicare coverage determinations are well established in the health policy literature. First, CMS does not have criteria by which it makes coverage decisions. Second, CMS does not conduct cost effectiveness analysis in making these determinations.⁵ Many health policy scholars argue that CMS should adopt formal, public criteria for coverage and that those criteria should include cost effectiveness analysis. The author agrees that CMS should publish coverage criteria and should include cost effectiveness among them, but argues that at least the strong version of both basic “facts” cannot be correct. Although CMS approves coverage of most treatments it is asked to evaluate--99 percent of the time in one study⁶--it does deny coverage of some procedures and devices.⁷ Therefore, *some* criteria for denying ⁵¹⁶ coverage must exist, even if they are not published or otherwise formalized.⁸ As an empirical matter, CMS does also use cost in some coverage determinations, even though it may not acknowledge that it does so.⁹ Medicare providers, beneficiaries and taxpayers are ill served by this disconnect between rhetoric--no criteria and no cost concerns--and reality--the opposite. CMS argues that it already provides sufficient explanation of its coverage determinations without publishing a formal standard. This article demonstrates that, as both a legal and policy matter, these explanations are inadequate.

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Part I briefly describes cost effectiveness analysis, why policy analysts largely view it as necessary in Medicare, and what the popular objections to it are. This first part concludes with a discussion of how Medicare uses cost in coverage determinations while claiming to avoid the practice. Part II describes how the lack of public criteria for coverage determinations hampers the debate on cost effectiveness. CMS must have some criteria in mind when it makes coverage determinations, or else those decisions would constitute illegally arbitrary and capricious action. As a general matter, agencies are free to develop such criteria in the process of making decisions; they need not first publish the criteria. Both Congress and the courts, however, have instructed CMS to make its criteria

more clear, and CMS has refused.¹⁰ This illegal result is the consequence of a decades-long project of political avoidance. Neither Congress nor CMS wants to take responsibility for imposing cost effectiveness analysis on Medicare. If no one discusses what the criteria are for denying coverage, the public cannot even begin to consider whether cost effectiveness should be one of those criteria. Part III concludes that Congress, CMS and the courts can play a role in remedying this unsustainable situation.

I. COST EFFECTIVENESS ANALYSIS IN MEDICARE

Generically, cost effectiveness analysis is the evaluation of alternative treatments in terms of the cost of an equivalent amount of benefit. In health policy, cost effectiveness analysis is used to compare the cost of various procedures, devices or drugs, given how much clinical benefit they produce.¹¹ The clinical benefit might be an absolute gain in life expectancy, a gain in quality-adjusted life years, or an effect on some intermediate target, such as cholesterol level.¹² The virtues of cost effectiveness ^{*517} analysis are straightforward; given scarce resources, the analysis tells a planner where to allocate those resources most productively. Such analysis is, of course, only useful if there are meaningful constraints on resources.¹³ Though many patients and physicians might hope to spend any price to save a life, the author assumes there are meaningful limits to the amount of money that can be spent on healthcare by public programs. Even on an individual level, healthcare spending without regard to cost could be counter productive if it crowds out spending on nutrition, housing or other health-promoting programs.¹⁴ More specifically, the author assumes that beyond some point Congress will be unwilling to borrow or raise taxes in order to pay for more expensive Medicare benefits. (Naturally inherent in this discussion is also the assumption that cost effectiveness analysis is methodologically precise enough to provide useful data.)¹⁵ Cost effectiveness analysis thus raises the specter of rationing, which like so much policy debate in Medicare has made it a political “third rail.”¹⁶ Whereas individual patients likely will accept being denied access to a particular treatment because its clinical risks outweigh its benefits, they will be more resistant to being denied treatment because a central planner has determined that money spent to provide the treatment could be more efficiently spent caring for other people.¹⁷ This conflict between an economic reality and its unfortunate consequences has driven politicians and bureaucrats alike simply to avoid explicit discussion of cost effectiveness analysis, as discussed in this Part. In lieu of directly addressing cost effectiveness, CMS has tried various strategies to reduce costs that are superficially not about cost effectiveness analysis. This sub rosa cost effectiveness analysis is legally questionable.

