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Essential Health Benefits and the Affordable Care Act: Law and Process

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The Affordable Care Act (ACA) creates dozens of new programs that require some kind of implementation at the agency level (P.L. 111–148 [2010], 124 Stat. 119–1025). By and large, the regulations governing these new programs have been promulgated through relatively formal notice-and-comment procedures and subjected to review coordinated by the Office of Information and Regulatory Affairs (OIRA). But the federal agencies implementing the ACA have at times eschewed notice-and-comment rulemaking even where it might have seemed appropriate. They have instead announced a number of critically important policies through guidance documents—a broad category that encompasses bulletins, memoranda, and letters to state officials. These guidance documents are typically published not in Federal Register notices, but on agency websites.

This implementation strategy raises questions—perennials in administrative law—about the virtues and vices of substituting guidance for notice-and-comment rulemaking. Does the use of guidance reflect the zealous pursuit of good policy by government officials reluctant to get bogged down in ritualistic bureaucratic exercises? Or does it represent an effort to avoid the rough-and-tumble of public deliberation over the merits of particular rules?

We consider this question in the context of a case study. Beginning in 2014, the ACA will require private insurance plans sold in the individual and small-group markets to cover a roster of “essential health benefits.” Precisely which benefits should count as essential, however, was left to the discretion of the Department of Health and Human Services (HHS). The matter was delicate. An expansive bundle of mandatory services would assure comprehensive coverage, but would also raise the cost of insurance and could impede efforts to achieve near-universal coverage. Whatever HHS eventually decided, its choice would “influence the nature of coverage available to millions of people in the United States” (Institute of Medicine 2011b: 17).

In December 2011, HHS released its first official communication on essential health benefits: a 13-page bulletin posted on the agency’s website. The bulletin announced HHS’s intention of allowing each state to define essential benefits for itself by choosing a “benchmark” plan modeled on existing plans in the state. The benefits included in that benchmark plan (subject to some adjustments) would be considered essential within the state.

On both substance and procedure, the move was surprising. The benchmark approach departed from the uniform, federal standard that the ACA appears to anticipate and that many informed observers expected HHS to adopt. And announcing the policy through an internet bulletin came under immediate criticism because it allowed the agency to sidestep conventional administrative procedures—including notice and comment, immediate review in the courts, and OIRA oversight—notwithstanding the ACA’s command that HHS “provide notice and an opportunity for public comment” on the definition of essential health benefits (section 1302). By the time HHS issued a notice of proposed rulemaking (NPRM) on essential health benefits in November 2012, the deadline for states to submit their proposed benchmark plans to the agency was already two months in the past.

What are we to make of this? The story of essential health benefits offers insight into the merits of using guidance documents; it is also interesting in its own right, both because of the importance of the policy question and because of HHS’s unexpected decision. In this essay, we explore two questions. First, is the benchmark approach a lawful exercise of HHS’s authority under the ACA? Although HHS has brushed up against the limits of its discretionary authority, we conclude that the approach likely will (and, in our view, should) be upheld in the event of a challenge. Second, did HHS’s announcement of the benchmark approach through an internet bulletin allow the agency to sidestep the administrative procedures that are meant to shape the exercise of its discretion? The answer, we believe, is no. In fact, the agency’s unconventional process was *more* open to public scrutiny and external oversight than conventional rulemaking would have been.

Defining Essential Health Benefits

Starting in 2014, the ACA requires new health-insurance plans in the individual and small-group markets to cover a minimum set of services that the ACA terms “essential health benefits.”¹ This requirement applies to plans sold on state health-insurance exchanges and also to individual and small-group plans sold outside the exchanges. The statute (section 1302) enumerates ten different categories of services that essential health benefits must, at a minimum, include:

1. Ambulatory patient services.
2. Emergency services.
3. Hospitalization.
4. Maternity and newborn care.
5. Mental health and substance use disorder services, including behavioral health treatment.
6. Prescription drugs.
7. Rehabilitative and habilitative services and devices.
8. Laboratory services.

¹Large-group plans, such as those provided by large employers, are not required to provide essential health benefits, although they are subject to a different set of requirements governing the actuarial value of coverage.

9. Preventive and wellness services and chronic disease management.
10. Pediatric services, including oral and vision care.

Many of these inclusions are significant—for example, a more bare-bones approach might have excluded prescription drugs and pediatric dental care—but the list, by design, leaves much detail to be specified by subsequent regulation. For example, does the “habilitative services” category include behavioral treatment for autism, an expensive therapy with mixed evidence of effectiveness (Reichow 2012)? What do “preventive and wellness services” encompass beyond the ones that another provision of the ACA requires all plans to cover without cost-sharing (sections 1001, 2713)?

Sensitive to the need for greater detail, the ACA instructs the Secretary of HHS to flesh out the definition of essential health benefits. Specifically, the statute directs her to “ensure that the scope of the essential health benefits ... is equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary.” Congress also instructed the Secretary of Labor to survey insurance plans “to determine the benefits typically covered by employers” and report back to the Secretary of HHS. “In defining the essential health benefits,” the statute further provides, “the Secretary shall provide notice and an opportunity for public comment” (section 1302).

In the normal course of regulatory events, HHS might have been expected to launch an orderly rulemaking process not long after the ACA’s enactment. It is hard to say exactly what a reasonable timeframe for this might have been, but the ACA required states to demonstrate to HHS by January 2013 that they would have health insurance exchanges up and running within a year. To make such a demonstration, states would have to know well in advance about the scope of benefits that plans on the exchanges would have to cover. Working backward, a notice of proposed rulemaking would probably have had to issue by the end of 2011, followed by a final rule in mid-2012, to have any hope of giving states the certainty they needed to create their exchanges. That is not, however, what happened.

Shortly after the ACA’s enactment, HHS turned to the Institute of Medicine (IOM) for “advice on a process and considerations the Department needs to take into account in its initial establishment of [essential health benefits] and in updating them over time” (Institute of Medicine 2011a). In other words, HHS asked IOM not to define essential benefits, but to offer suggestions on how HHS might do so. The IOM report was expected to be complete in the fall of 2011. Enlisting help from IOM bought HHS time during which it might reasonably do nothing. Assuming the agency was prepared to issue a notice of proposed rulemaking soon after the release of the IOM report, the formal rulemaking process could proceed on a time frame that would allow for meaningful interaction with states and other interested parties—including insurers, health-care providers, and consumer-advocacy groups—before bumping into deadlines for health-insurance exchanges.

