PETITION FOR RULEMAKING TO PROMULGATE REGULATIONS PROHIBITING THE ISSUANCE, RELIANCE ON, OR DEFENSE OF IMPROPER AGENCY GUIDANCE

SUBMITTED TO THE UNITED STATES DEPARTMENT OF HEALTH & HUMAN SERVICES

SEPTEMBER 6, 2018

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[1] The Food and Drug Administration received an FDA-specific Petition for Rulemaking from NCLA on July 31, 2018, Docket No. FDA-2018-P-2997. The FDA Petition is substantively identical to this Petition.

I. Statement of the Petitioner

Pursuant to the Administrative Procedure Act (APA), 5 U.S.C. § 553(e), and the agency-specific statutory and regulatory authority that vests the Department of Health and Human Services (the "Office of the Secretary") and the 11 agencies (the "Operating Divisions") under its auspices (collectively, "HHS" or the "Department") with the power to engage in rulemaking, the New Civil Liberties Alliance (NCLA) hereby petitions HHS to initiate a rulemaking process to promulgate regulations prohibiting any HHS component from issuing, relying on, or defending improper agency guidance (the "Petition for Rulemaking"). The proposed rule would formalize and make more permanent policies and best practices from other agencies concerning any agency guidance that improperly attempts to create rights or obligations binding on persons or entities outside the Department. Additionally, the proposed rule would provide affected parties with a means of redress for improper agency action.

II. Summary of the Petition

Even though both the Constitution and the Administrative Procedure Act prohibit the practice, federal agencies often engage in the "commonplace and dangerous" acts of issuing informal interpretations, advice, statements of policy, and other forms of "guidance" that "make law simply by declaring their views about what the public should do." Philip Hamburger, *Is Administrative Law Unlawful?* 260, 114 (2014). This practice evades legal requirements and often is "used for the purpose of coercing persons or entities outside the federal government into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or regulation." *Ibid.* And despite being prohibited by law, improper guidance is typically "immuniz[ed]" from judicial review by procedural limits. *See Appalachian*

Power Co. v. Envtl. Prot. Agency, 208 F.3d 1015, 1020 (D.C. Cir. 2000). This conduct results in a form of illegal and unconstitutional "extortion" where agencies obtain compliance through "extralegal lawmaking." Hamburger, *supra*, at 260, 114-15.

To rein in these abuses, NCLA proposes that HHS issue a formal rule prohibiting the Office of the Secretary and the Operating Divisions from issuing, relying on, or defending the validity of improper guidance. The proposed rule not only adopts existing legal limitations on such improper agency action, but, critically, also creates a permanent and binding set of limits on future agency practice. The proposed rule also sets out a means to enforce these limits by empowering regulated parties to petition HHS to rescind improper guidance and to seek judicial review of improper agency actions.

NCLA maintains that since the proposed rule is of universal applicability to the entirety of the Department, the proper venue for consideration and promulgation of the rule is the Office of the Secretary, rather than each of HHS's separate Operating Divisions. Likewise, NCLA maintains that the proper scope of this rule is Department-wide. If, however, the Office of the Secretary chooses to exempt one or two Operating Divisions from the Department-wide proposed rule for prudential reasons to facilitate quicker promulgation of a broadly applicable rule, NCLA will not object.[2] NCLA has concurrently submitted courtesy copies to the heads of each agency to facilitate immediate Operating Division-level consideration of this same rule for any division left behind by the the Department-wide proposed rule.

[2] NCLA appreciates that an HHS agency's enabling statute may require that agency-specific language, terms, or exceptions be reflected in the text of the Petition's proposed rule. Thus, NCLA is committed to working with HHS and its exempted agency, should one exist, to formulate language to suit the agency's unique statutory needs in a subsequent agency-specific Petition for Rulemaking to prohibit guidance that improperly attempts to create rights or obligations binding on persons or entities outside the HHS agency.

III. 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, and other means. The "civil liberties" of the organization's name include rights at least as old as the United States Constitution itself, such as trial by jury, due process of law, the right to live under laws made by the nation's elected lawmakers rather than by prosecutors or bureaucrats, and the right to be tried in front of an impartial and independent judge.

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 was framed 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 therefore the focus of NCLA's efforts.

Even where NCLA has not yet brought a suit to challenge an agency's unconstitutional exercise of administrative power, it encourages agencies themselves to curb the unlawful exercise of such power by establishing meaningful limitations on administrative rulemaking, guidance, 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, guidance, adjudication, and enforcement comply with the APA and with the Constitution.

NCLA is thus an "interested" party concerning the proposed rule set out in this Petition for Rulemaking. *See* 5 U.S.C. § 553(e).

IV. Legal Authority to Promulgate the Rule

This Petition for Rulemaking is submitted pursuant to 5 U.S.C. § 553(e), which provides any "interested person the right to petition [an agency] for the issuance ... of a rule." "The Department [of Health and Human Services] reviews these petitions to decide whether to take action." Dept. of Health & Human Servs., *Regulation Toolkit*, https://www.hhs.gov/regulations/regulations-toolkit/index.html (last visited Aug. 5, 2018). Moreover, it is HHS's stated goal to encourage public participation in the rulemaking process. *See* Dept. of Health & Human Servs., *Unified Agenda*, 80 Fed. Reg. 240 at 77960 (Dec. 15, 2015) (conducting HHS's semiannual inventory of rulemaking as required by Executive Order 12866 (Sept. 30, 1993)).

The Office of the Secretary, as well as the individual HHS Operating Divisions, are "agencies" as the APA defines the term. *See* 5 U.S.C. § 551(1). Consistent with the APA, NCLA's proposed rule is an HHS statement of general applicability and future effect, designed to prescribe procedure and practice requirements applicable to the entire Department, including the Office of the Secretary and all Staff and Operating Divisions. *See* 5 U.S.C. § 551(4). When any agency engages in rulemaking procedures it must abide by the requirements set out in 5 U.S.C. § 553.