The same forces that have driven private insurers to focus on costs also affect Medicare: medical technology has gotten vastly more sophisticated and expensive, driving up healthcare costs to more than 15 percent of gross domestic product.¹⁸ Medicare, however, has additional burdens that private insurers do not have, especially an intergenerational funding structure that will require an ever greater subsidy from general U.S. Treasury funds.¹⁹ A central policy debate over Medicare--one that is sure to become ever more central as the Obama Administration moves to expand government-financed healthcare--is whether Medicare should evaluate the cost effectiveness of the treatments it funds. The federal stimulus package included \$1.1 billion for research into comparative effectiveness, a related, but less controversial ^{*518} policy tool.²⁰ Comparative effectiveness research determines the relative effectiveness of alternative health strategies, without a focus on cost.²¹ The consequence of cost effectiveness evaluation might be that the government would be more aggressive in denying funding for treatments; even though certain treatments are approved by the Food and Drug Administration (FDA) as safe and effective or recommended by a treating

physician, CMS could determine that the treatments do not provide enough health benefit on a population basis to justify their cost.²² This would be a dramatically different world than the current scheme, in which as many as 99 percent of devices and procedures that seek Medicare coverage are funded.²³ Indeed, at some points Medicare has treated its “reasonable and necessary” standard as equivalent to FDA’s “safe and effective.”²⁴ Under such an interpretation, any drug or device approved by FDA should meet the CMS standard for reimbursement.

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Social health programs in Europe, Canada and Australia explicitly consider cost effectiveness when designing their benefits, but Medicare never has.³⁰ The principal tool Medicare has to deny coverage is a statutory mandate to deny coverage of services and items that are not “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”³¹ The Medicare statute adopted this language in 1965 from an Aetna *519 private health insurance policy.³² At the time, both social and private insurance was highly deferential to the medical judgment of individual physicians: if a treating physician believed care was appropriate, an insurer would rarely deny coverage.³³ Indeed, the HCFA did not bother interpreting the “reasonable and necessary” language until 1977.³⁴ In the decades since 1965, private insurers have taken aggressive steps to contain healthcare costs, specifically delineating the circumstances under which they will pay for given treatments. Insurance company medical directors have even complained that when deciding whether to fund treatment using new technology they have lacked adequate cost-effectiveness data to make such a decision.³⁵ Medicare has maintained the vague “reasonable and necessary” standard.³⁶

There are some cost-based restraints on Medicare coverage, but these are fundamentally different than those envisioned under a regime of explicit cost effectiveness analysis. For example, the Medicare statute has always required doctors to certify that items and services they are prescribing are necessary, and for some expenses an institutional utilization review committee must also certify that the treatment is appropriate.³⁷ This sort of review is focused on whether doctors are over-utilizing reasonable services. This utilization review does not reach the question of whether a particular service, regardless of the volume in which it is provided, is simply too expensive to offer at all.

HCFA had through the years attempted to publish coverage criteria that would include cost, but political forces intervened to block the agency each time. In 1980, HCFA developed a draft coverage policy that would have considered “safety, economics, and ethical and social factors,” but in the heat of a presidential election the policy was never formally proposed.³⁸ The Reagan Administration abandoned the draft policy, at the behest of device manufacturers and doctors.³⁹ But as the Reagan Administration left office it returned to the topic, publishing a notice of proposed rulemaking that would have officially established cost effectiveness as a coverage criterion.⁴⁰ When a leaked final draft of the rule showed up in a *New York Times* story that warned that the rule could lead to “rationing,” public-- and industry--pressure mounted against the rule. President Bush’s Secretary of HHS killed the rulemaking in March 1992.⁴¹ In 1996, the Clinton Administration tried to adopt a coverage rule that used “comparability” instead of cost effectiveness, but industry again mobilized to bury the rule.⁴² Finally, in 2000, the Clinton Administration again proposed a rule, with the criteria now being “medical benefit” and “added value.”⁴³ This second criteria again sounded too much like cost effectiveness and doomed the rule.⁴⁴