IOM tackled its assignment with dispatch, quickly convening an expert panel to write a report recommending methods for determining and updating essential benefits. It also invited members of the public to submit comments online, and held two public conferences, one in Washington, DC in January 2011 and another in Costa Mesa, California in March

2011. These conferences featured presentations by an impressive range of experts and stakeholders, and were summarized in a volume that IOM released to the public (Institute of Medicine 2011b).

Meanwhile, in April 2011, the Department of Labor (DOL) delivered its report on employer-sponsored coverage to HHS (Department of Labor 2011). Unfortunately, the DOL surveys on which the report was based relied on “summary plan descriptions” that employers provide to their workers—and those descriptions lack detailed information about the scope of coverage for specific services. The report therefore gave HHS little to guide its decision; it certainly provided no help on whether, say, a “typical” employer plan covered behavioral treatment for autism.

IOM went considerably further. On October 6, 2011, the expert panel released a 256-page report recommending a method for determining essential benefits (Institute of Medicine 2011a). Somewhat controversially, the report proposed a “premium target” approach in which a single national package of essential benefits would be tied to the cost of a typical benefits package in the small group market. That national package would then be updated over time to reflect innovation and public deliberation.

Following the release of the IOM report, the agency announced that it would hold a series of “listening sessions” over the subsequent months. These sessions—two-hour meetings at which members of the public could share their opinions with HHS officials—were conducted in each of ten HHS-defined regions. Sessions took place in Chicago, Boston, Philadelphia, Dallas, New York, Kansas City, Atlanta, Seattle, Denver, and, finally, on the Monday before Thanksgiving, San Francisco.

Three-and-a-half weeks later, reports began to circulate that HHS intended to release a “prerule” on essential health benefits, although the term “prerule” created confusion. “Not even the most seasoned Washingtonians seem to know what it means,” reported *Politico* (Feder and Millman 2011). Finally, on December 16, 2011, the prerule was posted on HHS’s website with the title “Essential Health Benefits Bulletin” (Center for Consumer Information and Insurance Oversight 2011).

Although the medium may have created some confusion, the bulletin’s message was both concise and surprising. Rather than specify a uniform national benefits package, the bulletin proposed to allow states to choose a “benchmark plan” to define essential health benefits. This approach was modeled on how states choose benefits under the State Children’s Health Insurance Program, also known as SCHIP (Kaiser Family Foundation 2007). A modified version of the same policy was introduced into Medicaid by the Deficit Reduction Act of 2005. Under the Medicaid version of the benchmark approach, states were allowed to offer a modified set of benefits, linked to a state-selected benchmark, to some groups of adult Medicaid enrollees (Kaiser Family Foundation 2010).

Adapting the benchmark approach for essential health benefits, the bulletin proposed allowing each state to choose a “benchmark plan” from a menu of options, including the three largest insurance plans in the state’s small-group market and the three largest plans available to state employees. The default benchmark, for states that failed to select one,

would be the largest small-group plan in the state. Subject to adjustments to assure their conformity with the ACA's list of coverage requirements, these benchmark plans would define essential benefits within the states. At just thirteen pages long, the bulletin provided few details. Additional information, the bulletin suggested, would be forthcoming in the full-dress rulemaking proceeding.

Responses to the Bulletin

The benchmark approach was front-page news, described by the *New York Times* as a “major surprise” (Pear 2011). As we explain in greater detail below, the ACA was drafted on the assumption that HHS would choose a single, national definition of essential health benefits. The Congressional Budget Office, for one important example, had scored it on that assumption (Congressional Budget Office 2012: 8). Most expert observers had never seriously considered a state-specific benchmark and the IOM report nowhere raised it as a possibility.²

Why did HHS take such an unanticipated approach to essential health benefits? Politics certainly played a role. The benchmark approach gave states flexibility at a time when many were complaining about the lack of it. In addition—and although we lack the space here to thoroughly examine the question—smart politics may have made for smart policy. Because most health insurance plans “do not differ significantly in the range of services they cover” and “generally cover health care services in virtually all of the 10 statutory categories,” no state could select a threadbare benchmark plan that would thwart the ACA's effort to guarantee the availability of comprehensive coverage (Center for Consumer Information and Insurance Oversight 2011: 4). And tying local benefits to local market conditions would probably result in less distortion (i.e. greater efficiency) than if benefits were required to be uniform.

The benchmark approach does create winners and losers. Because of the way premium subsidies and tax-sharing credits are calculated, recipients of subsidized coverage in states with generous benefits will receive modestly more federal support than those in less generous states. But many policies give rise to that kind of differential treatment; variation across states is simply a feature of our federal system. Even John Ball, the chair of the IOM panel that recommended tying essential health benefits to a premium target, offered only gentle criticism of the benchmark approach. “Given where the department is coming from, giving flexibility to the states is a good thing,” he told *Politico*. “But I do think they missed an opportunity to take a crack at getting costs under control” (Millman 2011b).

Leading Republicans reacted much more harshly, not to the substance of the policy but to the manner in which it was announced. In a letter to HHS, five influential Republican senators and congressmen offered the following objections:

By issuing a “bulletin” rather than a proposed rule, the administration has sidestepped the requirement to publish a cost-benefit analysis estimating the impact

²The IOM did, however, explore the possibility of allowing states to deviate on a piecemeal basis from the national definition of essential benefits (Institute of Medicine 2011a: 129).

these mandates will have on health insurance premiums and the increased costs to the federal government... [T]he administration is not required to respond to comments received regarding this “bulletin.” Publishing a “bulletin” rather than a proposed rule is the antithesis of an “open and transparent” process....

The bulletin also does not have the force of law and cannot, therefore, be considered an indication of what the proposed or final rule will decree. Thus, states still have many unanswered questions and no more certainty than they had before the “bulletin” was released.... It is unreasonable to expect states to be ready to implement such draconian changes by 2014, if the Administration is not even ready to issue a proposed rule on such an integral part of the functioning of the law (Enzi et al. 2012).