V. Reasons for Creating the Rule

A. Legal Background

No agency has any inherent power to make law. Article I, § 1 of the U.S. Constitution vests "[a]ll legislative powers" in the Congress, and "the lawmaking function belongs to Congress ... and may not be conveyed to another branch or entity." *Loving v. United States*, 517 U.S. 748, 758 (1996). This is a constitutional barrier to an exercise of legislative power by an agency. Further, "an agency literally has no power to act ... unless and until Congress confers

power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986). Thus, even if an agency could constitutionally exercise legislative power, it cannot purport to bind anyone without congressional authorization.

And, instead of conferring such power, Congress has categorically prohibited the issuance of binding guidance. Congress passed the Administrative Procedure Act in 1946 in order "to introduce greater uniformity of procedure and standardization of administrative practice among the diverse agencies whose customs had departed widely from each other." *Wong Yang Sung v. McGrath*, 339 U.S. 33, 41 (1950). As a result, it sets out a comprehensive set of rules governing administrative action.

Consistent with this design, the APA established a process by which agencies could engage in "rule making." 5 U.S.C. § 553. The APA explains that a "rule" "means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency[.]" 5 U.S.C. § 551(4).

Rules, by and large, may be promulgated by agencies only following notice-and-comment procedures. First, an agency must post a "general notice" of the proposed rulemaking in a prominent place and seek commentary from private parties. 5 U.S.C. § 553(b). This notice must set out "the time, place and nature" of the proposed "public rule making proceedings," "the legal authority under which the rule is proposed," and "either the terms or substance of the proposed rule or a description of the subjects and issues involved." *Id.* at § 553(b).

After the notice has been set out, the agency must "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." *Id.* at § 553(c). "An agency must consider and respond to significant comments received during the

period for public comment." *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015). In response to submitted comments, a "general statement" of the purpose of the rules must also be "incorporate[d] in the rules adopted." 5 U.S.C. § 553(c).

The APA's notice-and-comment period "does not apply ... to interpretive rules, general statements of policy, or rules of agency organization procedure, or practice." *Id.* at § 553(b). Instead, this requirement applies only to "substantive rules," which are sometimes referred to as "legislative rules." *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014); *see also* 5 U.S.C. § 553(d) (distinguishing between "substantive" and "interpretive" rules for publication and service).

A "substantive" or "legislative" rule is any "[a]gency action that purports to impose legally binding obligations or prohibitions on regulated parties[.]" *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014). Stated differently: "A rule is legislative if it supplements a statute, adopts a new position inconsistent with existing regulations, or otherwise effects a substantive change in existing law or policy." *Mendoza*, 754 F.3d at 1021. Such "legislative rules" have the "force and effect of law." *Chrysler Corp. v. Brown*, 441 U.S. 281, 302-03 (1979). Legislative rules are also accorded deference from courts. *See United States v. Mead Corp.*, 533 U.S. 218, 230 (2001).

In contrast, "interpretive rules" are not subject to notice-and-comment requirements. *See Mendoza*, 754 F.3d at 1021. Interpretative rules "do not have the force and effect of law and are not accorded that weight in the adjudicatory process." *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995).

An interpretative rule is any "agency action that merely interprets a prior statute or regulation, and does not itself purport to impose new obligations or prohibitions or requirements

on regulated parties[.]" *Nat'l Mining Ass'n*, 758 F.3d at 252. "[I]nterpretive rules ... are issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." *Perez*, 135 S. Ct. at 1204 (internal citation and quotation marks omitted). Such a rule simply "describes the agency's view of the meaning of an existing statute or regulation." *Batterton v. Marshall*, 648 F.2d 694, 702 n.34 (D.C. Cir. 1980).

Aside from being a technical requirement under the APA, the notice-and-comment process serves important purposes. As the Supreme Court has explained, "Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force." *Mead Corp.*, 533 U.S. at 230. "APA notice and comment" is one such relatively formal procedure, "designed to assure due deliberation." *Ibid* (quoting *Smiley v. Citibank (South Dakota) N.A.*, 517 U.S. 735, 741 (1996)).

Informal interpretations, such as policy statements, agency manuals, enforcement guidelines and opinion letters "lack the force of law" and warrant, at best, only limited "respect" from courts concerning matters of interpretation. *Christensen v. Harris Cnty.*, 529 U.S. 576, 587 (2000). Further, to the extent that a court grants any "respect" to these interpretations, the strength of such respect varies widely depending on the degree of formality employed by the agency. *See Mead Corp.*, 533 U.S. at 228 (discussing the deference owed to agency decisions). It depends in many instances on an agency's use of "notice-and-comment rulemaking or formal adjudication." *Id.* at 228-30 (internal citation and quotation marks omitted). A court gives the least amount of respect to "agency practice [that lacks] any indication [the agency] set out with a lawmaking pretense in mind" when it acted. *Id.* at 233.

Despite the relatively straightforward legal distinction, it is not always easy for courts or regulators to draw practical distinctions between "legislative" and "interpretive" rules. Because each agency action is unique, determining whether a given agency action is a legislative rule or interpretive rule "is an extraordinarily case-specific endeavor." *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987).

