New Civil Liberties Alliance

December 17, 2018

VIA FIRST CLASS MAIL
AND *www.regulations.gov*

Alex M. Azar II, HHS Secretary
Seema Verma, Administrator
Cheri Rice, Deputy Director
Centers for Medicare & Medicaid Services
Department of Health & Human Services
ATTN: CMS-4187-P
P.O. Box 8013
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Re: Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency Proposed Rule CMS-4187-P

Dear Secretary Azar, Administrator Verma, and Director Rice,

The New Civil Liberties Alliance (NCLA) submits the following comments in response to the Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services's (CMS) Proposed Rule CMS-4187-P, Regulation to Require Drug Pricing Transparency (the "Drug Pricing Rule" or the "Rule"). NCLA sincerely appreciates this opportunity to comment and express its concerns regarding the Proposed Rule.

I. Introduction & Summary

The Drug Pricing Rule is fatally flawed in two principal ways. First, CMS lacks the statutory authority to regulate the subject matter of the proposed Rule, pharmaceutical market efficiency. Second, even if CMS has the authority to regulate the subject matter, it lacks the statutory authority to implement the proposed regulatory means, restricting television advertisements.

While the Secretary may have "broad rulemaking authority" to administer Medicare and Medicaid programs, vague allusions to "broad rulemaking" in CMS's enabling statute do not grant CMS the authority to use all means necessary to advance the enabling statute's goals. Specifically, Congress has not authorized CMS to compel private parties to make public disclosures of drug pricing nor to regulate drug advertising on television. Without such prescriptive authority over the means of achieving CMS's statutory goals, CMS lacks the authority to promulgate the Drug Pricing Rule.

To be sure, the Drug Pricing Rule has other practical and legal defects, not the least of which include its unproven assertions regarding the Rule's ability to reduce drug prices to consumers, and the troubling burdens it places on free speech by compelling content-based expression. While these are important objections too, NCLA's comments focus upon the incipient and dispositive issue of CMS's lack of statutory authority. NCLA reserves the right to provide further comment or to challenge practical, constitutional, or legal defects associated with the Drug Pricing Rule, in any appropriate venue of competent jurisdiction in the future.

II. NCLA's Statement of Interest

The New Civil Liberties Alliance is a nonprofit civil rights organization founded to defend constitutional rights through original litigation, amicus curiae briefs, the filing of regulatory comments, and other means. The "civil liberties" of the organization's name include rights at least as old at the U.S. Constitution itself, such as the due process of law, the right to trial by jury, the right to live under laws made by elected lawmakers rather than by prosecutors or bureaucrats, and the right to be tried in front of an impartial and independent judge whenever the government brings cases against private parties.

NCLA defends civil liberties by asserting constitutional constraints on the administrative state. Although Americans still enjoy the shell of their Republic, there has developed within it a very different sort of government—a type, in fact, that the Constitution's design sought to prevent. This unconstitutional administrative state within the Constitution's United States violates more rights of more Americans than any other aspect of American law, and it is thus the focus of NCLA's efforts.

Where NCLA has not yet brought suit to challenge an agency's unconstitutional exercise of administrative power, it encourages agencies themselves to curb their own unlawful exercise of such power by establishing meaningful limitations on administrative rulemaking, adjudication, and enforcement. The courts are not the only government bodies with the duty to attend to the law. Even more immediately, agencies and agency heads have a duty to follow the law, not least by avoiding unlawful modes of governance. NCLA therefore advises that all agencies and agency heads must examine whether their modes of rulemaking, enforcement, and adjudication comply with the Administrative Procedure Act (APA) and with the Constitution.

III. NCLA's Commentary

At its core, the proposed Rule requires certain prescription drug and biological product television advertisements to include a statement indicating the wholesale acquisition cost (WAC) for a typical 30-day regimen or course of treatment. Proposed Drug Pricing Transparency Rule, 83 Fed. Reg. 202, 52794 (Oct. 18, 2018). The Rule's Federal Register posting states that "an administrative agency's power to regulate … must always be grounded in a valid grant of authority from Congress." *Id.* at 52790 (quoting *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000) (internal quotations omitted)). Moreover, the entry correctly notes that "[a]gencies are … bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes." *Ibid.* (quoting *Colorado River Indian Tribes v. Nat'l Indian Gaming Comm'n*, 466 F.3d 134, 139-40 (D.C. Cir. 2006) (internal quotations and citations omitted)). CMS's Drug Pricing Rule satisfies neither of these self-acknowledged rulemaking prerequisites.