These concerns notwithstanding, the bulletin prompted many states to launch their own administrative processes for selecting benchmark plans. And that was the point: “By releasing the bulletin now,” the Secretary of HHS explained, “we’re giving families, employers and states plenty of time to take this information into account as they plan for the big improvements the health care law will make to the insurance market in 2014” (Sebelius 2011). With just over a year to go before the January 2013 deadline for demonstrating readiness to run an exchange, and other reform-related tasks to complete at the same time, any state interested in running its own exchange could not really afford to wait.

To be sure, some states declined to participate in this process. State officials cited the lack of guidance from HHS on essential health benefits and other exchange-related issues as one of their ostensible reasons. In September 2012, Michael Consedine, the Insurance Commissioner for the state of Pennsylvania, stated in testimony before the Health Subcommittee of the House Ways and Means Committee that “[t]he lack of detailed information from HHS has put Pennsylvania, and many other states, in a very difficult position. We are traveling down a road, directionless, while knowing the road will end very soon—January 2014 is right around the bend.” Robert Bentley, the Republican Governor of Alabama, was even more pointed in a letter sent a month later to the Secretary of HHS:

Your office released essential health benefits guidance on December 16, 2011, with the promise of more to come. It has yet to arrive. It has become clear to me that the states have been left to decide the fate of their insurance marketplaces with no additional guidance or regulations on essential health benefits. This places governors and other leaders in the untenable position of making a critical decision based on little more than vague guidance and guesswork.... I decline to make a decision on the essential health benefits benchmark plan. There is simply not enough valid information available now to make an informed choice for such an important decision.

Ultimately, 27 states held a public comment period on the subject of the benchmark plan as part of the selection process, and 24 states submitted their proposed benchmark plans to HHS by the October 1, 2012 deadline (Avalere Health 2012; Schwartz 2012). Alabama and Pennsylvania were not among them.

On November 26, 2012—twenty days after the re-election of President Obama and almost a year after the release of the bulletin—HHS published in the Federal Register a notice of proposed rulemaking on essential health benefits. The NPRM formally proposed the benchmark approach that the bulletin had previewed. In its discussion of regulatory alternatives, the NPRM said that,

[a]t the request of some commenters, HHS considered one national definition of [essential health benefits] that would have applicable issuers offer a uniform list of benefits. However, this approach would not allow for state flexibility and issuer innovation in benefit design, would require a burdensome overhaul for issuers, and would disrupt the market” (NPRM 2012: 70,665).

These two sentences represent the entirety of the NPRM’s discussion of the policy wisdom of the benchmark approach. The final rule, issued on February 25, 2013, deviated little, if at all, from the NPRM. On the possibility of a single national definition of essential health benefits, the final rule repeated the two sentences from the NPRM that are quoted above, without further elaboration. (Final Rule 2013: 12,861).

Legality of the Benchmark Approach

Because the ACA does not explicitly contemplate a state-based benchmark approach to essential health benefits, the question arises whether the approach is consistent with statute. In other words, has the Secretary exceeded the bounds of her discretionary authority? Notwithstanding its considerable importance, the question has received scant public attention.

HHS has not yet offered a legal defense of the benchmark approach, but its argument will probably run something like this: Where agencies interpret open-ended phrases through notice-and-comment rulemaking, courts typically give agencies a lot of leeway. This practice is known as “*Chevron* deference” after the landmark case establishing it (*Chevron U.S.A. v. Natural Res. Def. Council*, 467 U.S. 837 [1984]). Here, Congress delegated to the Secretary of HHS broad authority to flesh out the meaning of “essential health benefits.” Under *Chevron*, the Secretary’s interpretation of the statutory phrase will be upheld so long as that interpretation offers a reasonable construction of the ACA. Nothing in the statute precludes the Secretary either from linking those benefits to state health plans or from giving the states the flexibility to select benchmark plans. Given congressional silence on those points, the Secretary’s exercise of her authority is fully consistent with the ACA.

This argument is a powerful one. There are, however, two ways in which the benchmark approach is arguably difficult to square with the text of the ACA. The first is obvious. In a statute that attends carefully to the division of regulatory labor between the federal government and the states, the ACA repeatedly confirms that “*the Secretary shall define the essential health benefits*” (section 1302). This is not casual language: in three separate places in the same statutory section, the Act contemplates that the Secretary would be the one “defining” and then “revising” what counts as essential health benefits. The ACA even instructs the Secretary to “ensure that the scope of essential health benefits ... is equal to the scope of benefits provided under a typical employer plan, *as determined by the Secretary.*”

The phrase “as determined by the Secretary” would do no work unless it was the Secretary—not the states—doing the determining.

This objection, however, is not terribly persuasive. Although a federal agency cannot delegate its powers to the states, it “may turn to an outside entity for advice and policy recommendations, provided the agency makes the final decisions itself” (*U.S. Telecom Ass’n v. F.C.C.*, 359 F.3d 554 [D.C. Cir. 2004]). Here, the Secretary gave the states a constrained set of options (e.g., choose a benchmark plan from among the three largest small-group plans in the state) and retained the authority to select a benchmark for any state that either does not pick a benchmark or chooses an inappropriate one (NPRM 2012: 70,667). As such, the Secretary remains firmly in control. Nothing in the ACA prevents her from deferring to states that select benchmark plans from among the few options she has provided. That choice to defer is itself an exercise of her delegated powers.

The second potential objection to the benchmark approach is both less obvious and more substantial. Notwithstanding the Secretary’s wide discretion to define essential health benefits, there are limits to the deference that courts afford to agencies that interpret open-ended statutory language. As the D.C. Circuit has explained, the notion that an agency interpretation is permissible just because the statute in question “does not expressly negate the existence of a claimed administrative power (i.e. when the statute is not written in ‘thou shalt not’ terms), is both flatly unfaithful to the principles of administrative law ... and refuted by precedent” (*Ry. Labor Executives’ Ass’n v. Nat’l Mediation Bd.*, 29 F.3d 655 [D.C. Cir. 1994]). “[T]he question,” the Supreme Court has recently emphasized, “is always whether the agency has gone beyond what Congress has permitted it to do.” (*City of Arlington v. FCC*, 133 S.Ct. 1863 [2013]). In other words, agencies may fill in statutory gaps—but only up to a point. Where an agency’s interpretation of an open-ended provision clashes with the statutory scheme as a whole, the courts will not presume that Congress meant to authorize the agency to so interpret the statute (*Brown v. Gardner*, 513 U.S. 115 [1994]).