*520 What is happening at CMS in lieu of cost effectiveness analysis? Actions that look a lot like cost effectiveness analysis. In 1990, a lawyer representing Medicare Part B physicians complained that HCFA was denying coverage for items as unnecessary in a veiled cost-containment strategy.⁴⁵ The agency also encouraged its contractors to be vigilant about screening “expensive and inappropriately used services.”⁴⁶ Although this sounds like a step toward cost effectiveness analysis, it may just have been a call to avoid waste. Even inexpensive, but medically appropriate [sic] treatments should be denied coverage. In 1997, Bruce Vladeck, HCFA’s Administrator, insisted before the House Ways and Means Committee that HCFA does not make coverage decisions on the basis of cost effectiveness, but “[o]n the other hand, if a new service or technique is no more effective and less cost effective than the current technology in place, we believe we should pay no more for it than we do for existing technology.”⁴⁷ Vladeck was unable even to explain his policy without using the phrase “cost effective.”

In some cases, laws of nature have allowed Medicare to contain costs. In the 1980s, Medicare became worried that the high costs of heart transplants could quickly bankrupt the program. Not only was the procedure itself expensive, but organ transplants at the time could generate up to \$15,000 a year per patient in ongoing costs for postsurgery treatment.⁴⁸ But Medicare was saved because so few hearts were available. The coverage determination found transplants to be reasonable and necessary mostly for patients younger than the Medicare (65 and older) population, because that population would receive the most benefit from a heart transplant.⁴⁹ Rationing was acceptable for such a palpably scarce commodity as human hearts.⁵⁰ Healthcare dollars perhaps will need to be that scarce before explicit cost effectiveness considerations become politically tenable.

While not calling it “cost effectiveness analysis,” CMS has still tried to consider cost in coverage decisions. Because these tactics inevitably involve using CMS’s non-coverage decision legal authority to try to dissuade beneficiaries from using expensive treatment, the strategy runs into legal trouble, as CMS’s recent failure to reduce its costs on certain services demonstrates. For durable medical equipment and related services, CMS adopted a “least costly alternative” policy. Under this policy, if there are two devices or services for a similar diagnosis and one has not been shown to be more medically effective than the other, then both treatments will be reimbursed at the price of the least costly treatment.⁵¹ The consequence of such a policy is that the more costly, but no more effective treatments will not be used, a form of back-door cost effectiveness analysis. Critically, the policy is cast as using cost as part of payment decisions, not coverage decisions. The inevitable consequence, however, is for cost to become factored into coverage decisions. A federal district court in the District of Columbia recently struck down the policy.⁵² *521 In *Hays v. Leavitt*,⁵³ a Medicare beneficiary petitioned the court to overturn the reimbursement rate CMS set for the inhalation drug DuoNeb. DuoNeb, which treats chronic obstructive pulmonary disease, is administered through a nebulizer and contains two drugs that are also available separately, albuterol and ipratropium. Because the two drugs separately are cheaper than DuoNeb and DuoNeb has not been proven to be more medically effective, a CMS contractor concluded that DuoNeb should only be reimbursed at the lower rate of the two individual drugs.⁵⁴ The beneficiary argued in district court that CMS is not entitled to impose the least costly alternative policy, because Congress has set a statutory payment scheme that is inconsistent with the CMS policy.⁵⁵ CMS argued that the least costly alternative policy is a permissible construction of the “reasonable and necessary” clause. The court disagreed, concluding that the “reasonable and necessary” clause was about coverage decisions, not payments. Because CMS was, at least explicitly, making a payment decision, its incidental effect on coverage did not mean that CMS was excused from the clear statutory language

