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Delegation Dilemma: Can HHS Require Medicare ACOs To Undergo Pre-Clearance by the Antitrust Agencies?



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One of the most anticipated aspects of last year's health reform legislation, the Patient Protection and Affordable Care Act (PPACA), is the Medicare Shared Savings Program.¹ That program seeks to cut Medicare costs and promote quality care through the use of accountable care organizations (ACOs). ACOs are groups of otherwise independent health care providers and suppliers who coordinate and integrate their delivery of services in order to improve the quality and cost-effectiveness of the care they provide for Medicare beneficiaries. As an incentive, the legislation provides that ACOs that meet defined quality benchmarks can receive a portion of any cost savings generated by their collaboration. The hope is that ACOs, by allowing pro-

viders the organizational support to coordinate patient care and the financial incentive to maximize efficiency, can put Medicare on the path to solvency while increasing the quality of care for beneficiaries.

Under PPACA, the Secretary of Health and Human Services (HHS) is responsible for implementing the Shared Savings Program. On April 7, 2011, HHS's Centers for Medicare and Medicaid Services (CMS) issued a notice of proposed rulemaking detailing how it plans to implement the program.² As expected, the proposed regulations build significantly on the core requirements for ACOs set forth in PPACA itself. One novel feature of the proposed regulations is the role that CMS carves out for the federal antitrust agencies—the Federal Trade Commission (FTC) and the Antitrust Division of

¹ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3022, 124 Stat. 119, 395 (2010) (to be codified at 42 U.S.C. § 1395jjj).

² Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 19,528 (Apr. 7, 2011) (notice) [hereinafter Proposed ACO Regulations], available at <http://www.gpo.gov/fdsys/pkg/FR-2011-04-07/pdf/2011-7880.pdf>.

the Department of Justice (DOJ)—neither of which is mentioned in PPACA’s ACO provisions.

Specifically, under the proposed regulations, any ACO that exceeds defined “market share” thresholds must undergo antitrust scrutiny by FTC or DOJ before CMS will consider the organization’s application to become a Medicare ACO.³ Because many (if not most) ACOs will likely exceed these thresholds in at least one medical specialty, the proposed regulations effectively place the antitrust agencies in the role of gatekeepers to the Shared Savings Program.

The policy justifications for taking antitrust considerations into account in the ACO context are not difficult to ascertain. Even before PPACA was enacted, some observers raised concerns that ACOs could have the potential to exercise market power in commercial health care markets where, unlike Medicare, fees are privately negotiated rather than established by regulation.⁴ Following the enactment of PPACA, these concerns prompted representatives of FTC and DOJ to announce that they were in discussions with HHS to work out a coordinated regulatory approach.⁵

The approach they settled upon represents a remarkable example of cooperation across three federal agencies. But is this approach lawful? Under the so-called “subdelegation doctrine,” courts have placed limits on the ability of federal agencies to transfer their statutory authority to outside entities, including other federal agencies. This article explains these limitations and concludes that the proposed ACO regulations, to the extent they make the antitrust agencies the final arbiters of whether certain proposed ACOs qualify to participate in the Medicare Shared Savings Program, likely exceed HHS’s statutory authority.

I. Statutory and Regulatory Background

PPACA sets out certain requirements that potential ACOs must meet in order to participate in the Shared Savings Program.⁶ Among other things, an ACO must adopt processes to promote evidence-based medicine,⁷ improve coordination of care,⁸ and meet patient-

centeredness criteria established by HHS.⁹ In addition, an ACO must agree to a minimum three-year period of participation in the Shared Savings Program.¹⁰ Apart from the specific statutory requirements, PPACA leaves to the Secretary of HHS the task of specifying the criteria that groups of providers must meet to serve together as a Medicare ACO.¹¹

The regulations CMS proposed on April 7 are designed to comply with HHS’s duty to establish eligibility criteria for the Shared Savings Program. One such requirement is that, with limited exception, an ACO with a combined share greater than 50 percent of any Primary Service Area (PSA)—as defined in the antitrust agencies’ proposed joint Statement of Antitrust Enforcement Policy Regarding ACOs—is required first to undergo review by the antitrust agencies.¹² A favorable response from FTC or DOJ is a prerequisite to CMS’s approval of the ACO’s application.¹³ An ACO that receives a letter stating that the antitrust agency “will likely challenge or recommend challenging the ACO” is deemed by CMS to be “ineligible” to participate in the Shared Savings Program.¹⁴