Perhaps because of this difficulty, or perhaps for more invidious reasons, agencies continue to promulgate legislative rules under the guise of being mere guidance, without following the notice-and-comment requirements of the APA. Accordingly, courts have often struck down such rules. *See, e.g.*, *Mendoza*, 754 F.3d at 1025 (vacating guidance documents as legislative rules that failed to comply with APA notice-and-comment requirements); *Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec.*, 653 F.3d 1, 8 (D.C. Cir. 2011) (same); *Hemp Indus. Ass'n v. Drug Enforcement Admin.*, 333 F.3d 1082, 1091 (9th Cir. 2003) (same); *Nat'l Family Planning & Reprod. Health Ass'n, Inc. v. Sullivan*, 979 F.2d 227, 231 (D.C. Cir. 1992) (same); *Time Warner Cable Inc. v. FCC*, 729 F.3d 137, 168 (2d Cir. 2013) (same). Indeed, federal courts routinely invalidate HHS guidance when the Department ignores mandatory notice-and-comment requirements for promulgating legislative rules. *See, e.g.*, *Texas Children's Hosp. v. Azar*, No. 14-2060, 2018 WL 2464462, *12 (D.D.C. June 1, 2018) (invalidating an HHS FAQ that made a substantive change in calculating a hospital's disproportionate-share limit because the FAQ altered rights and duties without promulgation through APA notice-and-comment procedures).

But the prevalence of court invalidation of improper guidance vastly understates the problem, as "extralegal" agency action "usually occurs out of view." Hamburger, *supra*, at 260. "To escape even the notice-and-comment requirement for lawmaking interpretation, agencies

increasingly make law simply by declaring their views about what the public should do." *Id.* at 114. Such improper guidance statements are often deliberate "evasions" of legal requirements, and "an end run around [an agency's] other modes of lawmaking." *Ibid* (internal citation and quotation marks omitted). In many instances, an agency's "guidance" is actually a means of "extralegal lawmaking." *Id.* at 115.

Agencies have strong incentives to resort to this kind of extralegal lawmaking. The "absence of a notice-and-comment obligation makes the process of issuing interpretive rules comparatively easier for agencies than issuing legislative rules." *Perez*, 135 S. Ct. at 1204. An agency operating in this fashion can issue rules "quickly and inexpensively without following any statutorily prescribed procedures." *Appalachian Power Co.*, 208 F.3d at 1020. But, this results in a scenario where "[l]aw is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations." *Ibid.*

More troubling, "[w]hen agencies want to impose restrictions they cannot openly adopt as administrative rules, and that they cannot plausibly call 'interpretation,' they typically place the restrictions in guidance, advice, or other informal directives." Hamburger, *supra*, at 260. This is "a sort of extortion," because an agency can secure compliance by "threatening" enforcement or other regulatory action, even if the agency has no genuine authority to act in the first place. *Id.* at 260-61. An agency's informal "views about what the public should do," almost always comes "with the unmistakable hint that it is advisable to comply." *Id.* at 114.

This extortion is enabled, primarily, by the unreviewability of improper guidance. Indeed, an agency often realizes that "another advantage" to issuing guidance documents, is "immunizing its lawmaking from judicial review." *Appalachian Power Co.*, 208 F.3d at 1020.

As discussed above, legislative rules will only be invalidated for failure to conform to the notice-and-comment process after they have been determined to be legislative in the first place. This is neither a simple nor a quick task.

Simultaneously, even invalid, binding legislative rules may escape judicial review. The APA typically allows review only of "final agency action." 5 U.S.C. § 704. "[T]wo conditions must be satisfied for agency action to be final: First, the action must mark the consummation of the agency's decisionmaking process ... And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (internal citations and quotation marks omitted).

But "an agency's action is not necessarily final merely because it is binding." *Appalachian Power Co.*, 208 F.3d at 1022. An initial or interim ruling, even one that binds, "does not mark the consummation of agency decisionmaking" and thus might not constitute final agency action. *Soundboard Ass'n v. Fed. Trade Comm'n*, 888 F.3d 1261, 1271 (D.C. Cir. 2018); *see also Ctr. for Food Safety v. Burwell*, 126 F. Supp. 3d 114, 118 (D.D.C. 2015) (Contreras, J.) (discussing binding "Interim Policy" of agency that was in effect for 17 years but evaded judicial review as non-final action).

Aside from finality concerns, courts rarely consider the genuinely coercive effects of guidance documents as sufficiently binding to permit review. For example, a warning letter issued by an agency to a party, alleging a violation of a regulation, and even threatening the initiation of enforcement action, will not establish sufficient concrete "legal consequences" to permit review of final agency action. *Holistic Candlers & Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940, 944 (D.C. Cir. 2012). Indeed, "practical consequences, such as the threat of having to defend itself in an administrative hearing should the agency actually decide to

pursue enforcement, are insufficient to bring an agency's conduct under [a court's] purview." *Indep. Equip. Dealers Ass'n v. Envtl. Prot. Agency*, 372 F.3d 420, 428 (D.C. Cir. 2004) (internal citation and quotation marks omitted). Even to the extent that such action coerces compliance from a regulated entity, and even to the extent this might result in "a dramatic impact on the [affected] industry," it still may not be considered final action subject to review. *Soundboard Ass'n*, 888 F.3d at 1272; *see also Nat'l Mining Ass'n*, 758 F.3d at 253 (agency action is not final even if a regulated entity "really has no choice when faced with [] 'recommendations' except to fold," and might "feel pressure to voluntarily conform their behavior because the writing is on the wall").

This use of guidance thus results in "commonplace and dangerous" abuses of administrative power, and "often leaves Americans at the mercy of administrative agencies." Hamburger, *supra*, at 260, 335. "It allows agencies to exercise a profound under-the-table power, far greater than the above-board government powers, even greater than the above-board administrative powers, and agencies thuggishly use it to secure what they euphemistically call 'cooperation.'" *Id.* at 335. This results in an "evasion" of the Constitution, and an affront to the basic premise that laws can only be made by the Congress. *Id.* at 113-14; *see also La. Pub. Serv. Comm'n*, 476 U.S. at 374. It is also statutorily forbidden. *See Mendoza*, 754 F.3d at 1021. And it often results in violations of the due process of law. Hamburger, *supra*, at 241, 353. But, perhaps by design, such improper agency conduct routinely occurs without any hope of judicial intervention. *See Appalachian Power Co.*, 208 F.3d at 1020.

