



December 16, 2021

The Honorable Xavier Becerra  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

**Re: Securing Updated and Necessary Statutory Evaluations Timely; Proposal To Withdraw or Repeal**

Dear Secretary Becerra:

Thank you for the opportunity to comment on this proposed rule to withdraw or repeal the final rule entitled "Securing Updated and Necessary Statutory Evaluations Timely" (SUNSET rule).

The American Lung Association is the oldest voluntary public health association in the United States, representing the millions of Americans living with lung diseases. The Lung Association is the leading organization working to save lives by improving lung health and preventing lung disease through research, education and advocacy.

In December 2020, the Lung Association filed comments with patient advocacy and tobacco control partners expressing our grave concerns with the proposed SUNSET rule and urging the Department to immediately withdraw it (Attachments A and B). The rule, which was finalized in January 2021, would significantly disrupt the ability of the Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS) to protect individuals from harmful tobacco products and administer critical healthcare programs such as Medicaid, the Children's Health Insurance Program (CHIP), and the Affordable Care Act (ACA) marketplaces. The Lung Association is now a plaintiff in *County of Santa Clara v. U.S. Department of Health & Human Services*, in which we have argued that the Sunset Rule is both procedurally and substantively invalid under the Administrative Procedure Act (APA), the Regulatory Flexibility Act (RFA), and many other substantive statutes (see Attachment C).

The Lung Association appreciates that the Department has reconsidered the comments submitted on the original proposal, as the original rulemaking process did not appropriately consider widespread concerns with the SUNSET rule, and we urge you to make all of the original comments part of the administrative record for the current rulemaking. We strongly support the current rulemaking to repeal the SUNSET rule and offer the following comments on the proposal:

**The SUNSET Rule Exceeds the Department's Authority and is Contrary to Law**

The Lung Association has outlined the legal deficiencies with the SUNSET rule in detail in the *Santa Clara* complaint but will summarize some of the key deficiencies here. First, the Sunset Rule schedules automatic rescission of pre-existing regulations without any consideration of the pre-existing regulation itself, a plan that is invalid under the APA and relevant administrative

law. For example, the authority for issuing Medicaid and CHIP regulations is found in section 1102 of the Social Security Act, which expressly directs the Secretary of HHS to issue regulations “not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which [s/he] is charged under this Act.” This section does not give the Secretary the authority to write automatic expiration dates into regulations. In fact, the risk of automatic expiration if an assessment and review is not conducted within a specified time frame is flatly inconsistent with the “efficient administration” of Medicaid and CHIP. It would force CMS to engage in an endlessly repeating and highly inefficient cycle of assessments of all regulations and reviews of those determined to have a significant economic impact upon a substantial number of small entities.

The SUNSET Rule also schedules automatic rescission of regulations that are required by statute. For example, the Social Security Act directs HHS to issue regulations defining the requirements for state plans under the Medicaid program. While Congress left the Department considerable discretion in the regulations’ content, HHS is required to issue such regulations, and such regulations are necessary for states to be able to participate in Medicaid. By putting critical regulations like these at risk for automatic expiration, the SUNSET rule puts HHS on track to violate the Social Security Act and other similar statutory schemes, as well undermine patients’ access to care.<sup>1</sup>

Finally, it is inherently arbitrary and capricious to use the threat of eliminating public health regulations as an incentive for the Department to conduct RFA reviews at a faster pace. The SUNSET Rule seeks to spur action by government agencies, political officials, and career government employees by threatening harm to millions of individuals who receive their healthcare coverage through the ACA, Medicaid and CHIP, including those who are low-income, people of color and individuals with pre-existing conditions, and millions more who are at risk from harm from tobacco products. This misaligned incentive places the burden of failure on a party that is separate and distinct from the party with control over the action and is fundamentally irrational.

### **The SUNSET Rule Must be Withdrawn or Repealed, Not Revised**

HHS seeks comment on whether the Department should consider modifying, rather than withdrawing or repealing, the SUNSET Rule. The Lung Association strongly opposes any revision to the SUNSET Rule and urges HHS to withdraw or repeal the rule in its entirety before March 22, 2022, the date on which the stay expires in the *Santa Clara* litigation. Any additional rulemaking on this issue should be entirely separate from the withdrawal of the SUNSET Rule.

The SUNSET rule creates uncertainty for federal regulations that are essential to the management of healthcare programs including Medicaid, CHIP, and the Marketplace because it is impossible for stakeholders to know *which* HHS regulations will remain in place and which ones will not. These programs are the source of health insurance coverage for millions of people with serious and chronic conditions. The Medicaid and CHIP programs are complex,

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<sup>1</sup> The Sunset Rule did not exempt such regulations from automatic rescission because HHS has discretion “as to what is prescribed” by the regulation. 86 Fed. Reg. at 5,729, 5,764.

federal-state health insurance programs that affect not only millions of beneficiaries, but also all of the states and territories, tens of thousands of providers, and hundreds of managed care plans. The Marketplace facilitates the enrollment of millions of consumers across all of the states into private coverage sold by dozens of insurers, while the private insurance regulations promulgated by HHS establish the ground rules for coverage in the broader individual and group health insurance markets on which millions more individuals depend.

Similarly, uncertainty for federal regulations like the “deeming rule” that gives the agency authority to regulate the manufacturer, sales and marketing of e-cigarettes, cigars, little cigars, pipe tobacco (including hookah/waterpipe) and all other classes of tobacco products not under FDA’s original authority would undermine public health. This rule sets an important foundation upon which additional rules necessary to protect the public health from these products will be promulgated. Future rules that require FDA to have regulatory authority over these products, including a rule the Biden Administration announced it would propose by April 2022 that would require flavored cigars to be removed from the marketplace, build on the deeming rule. Continued uncertainty over the SUNSET rule weakens these important efforts to protect the public’s health.

HHS itself has acknowledged that uncertainty caused by the SUNSET Rule, and combining a new procedural proposal with the withdrawal, or otherwise delaying complete withdrawal of the SUNSET Rule, would only further exacerbate the uncertainty and continuing harm that already exists.

### **Conclusion**

The Lung Association strongly supports the Department’s current rulemaking to withdraw the SUNSET rule and urges you to finalize the repeal no later than March 22, 2022. Thank you again for the opportunity to comment on the proposed rule.

Sincerely,

A handwritten signature in black ink that reads "Harold Wimmer". The signature is written in a cursive, flowing style.

Harold P. Wimmer  
National President and CEO

## Attachment A



December 4, 2020

Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Docket No. HHS-OS-2020-0012: Securing Updated and Necessary Statutory  
Evaluations Timely: Notice of Proposed Rulemaking

Comments on Proposed Rule and Request for Extension of Comment Period  
under 21 C.F.R. § 10.40(b)(3); RIN 0991-AC24

Dear Sir or Madam:

The undersigned organizations, committed to protecting and promoting the public health by reducing the use of tobacco products, respectfully submit comments on the proposed rule, “Securing Updated and Necessary Statutory Evaluations Timely.” 85 Fed. Reg. 70,096 (Nov. 4, 2020) (the “Proposed Rule”).

HHS should withdraw the Proposed Rule because it violates the Administrative Procedure Act (“APA”). In addition, if adopted it would force the Food and Drug Administration (“FDA”), and its Center for Tobacco Products (“CTP”) in particular, to dedicate substantial resources and attention to the required “Reviews” and “Assessments” rather than focusing on its mission of protecting Americans from harmful tobacco products. If HHS declines to withdraw the Proposed Rule, it should at minimum extend the comment period by at least another 90 days. For a proposed rule that effectively amends 18,000 regulations and may significantly impair CTP’s ability to perform its regulatory role, the unjustifiably short comment period flouts the APA’s requirement that interested parties be given a meaningful opportunity to assess and comment on the proposal.

#### **A. The Proposed Rule Violates the APA.**

The Proposed Rule is subject to the rulemaking requirements imposed by the APA as interpreted by the courts over the more than seventy years since Congress enacted the APA. In section 701(a) of the Federal Food, Drug and Cosmetic Act, Congress authorized FDA to adopt regulations which, once adopted, have the force of law. When developing a regulation, the APA requires that FDA issue a proposed rule explaining what the proposal would accomplish and its impact, to allow a meaningful opportunity for public comment, and to consider all relevant comments. 5 U.S.C. § 553(b)-(c).<sup>1</sup>

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<sup>1</sup> It is notable that, at the November 23, 2020 public hearing on the Proposed Rule, every one of the approximately twenty participants—representing public health organizations, industry trade

The Proposed Rule effectively amends 18,000 regulations to add a date on which each regulation will automatically expire unless the agency has completed the resource-intensive review. According to the Proposed Rule, 12,400 rules would have to undergo review in the first two years the rule is effective or expire automatically. This blanket amendment in the Proposed Rule would violate the APA, because it violates the statute’s procedural requirements by not allowing an adequate opportunity for comment and is substantively arbitrary and capricious. The mandatory sunset provision inevitably will vary in its impact for each of the thousands of rules promulgated by HHS and covered by the Proposed Rule. Yet the Proposed Rule asserts that, as to *every* covered regulation—no matter how important to the public health—“the risk of a Regulation inadvertently expiring is outweighed by the benefit of institutionalizing retrospective review.” 85 Fed. Reg. at 70,106. The Proposed Rule offers no analysis of specific rules and thus no reasoned assessment as to each of the thousands of regulations impacted by the proposal. But that is what the APA requires when a regulation is revoked or amended. *See, e.g., Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42-43 (1983) (in revoking a rule “the agency must examine the relevant data and articulate a satisfactory explanation for its action”).

Thus, if the Proposed Rule were finalized, the APA would be violated every time a rule automatically expires because the expiration will occur without the required notice and comment opportunity and without an examination by FDA of whether expiration of the rule is justified by the relevant science and in light of public health considerations. Moreover, the ensuing litigation could clog the courts and paralyze the agency.

## **B. The Proposed Rule Will Divert FDA and CTP from Their Public Health Activities.**

Instead of allowing CTP to focus on protecting Americans from deadly tobacco products, this rule, if finalized, would divert FDA’s and CTP’s attention and resources.