As we have discussed, the ACA was enacted on the assumption that HHS would establish a nationally uniform slate of essential health benefits. Under the benchmark approach, however, there will now be dozens of state-specific sets of essential health benefits. Many provisions of the ACA are inscrutable, extraneous, or impossible to implement in the face of that kind of variation. Consider again, for example, the requirement that essential health benefits must be “equivalent to the scope of benefits provided under a typical employer plan” (section 1302). How can a variable roster of state-specific essential health benefits be equivalent to the scope of benefits provided under “a” (which is to say, one) employer plan?

Nowhere is the problem more apparent than in provisions governing state coverage mandates. Some states require insurers to cover specific benefits—for example, applied behavior analysis for autism or in vitro fertilization services—that Congress anticipated might exceed what the Secretary would deem essential. Congress, however, did not want to devote the tax credits and cost-sharing payments available on the exchanges to the coverage of these state-mandated benefits. The ACA therefore limits federal subsidies to defraying the costs of essential health benefits (section 1401). States must pick up the rest of the tab to

assure that exchange plans that include extra state-mandated benefits remain affordable (section 1311).

Under the benchmark approach, however, this cost-sharing arrangement becomes irrelevant. A state's benchmark plan will inevitably cover the treatments or services that the state has mandated. As such, a state's essential health benefits will by definition include all of the benefits for which the state mandates coverage. State coverage mandates can therefore never exceed essential health benefits, and states with extensive coverage mandates will never assume the additional costs that the ACA anticipates they will assume. Did Congress really intend its cost-sharing provisions to do no work at all?

The benchmark approach also raises questions about certain specialized insurance plans that will be sold on the exchanges. For the most significant example, the ACA instructs the Office of Personnel Management (OPM) to enter into contracts with health insurers to sell at least two "multi-state plans" on each state exchange. Those insurers must "offe[r] a benefits package that is uniform in each State and consists of the essential [health] benefits" (section 10104). Where essential health benefits vary from state to state, however, a multi-state plan cannot both be uniform and cover only the essential health benefits.

In proposing regulations for multi-state plans, OPM recognized this problem. Its solution was to read the "uniform in each State" language to require that "the benefits for each [multi-state plan] must be uniform within a State, but not necessarily uniform among States" (NPRM 2012: 72,589). The bare language of the uniformity provision is perhaps amenable to this interpretation. Other statutory clues, however, suggest that Congress meant uniformity among states. Congress specified, for example, that a state can require a multi-state plan to cover state-mandated benefits, but only if the state picks up the increased expense (section 10104). There would have been no need for Congress to bless that limited inroad on uniformity *among* the states if the ACA only required uniformity *within* each state.

In short, the benchmark approach to essential health benefits fits poorly with a number of provisions of the ACA. That poor fit raises the prospect of a legal challenge: perhaps it suggests that HHS exceeded its delegated powers in adopting the benchmark approach. In this, the claim is reminiscent of *FDA v. Brown & Williamson Tobacco Corp.* (529 U.S. 120 [2000]), where the Supreme Court rejected FDA's effort to assert jurisdiction over tobacco. If FDA could regulate tobacco products, the Court reasoned, the agency's statutory mandate to assure that such products were "safe" would require FDA to ban cigarettes outright. The Court thought it unimaginable that Congress meant to arm FDA with that sweeping power. The agency countered by arguing that it could continue to allow cigarettes to be sold because banning them would cause a shift to dangerous black-market cigarettes, harming overall public health. The Court rejected this public-health interpretation as "incompatible" with several other provisions of the statute that asked the agency to weigh the therapeutic benefits and potential harms of individual products—not to address general questions of public health. The benchmark approach is subject to similar criticism for its incompatibility with provisions of the ACA that anticipate a single, uniform standard for essential health benefits.

In the final estimation, however, demonstrating the unlawfulness of HHS's approach requires more than a showing that its interpretation aligns awkwardly with scattered provisions of the ACA. The question remains whether the fit is so poor that it justifies the inference that Congress could not have meant to allow HHS to interpret the ACA in the manner that it did (*California Indep. Sys. Operator Corp. v. F.E.R.C.*, 372 F.3d 395 [D.C. Cir. 2004]). We think not, although the question is close. Unlike *Brown & Williamson*, this is not a case where HHS has exploited statutory ambiguity in an effort to intrude into regulatory domains that Congress never intended it to enter (*American Bar Ass'n v. F.T.C.*, 430 F.3d 457 [D.C. Cir. 2005]). The agency has just chosen to involve the states in defining a statutory term that Congress gave it wide latitude to define. Congress may not have contemplated that HHS would adopt a benchmark approach, but so what? Agencies routinely discharge their statutory obligations in ways that Congress never anticipated, particularly in complex and fast-changing regulatory environments.

While HHS's interpretation does fit uneasily with several provisions of the ACA, the agency could always shift course, and provisions that do no work today may be crucial tomorrow. More importantly, the interpretation of a complex statute is a messy business. Some statutory provisions will inevitably prove to be less significant than they would have been under alternative readings. An agency's choice is not usually deficient for that reason alone (*Babbitt v. Sweet Home Chapter, Communities for Great Ore.*, 515 U.S. 687 [1995]). Something more than the statutory tension that the Secretary's interpretation creates—something closer to the incompatibility found in *Brown & Williamson*—would be necessary to conclude that Congress meant to preclude HHS from establishing essential health benefits with reference to state benchmarks.

Process-Based Concerns

Setting aside the legality of the benchmark approach, the fact remains that HHS used a guidance document—a 13-page bulletin posted on its website—to announce its new policy. As is typically the case with such a policy statement, the bulletin nowhere committed the agency to the approach that it outlined. As a formal legal matter, it had no more significance than an advance notice of proposed rulemaking or a press release.

