November 19, 2021

VIA REGULATIONS.GOV
Daniel J. Barry
Acting General Counsel
Department of Health and Human Services
200 Independent Ave., SW
Washington, DC 20201

Re: *Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures*, RIN-0991-AC29

Mr. Barry:

The New Civil Liberties Alliance ("NCLA") submits the following comment in response to the notice of proposed rulemaking issued by the Department of Health and Human Services ("HHS"), *Department of Health and Human Services Proposed Repeal of HHS Rules on Guidance, Enforcement, and Adjudication Procedures*, 86 Fed. Reg. 58,043 (Oct. 20, 2021) ("Proposed Rule"). Among other things, the Proposed Rule would rescind regulations at 45 C.F.R. §§ 1.6, 1.7, and 1.8 (collectively "Fair Notice Regulations"), which were promulgated to ensure fair notice to regulated persons in enforcement actions. NCLA appreciates this opportunity to express its concerns about the Proposed Rule. As explained below in more detail, the proposed rescission of Fair Notice Regulations is arbitrary and capricious under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), for at least two reasons: (1) HHS failed to provide a reasoned explanation for their rescission; and (2) it failed to account for regulated persons' legitimate reliance on the Fair Notice Regulations.

## STATEMENT OF INTEREST

NCLA is a nonpartisan, nonprofit civil-rights organization and public-interest law firm devoted to defending constitutional freedoms. The administrative state poses an especially serious threat to civil liberties. No other current aspect of American law denies more rights to more people. Although Americans still enjoy the shell of their Republic, a vastly different sort of government has developed within it—a type, in fact, that the Framers designed the Constitution to prevent.[1] This unconstitutional state within the United States is the focus of NCLA's attention.

In addition to suing agencies to enforce constitutional limits on the exercise of administrative power, NCLA encourages agencies 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 have a duty to follow the law and avoid unlawful modes of governance. All agencies must ensure that their modes of rulemaking, adjudication, and enforcement comply with the APA and the Constitution.

## BACKGROUND

On January 14, 2021, HHS issued a final rule entitled *Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions*, 86 Fed. Reg. 3,010 (Jan. 14, 2021) ("Civil Enforcement Rule"). The Civil Enforcement Rule was issued "[t]o provide regulated parties with greater transparency and fairness in administrative actions," and added three Fair Notice Regulations to 45 C.F.R. Part 1:

- 45 C.F.R. § 1.6 prohibits HHS from relying on non-binding guidance to allege or establish violations of law in enforcement actions. Rather, HHS "must allege or establish the violation of law by applying statutes or regulations." *Id.*
- 45 C.F.R. § 1.7 states that, in enforcement actions, "the Department may only apply standards or practices that have been publicly stated in a manner that would not cause

[1] *See generally* Philip Hamburger, *Is Administrative Law Unlawful?* (2014).

unfair surprise."[2] This provision reflects the Department's legal interpretation of *Christopher v. SmithKline Beecham*, 567 U.S. 142, 156 (2012), cited at 84 Fed. Reg. 3011-12, which held that principles of fair notice would be violated if the Court deferred to an agency's legal interpretation articulated publicly for the first time in an enforcement action.

- 45 C.F.R. § 1.8 requires HHS to give regulated persons fair notice by publishing any agency adjudication decisions and non-public litigation documents it relies on to expand its enforcement jurisdiction. Similarly, HHS may not seek judicial deference to its interpretation of a non-public litigation document to expand its own jurisdiction without first publishing a notice and explanation.

These Fair Notice Regulations protect due-process rights of regulated persons by providing grounds to challenge unfair enforcement. The Civil Enforcement Rule also contained a procedural regulation at 45 C.F.R. § 1.9 providing for pre-enforcement hearings in certain situations.[3]

On January 20, 2021, the incoming President issued an executive order directing agencies to rescind regulations that "threaten to frustrate the Federal Government's ability to confront urgent challenges facing the Nation, including the coronavirus disease 2019 pandemic, economic recovery, racial justice, and climate change." *Revocation of Certain Executive Orders Concerning Federal Regulations*, 86 Fed. Reg. 7,049 (Jan. 25, 2021) (E.O. 13,892). The Proposed Rule cites this executive order and two others—*Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*, 86 Fed. Reg. 7,009 (Jan. 25, 2021) (E.O. 13,985) and *Strengthening Medicaid and the Affordable Care Act*, 86 Fed. Reg. 7,793 (Feb. 2, 2021) (E.O. 14,009)—as reasons for rescinding the Fair Notice Regulations. 86 Fed. Reg. 58,044-45.