Cigarette smoking is the leading cause of preventable disease and death in the United States, killing more than 480,000 Americans every year.<sup>2</sup> Over 16 million Americans suffer from tobacco-related disease.<sup>3</sup> According to the most recent CDC data, 34.1 million U.S. adults still smoke cigarettes.<sup>4</sup> And over the last several years, e-cigarette use among youth has reached epidemic proportions, with about 1 in 5 American kids now using these highly-addictive

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associations, physician organizations, and consumer groups—opposed the Proposed Rule and urged HHS to withdraw it and at minimum to extend the comment period.

<sup>2</sup> Office of the Surgeon General (OSG), U.S. Department of Health and Human Services (HHS), *The Health Consequences of Smoking - 50 Years of Progress: A Report of the Surgeon General* 2 (2014), <https://www.hhs.gov/sites/default/files/consequences-smoking-exec-summary.pdf>.

<sup>3</sup> Center for Disease Control and Prevention (CDC), *Smoking & Tobacco Use*, [http://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/fast\\_facts/index.htm#toll](http://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm#toll) (last visited Nov. 30, 2020).

<sup>4</sup> CDC, *Tobacco Product Use Among Adults – United States, 2019*, 69 Morbidity & Mortality Wkly. Rep. 1736, 1737 (Nov. 20, 2020), <https://www.cdc.gov/mmwr/volumes/69/wr/mm6946a4.htm>.

products.<sup>5</sup> It is essential that FDA be allowed to focus on its critical task of protecting the American people from addictive and deadly tobacco products.

Since the enactment of the Family Smoking Prevention and Tobacco Control Act (the “TCA”) in 2009, CTP has issued 11 final regulations and 14 proposed regulations.<sup>6</sup> While several of those rules were statutorily mandated, and thus would be exempt under the Proposed Rule, others would be subject to its automatic repeal provisions. At this point, more than 10 years after enactment of the TCA, the story of tobacco product regulation is not one of unnecessary regulatory burdens on small businesses, but rather of FDA’s failure to use its regulatory authority to protect public health and, particularly, to protect our kids. For example, FDA has had the authority to establish tobacco product standards to make tobacco products less harmful, less addictive, and less appealing, especially to kids. *Yet FDA has yet to finalize a single product standard.*

The youth e-cigarette epidemic resulted in significant measure from FDA’s failure to take timely action on e-cigarettes. In April 2011, FDA first announced its intention to regulate e-cigarettes as tobacco products.<sup>7</sup> But FDA did not extend its authority to e-cigarettes until May 2016.<sup>8</sup> During this five-year delay, e-cigarettes gained a foothold in the American market, with a particular appeal to kids. Youth use of e-cigarettes then accelerated dramatically beginning in 2017, after FDA suspended its public health review of these products.

FDA has issued several advanced notices of proposed rulemaking on important issues, including a product standard on nicotine in combusted cigarettes and the regulation of flavors in tobacco products. The public health of the nation, particularly its youth, would be far better served by CTP dedicating its finite resources to make progress on those initiatives, rather than on the “Assessments” and “Reviews” described in the Proposed Rule. These “Assessments” and “Reviews” would impose unjustifiable costs on the regulatory process, and if subject to legal challenge under the APA as the rule envisions, would further distract FDA from its public health mission.

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<sup>5</sup> CDC, *E-cigarette Use Among Middle and High School Students – United States, 2020*, 69 Morbidity & Mortality Wkly. Rep. Surveillance Summaries (Sept. 9, 2020), <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6937e1-H.pdf>.

<sup>6</sup> FDA, Rules and Regulations, <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/rules-and-regulations> (last visited Nov. 30, 2020).

<sup>7</sup> FDA, *Regulation of E-Cigarettes and Other Tobacco Products* (Apr. 25, 2011), <http://web.archive.org/web/20110530152010/http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm252360.htm>.

<sup>8</sup> Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974, 29,037 (May 20, 2016) (to be codified at 21 C.F.R. pt. 1100, 1140, 1143) (“Deeming Rule”).

Therefore, because the Proposed Rule would impose extraordinary burdens on FDA and its regulation of tobacco products, with no benefits to the public health, and because it violates the APA, the undersigned organizations urge HHS to withdraw the Proposed Rule.

**C. At Minimum, HHS Should Extend the Comment Period.**

Under HHS and FDA regulations, the agency ordinarily allows 60 days for public comment on a proposed rule. *See, e.g.*, 21 C.F.R. § 10.40(b)(2). While HHS and FDA can shorten the time for “good cause,” the Proposed Rule offers no justification for such an abbreviated comment period. In fact, a longer comment period is required given (i) the potential impact of the Proposed Rule on thousands of existing rules and on HHS/FDA/CTP’s ability to perform its public health mission, and (ii) the abbreviated comment period falls in the midst of the novel coronavirus pandemic. Accordingly, the Proposed Rule’s 30-day comment period itself violates the APA because it denies meaningful “opportunity to participate in the rule making” required by 5 U.S.C. § 553(c). *See N. Carolina Growers’ Ass’n, Inc. v. United Farm Workers*, 702 F.3d 755, 770 (4th Cir. 2012) (APA requires “meaningful” opportunity to comment); *Petry v. Block*, 737 F.2d 1193, 1201 (D.C. Cir. 1984) (relying on Administrative Conference of the United States’s view that 30-day comment period is inadequate and 60-day comment period is the reasonable minimum time for comment). In light of the far-reaching scope of the Proposed Rule and the ongoing COVID-19 public health crisis, HHS should extend the comment period by at least 90 days beyond the current December 4, 2020 deadline.

Respectfully submitted,

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative



## Attachment B



December 4, 2020

The Honorable Alex Azar  
 Secretary  
 U.S. Department of Health and Human Services  
 200 Independence Avenue SW  
 Washington, DC 20201

**Re: Securing Updated and Necessary Statutory Evaluations Timely (RIN 0991–AC24, Docket No. HHS–OS–2020–0012)**

Dear Secretary Azar:

Thank you for the opportunity to comment on proposed rule, Docket No. HHS–OS–2020–0012, “Securing Updated and Necessary Statutory Evaluations Timely,” RIN 0991-AC24.

The undersigned organizations represent millions of patients facing serious, acute, and chronic health conditions across the country. Our organizations have a unique perspective on what patients need to prevent disease, cure illness, and manage chronic health conditions. Our diversity enables us to draw upon a wealth of knowledge and expertise that can be an invaluable resource in this discussion. We urge the Department of Health and Human Services (HHS) to make the best use of the knowledge and experience our patients and organizations offer in response to this proposed rule.

In March of 2017, our organizations agreed upon three overarching principles<sup>1</sup> to guide any work to reform and improve the nation's healthcare system. These principles state that: (1) healthcare should be accessible, meaning that coverage should be easy to understand and not pose a barrier to care; (2) healthcare should be affordable, enabling patients to access the treatments they need to live healthy and productive lives; and (3) healthcare must be adequate, meaning healthcare coverage should cover treatments patients need, including all the services in the essential health benefit (EHB) package.

Our organizations urge the Department to immediately withdraw the proposed rule. The proposed rule's impact on programs that provide coverage to millions of Americans, including those who are low-income, people of color and individuals with pre-existing conditions, is unacceptable to our organizations. In addition to the broad and indiscriminate reach of this proposal, the Department's truncated 30-day comment period is insufficient and demonstrates a lack of seriousness in evaluating regulations that govern how and when individuals and families can obtain the coverage they need to maintain and improve their health. Instead of undermining the operation of these health coverage programs and regulation of the individual health insurance market for millions of our nation's most vulnerable in the middle of a pandemic, the Department should continue to implement its existing Final Retrospective Review Plan, adopted in August 2011 and posted on the Department's website.<sup>2</sup>

The Department proposes to use automatic expiration of rules as a forcing mechanism to compel, within the next two years, the assessment and, if applicable, the review of nearly all Departmental regulations that have been in force for more than 10 years. The imposition of such a mechanism would significantly disrupt the ability of the Centers for Medicare & Medicaid Services (CMS) to administer critical healthcare programs such as Medicaid, the Children's Health Insurance Program (CHIP), and the Affordable Care Act (ACA) over the next two years. Our organizations offer the following comments in opposition to the proposed rule:

#### **Authorities Exist for Periodic Review of Regulations**

The Department has an existing mechanism for periodic review of significant regulations and does not need to implement this proposed rule, which unnecessarily jeopardizes key programs, to phase out or update regulations. In August 2011, the Department issued a Final Retrospective Review Plan to implement Executive Order 13563.<sup>3</sup> The Plan has five goals: (1) streamline or eliminate unjustified costs and burdens; (2) increase transparency in the retrospective review process; (3) increase opportunities for public participation; (4) set clear retrospective review priorities; and (5) strengthen analysis of regulatory options. Between January 2012 and February 2016, the Department issued ten updates on the regulatory reviews it conducted.<sup>4</sup> The preamble to the proposed rule does not contain any reference to the Department's August 2011 plan or to any of the updates, nor does it justify why the plan is ineffective or why the updates were discontinued in 2016.

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<sup>1</sup> Consensus Health Reform Principles. Available at: <https://www.lung.org/getmedia/aafde78d-da8f-4067-ad6a-6b3429fac1b9/100720-healthcare-principles43logos.pdf>.

<sup>2</sup> <https://www.hhs.gov/open/retrospective-review/index.html>

<sup>3</sup> [https://wayback.archive-it.org/org-745/20141203143033/http://www.hhs.gov/open/execorders/13563/hhs\\_final\\_retrospective\\_review\\_plan\\_8-19-11\\_4.pdf](https://wayback.archive-it.org/org-745/20141203143033/http://www.hhs.gov/open/execorders/13563/hhs_final_retrospective_review_plan_8-19-11_4.pdf)

<sup>4</sup> <https://www.hhs.gov/open/retrospective-review/index.html>

### **The Rule Creates Unnecessary Confusion**

If implemented, the proposed rule would create uncertainty for Federal regulations that are essential to the management of healthcare programs including Medicaid, CHIP, and the Marketplace. These programs are the source of health insurance coverage for millions of people with serious and chronic conditions. As a result, our organizations are deeply concerned about the uncertainty this rule would create for the patients that we represent.