Why, then, was HHS's "atypical approach" so "widely criticized" (Cassidy 2011)? Given the looming deadlines for the exchanges, states and insurers understood that the benchmark approach outlined in the bulletin was not just one possibility among many. It was almost certainly the rule. HHS not only said as much when, in a call with reporters on the day the bulletin issued, agency officials categorically rejected any suggestion that they might change their mind and bluntly said that "[t]his is our intended regulatory approach" (Glied 2011). More significantly, the agency began the traditional rulemaking process required under the Administrative Procedure Act (APA) *after* the states' deadline for selecting benchmark plans had passed and *after* insurers started developing new insurance products for the exchanges. Given the massive technical challenges of launching the exchanges and the political imperative of avoiding a train wreck, it was almost inconceivable that the agency would court disruption in the midst of implementation by revisiting the benchmark approach.

The federal courts have a practice of asking whether policy statements, although they nominally lack the force of law, are nonetheless binding as a practical matter (*Community Nutrition Inst. v. Young*, 818 F.2d 943 [D.C. Cir. 1987]). Where policy statements have such binding effect, they can be deemed “legislative rules” and, if challenged, invalidated for failure to go through notice-and-comment rulemaking. Although the line separating policy statements from legislative rules is not crisp (Gersen 2007: 1712), two factors are especially important in suggesting that the line has been crossed: first, when the policy statement has “present effect” by imposing “obligations” on the regulated community; and second, when the policy statement does not “genuinely” afford the agency the opportunity to change its mind (*American Bus Assoc. v. United States*, 627 F.2d 525 [D.C. Cir.1980]). Judged by this standard, the bulletin arguably became a legislative rule once states, insurers, and employers realized that they had no choice but to conform to it and HHS had no time left to rethink it.

The bulletin, however, did not go through the formal rulemaking process. From this perspective, HHS’s procedural approach—a bulletin, followed by a long wait and then a hurried notice-and-comment session—seems to confirm the fears of those who worry that agencies will use guidance to avoid administrative procedures and, at low cost and with relative ease, dictate to regulated entities how they must order their affairs (Anthony 1992).

But what, exactly, did the use of guidance allow HHS to avoid? We consider three procedural requirements that would have applied in a conventional rulemaking setting, but to which the bulletin, as a guidance document, was not subject: notice and comment, immediate judicial review, and OIRA review. What is most notable about HHS’s unorthodox process, however, is not that the agency avoided these procedures. It is that the agency voluntarily subjected itself to most of the obligations that adherence to the procedures would have entailed.

Notice and comment

The APA’s notice-and-comment process is meant to allow for public feedback on proposed rules, to supply agencies with information that can aid them in revising those rules, and to publicly legitimate the rules they finally adopt (Breyer et al. 2002: 658). Notice and comment, however, can serve those purposes only if agencies are open to revisiting their proposed rules when they receive feedback. In the case of essential benefits, HHS committed itself to the benchmark approach long before issuing its notice of proposed rulemaking. That transformed the comment period—at least with respect to the high-level policy choice of whether to adopt the state-based benchmark approach—into an empty formality. HHS’s curt dismissal in the final rule of comments suggesting a single, nationwide standard may have signaled its unwillingness at that late stage even to entertain the possibility.

Still, it does not appear that HHS used the bulletin to avoid public feedback on the benchmark approach. Well before issuing the bulletin, HHS held a number of well-attended “listening sessions” where it sought views from states, insurers, providers, and consumer representatives. Additionally, starting in April 2010, HHS held weekly calls with state officials about implementation of the ACA, calls that informed its thinking about essential health benefits (NPRM 2012: 70,667). Around the same time, HHS also made it known to

outside groups that it was toying with the idea of delegating authority to the states to establish their own essential health benefits. That provoked a consortium of about six dozen public-interest groups, led by the National Health Law Program (NHeLP), to submit a lengthy letter to HHS—four months before the bulletin was issued—objecting preemptively to any sort of state-based approach (NHeLP 2011). These public discussions and the responses they engendered came on top of both the conferences that IOM had organized and the notice-and-comment processes that 27 states used to select their benchmark plans.

The agency had no obligation to do any of this public outreach. Without informing anyone of its thinking, HHS could simply have issued a notice of proposed rulemaking announcing the benchmark approach. After receiving comments and issuing a final rule, HHS would then have complied with all of the APA's notice-and-comment requirements. Paradoxically, however, formal compliance might have undermined HHS's effort to seek and receive meaningful public input on its proposed approach. Because courts insist that agencies provide a fulsome explanation of the basis for their proposed rules, HHS would have had to elaborate its benchmark approach in a lengthy notice of considerable specificity (Elliott 1992: 1494). HHS could then have discarded that approach only if it went through the laborious process of issuing a new notice of proposed rulemaking (*Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250 [D.C. Cir. 2005]). But with statutory deadlines looming, the agency could have ill-afforded the delay associated with restarting the notice-and-comment process.

Instead, HHS used the bulletin to secure public input during the brief window where it could have reconsidered the benchmark approach. Although agencies do not have to solicit feedback on guidance documents, the bulletin's very first sentence explicitly invited comments from the public. In response, the agency received more than 11,000 comments (NPRM 2012: 70,646). HHS did not respond publicly to those comments, as the APA would have required in connection with a rulemaking. But HHS surely understood that the comments it received would preview the concerns voiced during the official notice-and-comment process—and that it would have to address those comments in issuing a final rule. Nor does it seem that the absence of a requirement to publish comments received in response to the bulletin silenced any criticism. Just as the internet allowed HHS to make the bulletin immediately available to the public, the internet allowed commenters to publicize their concerns. A number of advocacy groups and state governments—like NHeLP and the officials in Alabama and Pennsylvania—did just that.

Posting the bulletin was an ingenious way to invite public comment without irrevocably committing the agency to the benchmark approach. The bulletin served as a trial balloon—an effort to see if the approach would provoke the sort of outcry or incisive criticism that called for a change in thinking. If there was cause for serious concern, the informality of the pre-notice process—in contrast to the rigidity of notice-and-comment rulemaking—would have afforded the agency an opportunity to quickly shift course. When reports surfaced just a week after the bulletin issued that “there was no backlash” to speak of, HHS learned something valuable about the acceptability of its chosen approach (Millman 2011a).