concerning payments that contradicted the policy.⁵⁶

The least costly alternative policy demonstrates the failings of back-door cost effectiveness analysis. Because CMS is apparently loathe to admit that it is using cost as a criteria in coverage decisions, CMS is forced to be dishonest about why it is making certain policy choices. As *Hays* demonstrates, this obfuscation leaves policy choices vulnerable to legal challenge, because the agency appears to be acting not in accordance with the Medicare statute. Even if not directly contradicted by the statute, such action might be struck down as arbitrary and capricious, because the agency is trying to make coverage decisions based on cost, but uses some other less sensible explanation for why coverage is being denied.⁵⁷ CMS would not be vulnerable to these same legal attacks if it explicitly adopted cost as a consideration in coverage decisions. *Hays* concludes that the “reasonable and necessary” language does not permit CMS to set price; it does not reach the question of whether that language would allow cost to be used in coverage decisions. The author discusses that question, among other potential routes for adopting cost effectiveness analysis, in Part III.

II. COVERAGE POLICY WITHOUT PUBLISHED CRITERIA

CMS and Congress have been able to avoid confronting the cost effectiveness question because they have done such a good job of avoiding discussion of coverage criteria entirely. This Part, distinguishes a coverage “policy” from coverage “criteria.” CMS must, as a practical matter, have a coverage policy, because it does make coverage decisions, and those decisions clearly are based on some standard. This part shows that as a legal matter CMS need not publish that policy as public criteria. Still, for both legal and non-legal reasons the author argues that CMS has an obligation to be clearer about what its coverage policy is. Without a clear understanding of the current coverage policy, the political debate over cost effectiveness analysis and other coverage decisions will be hopelessly stymied.

Congress has limited CMS to two routes for making policy: national coverage determinations, which set coverage policy while deciding whether to cover an individual ^{*522} treatment, or notice-and-comment rulemakings, which ex ante set broad coverage regulations.⁵⁸ CMS says it has no plans to issue across-the-board coverage rules, but insists that it is adequately explaining its policy via its determinations on individual services, in a “case law” method.⁵⁹ The Supreme Court has held in *SEC v. Chenery*⁶⁰ that, as a legal matter, agencies are free to set policy in whatever manner they choose: “[T]he choice made between proceeding by general rule or by individual, ad hoc litigation is one that lies primarily in the informed discretion of the administrative agency.”⁶¹ Nevertheless, Congress and courts may still constrain the ways agencies set policy. Even within the broad discretion Congress and the courts have given CMS to shape Medicare coverage policy, the agency has failed to obey congressional and judicial mandates to explain its decisionmaking.

Chenery held that under the Administrative Procedure Act executive agencies are free to choose the form of their policymaking.⁶² However, Congress may impose particular restraints on how agencies make decisions.⁶³ Although this has not been widely recognized, Congress did impose such a restraint on CMS’s coverage determinations in a brief section of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, commonly referred to as the Medicare Modernization Act or “MMA.”⁶⁴ The MMA is best known for creating Medicare Part D, the prescription drug benefit program.⁶⁵ But § 731 of the MMA also instructs the Secretary of HHS, who supervises CMS, to “make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary.”⁶⁶ CMS is free to

continue setting its coverage policy via individual determinations, but under this statutory language it must at least tell the public--outside the context of an individual determination--how it intends to make those determinations.