The Medicaid and CHIP programs are complex, federal-state health insurance programs that affect not only millions of beneficiaries, but also all of the states and territories, tens of thousands of providers, and hundreds of managed care plans. The Marketplace facilitates the enrollment of millions of consumers across all of the states into private coverage sold by dozens of insurers, while the private insurance regulations promulgated by HHS establish the ground rules for coverage in the broader individual and group health insurance markets on which millions more individuals depend.

Each of these stakeholders has an interest in—and legitimate expectation of—stability in the federal regulatory guidance on which they rely in administering or participating in these programs and markets. By providing for automatic expiration if CMS does not conduct timely assessments and reviews, the proposed rule's forcing mechanism would unnecessarily and illegally create uncertainty on the part of stakeholders as to whether they should continue to rely on federal regulations for policy and operational guidance.

### **The Proposed Rule is Inconsistent with Federal Statute**

The authority for issuing Medicaid and CHIP regulations is found in section 1102 of the Social Security Act, which expressly directs the Secretary of HHS to issue regulations “not inconsistent with this Act, as may be necessary to the efficient administration of the “functions with which [s/he] is charged under this Act.” This section does not give the Secretary the authority to write automatic expiration dates into regulations. In fact, the risk of automatic expiration if an assessment and review is not conducted within a specified time frame is flatly inconsistent with the “efficient administration” of Medicaid and CHIP. It would force CMS to engage in an endlessly repeating and highly inefficient cycle of assessments of all regulations and reviews of those determined to have a significant economic impact upon a substantial number of small entities.

The preamble to the proposed rule repeatedly cites the Regulatory Review Act at 5 U.S.C. 610 as authority for the forcing mechanism. Our organizations believe this to be a clear misreading of the statute. Section 610 does not require, much less authorize, the blanket imposition of automatic expiration dates on almost all regulations, as the proposed rule would do. Section 610 only requires that agencies have a “plan for the periodic review of rules that have or will have a significant economic impact upon a substantial number of small entities.” That is exactly what the Department already has in the form of its August 2011 Final Retrospective Review Plan.

### **The Proposed Rule is Wasteful**

The proposed rule will force HHS to divert limited staff resources to reviewing long-standing regulations over the next two years, disrupting its administration of Medicaid, CHIP, and the Marketplace during the coronavirus pandemic. If the proposed rule is issued in final form in January 2021, any regulation issued

before 2013 would have to be assessed and, if applicable, reviewed before the end of 2023, or it would automatically expire. The proposed rule would define “regulation” as a section of the Code of Federal Regulations. It does not explain how many Medicaid, CHIP or Marketplace regulations CMS would need to assess and, if necessary, review over the next two years.

The regulations implementing the Medicaid program are found at 42 CFR Parts 430 to 436, 438, 440-442, 447, and 455-456. These 14 parts alone contain 1,044 separate CFR sections. Most of those sections are at least ten years old, which means that they would each have to be assessed and, if necessary, reviewed before 2023, or they would expire. The remaining eight parts contain hundreds more sections. The regulations implementing the CHIP program are found in 42 CFR Part 457. That part has over 155 separate sections, the large majority of which were promulgated over ten years ago. In short, these “regulations” represent long-standing policy on which stakeholders have been relying on – in some cases, for over a decade. The proposed rule would require that, over the next two years, CMS assess and, if necessary, review in the neighborhood of a thousand Medicaid and CHIP regulations in order to avoid or postpone their automatic expiration. Setting this expectation, understanding that the Department does not have sufficient resources to appropriately facilitate this process, is unreasonable and unacceptable.

Key provisions of the ACA affecting states, consumers, providers, and insurers would soon be up for review and require regular review and updates to ensure coverage options and consumer protections remain in place. Rules establishing health insurance marketplaces — the sole place where individuals can access federal financial assistance — were issued and updated regularly in the years following the ACA’s enactment in 2010. The market reforms governing individual and group market coverage would also come under review. Under the proposed rule, unless the agency performed an affirmative act to prevent the expiration of these regulations, the result of the proposed rule would be to put at risk guaranteed issue and renewal of coverage, broad protections for people with preexisting conditions and comprehensive coverage requirements, among other key regulations implementing the ACA.

A review of these regulations would be an indefensible waste of resources, especially in the midst of the COVID-19 pandemic. The preamble states at p. 70111: “The Department recognizes that this proposed rule requires the Department to undertake certain tasks. But the Department believes that retrospective review of regulations should be a priority, and is willing to commit the necessary resources towards performing the Assessments and Reviews.” In the midst of a pandemic, when Medicaid, CHIP and Marketplace coverage are so important to the communities most at risk, including people of color, people with disabilities, and many low-wage health care workers, we disagree that “performing the Assessments and Reviews” of hundreds of current program regulations “should be a priority” for HHS and CMS. The priority for CMS over the next two years should be ensuring Medicaid and CHIP coverage are operating as effectively as possible in making COVID-19 testing, treatment, and vaccinations available to all Americans, and ensuring continued federal protections for all people who need the guarantees of the ACA to buy and maintain private coverage.

## **Conclusion**

The Department should withdraw this proposed rule and continue the periodic review of regulations it conducted between 2012 and 2016. Given the broad scope and potential harm of this proposal, the

Department's truncated 30-day comment period was insufficient. The proposed forcing mechanism would disrupt the operation of healthcare programs including Medicaid, CHIP, and the Marketplace by creating regulatory uncertainty for stakeholders, and it would divert CMS resources from what should be the highest priority: ensuring that these programs respond effectively as possible to the pandemic.

Thank you again for the opportunity to comment on the proposed rule. Please contact Hannah Green of the American Lung Association at [hannah.green@lung.org](mailto:hannah.green@lung.org) if you have any questions or if we can be of further assistance.

Sincerely,

American Cancer Society Cancer Action Network  
American Heart Association  
American Lung Association  
American Kidney Fund  
ALPHA-1 Foundation  
Arthritis Foundation  
Asthma and Allergy Foundation of America  
CancerCare  
Cancer Support Community  
Cystic Fibrosis Foundation  
Epilepsy Foundation  
Hemophilia Federation of America  
Leukemia & Lymphoma Society  
Muscular Dystrophy Association  
National Alliance on Mental Illness  
National Patient Advocate Foundation  
National Health Council  
National Hemophilia Foundation  
National MS Society  
National Organization for Rare Disorders  
Pulmonary Hypertension Association  
Susan G. Komen  
The AIDS Institute  
United Way Worldwide

## Attachment C

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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN JOSE DIVISION

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

*Plaintiffs,*

*vs.*

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

Case No. 5:21-cv-01655

**COMPLAINT FOR DECLARATORY  
AND INJUNCTIVE RELIEF**

Administrative Procedure Act Case



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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

1 hospitals and nurse practitioners, will be unable to plan their operations to the financial and  
2 physical detriment of patients. All Plaintiffs will have to divert significant resources to  
3 monitor the progress of each regulation that affects them and to attempt to stem the effects  
4 of potential automatic expiration.

5         7. If the Rule takes effect, it will require substantial, and likely unachievable,  
6 efforts on the part of HHS to prevent regulations from expiring. The resulting cost to  
7 society is steep. To simply keep its existing regulatory framework, HHS and its  
8 subagencies will need to redirect significant resources away from such vital work as  
9 combatting the COVID-19 pandemic and protecting the country against future public  
10 health emergencies.

11         8. The Sunset Rule violates the APA, the RFA, and the statutory authorities  
12 underlying the Department's original regulations.

13         9. First, the Rule was issued without procedures or tribal consultation required  
14 by law. The Department promulgated the Rule after a rushed notice-and-comment period  
15 that hundreds of commenters decried as providing inadequate time for them to  
16 meaningfully participate. The limited public process was particularly problematic because  
17 affected parties were asked to discern, and comment on (over the holidays, no less), the  
18 impacts of a sweeping and vague proposal in the middle of a global pandemic, which was  
19 appropriately the primary focus of their efforts. HHS also refused to consult with Indian  
20 tribes, as required under HHS policy and the federal government's tribal trust  
21 responsibilities, despite the Rule's significant and direct effects on tribes and funding for  
22 tribal programs.

23         10. Second, the Sunset Rule is contrary to law and in excess of the  
24 Department's authority. It relies on the RFA, which by the Department's own estimate  
25 does not authorize review of 89% of the regulations amended. And it schedules  
26 elimination of nearly all HHS regulations without consideration of the factors required by  
27 that statute. It also expressly relies on the myriad HHS substantive statutes for authority,  
28

1 but in fact eliminates regulations required by those statutes and fails to address factors  
2 mandated by those statutes and the APA.

3 11. Third, the Rule violates the APA's prohibition against arbitrary and  
4 capricious agency action. Among other things, the Department's justification for the  
5 Rule—to "incentivize" retrospective regulatory review—is irrational on its face. It  
6 assumes without support that HHS can induce itself to increase its pace of review 20-fold  
7 merely by imposing on the general public the severe consequence of losing needed  
8 regulations. Moreover, the Department did not plausibly show that it *can* meet the  
9 contemplated review schedule or meaningfully consider the harm and costs the "incentive"  
10 would cause.

11 12. Plaintiffs respectfully request that the Court declare that the Sunset Rule  
12 violates the APA because it was issued without procedures or consultation required by law,  
13 is contrary to law, and is arbitrary and capricious. The Rule should be vacated and set  
14 aside.

### 15 PARTIES

16 13. Plaintiff County of Santa Clara (the "County") is a charter county and  
17 political subdivision of the State of California, located in the Northern District of  
18 California. The County is home to almost two million people who rely on the County to  
19 provide essential healthcare services and to oversee regional public health. The County  
20 owns and operates the County of Santa Clara Hospitals and Clinics, a network of safety-net  
21 hospitals and medical clinics that provide specialized, preventative, primary, and routine  
22 healthcare services, primarily to underserved patients. Together, the County's public  
23 hospitals and clinics serve nearly 200,000 individual patients per year. The County also  
24 operates a Social Services Agency that provides a wide array of essential safety-net  
25 services; an Emergency Medical Services Agency that accredits emergency responders and  
26 oversees all 911 ambulance response countywide; a Behavioral Health Services  
27 Department that provides mental health and substance use prevention and treatment  
28 services to tens of thousands of patients each year; a health insurance plan called Valley

1 Health Plan; and a Public Health Department that is responsible for regional public health  
2 services throughout Santa Clara County, including managing the County's response to the  
3 COVID-19 pandemic.