From the perspective of meaningfully involving the public in agency decision-making, then, the bulletin-followed-by-rulemaking approach was superior to a routine process of APA notice-and-comment rulemaking. Significantly, it cleared a route for the agency to receive public comment at the critical pre-notice phase of agency rulemaking. Commentators regularly lament that well-organized groups with concentrated interests have better access than diffuse public-interest groups to this pre-notice process where most important choices are made (Elliott 1992: 1492). The bulletin addressed this imbalance by telling everyone that the agency was open to hearing from them.

Judicial review

By using a guidance document to announce the benchmark approach, HHS also arguably circumvented judicial review. Per §702 of the APA, final rules issued through notice-and-comment rulemaking can usually be challenged in court by those whose conduct the rule affects. In contrast, challenging guidance is much more difficult. Courts often conclude either that guidance is not final agency action or that it is not ripe for review (Mendelson 2007: 411). Perhaps the perceived difficulty with challenging guidance—and the expectation that the agency would soon resort to rulemaking, mooted any challenge that might be brought to the guidance—explains why no one tried to invalidate the bulletin.

One purpose of judicial review is to assure that agencies do not force regulated interests to comply with rules that agencies lack the authority to issue (*Abbott Laboratories v. Gardner*, 387 U.S. 136 [1967]). It is therefore arguably worrisome that states, employers, and insurers did not have an opportunity to challenge HHS's benchmark approach before making costly efforts to conform to that approach. Had HHS issued a proposed rule instead of the bulletin, the agency could have finalized the rule sometime in 2012 or early 2013. A more-regular process would therefore have given affected interests an opportunity to challenge the final rule before the requirement to cover essential health benefits sprang into force in January 2014.

There's something to this—but not much. The benchmark approach embodied in the bulletin will not evade pre-enforcement review altogether. At most, HHS's decision to outline its approach in a bulletin allowed the agency to delay the date on which it issued a final rule. Now that the final rule has issued, *someone* will probably bring a pre-enforcement challenge. Perhaps the plaintiff will be the mother of an autistic child who can find no insurance plan in her state that covers needed services, but who believes that, had the agency gone through the process of establishing a uniform federal standard, HHS might have included such services in the package of essential health benefits. Or perhaps it will be a California insurance company complaining that it must cover acupuncture services. The important point is that HHS knew when it issued the bulletin that any final rule adopting the benchmark approach would eventually be challenged. The agency's choice was therefore disciplined by the near-certainty that the courts would one day scrutinize that choice. HHS's reliance on the bulletin just delayed when judicial review would occur.

Nor is it especially worrisome that some states and insurers had to take immediate steps to comply with the approach that HHS outlined in the bulletin. Even in the absence of final agency action, parties often structure their affairs in anticipation of governmental action.

Earlier review might have avoided some sunk costs: if the benchmark approach is invalidated, the efforts of states to select benchmark plans and of insurers to fashion new insurance products will have been wasted. Yet states and insurer could always have challenged the bulletin on the ground that it was a legally binding legislative rule. More significantly, there is no guarantee that HHS would have finalized its rule any more promptly had it issued a notice of proposed rulemaking instead of a bulletin. The agency might still have waited until the eleventh hour, devoting scarce resources to other pressing problems associated with implementation of the ACA. Against this backdrop, the notion that HHS used the bulletin to avoid judicial scrutiny is something of a stretch.

OIRA review

Pursuant to Executive Order 12866, most important agency regulations are subject to OIRA review. Guidance documents are not. Late in his administration, President George W. Bush did issue an order subjecting guidance documents to OIRA review because they might otherwise “not receive the benefit of careful consideration accorded under the procedures for regulatory development and review.” (OMB 2007: 3432). President Obama, however, rescinded that order shortly after taking office (Obama 2009). Although a memorandum from his budget director clarified that significant guidance documents remain subject to review (Orszag 2009), review of guidance is in practice unsystematic and spotty (Nou 2013).

Perhaps, then, HHS used a guidance document to sidestep the centralized oversight that is supposed to enhance the rationality and democratic legitimacy of agency decision-making. In particular, because OIRA enforces the requirement that agencies undertake a rigorous, transparent regulatory impact analysis prior to taking significant actions, resorting to guidance allowed the agency to delay for more than a year any public effort to assess the costs and benefits of the benchmark approach.

But did the delay of the regulatory impact analysis matter in practice? Some scholars have questioned whether such analysis has much effect at all on regulation (Hahn & Tetlock 2008). In the case of essential benefits, the delay in releasing the analysis may have been particularly inconsequential. Neither the analysis accompanying the NPRM in November 2012 nor the one accompanying the final rule in February 2013 even bothered to estimate how costs and benefits might have differed if HHS chosen a national, uniform definition of essential health benefits. Had they done so, it would probably not have made much of a difference to the estimated impacts. Because the scope of benefits under employer plans varies little across states, giving states the authority to select benchmark plans does not greatly affect the scope of the obligation to cover essential health benefits. The delay in providing a regulatory impact analysis, then, seems of little consequence.

More generally, considerable evidence suggests that HHS did not “go rogue” and use guidance to evade presidential oversight. For one thing, HHS did share its bulletin with the White House. OIRA’s website reports that it received the bulletin from HHS on December 14, 2011 and cleared it (with some revisions) two days later—the same day that HHS released it (OIRA 2011). Sources inside the administration have confirmed that White House involvement ran much deeper. Administration officials were consulted about the

benchmark approach as early as the summer of 2011, more than five months before the bulletin was issued. This close involvement is unsurprising. Deciding what counts as essential health benefits is perhaps the single most consequential policy choice that HHS will make in connection with the implementation of President Obama's signal legislative achievement. As a matter of practical politics, HHS had no choice but to vet the bulletin at the very highest levels.

Discussion

At first blush, HHS's release of a terse bulletin to announce a major regulatory decision looks unusual, even improper. It seems to reinforce the concern that agencies routinely use guidance documents to establish binding rules while evading the procedural obstacles that might otherwise deter them from acting (House Committee on Government Reform 2000). And it appears to confirm the wisdom of the academic consensus that guidance documents should be tolerated only grudgingly. Banning all guidance would be imprudent—better that regulated entities have some inkling of how agencies will carry out their duties than that they have none—but too much guidance risks undermining the procedural regularity of the administrative state (Mendelson 2007: 413; Raso 2010: 787).