Congress did not intend for these published criteria to bind CMS; Congress said the criteria could be issued in guidance documents similar to those issued by FDA, which are not binding on the agency, but which the agency complies with absent good cause to do otherwise.⁶⁷ Despite the somewhat limited nature of the requirements of this section, it was still seen as a dramatic step: CMS was being required to make clear what had been vague for decades. Professor Jacqueline Fox wrote that the publication of criteria would generate intense debate about cost effectiveness analysis, which might be implicit in any criteria: “This law has the potential to force in the open this implicit process, exposing a problem that has been simmering under cover almost since the beginning of the Medicare program.”⁶⁸

*523 The expected debate over the Medicare coverage criteria never happened, because CMS ignored the law and never published its coverage criteria. Instead, on September 24, 2004, CMS published a notice in the *Federal Register* explaining how it intended to produce the guidance documents that would explain “the NCD process and other issues involved in making coverage determinations.”⁶⁹ The guidances would describe the timeline and general process for requesting a coverage determination and would describe “[w]hat types of scientific and other information are considered in the process” and “[h]ow various types of evidence are evaluated for reasonable and necessary determinations.”⁷⁰ Unfortunately, by April 2006, when CMS began issuing these guidances, the agency seemed to have forgotten that it was required to explain “the factors considered in making national coverage determinations.” Instead, the agency focused entirely on the procedure involved in requesting a coverage determination. The CMS website lists four “coverage guidance documents.”⁷¹ The only one of those four guidances that appears to be an attempt to explain its coverage criteria is titled “Factors CMS Considers in Opening a National Coverage Determination.”⁷² As the title indicates, the guidance focuses almost exclusively on the procedure a provider or beneficiary should undertake to get CMS to issue an NCD--not the frank discussion of the factors involved in the determination itself that Congress was calling for. CMS is careful to say, “Cost effectiveness is not a factor CMS considers in making NCDs. In other words, the cost of a particular technology is not relevant in the determination of whether the technology improves health outcomes or should be covered for the Medicare population through an NCD.”⁷³ But the document never affirmatively states what the factors are that CMS uses in making national coverage determinations. Instead, the guidance is filled with advice on how to submit requests to CMS for determinations, including requesting from applicants “a full compilation of the supporting medical and scientific information currently available that measures the medical benefits of the item or service.”⁷⁴ The guidance said this requirement will be explained in a forthcoming guidance on evidentiary standards. Three years later, and six years after Congress ordered CMS to explain how it makes coverage determinations, this guidance is still not available. The guidance explains the circumstances when CMS will issue a national coverage determination, as opposed to letting its local contractors decide whether an item or service will be covered. But these factors don’t explain whether an item is covered as “reasonable and necessary,” only the conditions under which CMS will decide to make such a decision.

This almost entirely procedural explanation could not have been what Congress was instructing CMS to do. For three reasons it is clear that CMS is not following the statute: the statutory language itself, its legislative history, and the regulatory context within which the statute was enacted.

First, the statute could not be clearer that Congress was asking CMS to explain the “factors considered in making national coverage determinations of whether an item or service is reasonable and necessary.” Although the phrase “reasonable and necessary” appears six times in 2006 guidance, nowhere is it used as part of *524 a description of what the agency’s calculus is in determining whether an “item or service” fits this description.

Second, the legislative history is clear that Congress was calling on CMS to publicly discuss the substantive criteria it considers in making these determinations, not just the process used to determine whether making a determination is appropriate. The conference committee that reconciled the House and Senate versions of the MMA said, regarding this section of the bill: “The conference agreement requires the Secretary to make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary.”⁷⁵ The House Ways and Means Committee, when it reported out the MMA, said that this portion of the statute was enacted in response to an April 2003 report of the GAO that reported problems in the coverage process.⁷⁶ That GAO report quite explicitly criticized CMS for failing to explain how it makes coverage decisions: “the agency has not published the criteria that it uses in the national process to determine whether a service or item is reasonable and necessary, nor has it provided information that outlines the evidence needed to demonstrate that a procedure or device is clinically beneficial.”⁷⁷ CMS had told GAO that interested parties could infer the criteria that CMS was using from the documentation accompanying coverage decisions, but GAO concluded “having beneficiaries, physicians, and device manufacturers infer criteria that may apply to coverage policies from coverage memorandums does not substitute for specifying, and making public, clear criteria.”⁷⁸ Congress, having read this GAO report, told CMS to explain the factors it considers in making coverage determinations, and yet even after reading the 2006 guidance the public is still left to infer what those factors might be. This could not have been what Congress intended.