First, Congress has not granted CMS the authority "to reduce the price to consumers of prescription drugs and biological products." CMS asserts that the downstream benefit to greater price transparency is a more efficient pharmaceutical marketplace in which consumers will price shop to secure the best value for their needs. *See id.* at 52789-90. Irrespective of whether CMS is right or wrong on this point, CMS's legislative mandate is to ensure the efficient *administration* of the Medicare and Medicaid programs, not efficient *markets* feeding these programs. *See* 42 U.S.C. § 1302(a) *and* 42 U.S.C. § 1395hh. While there is no doubt that lower drug prices would aid CMS in its administration of Medicare and Medicaid, regulating the pharmaceutical marketplace is far too attenuated a subject matter to fit within CMS's mandate.

CMS, however, claims "broad rulemaking authority" under 42 U.S.C. § 1302(a). Proposed Rule, 83 Fed. Reg. at 52790. It further justifies its claim by citing *Thorpe v. Housing Auth. of Durham*, 393 U.S. 268 (1969). *Ibid. Thorpe* does not, however, support the proposition that CMS attributes to the decision. In *Thorpe*, the Supreme Court acknowledged that some agencies have broad rulemaking power, but the rules promulgated must bear a reasonable relationship to the enabling legislation. *See Thorpe*, 393 U.S. at 280. The *Thorpe* Court reasoned that since "[o]ne of the specific purposes" of HUD's enabling statute is to provide decent homes to families who could not otherwise afford them, HUD's rule that required notice to tenants before eviction had a reasonable relationship to HUD's enabling legislative directive to provide housing. *Ibid.*

Existing prudential considerations—rightly or wrongly—suggest that CMS's rulemaking authority is indeed broad, but "broad" does not mean "unlimited." CMS's rulemaking extends only as far as "may be necessary to the *efficient administration of the functions* ... under this Act."[1] 42 U.S.C. § 1302(a) (emphasis added). *See also* 42 U.S.C. § 1395hh(a)(1) ("The [HHS] Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under [the SSA]."). Indeed, as one court has pointed out, vague allusions to rulemaking "not inconsistent" with the SSA or to rules that are "necessary to carry out the [Medicare program] administration" are the "weakest" basis of CMS rule legitimacy. *See Am. Health Care Ass'n v. Burwell*, 217 F. Supp. 3d 921, 934 n.3 (N.D. Miss. 2016). Moreover, CMS cannot credibly argue that the Rule is an administrative efficiency regulation since the administrative benefit, lower drug costs, is merely a speculative consequence of CMS's stated purpose "to reduce the price to consumers of prescription drugs and biological products." *See* Proposed Rule, 83 Fed. Reg. at 52789. Thus, since the Drug Pricing Rule does not relate to the administrative efficiency of Medicare and Medicaid programs, CMS lacks the requisite statutory authority to proceed with rulemaking.

Second, even assuming for the sake of argument that CMS's rulemaking authority may be read so broadly as to permit CMS to regulate market efficiency rather than just administrative efficiency, Congress has not bestowed on CMS the means CMS proposes to employ to achieve its regulatory goal. The Drug Pricing Rule proposes to use compelled disclosure of pricing information in prescription drug direct-to-consumer television ads. *See id.* at 52789-90. CMS itself admits that not only must its rules be faithful to the ultimate purpose of Congress's grant of rulemaking authority, but

[1] While beyond the scope of these Comments, NCLA would be remiss if we failed to note that even where Congress has expressly ceded lawmaking authority to administrative agencies, such divestment of legislative power may be unconstitutional under Article I, Section 1 of the United States Constitution. U.S. Const., art. I, § 1 ("*All legislative powers* herein granted shall be vested in a Congress of the United States[.]") (emphasis added).

the agency also must employ means that Congress has deemed appropriate and has prescribed in the pursuit of CMS's regulatory goal. *See id.* at 52790. While CMS does not directly address this issue, it appears to claim implicitly that its rulemaking authority is so broad that the means may simply be justified by the regulation's ends.