4 14. Plaintiff California Tribal Families Coalition ("CTFC") is an Internal  
5 Revenue Code ("IRC") Section 501(c)(4) nonprofit membership association and an  
6 "Indian organization" under the Indian Child Welfare Act. Its members are 42 federally  
7 recognized sovereign tribes and 3 statewide tribal leader associations from across  
8 California, and it is led by a 12-member Board of Directors chosen from among the duly  
9 elected tribal leaders of CTFC's member tribes. CTFC's mission is to protect the health,  
10 safety, and welfare of tribal children and families, which are inherent tribal governmental  
11 functions and are at the core of tribal sovereignty and tribal governance. CTFC's member  
12 tribes are governments entitled under the Indian Self-Determination and Education  
13 Assistance Act, Pub. L. No. 93-638, 88 Stat. 2203, to request that operation of, and funding  
14 for, federal programs be transferred to tribal administration. CTFC's member tribes are  
15 affected by nearly all HHS programs. Among other things, they receive HHS funding for  
16 operation of tribal health services and/or receive services directly from Indian Health  
17 Services programs, substance abuse programs, and social programs, such as Temporary  
18 Assistance for Needy Families. HHS regulations govern the member tribes' funding for  
19 and operation of such programs. One of CTFC's core missions is to advocate for the  
20 incorporation of tribal concerns into regulations, including HHS regulations of great  
21 importance to its tribal members, such as regulations on healthcare, mental health,  
22 substance abuse, programs for the elderly, child welfare, and foster care.

23 15. Plaintiff National Association of Pediatric Nurse Practitioners ("NAPNAP")  
24 is an IRC Section 501(c)(6) nonprofit professional membership association, representing  
25 more than 8,000 healthcare practitioners, with 18 specialty practice issues groups and 53  
26 chapters. It is the nation's only professional association for pediatric nurse practitioners  
27 and their fellow pediatric-focused advanced practice registered nurses, who are dedicated  
28 to improving the quality of health care for infants, children, adolescents, and young adults.

1 NAPNAP's members treat millions of patients a year in a wide variety of healthcare  
2 settings, including pediatric offices, hospitals, specialty clinics, public or school-based  
3 healthcare facilities, and others. They are regulated and affected by thousands of HHS  
4 regulations under such programs as Medicaid and the Children's Health Insurance  
5 Program. NAPNAP's mission is to empower pediatric-focused advanced practice  
6 registered nurses and key partners to optimize child and family health.

7 16. Plaintiff American Lung Association ("ALA") is an IRC Section 501(c)(3)  
8 nonprofit voluntary health organization incorporated in the State of Maine, with its  
9 principal place of business in Chicago, Illinois. One of ALA's core missions is to advocate  
10 for policies that improve the prevention and cure of lung disease and that improve the  
11 quality of life of people living with lung disease. These include policies that reduce the  
12 burden of asthma, expand access to affordable healthcare for patients with or at risk for  
13 lung diseases, reduce tobacco use through tobacco regulation and cessation efforts, and  
14 increase screening for those at high risk of lung cancer. ALA has spent substantial  
15 resources advocating for such programs before HHS. For example, in 2015, ALA testified  
16 at a hearing to urge HHS to expand Medicare coverage to include early detection computed  
17 tomography ("CT") scans for high-risk Medicare beneficiaries. ALA also works to  
18 improve public education on HHS programs that benefit at risk populations. For example,  
19 ALA generates and maintains a lung cancer screening toolkit that tracks coverage of and  
20 barriers to low-dose computed tomography ("LDCT") lung cancer screening under state  
21 Medicaid fee-for-service programs. Similarly, ALA depends on HHS regulations  
22 governing tobacco products, such as a 2016 regulation deeming e-cigarette subject to the  
23 Tobacco Control Act, which significantly affects ALA's Not On Tobacco program,  
24 Freedom from Smoking program, and Lung Helpline cessation assistance service.

25 17. Plaintiff the Center for Science in the Public Interest ("CSPI") is an IRC  
26 Section 501(c)(3) nonpartisan nonprofit organization headquartered in Washington, DC,  
27 with approximately 450,000 members. CSPI is independently owned and operated and is  
28 not dominant in its field of public health advocacy. CSPI is a science-based consumer



1 advocacy organization that seeks to promote: (1) a healthy population with a reduced  
2 burden of preventable disease, and (2) an equitable food system in which healthy,  
3 sustainable food is accessible to all. CSPI values independence, scientific rigor, and  
4 transparency. A core aspect of CSPI's mission is ensuring that food, dietary supplements,  
5 and drugs are safe and transparently labeled. The FDA, an HHS sub-agency, administers  
6 several statutes relevant to this work, including the Federal Food, Drug and Cosmetic Act,  
7 Pub. L. No. 75-717, 52 Stat. 1040 (codified as 21 U.S.C. § 301, *et seq.*); the Nutrition  
8 Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353; the Dietary  
9 Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325;  
10 portions of the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148,  
11 124 Stat. 119; the Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885;  
12 and the Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-  
13 282, 118 Stat. 891.

14 18. Plaintiff Natural Resources Defense Council ("NRDC") is an IRC Section  
15 501(c)(3) national not-for-profit environmental and public health organization,  
16 headquartered in New York City, with more than three million members and online  
17 activists. One of NRDC's core missions is to conduct advocacy and educate the public to  
18 protect public health and the environment. In service of this mission, NRDC advocates for  
19 health-protective regulations at FDA (including the regulation of food additives, 21 C.F.R.  
20 §§ 170.3-180.37; bottled water, *id.* §§ 129.1-129.80; and antibiotics in animal agriculture,  
21 *id.* §§ 556.1-556.770, 558.3-558.680) and HHS (including regulations that protect human  
22 test subjects, 45 C.F.R. part 46). NRDC also educates its members and the public about  
23 these and other HHS regulations.

24 19. Defendant United States Department of Health and Human Services  
25 ("HHS" or "Department") is a federal agency headquartered in Washington, DC, at 200  
26 Independence Avenue, SW, Washington, DC 20201. HHS is an "agency" within the  
27 meaning of the APA. 5 U.S.C. § 551(1). HHS is a cabinet-level department that  
28



## LEGAL AND STATUTORY BACKGROUND

### I. The Administrative Procedure Act (“APA”)

25. The APA allows a person “suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action” to seek judicial review of that action. 5 U.S.C. § 702. Under the APA, courts must “hold unlawful and set aside agency action, findings, and conclusions” that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,” *id.* § 706(2)(A), “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right,” *id.* § 706(2)(C), or “without observance of procedure required by law,” *id.* § 706(2)(D).

### II. The Regulatory Flexibility Act (“RFA”)

26. The RFA requires agencies to publish a “plan for the periodic review of the rules . . . which have or will have a significant economic impact upon a substantial number of small entities.” 5 U.S.C. § 610(a). The RFA does not authorize reviews of rules that lack “a significant economic impact upon a substantial number of small entities.” *See id.* §§ 602, 605, 610.

27. The purpose of RFA review is “to determine whether” covered regulations “should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact of the rules upon a substantial number of []small entities.” *Id.* § 610(a).

28. In conducting review under the RFA, the agency “shall consider” five statutory factors. *Id.* § 610(b). Those are: (1) the “continued need for the rule”; (2) the “nature of complaints or comments” concerning the rule; (3) the “complexity of the rule”; (4) the “extent to which the rule overlaps, duplicates or conflicts” with other rules; and (5) the “length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors” affecting the rule have changed. *Id.*

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## FACTUAL ALLEGATIONS

### **I. HHS Regulates Healthcare, Disease Control, and Food and Drug Safety.**

29. HHS was established as a cabinet level department in 1953, when it was called the Department of Health, Education, and Welfare. Its name was changed to the Department of Health and Human Services in 1980. The mission of HHS is to provide services that benefit the health and well-being of Americans and by fostering advances in the science underlying medicine, public health, and social services.<sup>2</sup>

30. HHS contains dozens of sub-agencies and offices, including the CDC, FDA, Centers for Medicare and Medicaid Services, Indian Health Service, Administration on Community Living, Administration for Children and Families, and National Institutes of Health.

31. HHS operates programs that affect every aspect of the U.S. healthcare system. These include, for example, the Medicare and Medicaid programs, which insure 139 million Americans, including 36.6 million children; the Children's Health Insurance Program, which insures over 7 million children; and the Healthcare.gov Insurance Marketplace, which enrolled nearly 8.3 million people in insurance plans in 2020 alone.

32. HHS administers almost every major federal statute governing healthcare, including, for example, the Medicare and Medicaid provisions of the Social Security Act, Pub. L. No. 74-271, 49 Stat. 620, which include hospital health and safety requirements; the ACA, which governs health insurance; the Health Insurance Portability and Accountability Act ("HIPAA"), Pub. L. No. 104-191, 110 Stat. 1936, which governs privacy and portability of health information; and the Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 115, which establishes programs for securing health information; in addition to the countless supplements and amendments to these statutes.

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<sup>2</sup> *About HHS*, <https://www.hhs.gov/about/index.html> (last visited Mar. 5, 2021).

1           33.     Other HHS-administered statutes regulate the safety and contents of food,  
 2 medications, vaccines, and medical devices, and protect the public from tobacco products,  
 3 such as the Nutrition Labeling and Education Act; the Dietary Supplement Health and  
 4 Education Act; the Food Safety Modernization Act; the Food Allergen Labeling and  
 5 Consumer Protection Act; the Federal Food, Drug and Cosmetic Act, Pub. L. 75-717, 52  
 6 Stat. 1040; and the Family Smoking Prevention and Tobacco Control Act, Pub. L. No.  
 7 111-31, 123 Stat. 1776.