In addition to mandatory pre-clearance by FTC or DOJ for ACOs with greater than 50 percent PSA shares, certain ACOs may elect to undergo voluntary pre-clearance. Specifically, an ACO with PSA shares between 30 percent and 50 percent may request review by the antitrust agencies and submit the resulting determination to CMS. Alternatively, the ACO may, if approved by CMS, begin to operate as a Medicare ACO but “remain subject to antitrust investigation if it presents competitive concerns.”¹⁵ If at any time the DOJ or FTC issues a letter indicating an intent to challenge the ACO, then “the ACO will be ineligible to participate in the Shared Savings Program.”¹⁶

The proposed CMS regulations do not provide for any review by CMS of the antitrust agencies’ decisions regarding Medicare ACOs. To the contrary, the proposed regulations provide that the antitrust agency’s determination is not subject to “reconsideration, appeals, or other administrative or judicial review.”¹⁷

II. The Subdelegation Doctrine

At one time, Congress’ ability to delegate rulemaking authority to federal agencies was a matter of significant constitutional debate. Since the New Deal era, however, courts have generally upheld an expansive congressional power to delegate legislative authority to federal agencies.¹⁸ The question that remained was whether

³ The criteria to be used by FTC and DOJ in performing their antitrust review of ACOs are set forth in a joint proposed policy statement issued concurrently with the CMS proposed regulations. Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 21,894 (Apr. 19, 2011) (notice [hereinafter Proposed Enforcement Policy]).

⁴ See, e.g., KELLY DEVERS & ROBERT BERENSON, CAN ACCOUNTABLE CARE ORGANIZATIONS IMPROVE THE VALUE OF HEALTH CARE BY SOLVING THE COST AND QUALITY QUANDARIES? 9 (2009), available at http://www.urban.org/uploadedpdf/411975_accountable_care_orgs.pdf; MEDPAC, REPORT TO CONGRESS: IMPROVING INCENTIVES IN THE MEDICARE PROGRAM 47, 55–56 (2009) [hereinafter MEDPAC REPORT].

⁵ See, e.g., Jon Leibowitz, Chairman, Fed’l Trade Comm’n, Remarks at the FTC/CMS Workshop for Accountable Care Organizations (Oct. 5, 2010), available at <http://www.ftc.gov/opp/workshops/aco/docs/leibowitz-remarks.pdf>; Christine A. Varney, Assistant Attorney Gen., Antitrust Div., U.S. Dep’t of Justice, Remarks at the American Bar Association/American Health Lawyers Association Antitrust in Healthcare Conference (May 24, 2010), available at <http://www.justice.gov/atr/public/speeches/258898.pdf>.

⁶ PPACA § 3022 (to be codified at 42 U.S.C. § 1395jjj(b)).

⁷ *Id.* (to be codified at 42 U.S.C. § 1395jjj(b)(2)(G)).

⁸ *Id.*

⁹ *Id.* (to be codified at 42 U.S.C. § 1395jjj(b)(2)(H)).

¹⁰ *Id.* (to be codified at 42 U.S.C. § 1395jjj(b)(2)(B)).

¹¹ *Id.* (to be codified at 42 U.S.C. § 1395jjj(a)(1)).

¹² Proposed ACO Regulations, 76 Fed. Reg. at 19,642 (proposed 42 C.F.R. § 425(d)(2)).

¹³ *Id.* (proposed 42 C.F.R. § 425).

¹⁴ *Id.* (proposed 42 C.F.R. § 425.5(d)(2)(i)(A)).

¹⁵ *Id.* (proposed 42 C.F.R. § 425.5(d)(2)(ii)).

¹⁶ *Id.* (proposed 42 C.F.R. § 425.5(d)(2)(iv)).

¹⁷ *Id.* (proposed 42 C.F.R. § 425.15(a)(7)).

