

 New Civil Liberties Alliance

September 16, 2020

**VIA REGULATIONS.GOV**

Ms. Brenna Jenny  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Room 713-F  
Washington, DC 20201

Re: *Department of Health and Human Services Good Guidance Practices,*  
Docket Number HHS-OS-2020-0008

Dear Ms. Jenny,

The New Civil Liberties Alliance (NCLA) submits the following comment in response to the Department of Health and Human Services' (HHS) request for comment on its August 20, 2020 notice of proposed rulemaking. *See* Department of Health and Human Services Good Guidance Practices, 85 Fed. Reg. 51396 (Aug. 20, 2020) (to be codified at 45 C.F.R. subtitle A, subchapter A, pt. 1) (HHS Proposed Guidance Procedures Rule). Under its Proposed Guidance Procedures Rule, "HHS's response to any [petition for review of improperly issued guidance] would be considered final agency action reviewable in court."<sup>1</sup> *Id.* at 51399. NCLA commends HHS for including a finality

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<sup>1</sup> On September 6, 2018, NCLA submitted a petition for rulemaking and proposed rule to HHS, urging the department to promulgate formal guidance procedures in view of frequent misuse of agency guidance. *See* NCLA, Petition for Rulemaking to Promulgate Regulations Prohibiting the Issuance, Reliance on, or Defense of Improper Agency Guidance (Sept. 6, 2018), *available at* <https://nclalegal.org/wp-content/uploads/2019/01/2018-09-06-Petition-for-Rulemaking-HHS.pdf> (NCLA September 2018 Petition). The following year, President Trump issued Executive Order No. 13891 requiring agencies to curb such improper agency guidance practices and promulgate procedural rules to that end. *See* Promoting the Rule of Law Through Improved Agency Guidance Documents, Exec. Order No. 13891, 84 Fed. Reg. 55235 (Oct. 9, 2019). NCLA submitted an auxiliary letter in support of its September 2018 Petition to HHS on August 6, 2020, at which time the agency had yet to respond to NCLA's petition or comply with the Executive Order's directives (August 2020 Letter). Subsequently on August 20, 2020 HHS issued its Proposed Guidance Procedures Rule and invited comment, to which NCLA now responds.

statement in its proposed guidance rule—a procedural protection that is vital to regulated parties’ ability to have their rights adjudicated. NCLA also appreciates the agency’s invitation to comment on its Proposed Guidance Procedures Rule, which partly adopts suggestions made in NCLA’s [September 2018 Petition for Rulemaking](#). HHS’s partial incorporation of the procedures outlined in NCLA’s proposed rule signals that it is invested in meaningful regulatory reform that curbs abuses of administrative power—an issue central to NCLA’s mission.

NCLA incorporates and re-adopts the facts and reasoning set forth in both its September 2018 Petition and August 2020 Letter. This comment responds specifically to the portion of HHS’s Proposed Rule that would allow regulated parties to petition for withdrawal or modification of guidance documents—procedures germane to finality and judicial review of agency guidance.

## **I. Statement of Interest**

Having petitioned HHS for adoption of adequate agency guidance procedures, NCLA has a continuing interest in the adoption of aspects of the HHS Proposed Guidance Procedures Rule. NCLA is a nonpartisan, nonprofit civil rights organization and public-interest law firm devoted to defending constitutional freedoms. The “civil liberties” of the organization’s name include rights at least as old as the U.S. Constitution itself, such as a jury trial, due process of law (which includes fair notice of legal obligations), the right to be tried in front of an impartial and independent judge, and the right to live under laws made by the nation’s elected lawmakers through constitutionally prescribed channels. Yet these selfsame rights are also very contemporary—and in dire need of renewed vindication—precisely because Congress, federal administrative agencies, and sometimes even the courts have trampled them for so long.

NCLA views the administrative state as an especially serious threat to civil liberties. No other current aspect of American law denies more rights to more Americans. 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 designed to prevent.<sup>2</sup> This unconstitutional administrative state within the Constitution’s United States is the focus of NCLA’s attention.