B. HHS's Response to These Problems So Far

1. The Bulletin for Agency Good Guidance Practices

On January 18, 2007, the Office of Management and Budget for the Executive Office of the President addressed the ongoing problem caused by the issuance of "poorly designed or improperly implemented" "guidance documents" from administrative entities. Office of Mgmt. & Budget, Executive Office of the President, *Final Bulletin for Agency Good Guidance Practices*, 72 Fed. Reg. 3432, 3432 (Jan. 18, 2007) (OMB Bulletin). OMB explained that many stakeholders had ongoing "[c]oncern about whether agencies" had been improperly issuing guidance documents that actually "establish new policy positions that the agency treats as binding," without following the notice-and-comment requirements of the APA. *Id.* at 3433. In addition to promulgating formal rules with the effect of law, many "agencies increasingly have relied on guidance documents to inform the public and to provide direction to their staffs." *Id.* at 3432. While the bulletin characterized this practice as generally positive, it noted that many guidance documents do "not receive the benefit of careful consideration accorded under the procedures for regulatory development and review." *Ibid.* Worse, "[b]ecause it is procedurally easier to issue guidance documents, there also may be an incentive for regulators to issue guidance documents in lieu of regulations." *Ibid.* Some of these guidance documents also improperly "establish new policy positions that the agency treats as binding," despite failures to comply with the APA's notice-and-comment and judicial review provisions. *Id.* at 3433.

To combat this problem, OMB issued its Final Bulletin to help ensure that guidance documents issued by Executive Branch departments and agencies under the OMB's management would not improperly issue "legally binding requirements." *Ibid.*

First, the OMB Bulletin directed each agency to "develop or have written procedures for the approval of significant guidance documents," in order to "ensure that the issuance of significant guidance documents is approved by appropriate senior agency officials." *Id.* at 3436, 3440.

The OMB Bulletin also suggested that each significant guidance document adhere to the following:

a. Include the term "guidance" or its functional equivalent;

b. Identify the agenc(ies) or office(s) issuing the document;

c. Identify the activity to which and the persons to whom the significant guidance document applies;

d. Include the date of issuance;

e. Note if it is a revision to a previously issued guidance document and, if so, identify the document that it replaces;

f. Provide the title of the document, and any document identification number, if one exists;

g. Include the citation to the statutory provision or regulation (in Code of Federal Regulations format) which it applies to or interprets; and

h. Not include mandatory language such as "shall," "must," "required" or "requirement," unless the agency is using these words to describe a statutory or regulatory requirement, or the language is addressed to agency staff and will not foreclose agency consideration of positions advanced by affected private parties.

Id. at 3440.

Finally, the OMB Bulletin suggested that each agency establish procedures for improving public access and feedback for significant guidance documents. *Ibid.* In the case of "economically significant guidance documents," these suggestions included following notice-and-comment procedures in certain cases. *Id.* at 3438.

The OMB Bulletin was limited in two important ways. First, it only applied to the issuance of "significant guidance documents" by Executive Branch agencies. *Id.* at 3432. This was defined as a "document disseminated to regulated entities or the general public that may reasonably be anticipated to: (i) Lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (ii) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (iii) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (iv) Raise novel legal or policy issues arising out of legal mandates[.]" *Id.* at 3439.

Second, the OMB Bulletin did not create any means of review or redress should agencies choose to disregard it. *Id.* at 3439. Under a heading entitled "Judicial Review," the Bulletin provided that it was meant only "to improve the internal management of the Executive Branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person." *Ibid.*

2. The Justice Department's Policy Memoranda

Following the OMB Bulletin's lead more than a decade later, on November 16, 2017, Attorney General Jeff Sessions issued a memorandum for all Justice Department components entitled *Prohibition on Improper Guidance Documents* (Sessions Memo). This memo immediately prohibited all Department of Justice components from issuing agency guidance documents that "purport to create rights or obligations binding on persons or entities outside the

Executive Branch." Office of the Att'y Gen., *Prohibition on Improper Guidance Documents* at 1, *available at* https://www.justice.gov/opa/press-release/file/1012271/download.

The Sessions Memo explained that "the Department has in the past published guidance documents—or similar instruments of future effect by other names, such as letters to regulated entities—that effectively bind private parties without undergoing the rulemaking process." *Ibid.* It also explained that guidance documents might improperly "be used for the purpose of coercing persons or entities outside the federal government into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or regulation." *Ibid.* This practice often evaded "notice-and-comment" rules "required by law," and deprived the agencies "of more complete information about a proposed rule's effects than the agency could ascertain on its own." *Ibid.*

The new policy prohibited any agency operating within the Department of Justice from using regulatory guidance "as a substitute for rulemaking." *Ibid.* As such, guidance documents would no longer be promulgated that either "impose new requirements on entities outside the Executive Branch," or "create binding standards by which the Department will determine compliance with existing regulatory or statutory requirements." *Ibid.* Future guidance documents would only be issued to "educate regulated parties through plain-language restatements of existing legal requirements or provide non-binding advice on technical issues through examples or practices to guide the application or interpretation of statutes and regulations." *Ibid.*

To support these goals, Attorney General Sessions set out the following five "principles" to which all components "should adhere" "when issuing guidelines":

> [1] Guidance documents should identify themselves as guidance, disclaim any force or effect of law, and avoid language suggesting that the public has