This consensus, however, rests on an unflattering view of administrative motivation. On this view, agencies are staffed not by public officials anxious to assure that their choices are workable and publicly legitimate, but instead by bureaucrats trying to avoid procedural obstacles that stand in the way of doing what they think best. Guidance is tempting precisely because it allows those bureaucrats to avoid the sort of public input, judicial review, and executive oversight that, by fostering accountability to a broader public, could impede their efforts. To put it in terms more familiar to political scientists: to the extent that administrative procedures allow political principals to better control their agents (McCubbins et al. 1987), agencies will use guidance to evade those procedures and exploit the slack between them and their principals.

Doubtless this accurately describes some agencies some of the time. But what then should we make of the fact that HHS voluntarily replicated the very procedures that guidance is supposed to let it avoid? The agency may not have been driven only by a desire to secure public input on the benchmark approach—other motivations surely shaped the unusual regulatory process—but it is hard to conclude that the turn to guidance was a ploy to avoid accountability. What is more, HHS is hardly alone in adopting more administrative procedures than strictly necessary. Croley documents a series of important rulemakings from the late 1990s and early 2000s, including EPA's imposition of stringent controls on ozone and particulate matter, FDA's attempt to regulate tobacco products, and the Forest Service's efforts to curtail road building in national forests. Although not a representative sampling, Croley's examples "would all unquestionably make a short list of some of the most significant regulatory activity in more than a decade" (Croley 2006: 160). And in every case, the agency "provided more notice, data, and opportunities for participation than the APA (or any other legal authority) demanded" (Croley 2006: 160). Mendelson similarly identifies a number of agencies that make a habit of soliciting public input on guidance documents in the absence of legal compulsion to do so (Mendelson 2007: 425).

In other words, there is nothing especially unusual about what HHS has done here. Far from ducking procedural obligations wherever possible, agencies sometimes embrace them. Why? At least for salient policy questions of substantial importance—a small but critical slice of agency action—agencies have a number of incentives having little or nothing to do with formal legal requirements to secure public input and assure political oversight. Doing so provides the agencies with technical information that might otherwise be difficult to obtain about how to craft policies that are capable of implementation. It arms them with scientific data that can help them better calibrate their rules. It teaches them about the political acceptability—and hence long-term sustainability—of the regulatory initiative. It identifies wellsprings of potential political support (and opposition) for the rulemaking. It lends legitimacy to the regulatory initiative by assuring that all interested parties have had the opportunity to be heard both at the agency and in the courts. And it eases the concerns of those concerned that the agency is regulating by fiat. In sum, procedures can improve the workability and legitimacy of agency rules while protecting them from judicial or political attack (Croley 2006: 259).

Conclusion

What if anything does this essential health benefits case study teach us about the future process of ACA implementation? We close with three observations.

First, the intensely politicized nature of health reform will color anything and everything connected to implementing health-care reform. The essential health benefits rule, for example, was issued against a backdrop of fierce partisan tension. The Supreme Court had agreed just a month before HHS posted the bulletin that it would consider a constitutional challenge to the so-called “individual mandate”—a challenge that, if successful, could have brought down the rest of the law with it. At the same time, governors and other state officials hostile to health reform were bristling at what many perceived as heavy-handed federal implementation efforts. Although we have chosen not to dwell on this political conflict, it would be naïve to suggest that politics played no role in HHS’s decision-making. It would be equally naïve to think it will play no role going forward.

Second, ACA implementation will continue to depend on guidance. Part of the reason is the sheer volume of regulation that implementing the ACA requires. HHS, the Treasury Department, the Labor Department, and the other implementing agencies face daunting challenges rolling out the various programs that the ACA establishes. It is unrealistic to expect that each regulation will chart a clean course through the APA rulemaking process. As important, the digital revolution may itself encourage a turn to guidance. Long gone are the days when proposed rules were only put “on display” at the Office of the Federal Register—when there was a single point of official interaction between the regulators and the regulated. Agencies can now communicate directly with the public in ways that the formal regulatory process never envisioned. A vast literature considers how technology is transforming the relationship between government and its citizens (Mendelson 2011). Using the internet to publicize guidance is an excellent example of this phenomenon.

Third, the case study illuminates the larger debate about agency guidance. If agencies sometimes have powerful incentives to adhere voluntarily to administrative procedures, the distrust of guidance that runs like a leitmotif through much of the literature on administrative law seems misplaced. This is not to deny that agencies use guidance to avoid the costs of adhering to burdensome procedural requirements. Of course they do. That's why issuing guidance is attractive to begin with. But do agencies systematically use guidance to avoid scrutiny from the public, the courts, and the President? The story of essential health benefits suggests that such evasion is far from inevitable. Nor does the available empirical evidence—slim as it is—lend support to the story. A recent review of significant guidance documents issued by five agencies over the span of a decade finds no indication that agencies routinely use guidance to shirk public accountability (Raso 2010). Perhaps, then, administrative lawyers should temper the reflexive assumption that agencies turn to guidance to avoid answering for their actions. It may be worth exploring the possibility that agencies are often sincere about what they use guidance for: to give regulated entities insight into their thinking, to shape how line officials carry out their duties, and even—as with essential health benefits—to spur a public debate about the wisdom of a regulatory approach.