¹⁸ Compare *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935) (holding that the National Industrial Recovery Act unconstitutionally delegated legislative power to an executive agency) and *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935) (same), with *Mistretta v. United States*, 488 U.S. 361 (1989) (upholding Congress’ delegation of legislative power because the receiving agency was guided by an “intelligible principle”).

and to what extent a federal agency to which Congress had lawfully delegated policy-making authority could “subdelegate” that power to other agencies or entities.

Initially, courts were skeptical of agencies subdelegating power even within the agency itself, and refused to uphold such transfers in the absence of explicit statutory authority.¹⁹ Administrative necessity eventually won out, and by the 1960s subdelegation within an agency had become commonplace, with courts striking down such intra-agency transfers of authority only when expressly forbidden by Congress.²⁰

Courts, however, continue to take a dim view of efforts by an agency to transfer its decision-making authority outside of its “chain of command” to sister agencies, state or local governments, or other independent agencies. Such inter-agency subdelegation is problematic, courts explain, because “lines of accountability may blur,” diminishing an important “democratic check on government decision-making.”²¹ Moreover, the outside entity may not share the delegated agency’s national perspective or priorities, thus undermining Congress’ statutory scheme and causing “policy drift.”²²

For these reasons, courts have held that, absent express statutory authorization, a federal agency may not cede to another entity final authority to exercise the powers that Congress granted to the agency. The leading modern case concerning subdelegation, *U.S. Telecom Ass’n v. FCC (USTA II)*,²³ was issued by the D.C. Circuit in 2004. *USTA II* struck down regulations promulgated by the Federal Communications Commission (FCC) that granted state commissions broad authority, based on their review of local conditions, to overrule the FCC’s finding on a nation-wide basis that competition would be impaired if incumbent carriers did not offer competing carriers unbundled access to the incumbents’ local switches.²⁴ Because the FCC’s review of the state commissions’ decisions was neither “timely nor assured,” *USTA II* held that the FCC had unlawfully ceded to the states its “final reviewing authority.”²⁵

In reaching this decision, the D.C. Circuit narrowly interpreted two earlier cases that the FCC had argued gave it broad authority to subdelegate.²⁶ In *United States v. Matherson*, 367 F. Supp. 779, 782–83 (E.D.N.Y. 1973), a federal district court upheld a regulation requiring an applicant for a federal right-of-way

permit across tribal lands to first obtain the relevant tribal government’s approval. Similarly, in *S. Pac. Transp. Co. v. Watt*, 700 F.2d 550, 556 (9th Cir. 1983), the Ninth Circuit approved an agency’s requirement that applicants for a vehicular permit to drive on certain federal lands first obtain a permit from the neighboring town whose land had to be traversed to reach the federal property. As interpreted by *USTA II*, these decisions do not concern subdelegation, but instead reflect an agency’s reasonable decision to condition its exercise of broad discretion to permit certain activity on the decision of state, local, and tribal governments concerning matters of “obviously relevant local concern.”²⁷ Whereas these earlier cases sought the mere “input” of local entities on issues that bore a “reasonable connection” to the agency’s decision-making, the *USTA II* court found that the FCC had attempted to delegate to state commissions “almost the entire determination” that Congress tasked the FCC to make.²⁸

Following *USTA II*, the Second Circuit issued a decision, *Fund for Animals v. Kempthorne*, 538 F.3d 124, 133 (2d Cir. 2008), that suggests that it is not enough for a federal agency to retain authority to review an outside entity’s decisions; the authority granted to the outside entity must be circumscribed and consistent with the underlying statute. *Fund for Animals* upheld a federal regulation authorizing state and tribal entities to determine, subject to strict limitations, when and how to kill a certain species of migratory bird to protect local natural resources from predation by the birds.²⁹ The court explained that the regulation did not amount to unlawful subdelegation because, in addition to reserving the power to overturn local determinations, the federal agency had granted state and local entities a “far narrower band of discretion” than Congress granted to the federal agency.³⁰

III. Application to the Proposed ACO Regulations

PPACA delegates sole authority to HHS to implement the Shared Savings Program. None of the statute’s provisions related to ACOs mentions the antitrust agencies, nor do they address whether HHS may subdelegate authority to an outside agency. Under the case law, PPACA’s silence on this issue amounts to a prohibition on inter-agency subdelegation.³¹ The question remains whether the FTC/DOJ role envisioned by the proposed CMS regulations constitutes “subdelegation” or is merely a means for the antitrust agencies to provide input into CMS’s determination whether it will approve particular ACOs.