**RESCISSION OF FAIR NOTICE REGULATOINS IS ARBITRARY AND CAPRICIOUS**

The rescission of 45 C.F.R. §§ 1.6, 1.7, and 1.8 is arbitrary and capricious for two reasons. *First*, rescission was not accompanied by a reasoned explanation for HHS's sudden change in position regarding

[2] The term "unfair surprise" is defined at 45 C.F.R. § 1.2 as "a lack of reasonable certainty or fair warning from the perspective of a reasonably prudent member of regulated industry of what a legal standard administrated by an agency requires."

[3] The pre-enforcement hearing does "not apply where the Department, in its discretion, determines there is serious threat to health, safety or other similar emergency, or where a statute specifically authorizes proceeding without a prior opportunity to be heard." 45 C.F.R. § 1.9(c).

fair notice. *See FCC v. Fox Television Stations Inc.*, 556 U.S. 502, 515 (2009). *Second*, HHS failed to account for legitimate reliance interests. *See Dep't of Homeland Security v. Regents of the University of California*, 140 S. Ct. 1891, 1913 (2020).

**I. HHS Failed to Provide a Reasoned Explanation**

To avoid being arbitrary and capricious when changing policies, "the agency must show that there are good reasons for the new policy." *Fox*, 556 U.S. at 515. Additionally, when the "new policy rests on factual findings that contradict those which underlay its prior policy … a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Id.* The Proposed Rule fails to explain why it is disregarding HHS's original reasons for promulgating 45 C.F.R. §§ 1.6, 1.7, and 1.8.

To start, executive orders do not provide adequate justification for rescinding regulations. *See California v. Bernhardt*, 472 F. Supp. 3d 573, 605 (N.D. Cal. 2020) ("BLM's reliance on Executive Order 13783 falls short of supplying the required 'reasoned explanation' for the Rescission"). As such, HHS's reference to executive orders does not satisfy the APA's reasoned explanation requirement. *See* 86 Fed. Reg. 58,044-45 (citing E.O. 13,992, 13,985, and 14,009). HHS lists three additional reasons for rescinding §§ 1.6, 1.7, and 1.8: namely, they "(1) [c]reate[] unnecessary hurdles and roadblocks in agency actions, likely to the detriment of the public; (2) conflict[] with and undermine[] current agency processes; and (3) divert[] critical Department resources." *Id.* at 58.050. None is adequate.

*A. The Fair Notice Regulations Do Not Create Unnecessary Hurdles*

The "unnecessary hurdles" explanation focuses on pre-enforcement hearings under 45 C.F.R. § 1.9. 86 Fed Reg. 58,050-51. HHS did not even mention 45 C.F.R. § 1.6 in this part of its explanation, let alone explain why its prohibition against using noncompliance with guidance documents to establish violations presents an "unnecessary hurdle" in enforcement actions. HHS has repeatedly stated that its guidance documents are not legally binding. *See, e.g.*, *Clarian Health W., LLC v. Hargan*,

878 F.3d 346, 357 (D.C. Cir. 2017) ("[I]t is noteworthy that HHS has characterized its instructions as mere guidance … [that] have no binding effect[.]"); *Colwell v. Dep't of Health & Hum. Servs.*, 558 F.3d 1112, 1125 (9th Cir. 2009) ("Defendants, on the other hand, contend that the Policy Guidance is mere guidance to HHS in the exercise of its discretion and has no binding effect."). If, as HHS repeatedly claims, guidance documents have no legal effect, then noncompliance with them cannot establish violations of law. HHS must instead prove noncompliance with a statute or regulation—both of which have legal effect—to establish a violation of law. That is not a "hurdle" but rather a prerequisite for legal due process.