8           34.     HHS agencies operate programs that for prepare for, respond to, and help  
 9 the nation recover from public health emergencies under the Pandemic and All Hazards  
 10 Preparedness Act, Pub. L. No. 109-417, 120 Stat. 2831, and related statutes.

11           35.     The Department maintains programs dedicated to services for tribes both in  
 12 and outside the healthcare context, under such statutes as the Indian Health Care  
 13 Improvement Act, Pub. L. 111-148, § 10221, 124 Stat. 119, 935-37. Pursuant to the Indian  
 14 Self-Determination and Education Assistance Act, HHS formally transfers operation of,  
 15 and funds for, these and other HHS programs to tribes under certain circumstances.

16           36.     HHS also administers critical social-welfare programs, including the  
 17 Temporary Assistance for Needy Families program, Head Start, the Unaccompanied Alien  
 18 Children program, and programs addressing child support, child nutrition, adoption, foster  
 19 care, and the elderly.

20           37.     HHS oversees highly regulated industries through thousands of technical,  
 21 interdependent, and complex regulations that implement several notoriously “Byzantine”  
 22 statutes.<sup>3</sup> *Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981). Such regulations govern  
 23 the myriad real-life factors that affect individual and public health, such as medical device  
 24 standards, pharmaceutical manufacturing, and food contaminants.

25  
 26  
 27 <sup>3</sup> The Department’s substantive statutes have at times been “aptly described” as a “virtually  
 28 impenetrable thicket of legalese and gobbledygook.” *Lamore v. Ives*, 977 F.2d 713, 716  
 (1st Cir. 1992).

1        38. To date, HHS has promulgated approximately 18,000 active regulations to  
2 implement the entire range of statutes the Department administers.<sup>4</sup> 86 Fed. Reg. at 5,740.

3        **II. HHS Proposes Massive Deregulation of the Healthcare Industry in the Midst**  
4        **of a Pandemic, While Providing a Truncated Notice-and-Comment Period and**  
5        **Refusing to Consult with Indian Tribes.**

6        39. In 2020, the COVID-19 pandemic strained HHS, its sub-agencies, and the  
7 U.S. healthcare industry in new ways. The CDC led the investigation into how the disease  
8 spreads, advised the public on pandemic precautions, and monitored healthcare delivery  
9 systems. The FDA played a similarly crucial role in development and approval for  
10 vaccines and COVID-19 treatments. And HHS administered necessary funding to  
11 healthcare providers under the Coronavirus Aid, Relief, and Economic Security  
12 (“CARES”) Act, Pub. L. No. 116-136, 134 Stat. 281.

13        40. By the first week of November 2020, COVID-19 infection rates had begun  
14 to surge upward in what would become, over the next two months, the worst wave of the  
15 pandemic to date.<sup>5</sup>

16        41. That same week, on November 4, 2020, HHS announced for the first time a  
17 massive deregulation effort that would affect the entire Department and its sub-agencies.  
18 HHS had never previously disclosed this scheme to the public, identified it as a  
19 Department priority, or listed it in the administration’s Unified Agenda of Federal  
20 Regulatory and Deregulatory Actions.

21        42. That day, HHS issued a Notice of Proposed Rulemaking proposing that,  
22 subject to limited and vague exceptions, “*all* regulations” issued by HHS “in Titles 21, 42,  
23 and 45 of the CFR *shall expire*”—most in two years, the rest within ten years. Securing

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24        <sup>4</sup> In the Sunset Rule, HHS uses the word “regulation” to refer to an individual provision of  
25 the Code of Federal Register (“C.F.R.”). See 86 Fed. Reg. at 5,720, 5,740-41. The  
26 Department estimates that “roughly five regulations on average are part of the same  
rulemaking,” *id.* at 5,741, although the Sunset Rule does not say whether the average (*i.e.*,  
the arithmetic mean) is representative of most rulemakings.

27        <sup>5</sup> See *COVID Data Tracker*, Trends in COVID-19 Cases and Deaths in the US Reported to  
28 CDC, by State/Territory, CDC (Mar. 6, 2021), [https://covid.cdc.gov/covid-data-tracker/#trends\\_dailytrendscases](https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases).

Updated and Necessary Statutory Evaluations Timely, 85 Fed. Reg. 70,096, 70,097 (proposed Nov. 4, 2020) (the “Proposed Rule”) (emphasis added). HHS acknowledged that the proposal was “unprecedented,”<sup>6</sup> and then-HHS Chief of Staff Brian Harrison later described it as “one of the most significant regulatory reform efforts in the history of the federal government.”<sup>7</sup>

43. As authority, the Proposed Rule invoked the RFA’s requirement that agencies publish a “plan for the periodic review of rules which have or will have a significant impact upon a substantial number of small entities.” 85 Fed. Reg. at 70,097-98 (quoting 5 U.S.C. § 610(a)). HHS already operates under a 2011 plan for RFA review and has published an update on regulatory review every year through 2016.<sup>8</sup> The Proposed Rule also purported to rely on “the statutory authorities for the Department’s existing regulations,” although it did not identify the authorities associated with each regulation to be amended or how they authorized expiration dates. *Id.* at 70,103.

44. To avoid the scheduled expiration of a given C.F.R. section under the proposal, HHS would need to first perform an “Assessment” to determine whether the regulation has a significant impact on small entities under the RFA. *Id.* at 70,119. If so, HHS would need to conduct a “Review” to determine whether the regulation “should be continued without change, or should be amended or rescinded, consistent with the stated objectives of the applicable statutes, to minimize any significant economic impact of the

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<sup>6</sup> *HHS Proposes Unprecedented Regulatory Reform through Retrospective Review* (Nov. 4, 2020), <https://www.hhs.gov/about/news/2020/11/04/hhs-proposes-unprecedented-regulatory-reform-through-retrospective-review.html>.

<sup>7</sup> Brian Harrison, *A new rule requires HHS to get rid of regulations that aren’t helping the public*, Dallas Morning News (Jan. 14, 2021) <https://www.dallasnews.com/opinion/commentary/2021/01/14/a-new-rule-requires-hhs-to-get-rid-of-regulations-that-arent-helping-the-public/>.

<sup>8</sup> *Retrospective Review of Existing Rules*, HHS <https://www.hhs.gov/open/retrospective-review/index.html> (last visited Mar. 7, 2021). Notably, the Department’s RFA plan is much more limited in scope. For example, it requires HHS to create and prioritize a list of regulations that actually need to be reviewed but does not require review of every HHS regulation.



1 Regulations upon a substantial number of small entities.” *Id.* The Department envisioned  
2 a resource-intensive and time-consuming public notice-and-comment process, subject to  
3 judicial review, at both the Assessment and Review phases. *See id.* at 70,106-07, 70,110.  
4 The proposal would impose no obligation on HHS to undertake an Assessment and Review  
5 in the first place, and the proposed expiration dates would be self-executing if the  
6 Department failed to (or chose not to) complete the review process. *See id.*

7         45. The Proposed Rule neither explicitly identified the regulations HHS was  
8 proposing to amend, nor analyzed the harms and benefits of adding expiration dates to any  
9 particular regulation. Rather, it spoke in generalities and estimates. According to the  
10 proposal, HHS “has roughly 18,000 regulations, the vast majority of which it believes  
11 would need to be Assessed.” *Id.* at 70,113. Further, “[t]he vast majority of these would  
12 need to be Assessed within two years.” *Id.* HHS estimated that because some regulations  
13 are part of the same rulemaking, HHS would need to perform “roughly 2,480”  
14 Assessments in the first two years to prevent regulations ten years old or older from  
15 expiring. *Id.* And HHS offered no analysis of the impact on, or reliance interests of,  
16 regulated entities or the public from amending any of the roughly 18,000 individual  
17 regulations it proposed to amend.

18         46. The proposal also did not identify which regulations the Department  
19 believed to have “a significant economic impact upon a substantial number of small  
20 entities” such that they are subject to RFA review. *See* 5 U.S.C. § 610(a). Instead, HHS  
21 “conducted a random sample of its regulations.” 85 Fed. Reg. at 70,112-13. HHS  
22 assumed, based principally on a cursory review of ten sampled rulemakings (*i.e.*, less than  
23 a third of one percent) and an article written by an attorney with the American Petroleum  
24 Institute, that 11% of all HHS regulations would have a significant impact on small entities  
25 and thus fall under the requirements of the RFA. *Id.* at 70,115. Thus, although by the  
26 Department’s own account the RFA does not apply to *any* of the 89% of the Department’s  
27 regulations that HHS assumed lacked a significant impact on small entities, 5 U.S.C.



1 §§ 602, 610, HHS nonetheless proposed to add expiration dates to nearly all of those  
2 thousands of regulations. *See* 85 Fed. Reg. at 70,107.

3 **a. HHS provides only 30 days for most comments, despite widespread**  
4 **concern that this was inadequate time to meaningfully respond to a**  
5 **proposal of this scope.**

6 47. The APA requires that agencies provide “adequate time for comments” so  
7 that “interested parties [can] comment meaningfully.” *Fla. Power & Light Co. v. United*  
8 *States*, 846 F.2d 765, 771 (D.C. Cir. 1988); *see* 5 U.S.C. § 553(c); Exec. Order No. 13,563,  
9 § 2(b), 76 Fed. Reg. 3,821 (Jan. 18, 2011) (comment period for typical rulemaking should  
10 be a *minimum* of 60 days); Exec. Order No. 12,866, § 6(a), 58 Fed. Reg. 51,753 (Sept. 30,  
11 1993) (same). “90 days is the ‘usual’ amount of time allotted for a comment period.”  
12 *Becerra v. U.S. Dep’t of the Interior*, 381 F. Supp. 3d 1153, 1176 (N.D. Cal. 2019)  
13 (quoting *Prometheus Radio Project v. FCC*, 652 F.3d 431, 453 (3d Cir. 2011)). HHS has  
14 previously recognized that 30 days can be “an insufficient amount of time” for comment  
15 on a complex rulemaking.<sup>9</sup>

16 48. Despite the unprecedented scope of the Proposed Rule, the public was given  
17 only 30 days, until December 4, 2020, to comment on the proposal as it related to all non-  
18 Medicare regulations (that is, as to the vast majority of the Department’s regulations). 85  
19 Fed. Reg. at 70,096-97. The public was given 60 days, until January 4, 2020 (a period that  
20 included three federal holidays), to comment on the Proposed Rule’s effect on Medicare  
21 regulations. *Id.*

22 49. During the abbreviated comment period, hundreds of commenters  
23 representing virtually every type of entity with an interest in HHS regulations raised  
24 concerns about how the limited comment period affected their ability to meaningfully  
25 comment. For example, the Federation of American Hospitals explained that it was simply  
26 not possible to review a proposal of this magnitude “in a meaningful way with proper  
27 discussion and consideration” within the time allotted, particularly during a pandemic

28 <sup>9</sup> Adoption and Foster Care Reporting and Analysis System, 83 Fed. Reg. 11,450, 11451  
(proposed Mar. 15, 2018).