The argument that CMS’s proposal constitutes unlawful subdelegation is straightforward. Congress placed the authority to determine eligibility to participate in the Shared Savings Program squarely on the shoulders of the Secretary of HHS. Thus, “groups of providers . . . meeting criteria specified by the Secretary” may form ACOs and join the Program.³² Likewise, there are five categories of providers who are eligible to form ACOs, “as determined appropriate by the

¹⁹ See *Cudahy Packing Co. v. Holland*, 315 U.S. 357 (1942) (holding that the Wage-Hour Administrator could not subdelegate to a regional director the power to issue subpoenas).

²⁰ See, e.g., *Touby v. United States*, 500 U.S. 160, 169 (1991) (the Attorney General may subdelegate his powers under the Controlled Substances Act to any member of the Department of Justice “unless a specific limitation on that delegation authority appears elsewhere in the statute”); *U.S. Telecom Ass’n v. FCC*, 359 F.3d 554, 565 (D.C. Cir. 2004) (finding that agency officials may subdelegate within their agency as long as there is no evidence of contradictory congressional intent) [hereinafter *USTA II*]; *United States v. Mango*, 199 F.3d 85, 90 (2d Cir. 1999) (upholding an intra-agency subdelegation by the Secretary of the Army to district engineers, even though the statute only explicitly permitted the Secretary to subdelegate to the Chief of Engineers).

²¹ *USTA II*, 350 F.3d at 565–66.

²² *Id.*

²³ 359 F.3d 554, 565 (D.C. Cir. 2004).

²⁴ *Id.* at 564–65.

²⁵ *Id.* at 566–67.

²⁶ See *id.*

²⁷ *USTA II*, 359 F.3d at 567.

²⁸ *Id.*

²⁹ *Id.* at 132–34.

³⁰ *Id.* at 133.

³¹ See, e.g., *USTA II*, 359 F.3d 554, 566 (D.C. Cir. 2004).

³² PPACA § 3022 (to be codified at 42 U.S.C. § 1395jjj(a)(1)(A)).

Secretary.”³³ Other sections place obligations on the Secretary to establish quality benchmarks and reporting requirements; in each case, the responsibility is given to the Secretary alone.³⁴

Contrary to these statutory provisions, CMS’s proposed regulations place the antitrust agencies in a position to make the final determination of whether an ACO is eligible to participate in the Shared Savings Program. As noted above, many ACOs will be required to undergo scrutiny by the antitrust agencies, while others may choose to do so. If, following their review, the antitrust agencies issue a letter indicating that they intend to challenge an ACO under the antitrust laws, that ACO is ineligible to participate in the Shared Savings Program. CMS will not review the antitrust agencies’ decision or consider the merits of the ACO’s application. This delegation of unreviewable authority to the antitrust agencies is inconsistent with the principles set forth in *USTA II*.

Indeed, even if CMS were to reserve the right to overturn a decision by FTC or DOJ, the proposed regulations might not meet the requirement suggested in *Fund for Animals* that a federal agency must circumscribe the authority it grants outside agencies. Nothing in the CMS regulations attempts to limit the discretion of the DOJ and FTC or set forth criteria they must use in making their decision. Rather, CMS leaves the determination of substantive regulatory standards governing the pre-clearance process entirely up to the antitrust agencies.

In response, CMS may try to seize upon the grants of inter-agency input upheld in *Matherson* and *Southern Pacific* to justify its regulations. In each of these cases, the federal agency conditioned its exercise of discretion upon the approval of an outside entity. CMS may argue that, as in these earlier cases, its regulations simply allow for input by the antitrust agencies on an issue over which the outside entities have special expertise or control.

However, there are significant hurdles that CMS would have to clear to prevail on this argument. The first is that *Matherson* and *Southern Pacific* are older cases that *USTA II* treated as limited to their unique facts. Further, each of these cases concerned delegation to state, local, and tribal authorities with a unique understanding of “local concerns.” Coordinating the federal agency’s exercise of its powers with these local authorities avoided a potential clash of sovereign interests.