HHS's "unnecessary hurdle" explanation does discuss 45 C.F.R. § 1.7. According to HHS, § 1.7's prohibition against using non-public standards in an enforcement proceeding to cause unfair surprise "is inconsistent with settled case law." 86 Fed. Reg. 58,050. Specifically, HHS references the Supreme Court's "refus[al] to say that the [Securities and Exchange] Commission … was forbidden from utilizing [an adjudicative] proceeding for announcing and applying a new standard for conduct" in *SEC v. Chenery*, 332 U.S. 194, 203 (1947) ("*Chenery II*"), cited at 86 Fed. Reg. 58,050 n.6. This explanation, however, ignores the fact that HHS promulgated 45 C.F.R. § 1.7 to reflect the Supreme Court's more recent decision in *SmithKline*, 567 U.S. at 156, cited at 84 Fed. Reg. 3,011-12. The *SmithKline* Court said what the *Chenery* Court refused to say: allowing an agency to apply new legal standards in the context of an enforcement proceeding "would seriously undermine the principle that agencies should provide regulated parties fair warning of the conduct a regulation prohibits or requires." *Id.* (cleaned up).[4] At least since *SmithKline*, "settled case law" does not allow regulatory agencies to announce and apply new legal standards in enforcement proceedings. *See, e.g., ExxonMobil*

[4] *See also Chenery II*, 332 U.S. at 194 (Jackson, J., dissenting) ("But before transactions otherwise legal can be outlawed or denied their usual business consequences, they must fall under the ban of some standards of conduct prescribed by an agency of government authorized to prescribe such standards.") (quoting *SEC v. Chenery Corp.*, 318 U.S. 80, 92 (1943) ("Chenery I")).

*Pipeline Co. v. United States Dep't of Transp.*, 867 F.3d 564, 579 (5th Cir. 2017) (holding that applying agency's novel standard "in this enforcement action would constitute unfair surprise and deprive ExxonMobil of the fair notice to which it is entitled."). As such, HHS may not rely on "settled case law" to explain its rescission of 45 C.F.R. § 1.7. Any explanation for rescinding 45 C.F.R. § 1.7 must therefore include some rationale for why HHS has changed its legal understanding of *SmithKline*, which was the basis for that regulation. *See* 86 Fed. Reg. 3012. But the Proposed Rule does not even mention that seminal Supreme Court decision.

Finally, 45 C.F.R. § 1.8's requirement that HHS publish administrative decisions and non-public legal documents it relies on to expand jurisdiction ensures HHS's assertions of jurisdiction comply with fair notice and do not cause unfair surprise. HHS's "unnecessary hurdle" explanation makes no mention of 45 C.F.R. § 1.8, and as such does not provide a reasoned explanation for its rescission.

*B. The Fair Notice Regulations Do Not Create Conflict with or Undermine Current Agency Procedures*

Next, HHS's "conflict or undermine" explanation lists several enforcement procedures that it contends are incompatible with 45 C.F.R. § 1.9's pre-enforcement hearings. 86 Fed Reg. 58,051 (citing 21 C.F.R. part 17, 42 C.F.R. Part 488, 42 C.F.R. Part 498, and 45 C.F.R. Part 160, subpart E). But these supposed incompatibilities have nothing to do with the Fair Notice Regulations at 45 C.F.R. §§ 1.6, 1.7 and 1.8.