CMS asserts that the D.C. District Court's *Cottage Health System* decision held that the agency has "broad rulemaking authority with respect to the Medicare program." *Ibid.* (citing *Cottage Health Sys. v. Sebelius*, 631 F. Supp. 2d 80, 92 (D.D.C. 2009)). The *Cottage Health System* court's opinion is far more nuanced than CMS suggests, however. The court cautioned that although CMS has broad rulemaking authority by virtue of § 1395hh, the enabling legislation "does not speak to the precise question" of making the *specific* rule in the *Cottage Health System* case. *See Cottage Health Sys.*, 631 F. Supp. 2d at 92. In fact, the court observed that where enabling legislation is ambiguous, statutes with sweeping rulemaking authority serve to *underscore* the ambiguity. *Ibid.* Contrary to what CMS would have commentators believe, in such circumstances § 1395hh does not lead to the natural conclusion that CMS may promulgate a regulation utilizing any means necessary to achieve its otherwise legitimate goals. *Ibid.* (employing a *Chevron* analysis[2] to determine whether CMS's belief that it had the authority to promulgate the rule in question without precise statutory authority to do so was plainly reasonable).

Not surprisingly, instead of citing specific statutory authority justifying the Rule's proposed means of advancing Medicare and Medicaid administrative efficiency, CMS claims that there is "a clear nexus" between the Rule and the Social Security Act (SSA) that justifies the Rule's promulgation. Proposed Rule, 83 Fed. Reg. at 52791. While we could quibble over what is or is not "clear," one thing is certain—a nexus is not an express grant of authority from Congress. CMS reasons that since § 1927(b)(3)(A) of the SSA requires manufacturers to disclose pricing information to the government, and since § 1860(k)(1) requires plan sponsors to disclose the difference between the dispensed drug and the lowest priced generic equivalent, "Congress has generally endorsed" drug price disclosure to minimize program costs. *Ibid.* This argument fails to address how § 1927, § 1860—or any other section of the United States Code—sanctions CMS's regulation of broadcast, cable, streaming and satellite communications. Not to put too fine a point on it, Congress's *general endorsement* of an idea does not suffice—Congress must enact law to permit CMS to promulgate its Drug Pricing Rule.

IV. NCLA's Specific Recommendation and Conclusion

Since CMS lacks both the statutory authority to promulgate the Rule and congressional prescription to enforce the Rule's precepts, NCLA recommends that CMS withdraw the proposed Rule from the Federal Register and notify interested parties that CMS will not pursue compelled WAC disclosure in advertisements of any kind.

NCLA recognizes that the rapid rise of drug prices poses a challenge to efficient operation of the Medicare and Medicaid programs. But the Drug Pricing Rule, however well intended, appears to

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[2] NCLA does not concede that the *Cottage Health System* court was correct in using *Chevron* deference to hold that HHS's interpretation that it had the authority to promulgate the rule was neither arbitrary nor capricious. *See Cottage Health Sys.*, 631 F. Supp. 2d at 92. *Chevron* deference lies beyond the scope of these Comments, but HHS and CMS should note that the Supreme Court's most recent decisions suggest that the Court may be ready to do away with the unconstitutional *Chevron* regime.

be an extralegal attempt by CMS to regulate the efficiency of pharmaceutical markets when it only has legal authority to regulate administrative program efficiency.

Should CMS choose to promulgate internally applicable agency rules that seek to curb costs while enhancing the quality of services CMS provides to the public, NCLA will not object. NCLA cannot support, however, CMS's extralegal attempts to compel disclosure of private proprietary business data, especially where Congress has not expressly authorized it.

Thank you again for the opportunity to provide NCLA's perspective on these important issues. If you have any questions, comments or concerns, please feel free to contact me at mike.degrandis@ncla.legal.

Very truly yours,

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