1 when hospitals need “readily accessible guidance.”<sup>10</sup> The Consumer Brands Association,  
 2 an industry group representing “more than 1,700 iconic brands,” reported that  
 3 “stakeholders were not able to provide comments that are as thorough as necessary for a  
 4 proposed rule of this scope” in the time allotted in part because “many businesses were  
 5 closed or employees on leave” before the Thanksgiving holiday, and the Consumer Brands  
 6 Association was busy “navigating the challenges of the COVID-19 pandemic,” such as  
 7 worker safety and supply chain issues.<sup>11</sup> The Service Employees International Union  
 8 explained that a substantially longer comment period was necessary to give it a  
 9 “meaningful opportunity to provide input” on a “rule of this magnitude.”<sup>12</sup>

10 50. Many of these commenters requested more time. Plaintiff the County of  
 11 Santa Clara explained that more time was needed to simply “ascertain[] all the HHS  
 12 regulations that the County implements and depends upon” that would be affected by the  
 13 Proposed Rule, which HHS itself had not identified.<sup>13</sup> The American Herbal Products  
 14 Association reported that more time would allow it to provide examples of how HHS had  
 15 already met the RFA’s requirements for certain regulations.<sup>14</sup> Plaintiff ALA requested an  
 16 extension because the “brief comment periods are an inadequate amount of time for us to  
 17 prepare comments to appropriately respond” to the “wide range of complex and technical  
 18 issues” raised in the Proposed Rule, “especially during the time of this COVID-19  
 19 pandemic.”<sup>15</sup> Plaintiff CSPI requested 180 days to comment, explaining that “[s]uch a

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 21 <sup>10</sup> Federation of American Hospitals, Comment Letter on the Sunset Rule at 2, 3 (Dec. 4,  
 2020), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0196>.

22 <sup>11</sup> Consumer Brands Association, Comment Letter on the Sunset Rule at 1, 3, 7 (Dec. 4,  
 2020), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0280>.

23 <sup>12</sup> Service Employees International Union, Comment Letter on the Sunset Rule at 3 (Dec.  
 24 4, 2020), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0178>.

25 <sup>13</sup> County of Santa Clara, Comment Letter on the Sunset Rule at 4 (Jan. 4, 2021) (footnote  
 omitted), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0533>.

26 <sup>14</sup> American Herbal Products Association, Comment Letter on the Sunset Rule at 3 n.4  
 27 (Dec. 4, 2020), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0082>.

28 <sup>15</sup> American Lung Association, Comment Letter on the Sunset Rule (Nov. 20, 2020),  
<https://www.regulations.gov/comment/HHS-OS-2020-0012-0023>.

1 sweeping proposal is inappropriate for HHS to consider completing in the rushed manner  
 2 proposed, given its wide-ranging implications” and that “[s]aving lives” should instead be  
 3 the focus of the Department’s resources and attention.<sup>16</sup> Plaintiff NRDC urged HHS to  
 4 “provide a *minimum* of 60 days for the public to comment on this proposal.”<sup>17</sup>

5 51. During the comment period, the Department held only one public hearing  
 6 on the proposal, on November 23, 2020, the Monday before Thanksgiving.<sup>18</sup>

7 52. At the public hearing, commenter after commenter explained how the  
 8 Proposed Rule’s timing and truncated comment period impacted their ability to adequately  
 9 comment on a proposal of this breadth. The American Frozen Food Institute, which  
 10 “represents America’s frozen food and beverage makers” raised concerns that the  
 11 proposal’s scope, timing, and limited comment period “calls into question the fundamental  
 12 fairness principles underlying the Administrative Procedure[] Act, assuring a reasonable  
 13 opportunity to review and comment on new government actions.”<sup>19</sup>

14 53. Similar concerns were expressed by such disparate groups as the American  
 15 Medical Association,<sup>20</sup> the United Fresh Produce Association, which “represent[s] over  
 16 1,500 members of the fresh fruit and vegetable supply chain,”<sup>21</sup> and the National  
 17 Confectioners Association, “the leading trade association representing the nearly \$45  
 18 billion U.S. confectionary industry.”<sup>22</sup> As the American Medical Association explained, it  
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20 <sup>16</sup> Center for Science in the Public Interest et al., Comment Letter on the Sunset Rule at 1  
 21 (Dec. 4, 2020), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0158>.

22 <sup>17</sup> Natural Resources Defense Council, Comment Letter on the Sunset Rule at 10 (Dec. 4,  
 23 2020) (emphasis added), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0156>.

24 <sup>18</sup> See Transcript, Public Hearing on the Securing Updated and Necessary Statutory  
 25 Evaluations Timely Notice of Public Rulemaking, (Nov. 23, 2020),  
<https://www.regulations.gov/document/HHS-OS-2020-0012-0501>.

26 <sup>19</sup> *Id.* at 44, 46.

27 <sup>20</sup> *Id.* at 110-11.

28 <sup>21</sup> *Id.* at 70-71.

<sup>22</sup> *Id.* at 86, 88.

1 had been directing its resources “almost solely on the COVID-19 pandemic” and  
 2 “advocating for appropriate policies that would address” it.<sup>23</sup> “[W]ith only 30 days to  
 3 review the proposal and in the midst of everything else that’s going on, it’s extremely  
 4 difficult for organizations and interested parties to evaluate it and meaningfully comment  
 5 on it.”<sup>24</sup>

6 54. Despite the overwhelming requests for additional time from all corners of  
 7 the many industries affected by HHS, the Department refused to extend the comment  
 8 period. 86 Fed. Reg. at 5,706. Indeed, the Department sent the draft final rule to the  
 9 Office of Information and Regulatory Affairs on December 17, 2020, over two weeks  
 10 *before* the end of the 60-day period for commenting on the proposal’s impact on Medicare  
 11 provisions.<sup>25</sup>

12 55. While HHS often receives tens of thousands of comments on a single  
 13 rulemaking, the unjustifiably short comment period made a comparable response here  
 14 impossible; instead, HHS received only 530 comments on a proposal to amend thousands  
 15 of regulations.<sup>26</sup>

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21 <sup>23</sup> *Id.* at 111.

22 <sup>24</sup> *Id.*

23 <sup>25</sup> Final major federal rulemakings must be submitted to the Office of Information and  
 24 Regulatory Affairs for inter-agency review, pursuant to Executive Order 12,866. 58 Fed.  
 Reg. 51,735.

25 <sup>26</sup> *Compare, e.g.*, Nondiscrimination in Health and Health Education Programs or  
 26 Activities, Rulemaking Docket HHS-OCR-2019-00007,  
 27 <https://www.regulations.gov/docket/HHS-OCR-2019-0007> (nearly 156,000 comments  
 28 regarding a single proposed HHS rule), *with* Securing Updated and Necessary Statutory  
 Evaluations Timely Rulemaking Docket HHS-OS-2020-0012 (“Sunset Rule Docket”),  
<https://www.regulations.gov/document/HHS-OS-2020-0012-0001/comment#> (530  
 comments regarding the expiration of approximately 18,000 regulations).

**b. HHS refuses to consult with Indian tribes despite the proposal’s effect on tribal programs and tribal funding.**

56. HHS policy—and the federal government’s trust relationship with sovereign Indian tribes<sup>27</sup>—requires the Department to consult with tribes “[b]efore any action is taken that will significantly affect Indian Tribes” or that has “Tribal implications.”<sup>28</sup> Consultation is also required under Executive Order 13,175, Consultation and Coordination With Indian Tribes, which instructs agencies to “ensure meaningful and timely input by tribal officials in the development of policies that have tribal implications.” Exec. Order No. 13,175, § 5(a), 65 Fed. Reg. 67,249 (Nov. 6, 2000).

57. Plaintiff CTFC, representing 42 tribal governments and 3 statewide tribal leader associations, as well as other organizations representing tribes, raised concerns about the Department’s failure to consult with tribes and requested immediate consultation. *See* 86 Fed. Reg. at 5,711. Plaintiff CTFC explained that the Proposed Rule “would affect literally hundreds of ‘regulations’” that have tribal implications and substantial direct effects on tribes.<sup>29</sup> For example, the proposal would affect regulations under Title IV–E of the Social Security Act, which provides funds for states and tribes to provide foster care and transitional independent living programs for children; social programs of importance

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<sup>27</sup> The federal Indian trust responsibility is a legally enforceable fiduciary duty that has long been recognized by courts. *See Seminole Nation v. United States*, 316 U.S. 286, 295 (1942); Frequently Asked Questions, Bureau of Indian Affairs, <https://www.bia.gov/frequently-asked-questions> (last visited Mar. 7, 2021).

<sup>28</sup> HHS Tribal Consultation Policy at 3, *available at* <https://www.hhs.gov/sites/default/files/iea/tribal/tribalconsultation/hhs-consultation-policy.pdf> (last updated Dec. 12, 2010). “A unique government-to-government relationship exists between Indian tribes and the Federal Government. This relationship is grounded in the U.S. Constitution, numerous treaties, statutes, Federal case law, regulations, and executive orders that establish and define a trust relationship with Indian Tribes.” *Id.* at 1-2.