HHS also asserts that "procedural regulations already established within HHS comply with principles of due notice, fairness, and transparency." 86 Fed Reg. 58,051. But it does not actually identify any such regulations, let alone explain how they ensure fair notice and prevent unfair surprise to the same extent as 45 C.F.R. §§ 1.6, 1.7 and 1.8. HHS issued §§ 1.6, 1.7 and 1.8 "[t]o provide regulated parties with *greater* transparency and fairness in administrative actions" than existing regulations presumably provided. 86 Fed. Reg. 3,010 (emphasis added). HHS now contends

preexisting procedural regulations provide the *same* degree of transparency and fairness. 86 Fed Reg. 58,051 ("existing procedures established prior to the Civil Enforcement rule … provided [regulated persons] with sufficient notice"). While an agency is allowed to change its mind, "a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (quoting *Fox*, 556 U.S. at 515-16). Hence, HHS must explain why it discarded its prior belief that the Fair Notice Regulations provided "greater transparency and fairness" for its new belief that they provide no greater transparency and fairness than preexisting regulations. At minimum, HHS must identify what those preexisting regulations are to enable a comparison with the Fair Notice Regulations being rescinded. It instead offers threadbare assertions that fall far short of a reasoned explanation. *See Encino*, 136 S. Ct. at 2127 ("the Department's conclusory statements do not suffice to explain its decision").

HHS's conclusory assertion that 45 C.F.R. §§ 1.6, 1.7 and 1.8 provide the same fairness and transparency as preexisting regulations also contradicts its specious claim that those regulations somehow "conflict with or undermine" preexisting procedures. *See* 86 Fed. Reg. 58,050. The Fair Notice Regulations being rescinded cannot simultaneously be coextensive with and in conflict with preexisting enforcement regulations.

*C. The Fair Notice Regulations Do Not Divert Resources*

HHS contends that "the Civil Enforcement rule could require expenditure of significant resources to respond to spurious challenges to valid enforcement actions and adjudications." 86 Fed. Reg. 58,051. This explanation presumes challenges based on the Fair Notice Regulations are "spurious." Not so. For example, a challenge under 45 C.F.R. § 1.7 to HHS's reliance on a novel interpretation in an enforcement action as "unfair surprise" is plainly proper under clear-cut Supreme Court precedent. *SmithKline*, 567 U.S. at 156. Section 1.7's prohibition against unfair surprise "diverts

resources" only in the sense that it prevents HHS from taking unlawful shortcuts in enforcement actions.

When HHS promulgated the Fair Notice Regulations, it stated they were necessary to give regulated parties a method to challenge certain types of unfair enforcement. *See* 86 Fed. Reg. 3,011 ("The rule is designed to ensure accountability, fairness of how the Department uses guidance, proper use of guidance, … and to safeguard the important principles underlying the United States administrative law system"). HHS apparently changed its mind and now believes such challenges to unfair enforcement practices are "spurious." 86 Fed. Reg. 58,051. This turnabout requires a reasoned explanation, *Fox*, 556 U.S. at 515-16, but none is provided.

## II. HHS Failed to Consider Legitimate Reliance Interests

When an agency changes course, it is "required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Regents*, 140 S. Ct. at 1915. Instead of assessing "whether there were reliance interests," *id.*, HHS simply assumed there were none: "the Department doubts any serious reliance interests have accrued." 86 Fed. Reg. 58,050.

According to HHS, "regulated entities would have anticipated that the [fair notice] rules would be reconsidered and potentially rescinded, particularly after the revocation of [due process executive orders] on January 20, 2021," by an incoming presidential administration. But a change in administration cannot extinguish reliance interests. The Trump Administration, for instance, clearly opposed the Deferred Action for Childhood Arrivals ("DACA") program and attempted to end that program within months of taking power. *See Regents*, 140 S. Ct. at 1903. That did not, however, obviate the need to meaningfully consider reliance interests before rescinding DACA. *Id.* at 1915. Similarly, the Biden Administration's public statements disfavoring due process and fair notice in administration proceedings do not obviate HHS's need to afford reliance interests meaningful consideration.

**CONCLUSION**

For the foregoing reasons, HHS's proposal to rescind Fair Notice Regulations at 45 C.F.R. §§ 1.6, 1.7, and 1.8 is arbitrary and capricious. Any final rule HHS promulgates should preserve these regulations that ensure the due process of law accompanies any HHS enforcement proceedings.

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Thank you again for this opportunity to provide NCLA's views on this important issue. Should you have any questions, please contact Sheng Li at sheng.li@ncla.legal.

Sincerely,

**NEW CIVIL LIBERTIES ALLIANCE**

/s/ *Sheng Li*
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