> obligations that go beyond those set forth in the applicable statutes or legislative rules.
>
> [2] Guidance documents should clearly state that they are not final agency actions, have no legally binding effect on persons or entities outside the federal government, and may be rescinded or modified in the Department's complete discretion.
>
> [3] Guidance documents should not be used for the purpose of coercing persons or entities outside the federal government into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or regulation.
>
> [4] Guidance documents should not use mandatory language such as "shall," "must," "required," or "requirement" to direct parties outside the federal government to take or refrain from taking action, except when restating—with citations to statutes, regulations, or binding judicial precedent—clear mandates contained in a statute or regulation. In all cases, guidance documents should clearly identify the underlying law that they are explaining.
>
> [5] To the extent guidance documents set out voluntary standards (e.g., recommended practices), they should clearly state that compliance with those standards is voluntary and that noncompliance will not, in itself, result in any enforcement action.

Id. at 2.

The memo also defined "guidance documents" to include "any Department statements of general applicability and future effect, whether styled as guidance or otherwise that are designed to advise parties outside the federal Executive Branch about legal rights and obligations falling within the Department's regulatory or enforcement authority." *Ibid.* Notably, this definition excluded "internal directives [and] memoranda." *Id.* at 2-3.

In accordance with this new policy, the Attorney General also directed the Justice Department's Regulatory Reform Task Force "to work with components to identify existing guidance documents that should be repealed, replaced, or modified in light of these principles." *Id.* at 2.

Finally, the memo made clear that it "is an internal Department of Justice policy directed at Department components and employees. As such, it is not intended to, does not, and may not be relied upon to, create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal." *Id.* at 3.

Just over a month later, the Attorney General announced that he was applying his November memo and "rescinding 25 [guidance] documents that were unnecessary, inconsistent with existing law, or otherwise improper." Press Release, *Attorney General Sessions Rescinds 25 Guidance Documents*, Department of Justice, Office of Public Affairs, Press Release No. 17-1469 (Dec. 21, 2017) *available at* https://www.justice.gov/opa/pr/attorney-general-jeff-sessions-rescinds-25-guidance-documents. Then on July 3, 2018, the Attorney General rescinded 24 more improper guidance documents. Press Release, *Attorney General Jeff Sessions Rescinds 24 Guidance Documents*, Department of Justice, Office of Public Affairs, Press Release No. 18-883 (July 3, 2018) *available at* https://www.justice.gov/opa/pr/attorney-general-jeff-sessions-rescinds-24-guidance-documents. The Attorney General also said that the Department would "continu[e] its review of existing guidance documents to repeal, replace, or modify." *Ibid.*

On January 25, 2018, Associate Attorney General Rachel Brand, who was then the chair of the Department's Regulatory Reform Task Force, issued a memorandum entitled *Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases* (Brand Memo), for all Justice Department litigators. This memo echoed the Sessions Memo's concerns that Justice Department agencies had previously issued "guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch." *Id.* at 1, *available at* https://www.justice.gov/file/1028756/download.

Associate Attorney General Brand therefore directed that for all affirmative civil enforcement (ACE) cases, "the Department may not use its enforcement authority to effectively convert agency guidance documents into binding rules." *Id.* at 2. To accomplish this goal, the Brand Memo went further than the Sessions Memo, and applied to "guide Department litigators in determining the legal relevance of *other agencies'* guidance documents," including the Department of Health and Human Services. *Id.* at 1 (emphasis added). In addition, ACE litigators were also prohibited from "us[ing] noncompliance with guidance documents as a basis for proving violations of applicable law." *Id.* at 2. "That a party fails to comply with agency guidance expanding upon statutory or regulatory requirements does not mean that the party violated those underlying legal requirements; agency guidance documents cannot create any additional legal obligations." *Ibid.*

As with the Sessions Memo, the Brand Memo contained an elaborate disclaimer carefully setting out that it had no binding effect on any party outside the Department of Justice. "As such, it is not intended to, does not, and may not be relied upon to, create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal." *Ibid.*

3. The Current Status of Guidance at the Department of Health and Human Services

The Sessions and Brand Memoranda are unequivocal—Executive Branch departments and agencies must cease the unconstitutional practice of issuing guidance as a means of avoiding notice-and-comment procedures when promulgating substantive rules. Despite this directive, HHS has yet to take *any* action to curb its almost habitual proclivity for issuing *ad hoc* guidance. HHS's reticence to implement guidance reform is ironic, given that HHS was one of the first agencies to designate a Regulatory Reform Officer and establish a Regulatory Reform Task Force pursuant to Executive Orders 13771 and 13777 and OMB Guidance M-17-21 and M-17-

23. Deregulatory efforts, while important, are only one component of the Administration's larger strategy to reform the regulatory landscape and the relationship between the regulators and the regulated. The other component is transparent, open, and accountable notice-and-comment rulemaking where agencies seek to create, define, and regulate the rights, duties, and powers of private parties. The Supreme Court itself has stated that agencies cannot avoid notice-and-comment procedures when promulgating substantive rules because such procedures "were designed to assure fairness and mature consideration of rules of general application." *See NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 764 (1969).

Adopting the Justice Department's position on guidance—that all externally binding guidance is unconstitutional—would be in the best interest of HHS itself. Courts have exhibited no qualms about invalidating legislative rules promulgated by HHS, where the Department has failed to follow APA notice-and-comment procedures. For instance, in *Texas Children's Hospital v. Azar*—a case decided just two months ago—a court invalidated HHS's and the Centers for Medicare and Medicaid Services' FAQ No. 33, because it was not promulgated through the APA's notice-and-comment procedures. *See Texas Children's Hosp. v. Azar*, No. 14-2060, 2018 WL 2464462, *12 (June 1, 2018). HHS posted FAQ No. 33 to Medicaid.gov, informing disproportionate-share hospitals that the costs reimbursed by private insurance—previously not a factor in disproportionate-share calculations—must, as of the date of the post, be included in payment adjustment calculations. *Id.* at *3.