Third, CMS’s interpretation is implausible because HCFA had already made available similar information about the logistics of requesting a coverage determination and other information that was in the 2006 guidance.⁷⁹ If this was all that Congress was asking CMS to do in the MMA, then this provision would be less than useless--it would be generating just the sort of wasteful government work Congress perennially pledges to eliminate. Instead, Congress must have meant for CMS to describe the substantive standard it uses for making coverage determinations.

Even if CMS were not violating a direct congressional mandate to explain its coverage criteria, its behavior would still be legally problematic. When setting policy via individual adjudication, an agency’s rationale must be clear enough to survive judicial review. After a provider or beneficiary has exhausted an administrative appeals process, the appellant may seek judicial review of a coverage determination.⁸⁰ Courts are divided⁸¹ on whether to review coverage determinations under the “substantial evidence” test of the Social Security Act⁸² or the “arbitrary and capricious” test of the Administrative Procedure Act.⁸³ Regardless of which standard *525 is applied, courts could use their authority under either statute to strike down coverage determinations that do not adequately explain the criteria upon which the determinations are made.

Recently the Second Circuit did just that. In *Yale-New Haven Hospital v. Leavitt*,⁸⁴ the plaintiff hospital challenged CMS’s determination that treatment involving investigational cardiac devices should not be covered because the devices had not received premarket approval from FDA.⁸⁵ A 1986 coverage manual explained the exclusion to Medicare contractors: “Medical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and

are not reasonable and necessary for the diagnosis or treatment of illness or injury.”⁸⁶ The Second Circuit could not “clearly discern” why CMS had linked coverage to FDA approval, even though CMS said its “reasons for relying on the FDA are sufficient because they are implicit in the nature and scope of the FDA’s regulatory power.”⁸⁷ On the contrary, “‘reasonable and necessary’ is not obviously the same standard as ‘safe and effective’ [FDA’s standard for approving drugs and devices].”⁸⁸ “[T]he authority to determine which devices are reasonable and necessary (an inchoate and value-laden standard) is conferred by Congress upon Medicare ... not the FDA--an agency with a separate statutory purpose and agenda.”⁸⁹ The decision insists that CMS do a better job of explaining itself: “[I]t is hard to say ... that the rationale for the Secretary’s sole focus on FDA premarket approval, although unexpressed should be intuited and deemed obvious.”⁹⁰ The court was similarly disturbed that the agency had not explained why it adopted a per se rule that devices without premarket approval cannot be covered: “[W]hile an agency is obliged to neither answer all question nor to pose them, the 1986 Manual Provision constituted the type of policy choice that Medicare--while it likely has the authority to undertake-- must explain.”⁹¹ It remains to be seen whether this decision represents a warning shot to CMS that judges intend to demand more clarity from the agency across the board, or if this outcome was merely the result of the case’s particular circumstance.

Besides the confusion that not publishing coverage criteria generates and the legal requirements to publish criteria described above, policy reasons also weigh in favor of publication. First, publication of the coverage criteria would generate much-needed political debate over the wisdom of cost effectiveness analysis. Some amount of cost effectiveness analysis already occurs sub rosa in Medicare. Without public explanation of how CMS currently makes these determinations, it is impossible to describe how the process should be changed to incorporate explicit cost effectiveness analysis--or at least this discussion is severely hampered. Given perennial budget problems for Medicare and the increased burden that may be imposed on government-run insurers should the current health reform push in Congress succeed, CMS will be under increasing pressure to contain costs. But with unpublished coverage criteria and sub rosa cost analysis, CMS may be containing cost in inefficient or inequitable ways.⁹² Or CMS may be ignoring cost in areas that it ought to be considering it. President Obama has recently called for a “very *526 difficult democratic conversation” involving “doctors, scientists, [and] ethicists” to figure out how much end-of-life care America should pay for.⁹³ Such a conversation is not possible if America does not know how such coverage decisions are being made today.