Even if these earlier cases apply, CMS would still have to explain why requiring the antitrust agencies’ approval before it will consider many ACOs for the Shared Savings Program is reasonably connected to CMS’s exercise of its own discretion under PPACA. The policy justifications offered by CMS for its transfer of power to the antitrust agencies are set forth in the preamble to the proposed regulations. There, CMS articulates three possible justifications:

1. Competition to serve Medicare beneficiaries spurs providers to render high-quality, innovative care and offer beneficiaries a range of providers and therapies, all of which would be diminished if

ACOs with market power were allowed to participate in the Shared Savings Program.³⁵

2. ACOs with market power would also likely operate in the commercial market, where they could raise prices above competitive levels, and then would be apt to limit the numbers of Medicare patients they treat due to the disparity between high commercial prices and lower Medicare reimbursements.³⁶
3. Pre-clearance by the antitrust agencies will prevent ACOs with large market shares from failing to honor their three-year contracts with CMS in the event they are challenged by FTC/DOJ at a later date.³⁷

The first two of these justifications address the need for antitrust oversight of ACOs, but do not explain why the antitrust agencies need to be placed in a pre-clearance role. Both FTC and DOJ have independent authority under the Sherman Act, the Clayton Act, and the Federal Trade Commission Act to police ACOs. The unique feature of the CMS proposal is that it places the antitrust agencies in the role of gatekeepers, and final arbiters, of whether certain ACOs may participate in the Shared Savings Program. Neither of CMS’s first two rationales explains why the antitrust agencies cannot adequately police competition, consistent with ordinary agency practice, by bringing enforcement actions when they determine that anticompetitive effects have occurred or are likely to occur.

As to CMS’s third justification, there is likely truth to the argument that abrupt removal of an ACO from the Shared Savings Program prior to the end of its three-year contract would be more disruptive than simply removing problem ACOs from the beginning. But it is not immediately apparent that the avoidance of these inconveniences is sufficient to justify placing the antitrust agencies in a gatekeeper role, particularly when compared to the much weightier concerns presented in *Matherson* and *Southern Pacific*. Those cases involved not only a potential clash of sovereign interests, but situations in which, absent the outside entity’s approval, a grant of permission by the federal agency could be rendered meaningless. The interest in avoiding disruptions caused by after-the-fact enforcement actions by the antitrust agencies appears not to rise to the same level.

In the end, the question of whether HHS has statutory authority to place the antitrust agencies in a gatekeeper role for Medicare ACOs is one of congressional intent. As discussed above, in the absence of express legislative authorization, Congress is presumed not to approve a subdelegation of unreviewable authority from one agency to another. But even apart from that default rule, the structure and history of PPACA weigh against the CMS proposal. In creating the Shared Savings Program, Congress acted against the backdrop of a policy debate that included widespread consideration of ACOs in general and antitrust concerns about ACOs in particular.³⁸ PPACA balances a host of competing policy objectives including cost containment, promo-

³⁵ Proposed ACO Regulations at 19,630.

³⁶ *Id.*

³⁷ *Id.*

³⁸ See, e.g., Elliott S. Fisher et al., *Fostering Accountable Health Care: Moving Forward in Medicare*, HEALTH AFFAIRS, March 2009, at 219, available for a fee after registering at

³³ *Id.* § 3022 (to be codified at 42 U.S.C. § 1395jjj(b)(1)).

³⁴ See *id.* § 3022 (to be codified at 42 U.S.C. § 1395jjj(b)(3)).

tion of quality and innovation, and the preservation of competition. Yet Congress did not create a role for the FTC and DOJ. Instead, it placed sole authority for the program in the agency with expertise in Medicare: HHS.

Conclusion

In enacting PPACA, Congress appointed HHS as the sole agency with authority to implement and oversee the Shared Savings Program. Absent congressional authorization, HHS cannot subdelegate that authority to another federal agency. While HHS may seek input and advice from FTC and DOJ, it may not confer unreview-

able discretion on those agencies to make final decisions, even on matters within their substantive expertise. Because HHS's proposed ACO regulations confer unreviewable authority on the antitrust agencies to disqualify entities from participation in the Shared Savings Program, they appear to run afoul of the subdelegation doctrine.

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<http://content.healthaffairs.org/content/28/2/w219.full.html>;
MEDPAC, *supra* note 4, at 47, 55–56.