The court explained that the Medicaid Act "clearly" does not provide for an offset of private insurance payments. *Id.* at *5. The court proceeded to employ the four-part *American Mining Congress* test to determine whether the FAQ No. 33 was an interpretive or a legislative rule. *See id.* at 10-11. The court determined that "in the absence of [FAQ No. 33] there [was] no

adequate legislative basis for ... agency action ... to ensure performance of duties because neither the statute nor the 2008 Rule support[ed HHS's] policy." *Id.* at 11 (internal quotations omitted). Moreover, the court found that FAQ No. 33 substantively changed existing law by modifying the formula for calculating the hospital-specific limits not previously established. *See ibid.* Thus, "[b]ecause FAQ 33 was issued without notice and comment, it is an illegally promulgated rule, and the Court must set it aside." *Id.* at 12.

In a case decided just one year ago, *Allina Health Services v. Price*, the District of Columbia Circuit Court of Appeals invalidated an HHS Medicare "fractions" spreadsheet because it was not promulgated through the Medicare Act's notice-and-comment procedures. *See Allina Health Servs. v. HHS*, 863 F.3d 937, 945 (D.C. Cir. 2017). The new fractions changed the amount of reimbursement adjustments paid to hospitals that treated a disproportionately high number of low-income patients. *Id.* at 938. In an opinion written by Judge Kavanaugh, the court flatly rejected HHS's argument that the fractions were an interpretive rule, exempt from notice-and-comment rulemaking. *Id.* at 944. First and foremost, Judge Kavanaugh noted that the fractions were, "at the very least, a 'requirement.'" *Id.* at 943. Indeed, since "[f]iscal intermediaries [were] *commanded* to use HHS' Medicare fractions[,]" the fractions were "substantive law." *Ibid* (emphasis in original). As substantive law, the fractions created, defined, and regulated the rights, duties, and powers of the regulated parties. *Ibid.* Thus, "[b]ecause HHS did not undertake notice-and-comment rulemaking, the 2012 Medicare fractions [were] procedurally invalid." *Id.* at 944.

Texas Children's Hospital and *Allina Health Services* are two very recent examples (among many) that demonstrate why HHS should wholeheartedly welcome NCLA's proposed rule. *Allina Health Services* illuminates the precarious position in which HHS finds itself when

it seeks to avoid notice-and-comment rulemaking in a vast hydra-like bureaucracy. In that case, HHS violated the *Medicare Act's* notice-and-comment requirements, not the APA's. HHS oversees 11 agencies, and numerous offices under those agencies, governed by a myriad of statutes and regulations strewn across the United States Code and the Code of Federal Regulations. HHS administrators and directors need clearly defined processes in order to perform their job effectively—adopting NCLA's proposed rule at the departmental level would provide all of them with much-needed direction and prevent agencies from pursuing binding rulemaking through internally-inconsistent (and invalid) procedures and processes.

Texas Children's Hospital illuminates the profound disruption to HHS's regulatory priorities and agenda when it promulgates substantive, legislative rules without notice and comment. The court noted that between the time it granted a preliminary injunction against enforcement of FAQ No. 33 and the date of its decision invalidating HHS's binding guidance, *all* federal courts that had considered injunctions against enforcement of HHS's guidance granted the injunctions, including such diverse jurisdictions as the District Courts for New Hampshire and Minnesota, the Eastern District of Virginia, the Middle District of Tennessee, and the Western District of Missouri. *See Texas Children's Hosp.*, 2018 WL 2464462, *4. In promulgating its FAQ No. 33, HHS tried to save itself a few months by avoiding the notice-and-comment process—what did it get in return? It got litigation that wasted precious agency financial and human resources, that perpetuated regulatory uncertainty in the $7 trillion healthcare industry, and that resulted in HHS starting back at the beginning, not one step closer to a new rule regarding Medicare fraction calculations.

At times, notice and comment may take a little longer than *ad hoc* guidance, but in the long run, notice and comment are far more cost effective and time efficient for the Department.

HHS would do well to advance a new rule at the departmental level that would end its agencies' practice of issuing purportedly binding guidance without notice and comment.

C. The Need for the Rule—Meta-Guidance Is Insufficient

Given the legal background, the various reform efforts outlined above are important measures to rein in improper guidance documents. In particular, the OMB Bulletin and the Sessions and Brand Memos clearly identify some of the worst features of the guidance problem and provide a good start in the broader regulatory reform effort. However, even these documents do not go far enough to combat the pernicious harms caused by binding guidance, primarily because they constitute, at most, mere guidance on guidance. While these meta-guidance documents advance essential points and identify key regulatory pathologies, they are ultimately policy announcements within their supervised agencies. Hence, they should not be the sole model for HHS's reform efforts.