References

- Anthony, Robert A. Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like--Should Federal Agencies Use Them to Bind the Public. *Duke Law Journal*. 1992; 41(6):1311–1384.
- Avalere Health. EHB Implementation Progress. 2012. State Reform Insights, <http://www.avalerehealth.net/news/spotlight/index.php?year=2012> Updated October 4, 2012.
- Bentley, Robert. Governor of Alabama. 2012. Letter to Kathleen Sebelius, Secretary, Department of Health and Human Services. Oct 1. <http://governor.alabama.gov/>
- Breyer, Stephen G., et al. *Administrative Law and Regulatory Policy*, Fifth Edition. New York, N.Y: Aspen Publishers; 2002.
- Cassidy, Amanda. Health Policy Brief: Essential Health Benefits. *Health Affairs* (website). 2011 Apr 25. www.healthaffairs.org
- Center for Consumer Information and Insurance Oversight (CCIIO), Department of Health and Human Services. Essential Health Benefits Bulletin. 1–13. Washington, DC: CCIIO; 2011. http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf
- Congressional Budget Office (CBO). Updated Estimates for the Insurance Coverage Provisions of the Affordable Care Act. 1–12. Washington, DC: CBO; 2012. <http://www.cbo.gov/sites/default/files/cbofiles/attachments/03-13-Coverage%20Estimates.pdf>
- Croley, Steven P. *Regulation and Public Interests: The Possibility of Good Regulatory Government*. Princeton, N.J: Princeton University Press; 2008.
- Department of Labor. Selected Medical Benefits: a Report from the Department of Labor to the Department of Health and Human Services. 1–62. Washington, DC: Department of Labor; 2011 Apr 15. <http://www.bls.gov/ncs/ebs/sp/selmedbensreport.pdf>
- Elliott, E Donald. Re-Inventing Rulemaking. *Duke Law Journal*. 1992; 41(6):1490–1496.
- Enzi, Michael B., et al. U.S. Senators and Representatives. Letter to Kathleen Sebelius, Secretary, Health and Human Services. 2012 Jan 13. http://edworkforce.house.gov/uploadedfiles/1-13-12_letter_to_sebelius.pdf
- Gersen, Jacob. Legislative Rules Revisited. *University of Chicago Law Review*. 2007; 41:1705.
- Glied, Sherry. Conference Call Briefing. *Federal News Service*. 2011 Dec.16 PP-PP.
- Feder, JLester; Jason, Millman. Guidance By Any Other Name. *Politico Pro* (blog). 2011 Dec.15 www.politicopro.com.

- Final Rule. Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. 78 Fed. Reg. 12,834. 2013
- H. Comm. on Government Reform. Non-Binding Legal Effect of Agency Guidance Documents. 2000 H.R. Rep. 106-1009.
- Implementation of Health Ins. Exchanges & Related Provisions: Hearing Before the Subcomm. on Health of the H. Committee on Ways and Means. 112th Cong. 2d Sess. 9 (statement of Michael Considine, Commissioner, Pennsylvania Office of the Commissioner, Department of Insurance); 2012.
- Institute of Medicine (IOM). Essential Health Benefits: Balancing Coverage and Cost. 1–232. Washington, DC: IOM; 2011. <http://www.iom.edu/Reports/2011/Essential-Health-Benefits-Balancing-Coverage-and-Cost.aspx>
- Institute of Medicine (IOM). Perspectives on Essential Health Benefits: Workshop Report. 1–64. Washington, DC: IOM; 2011. <http://www.iom.edu/Reports/2011/Perspectives-on-Essential-Health-Benefits-Workshop-Report.aspx>
- Kaiser Family Foundation. State Children's Health Insurance Program (SCHIP) at a Glance. Menlo Park, CA: Kaiser Family Foundation; 2007. <http://www.kff.org/medicaid/upload/7610.pdf>
- Kaiser Family Foundation. Focus on Health Reform: Explaining Health Reform: Benefits and Cost-Sharing for Adult Medicaid Beneficiaries. Vol. 1–7. Menlo Park, CA: Kaiser Family Foundation; 2010. www.kff.org/healthreform/upload/8092.pdf
- McCubbins, Mathew D., et al. Administrative Procedures as Instruments of Political Control. *Journal of Law, Economics, and Organization*. 1987; 3(2):243–277.
- Mendelson, Nina. Regulatory Beneficiaries and Informal Agency Policymaking. *Cornell Law Review*. 2007; 92(3):397–452. [PubMed: 17410678]
- Mendelson, Nina. Rulemaking, Democracy, and Torrents of E-Mail. *George Washington Law Review*. 2011; 79:101.
- Millman, Jason. First Crack at Essential Health Benefits Draws No Backlash. *Politico* (blog). 2011 Dec.18 www.politico.com.
- Millman, Jason. Iom Authors Fault Hhs on Benefit Safeguards. *Politico Pro* (blog). 2011 Dec.21 www.politico.com.
- National Health Law Program (NHeLP). Letter to Kathleen Sebelius, Secretary, Department of Health and Human Services. 2011 Dec 2.
- Notice of Proposed Rulemaking [NPRM]. Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. 77 Fed. Reg. 70,644. 2012
- Nou, Jennifer. Agency Self-Insulation. *Harv. L. Rev.* 2013; 126(7):1755.
- Obama, Barack. Executive Order 13497. 74 Fed. Reg. 6113. 2009
- Office of Information and Regulatory Affairs [OIRA]. Historical Reports. Last modified January, 2013. <http://www.reginfo.gov/public/do/eoHistoricReport>
- Office of Management and Budget [OMB]. Final Bulletin for Agency Good Guidance Practices. 2007 Fed;72:3432. Reg.
- Orzag, Peter R. Director Office of Management, Budget. Memorandum to Heads and Acting Heads of Executive Departments and Agencies. 2009 Mar 4. www.whitehouse.gov/sites/default/files/omb/assets/memoranda_fy2009/m09-13.pdf
- Pear, Robert. Health Care Law Will Let States Tailor Benefits. *New York Times*. 2011 Dec 17.
- Raso, Conor N. Strategic or Sincere? Analyzing Agency Use of Guidance Documents. *Yale Law Journal*. 2012; 119(4):782–824.
- Reichow, Brian. Overview of Meta-Analyses on Early Intensive Behavioral Intervention for Young Children with Autism Spectrum Disorders. *Journal of Autism and Developmental Disorders*. 2012; 42(4):512–520. [PubMed: 21404083]
- Schwartz, Sonya. States Take a First Step on the Path to Essential Health Benefits. *Health Affairs blog*. 2012 Oct 3. <http://healthaffairs.org/blog/2012/10/03/states-take-a-first-step-on-the-path-to-essential-health-benefits/>
- Sebelius, Kathleen. Conference Call Briefing. *Federal News Service*. 2011 Dec.16 PP-PP.