<sup>29</sup> California Tribal Families Coalition, Comment Letter on the Sunset Rule at 2 (Dec. 4, 2020) (“CTFC Comment”), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0092>; *see also, e.g.*, Native American Rights Fund and the National Congress of American Indians, Comment Letter on the Sunset Rule (Dec. 4, 2020), <https://www.regulations.gov/comment/HHS-OS-2020-0012-0087>.

1 to tribes under the Temporary Assistance for Needy Families and programs addressing  
 2 mental health and care for the elderly; and laws that protect Indian children, such as the  
 3 Indian Child Welfare Act.<sup>30</sup> CTFC and others explained the devastating effects that would  
 4 result from automatic rescission of such regulations.<sup>31</sup>

5 58. Moreover, as CTFC explained, the proposal would set up an ongoing failure  
 6 to consult because it “create[s] a process by which regulatory provisions directly impacting  
 7 Indian Tribes could automatically terminate without notice to, or government-to-  
 8 government consultation with, affected Tribes.”<sup>32</sup> This “undermine[s] the federal  
 9 government’s trust responsibilities to Indian Tribes.”<sup>33</sup>

10 59. Multiple tribes and tribal groups requested immediate consultation on the  
 11 Proposed Rule. Nonetheless, HHS refused to consult with Indian tribes, despite  
 12 acknowledging that monitoring and participating in the review process alone would impose  
 13 \$3 million in costs on Indian tribes. *See* 86 Fed. Reg. at 5,711. HHS claimed that the Rule  
 14 “would have no direct impact on Indian Tribes” aside from monitoring costs because  
 15 “HHS *intends* that all rules will be Assessed and (if necessary) Reviewed timely” such that  
 16 they may not ultimately expire. *Id.* (emphasis added).

17 **III. Under the Final Sunset Rule, Approximately 17,200 Regulations Are Set to**  
 18 **Expire in 2026, but the Rule Does Not Specify Which Ones.**

19 60. Of the 530 publicly available comments the Department received<sup>34</sup>—  
 20 including 486 comments from a broad swath of “industry trade organizations, healthcare  
 21 providers, businesses, legal/policy think tanks, nonprofit public interest groups, and  
 22 members of the U.S. Congress,” *id.* at 5,704—approximately 522 of them opposed the  
 23

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24 <sup>30</sup> CTFC Comment at 2-3.

25 <sup>31</sup> *Id.*

26 <sup>32</sup> *Id.* at 1.

27 <sup>33</sup> *Id.*

28 <sup>34</sup> The Rule mentions 532 comments, 86 Fed. Reg. at 5,704, but only 530 comments reside  
 on the public online docket, *see* Sunset Rule Docket.

1 proposal or advised HHS to withdraw it. Patient advocate groups like the American Heart  
 2 Association, organizations representing hospitals like the Federation of American  
 3 Hospitals, groups representing healthcare professionals like the American Medical  
 4 Association and Plaintiff NAPNAP, insurers like Cigna and United Healthcare, business  
 5 and industry groups like the U.S. Chamber of Commerce and the National Association of  
 6 Manufacturers, and progressive advocacy organizations like Plaintiff CSPI all warned  
 7 HHS of practical and legal problems with the Proposed Rule.

8 61. Despite nearly uniform public opposition, on January 19, 2021, HHS  
 9 nonetheless published the final Sunset Rule without providing any further public process.  
 10 *Id.* at 5,694, 5,704. HHS scheduled the Rule to take effect on March 22, 2021, less than  
 11 five months after it was first mentioned to the public.

12 **a. The final Rule requires that nearly all HHS regulations will expire**  
 13 **unless HHS completes retrospective review for the thousands of**  
 14 **affected regulations.**

14 62. Under the finalized Rule,

15 [S]ubject to certain exceptions, *all* regulations issued by [HHS] in Titles  
 16 21, 42, and 45 of the C.F.R. *shall expire* at the end of (1) five calendar  
 17 years after the year that this final rule first becomes effective, (2) ten  
 18 calendar years after the year of the Section’s promulgation, or (3) ten  
 19 calendar years after the last year in which the Department Assessed and, if  
 20 required, Reviewed the Section, whichever is latest.

19 *Id.* at 5,694 (emphasis added). The only major substantive change from the Proposed  
 20 Rule’s core provisions is that the first expiration date is five years from the effective date  
 21 of the Rule, instead of two. *See id.* at 5,705.

22 63. To avoid expiration of a given C.F.R. section, HHS must first perform an  
 23 “Assessment” to determine whether “the Regulations issued as part of the same  
 24 rulemaking . . . currently have a significant economic impact upon a substantial number of  
 25 small entities.” 86 Fed. Reg. at 5,720. If it determines that a regulation has a significant  
 26 economic impact, HHS must then “Review” that regulation to determine whether it  
 27 “should be continued without change, or should be amended or rescinded, consistent with  
 28 the stated objectives of applicable statutes, to minimize any significant economic impact of



1 the Regulations upon a substantial number of small entities.” *Id.* Both Assessments and  
 2 Reviews would involve a burdensome and time-consuming process involving notice-and-  
 3 comment akin to reissuing the original regulations, and both would be subject to judicial  
 4 review. *See id.* at 5,724, 5,732, 5,764.

5 64. If HHS does not undertake an Assessment and/or Review—which the Rule  
 6 does not require it to do—the regulation automatically expires, without public comment or  
 7 notice. The public will have no opportunity to participate if the Department chooses to let  
 8 a regulation lapse without completing Assessment and/or Review, overlooks a regulation,  
 9 or simply cannot keep up.

10 65. Although HHS refused to specify which regulations are exempted under the  
 11 narrow exceptions from the Sunset Rule, *see infra* ¶ 69, it estimated that the “vast  
 12 majority” of its 18,000 regulations must be Assessed to prevent their automatic  
 13 elimination. *Id.* at 5,740. “[R]oughly 17,200” of these are more than five years old,  
 14 meaning that “the vast majority of these would need to be Assessed within five years of  
 15 [the Sunset Rule’s] effective date” to avoid expiration.<sup>35</sup> *Id.* at 5,741.

16 66. The result is that approximately 17,200 regulations are scheduled to be  
 17 automatically eliminated in 2026, unless HHS undertakes at least one notice-and-comment  
 18 process per original rulemaking that is akin to a full-fledged rulemaking. The remaining  
 19 hundreds will expire on a rolling basis in the five years after that. Using the Department’s  
 20 assumptions that a single rulemaking contains on average five regulations and that 11% of  
 21 Assessments will lead to Reviews, this means that HHS must perform roughly 3,440  
 22 Assessments and 378 Reviews over the next five years to prevent the first round of  
 23 scheduled expirations. *See id.* at 5,717, 5,741-42.

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 28 <sup>35</sup> *See* List of HHS Rulemakings by Date of Promulgation, HHS  
<https://www.hhs.gov/regulations/federal-registry/index.html> (last visited Mar. 5, 2021).



**b. The vague exceptions to the self-executing expirations make it impossible to determine which regulations have been amended and will expire without Assessment and Review.**

67. HHS did not specify *which* regulations have been amended to include expiration dates, purportedly because figuring it out and informing the public would be “unnecessarily burdensome and resource intensive.” 86 Fed. Reg. at 5,720. Instead, HHS declared that the Rule “‘shall be deemed to amend’ all regulations issued by” HHS unless subject to an exception. *Id.* But HHS also did not specify which regulations are excepted from the amendments.

68. In addition to exempting itself from expiration, the Sunset Rule exempts “Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section” and “Sections whose expiration pursuant to [the Rule] would violate any other Federal law.”<sup>36</sup> *Id.* at 5,729, 5,764. The Rule does not further define these exceptions except to note that they apply to “a very small category.” *Id.* at 5,731.

69. The Sunset Rule does not specify which regulations, in the Department’s view, “are prescribed by Federal Law such that the Department exercises no discretion” or which ones constitute “Sections whose expiration pursuant to this section would violate any other Federal law,” two often-litigated topics. HHS itself does not appear to know. Of its 18,000 regulations, HHS merely stated it believed “the vast majority” are not exempt and would need to be Assessed and/or Reviewed under the Rule to prevent expiration. *Id.* at 5,740.

70. Even the Department’s assessment of the Rule’s impact is based on a guess about the number of exempted regulations. “To help estimate the impact of this final rule, the Department conducted a limited randomized sampling of its regulations and assessed

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<sup>36</sup> The Sunset Rule also includes exceptions for certain regulations related to internal personnel management, military or foreign affairs, procurement, and regulations issued jointly with other agencies, as well as a handful of regulations that are already subject to review more frequently than every ten years. *See* 86 Fed. Reg. at 5,729-31. HHS similarly declined to specify which regulations fall within those exceptions.

1 whether the sampled regulations would be exempt from this final rule.” *Id.* at 5,741. HHS  
 2 sampled ten rulemakings—less than 0.3% of the 3,600 rulemakings the Department  
 3 estimates contain its 18,000 regulations—and found that “[n]one of the sampled  
 4 regulations would be exempt from this final rule.” *Id.* at 5,741-42. The Department’s best  
 5 estimate, based on unspecified data from a libertarian think tank,<sup>37</sup> is that “approximately  
 6 66 parts of the CFR,” which accounts for “less than 1% of the Department’s active parts”  
 7 are exempt from the Rule. *Id.* at 5,741.

8 71. The Sunset Rule’s identification of exempted regulations is so vague that it  
 9 does not satisfy the basic APA requirement to tell the public what the Rule does. *See* 5  
 10 U.S.C. § 553(b)(3) (agency must provide notice of “the terms or substance” of the rule).

#### 11 **IV. The Sunset Rule Is Unlawful, and the Department’s Purported Justifications** 12 **Lack Basic Rationality.**

##### 13 **a. The Sunset Rule schedules elimination of regulations regardless of their** 14 **impact on small entities and without RFA review or considerations** **required under substantive statutes and the APA.**

15 72. Regulations “must always be grounded in a valid grant of authority from  
 16 Congress.” *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000).