In order to truly solve the underlying problems, HHS should issue binding and final rules prohibiting any HHS component from issuing, relying on, or defending improper agency guidance.[3] The first and most significant problem with the previously mentioned meta-guidance documents is that none has any permanent or binding effect. Even though the OMB Bulletin was issued following notice-and-comment proceedings, it nevertheless serves only as a guide for good agency practice in future contexts. It provides non-binding suggestions for good practice, and specifically disclaims the creation of "any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person." OMB Bulletin, 72 Fed. Reg. at 3439. In other

[3] The proposed internal rule would be controlling only within HHS and is not strictly a "substantive" or "legislative rule" as that term is otherwise used in this document. Such rules should be considered "housekeeping" rules that have a controlling effect within the Department but cannot bind parties outside the Department without an additional grant of rulemaking authority. *Chrysler Corp.*, 441 U.S. at 310-11.

words, to the extent that the OMB Bulletin might be ignored, an affected party has no means of redress. And, notably, since the OMB Bulletin was issued, Executive Branch agency action has been promulgated in apparent defiance of the bulletin. *See, e.g.*, *Elec. Privacy Info. Ctr.*, 653 F.3d at 8 (invalidating Department of Homeland Security rule as legislative rule that failed to comply with APA notice-and-comment requirements); *Hemp Indus. Ass'n*, 333 F.3d at 1091 (same for DEA rule). Further, to the extent that improper guidance may escape judicial review for other reasons, one may only guess how many other improper guidance documents have been issued notwithstanding the bulletin. *See, e.g.*, *Soundboard Ass'n*, 888 F.3d at 1271-73 (agency documents issued in 2009 and 2016 could not be reviewed even if "regulated entities could assert a dramatic impact on their industry" resulting from the documents).

The Sessions and Brand Memos both disclaim that those documents even rise to the level of "guidance" at all and insist instead that they are mere "internal directives [and] memoranda." Sessions Memo at 2-3; Brand Memo at 1. Thus, to the extent offices or individuals within HHS ignore these guidelines, the Justice Department's stated policy is not to pursue a civil enforcement action against the private party allegedly violating HHS binding guidance, as the guidance could "not be relied upon to, create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal." Sessions Memo at 3; Brand Memo at 2.

Aside from constituting little more than noble policy goals, any of these documents could also be immediately rescinded at any time, and without seeking any input from affected entities. While the OMB Bulletin followed notice-and-comment procedures, it was not required to have done so, because it was not a binding legislative rule. *See* 5 U.S.C. § 553(b). And, if a new administration chose to summarily rescind it, it would be entitled to do so without any formal procedures. *See Perez*, 135 S. Ct. at 1203 (agency action not subject to mandatory notice-and-

comment procedures may be altered or rescinded at will). So too could the Sessions and Brand Memos be rescinded with little notice or fanfare.

Next, none of these efforts solved the underlying problem that prior, improperly-issued guidance documents evaded judicial review—and continue to do so. As discussed, even where "regulated entities could assert a dramatic impact on their industry," and even when such agency guidance is actually improper legislative rulemaking, it may nevertheless escape judicial review as non-final action. *See Soundboard Ass'n*, 888 F.3d at 1272. Add to this list the fact that an agency action might also violate the OMB Bulletin, and the result still remains the same. But the inability to subject the action to judicial review can have momentous, and even disastrous, consequences for regulated industries that might "feel pressure to voluntarily conform their behavior because the writing is on the wall." *Nat'l Mining Ass'n*, 758 F.3d at 253.

Finally, even to the extent that the documents genuinely confine improper rulemaking, each contains significant limitations to its scope. The OMB Bulletin only applies to "significant guidance" documents issued by the limited number of "Executive Branch departments and agencies," not to independent agencies. OMB Bulletin, 72 Fed. Reg. at 3433, 3436. Similarly, the Sessions Memo only applies to a subset of Department of Justice actions. Sessions Memo at 1. And while the Brand Memo has some effect when external agency guidance documents are relevant to DOJ action, it is still confined to an extremely narrow class of future "affirmative civil enforcement" cases. Brand Memo at 1. Only a new and clearly binding rule can reliably and predictably provide relief for those seeking clarity and certainty in HHS rule enforcement. For that reason, Petitioner has provided the text for an adequate and effective rule below.

D. Text of the Proposed Rule

While the most effective, efficient, and logical way to promulgate the following rule would be to do so at the departmental level, the following text could be readily changed by individual HHS agencies wishing to pursue reform on their own.

Section 1: Requirements for Issuance of Legislative Rules

a. Neither the Department of Health and Human Services nor any office operating within HHS may issue any "legislative rule" without complying with all requirements set out in 5 U.S.C. § 553.

b. Any pronouncement from the Department or any office operating within HHS that is not a "legislative rule" must:

i. Identify itself as "guidance" or its functional non-legislative equivalent, or as an internal HHS regulation as authorized by applicable enabling legislation;

ii. Disclaim any force or effect of law;

iii. Prominently state that it has no legally binding effect on persons or entities outside the agency or office itself;

iv. Not be used for purposes of coercing persons or entities outside the agency or office itself into taking any action or refraining from taking any action beyond what is already required by the terms of the applicable statute; and

v. Not use mandatory language such as "shall," "must," "required," or "requirement" to direct parties outside the federal government to take or refrain from taking action, except when restating—with citations to statutes or binding judicial precedent—clear mandates contained in a statute;

c. A regulated entity's noncompliance with any agency pronouncement other than a "legislative rule," issued from any agency (whether or not the agency or office is

operating within the Department), may not be considered by any entity within HHS in determining whether to institute an enforcement action or as a basis for proving or adjudicating any violation of applicable law.

d. No office operating within the Department may apply any "legislative rule," as defined by this rule, issued by HHS or any other agency, no matter how styled, which has not complied with all requirements set out in 5 U.S.C. § 553.

e. No office operating within the Department may defend the validity of any "legislative rule," as defined by this rule, issued by HHS or any other agency, no matter how styled, which has not complied with all requirements set out in 5 U.S.C. § 553, in any court or administrative proceeding.