Second, without formal criteria there is too much confusion about how decisions are made. In 1990, the Second Circuit, based on its reading of HCFA policies, concluded that the agency was permissibly using cost effectiveness analysis in its coverage determinations: “[W]e have no doubt that the Secretary may take into account not only *what kind* of services were provided, but also *where* those services were provided, i.e., whether those services were provided in the most appropriate, cost-effective setting.”⁹⁴ Given that CMS would later state that cost-effectiveness is not a consideration in coverage determinations⁹⁵--and this was apparently not a change in policy--the Second Circuit misunderstood what the existing criteria were. If a federal court of appeals cannot discern criteria from the agency’s preferred “case law” method, the undertaking is fatally flawed.

Third, current CMS practice, in the absence of published criteria, is to largely permit coverage for most treatments or devices that are safe and effective,⁹⁶ the standard FDA uses. Yet Congress must have intended CMS to do something different than what FDA does; otherwise Congress would have used the “safe and effective” language in the Medicare Act. Indeed, just three years before enacting

Medicare, Congress had used the “safe and effective” language to amend the Food, Drug and Cosmetics Act (FDCA) to require FDA to evaluate the effectiveness of drugs.⁹⁷ If the “reasonable and necessary” standard is intended to describe a different type of scrutiny than the “safe and effective” standard but does not include cost effectiveness analysis, it is a mystery what the criteria could be. CMS ought to end this confusion by publishing criteria.

Professor Fox writes that the implicit rationing may “when exposed, provoke a powerful reaction.”⁹⁸ Some might therefore argue that implicit rationing is a positive development and that it should remain implicit. If rationing were exposed, the political process might not permit it to continue. This explanation cannot be an acceptable defense of opacity in the coverage determination process. The Administrative Procedure Act reflects the well-established principle that when the government denies someone a benefit it must explain why it has done so.⁹⁹ The opacity in the current process may prevent interested parties from effectively negotiating with CMS. It may also be inequitable. Because it is unclear how CMS decides to deny ^{*527} coverage, the burden of this analysis may be falling disproportionately on those least able to compensate for the denials.

CMS’s own explanation of why it refuses to publish its coverage criteria is so thin, that one can only conclude that it is trying to shield from view its sub rosa cost effectiveness analysis. In response to the GAO’s 2003 call for Medicare to publish its coverage criteria, CMS wrote that it was publishing national coverage decisions on its website and this “practice yields a ‘case law’ type approach to helping stakeholders understand how CMS applies ‘reasonable and necessary’ in specific clinical instances. We are examining other options that may help stakeholders understand this topic, and our process, but have no plans to issue any specific document or guidance at this time.”¹⁰⁰

Political scientists David Epstein and Sharyn O’Halloran argue that Congress delegates to agencies when it decides that a difficult decision -- a decision that has no political upside -- needs to be made but Congress does not want to incur the political costs of making the decision itself.¹⁰¹ That is what has happened with coverage decisions in Medicare, except here the agency too has avoided making the decision despite Congress’s urging. Instead of delegation being a tool to make difficult decisions, delegation has become a tool to avoid them.

III. HOW TO PUBLISH COVERAGE CRITERIA AND BEGIN A DEBATE ON COST EFFECTIVENESS

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^{*530} IV. CONCLUSION

While health policy analysts have worried about both the absence of explicit coverage criteria in Medicare and the political resistance to adopting cost effectiveness analysis, administrative law scholars have largely ignored the Medicare coverage process as a subject for their consideration. As a consequence, the legally problematic elements of Medicare’s coverage strategy have been overlooked. This article has demonstrated the utility of applying administrative law analysis to health policy problems. It has identified these so-far overlooked legal problems and sketched ways the law itself can be used to address a persistent policy problem.

Footnotes

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