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15 UNITED STATES DISTRICT COURT
16 NORTHERN DISTRICT OF CALIFORNIA
17 SAN JOSE DIVISION

18 COUNTY OF SANTA CLARA, CALIFORNIA
19 TRIBAL FAMILIES COALITION,
NATIONAL ASSOCIATION OF PEDIATRIC
20 NURSE PRACTITIONERS, AMERICAN
LUNG ASSOCIATION, CENTER FOR
21 SCIENCE IN THE PUBLIC INTEREST, and
NATURAL RESOURCES DEFENSE
22 COUNCIL,

Plaintiffs,

23 vs.

24 U.S. DEPARTMENT OF HEALTH AND
HUMAN SERVICES and NORRIS
25 COCHRAN, in his official capacity as Acting
26 Secretary of Health and Human Services,
Defendants.

Case No. 5:21-cv-01655

**COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF**

Administrative Procedure Act Case

28

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1 Plaintiffs the County of Santa Clara, California Tribal Families Coalition, National
2 Association of Pediatric Nurse Practitioners, American Lung Association, the Center for
3 Science in the Public Interest, and Natural Resources Defense Council (collectively,
4 “Plaintiffs”), by and through undersigned counsel, hereby allege as follows:

5 **INTRODUCTION**

6 1. Plaintiffs bring this action under the Administrative Procedure Act
7 (“APA”), 5 U.S.C. § 500 *et seq.*, and the Regulatory Flexibility Act (“RFA”), 5 U.S.C.
8 § 601 *et seq.*, to challenge a final rule recently issued by the U. S. Department of Health
9 and Human Services (“HHS” or “Department”) entitled “Securing Updated and Necessary
10 Statutory Evaluations Timely,” 86 Fed. Reg. 5694 (Jan. 19, 2021) (“Sunset Rule” or
11 “Rule”). Under the guise of an RFA plan for periodically reviewing preexisting
12 regulations that significantly impact small entities, the Sunset Rule amends nearly all HHS
13 regulations to include self-executing expiration dates. The Rule’s impact is vast and
14 unprecedented. Absent separate Department action, approximately 17,200 regulations will
15 “expire” in 2026, with additional regulations automatically terminating afterward.

16 2. HHS, together with its subagencies—such as the Centers for Disease
17 Control and Prevention (“CDC”), the Food and Drug Administration (“FDA”), and the
18 Centers for Medicare and Medicaid Services—administers a broad range of statutory
19 programs that impact nearly every aspect of the American healthcare system, food and
20 drug manufacturing, and social services systems. These programs operate pursuant to
21 regulations that govern, for example, health insurance, hospitals and clinics,
22 pharmaceuticals and vaccines, mental health treatment, Medicare and Medicaid, public
23 health emergency prevention and preparedness, food safety, protections for children and
24 the elderly, and much more. The affected healthcare sector alone accounts for nearly one-
25 fifth of the U.S. economy.

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1 3. HHS has issued regulations implementing its substantive statutes since its
2 inception in 1953. To date, HHS has approximately 18,000 regulations on the books,
3 covering everything from ventilators to the privacy of personal and health information.

4 4. The Sunset Rule, which was proposed and finalized entirely during the
5 outgoing administration's lame-duck period, amends *nearly all* HHS regulations to add
6 self-executing expiration dates. Under the Rule, the vast majority of the Department's
7 existing regulations are set to expire automatically in 2026, with the remainder set to
8 expire over the following five years. The only way under the Rule to prevent expiration is
9 for HHS to conduct and finalize retrospective review of each regulation. This would
10 require a resource-intensive and time-consuming effort on par with full notice-and-
11 comment rulemaking, but at a pace 20 times faster than the Department has ever conducted
12 retrospective review in the past—all without any guarantee that the Department *will*
13 conduct such review. The Rule does not even specify which of the Department's 18,000
14 existing regulations are exempted under the limited exceptions. In other words, the
15 outgoing administration planted a ticking timebomb set to go off in five years unless HHS,
16 beginning right now, devotes an enormous amount of resources to an unprecedented and
17 infeasible task.

18 5. The Rule creates incalculable costs and chaos. It schedules rescission of
19 thousands of the regulations that structure Plaintiffs' highly technical operations and
20 obligations, delineate their and their members' rights, and protect the populations they
21 serve. It directly harms Plaintiffs and the general public, including the elderly, children,
22 healthcare professionals, tribal governments and members, and anyone who needs medical
23 care, is affected by pandemics or disasters, or simply eats food.

24 6. The Sunset Rule, moreover, creates immediate uncertainty and instability
25 throughout the healthcare system at the very time that the public most needs clear
26 guidelines due to a global pandemic. Plaintiffs have no guarantee that HHS will complete
27 retrospective review on such a mass scale and must assume that any, or all, of the
28 regulations that affect them will disappear. Regulated entities and individuals, such as

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