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, adjudication, and enforcement. The courts are not the only government bodies with the duty to attend to the law. Even

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<sup>2</sup> See generally Philip Hamburger, *Is Administrative Law Unlawful?* (2014).

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, adjudication, and enforcement comply with the Administrative Procedure Act (APA) and with the Constitution.

## **II. The Agency Should Amend the Proposed Rule to Expressly Provide for Availability of Judicial Review After the Final Disposition of Petition for Withdrawal or Modification of Guidance Documents and a Definite Timeline for Required Agency Response**

Finality and meaningful judicial review are recurring problems with respect to agency guidance documents.<sup>3</sup> In conformity with the requirements of Executive Order 13891, § 4, the HHS Proposed Guidance Procedures Rule has at least alluded to the agency’s intent to provide an avenue for judicial review of petitions for withdrawal or modification by noting—in the proposed rule’s precatory language—that “HHS’s response to any such petition would be considered final agency action reviewable in court.”<sup>4</sup> While NCLA commends HHS for its proposed treatment of petition dispositions as final agency action, mere precatory language does not go far enough to guarantee the opportunity for judicial review, and NCLA urges the agency to include such language in the body of the final rule itself. HHS’s adopting NCLA’s Petition would remedy this deficit and satisfy the requirements of Executive Order 13891, § 4 in full. Alternatively, NCLA recommends that HHS include an explicit judicial review provision in its final rule by adding the following language to section 1.5 of the proposed rule:

(f) *Judicial Review.* Any agency pronouncement, response, or failure to respond pursuant to subsections (d) and (e) of this section shall constitute final agency action under 5 U.S.C. § 704 and shall be subject to review pursuant to 5 U.S.C. § 702.

Thus, if it is the view of the agency that a court may review HHS’s disposition of a petition, then why not make the availability of judicial review both explicit and definite? Such a clear statement is useful to both the public and the courts and furthers the spirit and requirements of Executive Order 13891 and its companion, Executive Order 13892.<sup>5</sup>

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<sup>3</sup> See NCLA September 2018 Petition, at 9–11; see also *Appalachian Power Co. v. Envtl. Prot. Agency*, 208 F.3d 1015, 1020 (D.C. Cir 2000).

<sup>4</sup> HHS Proposed Guidance Procedures Rule, 85 Fed. Reg. at 51399.

<sup>5</sup> Promoting the Rule of Law Through Improved Agency Guidance Documents, Exec. Order No. 13891, 84 Fed. Reg. 55235 (Oct. 9, 2019); Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication, Exec. Order No. 13892, 84 Fed. Reg. 55239 (Oct. 9, 2019).

The HHS Proposed Guidance Procedures Rule also includes a suspension provision allowing the agency to postpone its 90-day response deadline in order to seek “additional information” for as long as it takes the Department to “complete consultation with other stakeholders.”<sup>6</sup> As proposed, section 1.5 affords regulated parties the right to contest agency rules but provides inadequate recourse for the petitioner whose request for withdrawal or modification prompts further agency inquiry. By failing to provide an ultimate deadline for agency response, particularly in complex cases where additional time may be necessary, the proposed rule risks relegating petitioners to administrative purgatory until some *unknown future date*. This arrangement creates the very same problematic avenues for agency avoidance of finality and judicial review as exist under the current scheme. To cure this defect, NCLA recommends that the proposed rule include an additional provision giving definite shape to any period of suspension and information gathering. Given that HHS abides by a 30-day public notice-and-comment procedure in other guidance-related instances, NCLA suggests that the agency incorporate an equivalent process for suspended petition responses to the language of section 1.5:

(d)(3) Any suspension and information-gathering period initiated under part (d) of this section shall take place through a maximum 90-day public notice-and-comment period on any petition for withdrawal or modification, and shall be published in the Federal Register and posted in the guidance repository.

### III. Conclusion

Thank you again for this opportunity to provide NCLA’s view on this important rulemaking proposal. Should you have any questions, please contact Kara Rollins, Litigation Counsel, at [kara.rollins@ncla.legal](mailto:kara.rollins@ncla.legal).

Kind regards,



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<sup>6</sup> HHS Proposed Guidance Procedures Rule, 85 Fed. Reg. at 51401.