Section 2: Judicial Review

a. Any "interested party" may petition any office operating within the Department to determine whether a prior agency pronouncement, no matter how styled, is a "legislative rule" as defined by this rule.

b. Such a petition for review shall be filed in writing with the agency or office, pursuant to the procedures set out in compliance with 5 U.S.C. § 553(e).

c. Any office operating within the Department must respond to such a petition for review within 60 calendar days of receipt of the petition.

d. The office operating within the Department must respond by either:

i. Rescinding the prior agency pronouncement; or

ii. Denying the petition for review on the basis that the agency pronouncement under review did not constitute a "legislative rule," or on the basis that the agency pronouncement was adopted in compliance with all of the requirements set out in 5 U.S.C. § 553.

e. Any agency determination under section (d) must be made in writing and must be promptly made publicly available and must include a formal statement of reasons for

determining that the pronouncement under review does or does not constitute a "legislative rule," or does or does not comply with 5 U.S.C. § 553.

f. If the office fails to respond to a petition for review within the 60-day period, such an action shall constitute a denial of the petition on the basis that the agency pronouncement under review did not constitute a "legislative rule."

g. If any agency or office pronouncement is determined to not be a "legislative rule" under parts (d), (e) or (f), the agency or office shall promptly announce that the pronouncement has no binding force.

h. Any agency pronouncement, action or inaction set out in parts (d), (e), (f) or (g), shall constitute final agency action under 5 U.S.C. § 704, and shall be subject to review pursuant to 5 U.S.C. § 702.

i. For purposes of this rule, no matter how styled or when issued and irrespective of any other agency determination, the issuance of any "legislative rule" by any agency or office operating within the Department shall be deemed final agency action under 5 U.S.C. § 704.

Section 3: Definitions

a. For purposes of this rule, the term "legislative rule" means any pronouncement or action from any covered agency or office that purports to:

i. Impose legally binding duties on entities outside the covered agency or office;

ii. Impose new requirements on entities outside the covered agency or office;

iii. Create binding standards by which the covered agency or office will determine compliance with existing statutory or regulatory requirements; or

iv. Adopt a position on the binding duties of entities outside the covered agency or office that is new, that is inconsistent with existing regulations, or that otherwise effects a substantive change in existing law;

b. For purposes of this rule, the term "interested person" has the same meaning used in 5 U.S.C. §§ 553, 555; *provided that* a person may be "interested" regardless of whether they would otherwise have standing under Article III of the United States Constitution to challenge an agency action.[4]

E. Benefits of the Rule

The proposed rule furthers the policy objectives of the OMB Bulletin, the Sessions and Brand Memos, and the Department's stated commitment to more transparent, open, and accountable processes. The proposed rule will establish HHS's position that all binding guidance is unlawful, and where HHS must act at the behest of Congress to promulgate rules that will have the force of law, it may only do so through APA notice-and-comment procedures.

Substantively, many of the proposed rule's edicts are found either in existing law or the OMB Bulletin and Sessions and Brand Memos. Consistent with these sources, Section 3(a) adopts a comprehensive definition of the term "legislative rule," which accurately encompasses the binding and coercive nature of such agency action, regardless of how it might be styled. Section 1(b) also adopts clear rules for how other agency actions must be undertaken and prohibits improper attempts at evading more formal rulemaking procedures.

But the proposed rule also fixes the gaps in those other policy statements. First, and most significantly, as a final rule, the proposed rule is binding and may not be rescinded at will. Section 1(a) directs that agencies may not bypass formal procedures when issuing legislative rules. Section 1(b) further sets out mandatory requirements for informal agency action. Section 1(c) also forbids improper coercive action. To that end, this section prohibits the Department

[4] *See Animal Legal Def. Fund, Inc. v. Vilsack*, 237 F. Supp. 3d 15, 21 (D.D.C. 2017) (Cooper, J.) (a party may be an "interested person" under the APA even without Article III standing).

from considering a party's decision to abstain from non-binding suggestions in guidance as somehow constituting evidence of a violation of an actual legal obligation, or as a basis for instituting an enforcement action. Section 1(d) prohibits the Department from applying any agency's legislative rules that do not conform to 5 U.S.C. § 553. Finally, Section 1(e) prohibits the Department from defending the validity of improper agency guidance, whether or not it was promulgated within HHS. These requirements are binding on the covered entities.

Critically, this proposed rule also creates a means to enforce these requirements, which applies to both new rules and those already in existence. Section 2 empowers interested parties to alert covered agencies or offices to improper action, whenever issued, and allows the agency or office to rescind such action without complication. This provision efficiently allows those most affected by agency action to share their institutional knowledge with the agency, and it also allows the agency to efficiently correct improper actions.

But if this voluntary process falls short, Section 2 also allows an interested person the opportunity to petition for judicial review. If an agency believes that its action is appropriate under this rule, it need only say so pursuant to Section 2(d), and explain why its action does not constitute improper legislative rulemaking. Sections 2(d), (e), (f) and (h) set out a process by which a court may decide this legal issue on the merits. Sections 2(g) and (h) also resolve the difficult finality question that commonly allows improper legislative rulemaking to evade judicial oversight. Section 2(g) designates an agency's decision on a petition for review as final, thus establishing a concrete cause of action. Section 2(h), meanwhile, resolves the problem that may exist when agency action is improperly binding, but nevertheless evades review because it is not yet final, by deeming any binding action necessarily one that is also final.

VI. Conclusion

Americans should never be "at the mercy" of the whims of administrative agencies, set out in extralegal and extortionate "guidance" for approved behavior. Hamburger, *supra*, at 260. Purportedly binding rules masquerading as guidance are unlawful and unconstitutional and are among the very worst threats to liberty perpetrated by the administrative state. The Department of Health and Human Services should enact clear rules that respect the limits set by the Constitution, the APA, and all other statutes applicable to HHS and its Operating Divisions regarding procedures for promulgating substantive, legislative rules. HHS should therefore prohibit the issuance, reliance on, or defense of improper agency guidance, and promulgate the proposed rule set out in this Petition.

Sincerely,

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