17 73. The Department purportedly issued the Sunset Rule to “enhance the  
 18 Department’s implementation of” the RFA requirements in 5 U.S.C. § 610(a) to review  
 19 regulations significantly impacting small entities. 86 Fed. Reg. at 5,694. Indeed, the  
 20 Department titled the Rule “Securing Updated and Necessary *Statutory* Evaluations  
 21 Timely” and claimed that its purpose was to “effectuate the desire for periodic  
 22 retrospective reviews expressed in the RFA.” *Id.* (emphasis added); *see also id.* at 5,704.

23 74. However, the Rule’s amendment to 18,000 regulations to add expiration  
 24 dates is neither consistent with, nor authorized by, the RFA. The RFA requires that  
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26 <sup>37</sup> HHS relies on “an analysis from the Mercatus Center,” a libertarian “free-market” think  
 27 tank, and cites generally to a non-government database website called Quantgov.org. 86  
 28 Fed. Reg. at 5,741 n.233. It is unclear what information from that database the Department  
 is relying on.

1 agencies review their regulations that have “a significant economic impact upon a  
2 substantial number of small entities” “*to determine whether*” those regulations should be  
3 “continued without change, or should be amended or rescinded.” 5 U.S.C. § 610(a)  
4 (emphasis added). Any such review “shall consider” five statutory factors, such as the  
5 continued need for the regulation. *Id.* § 610(b). Nothing in the RFA authorizes HHS to  
6 eliminate regulations that have a significant impact on small entities *without* consideration  
7 of the five RFA factors. Nor does it authorize the Department to schedule the elimination  
8 of regulations that *do not* have a significant impact on small entities. Nonetheless, by the  
9 Department’s own estimate, 89% of the regulations it amended do not affect a substantial  
10 number of small entities. *See* 86 Fed. Reg. at 5,742. Such regulations are thus outside the  
11 category of “Necessary Statutory Evaluations,” *id.* at 5,694, that the RFA authorizes and  
12 the Rule purports to target.

13         75. HHS also claimed that it had authority for the Rule under “the statutory  
14 authorities for the Department’s existing regulations.” *Id.* at 5,703. As in the Proposed  
15 Rule, HHS did not purport to include an exhaustive list of the authorities for amending  
16 each regulation. Instead, the Department simply referred to “[s]ome of the Department’s  
17 primary rulemaking authorities,” which “include” 21 U.S.C. § 371(a) of the Federal Food,  
18 Drug and Cosmetic Act; 42 U.S.C. § 1302 and 42 U.S.C. § 1395hh of the Social Security  
19 Act; and the Secretary’s general authority to “prescribe regulations for the government of  
20 his department” under 5 U.S.C. § 301. *Id.* at 5,703.

21         76. These statutes do not authorize the automatic *elimination* of regulations. To  
22 the contrary, on many occasions, Congress has expressly directed HHS to issue regulations  
23 to implement statutory provisions, often specifying the timeframe on which HHS must act.  
24 For example, 42 U.S.C. § 1396a of the Social Security Act directs HHS to issue  
25 regulations defining the requirements for state plans under the Medicaid program, leaving  
26 the Department considerable discretion in the regulations’ content. HHS is required to  
27 issue such regulations, and they are necessary for states to be able to participate in  
28 Medicaid. 42 U.S.C. §§ 1396a, 1396b. In a similar example, 42 U.S.C. § 655(f) generally

1 requires HHS to issue regulations establishing requirements that must be met by an Indian  
 2 tribe to be eligible for grants funding services for needy families with children. In another,  
 3 42 U.S.C. § 289 mandates that HHS issue regulations governing biomedical research  
 4 involving human test subjects. It requires generally that HHS establish “a program” and “a  
 5 process,” *id.*, but the details of that program and process are set forth by regulation, *see* 45  
 6 C.F.R. part 46. And in another example, the Federal Food, Drug and Cosmetic Act  
 7 requires certain chain restaurants to disclose food calorie content on their menus and  
 8 directs HHS to “establish by regulation standards for determining and disclosing the  
 9 nutrient content for standard menu items that come in different flavors, varieties, or  
 10 combinations.” 21 U.S.C. § 343(q)(5)(H)(iii), (v). Yet regulations under such statutory  
 11 provisions apparently do not fall within the Sunset Rule’s exception for regulations  
 12 “prescribed by Federal law” because HHS has discretion “as to what is prescribed” by the  
 13 regulations. *See* 86 Fed. Reg. at 5,729, 5,764.

14 77. When these regulations automatically expire, as designed under the Sunset  
 15 Rule, HHS will immediately be out of compliance with the relevant statute. *See, e.g.,*  
 16 *Oxfam Am., Inc. v. SEC*, 126 F. Supp. 3d 168, 172-73 (D. Mass. 2015); *Sierra Club v.*  
 17 *Johnson*, 374 F. Supp. 2d 30, 32 (D.D.C. 2005). The Sunset Rule therefore expressly sets  
 18 HHS on a path to violate numerous statutory mandates.

19 78. The mass amendment of thousands of regulations to schedule their  
 20 automatic elimination is also inconsistent with the APA and the regulations’ underlying  
 21 enabling statutes. The APA “mandate[s] that agencies use the same procedures when they  
 22 amend or repeal a rule as they used to issue the rule in the first instance.” *Perez v. Mortg.*  
 23 *Bankers Ass’n*, 575 U.S. 92, 101 (2015). Agencies changing their policies must consider  
 24 the “facts and circumstances that underlay or were engendered by the prior policy,” and  
 25 any “serious reliance interests . . . must be taken into account.” *FCC v. Fox Television*  
 26 *Stations, Inc.*, 556 U.S. 502, 515-16 (2009).

27 79. For many of the estimated 18,000 regulations encompassed by the Rule,  
 28 “the terms of the enabling statute . . . indicat[e] what relevant factors the agency must

consider in making its decision.” *C.K. v. N.J. Dep’t of Health & Human Servs.*, 92 F.3d 171, 182 (3d Cir. 1996); *see also Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 646 (1990). For example, the Nutrition Labeling and Education Act mandates that food products bear critical serving size and nutritional information, such as calories. 21 U.S.C. § 343(q)(1). HHS may issue regulations to add and remove nutrient information from food labels, but only if it determines either that the nutrient information will “assist” or “is not necessary to assist consumers in maintaining healthy dietary practices.” *Id.* § 343(q)(2). In another example, 21 U.S.C. § 341 requires HHS under certain circumstances to “promulgate regulations fixing and establishing for any food” a “standard of identity” and a “standard of quality” or “reasonable standings of fill of container.” When doing so, HHS must consider certain factors, such as the “need for necessary packing and protective material” and “the differing characteristics of the several varieties of [a] fruit or vegetable.” *Id.*

80. To amend each individual regulation to schedule automatic rescission, therefore, HHS was required to consider the original need for, considerations giving rise to, statutory requirements of, continuing need for, extent to which members of the public rely on, and impact of automatic rescission of the existing regulation. The Sunset Rule did none of this for any of the estimated 18,000 regulations affected.

**b. The Sunset Rule is arbitrary and capricious because, among other reasons, it purports to “incentivize” the Department to review regulations at an infeasible pace HHS has never achieved by eliminating regulations relied upon by the general public.**

81. The Department’s justification for the Sunset Rule is that because regulatory review under the RFA has previously been “deprioritized and relegated to rainy day activities,” “the Department believes a stronger incentive is needed to achieve the benefits of retrospective review.” 86 Fed. Reg. at 5,699-,700. The “incentive” is that thousands of regulations—many of them required by Congress and needed by Plaintiffs and the public—will disappear with no further process if federal employees and political officials at HHS are unable to, or choose not to, complete review.

1           82.     This justification is irrational on its face. It seeks to motivate career federal  
2 employees and political officials to do something by planting a timebomb set to eliminate  
3 regulations to the detriment of *someone else*, often the most vulnerable citizens among us.

4           83.     For example, 45 C.F.R. § 164.512(b)(1)(i) authorizes healthcare providers  
5 to disclose protected health information without a patient's consent to a public health  
6 authority for certain public health purposes. This regulation has been vital during Plaintiff  
7 County of Santa Clara's public health response to the COVID-19 pandemic (as well as that  
8 of public health departments around the nation). The Rule's supposed "incentive" works  
9 by taking away this and many other regulations that government entities like the County  
10 rely on, unless the Department's employees choose to take optional, time-consuming  
11 action.

12           84.     HHS also fails to acknowledge that there is no realistic probability that the  
13 Department will be able to conduct the number of reviews required to prevent automatic  
14 rescission. Under the Department's estimates, *supra* ¶ 66, HHS would need to "perform  
15 roughly 3,440 Assessments in the first five years" (688 per year, on average) plus 378  
16 Reviews to avoid mass regulatory expiration of up to 17,200 regulations in 2026. 86 Fed.  
17 Reg. at 5,741.

18           85.     By its own admission, HHS has never been able to conduct retrospective  
19 review at this pace. Despite a host of executive orders and agency initiatives, "the  
20 Department has only conducted retrospective review to a very limited extent" and never at  
21 the pace originally planned. *Id.* at 5,696. For example, "the Department planned 83  
22 retrospective analyses in 2012 and completed 33 analyses with final action by August 31,  
23 2013." *Id.* In another attempt, "[a]s of July 2016, the Department had 40 planned  
24 retrospective analyses and by April 2017 had completed analyses with final action on 19 of  
25 them." *Id.* HHS has not provided any information supporting its assumption that it can  
26 increase its rate of retrospective review 20-fold simply by artificially creating  
27 consequences for third parties. Indeed, in the time HHS took to issue the Rule, the  
28 Department could not even identify the regulations subject to its requirement because that

1 was too “burdensome and resource intensive.” *Id.* at 5,720. There is no factual support for  
2 the conclusion that it can now reasonably identify all the relevant regulations and conduct  
3 thousands of Assessments and Reviews in the coming years.

4 86. The Department’s estimate of the work needed to undertake the required  
5 reviews is similarly arbitrary. HHS “assumes” that some regulations will take “40 to 100  
6 hours” to review while others will take “between 250 to 500 hours” to review, but it  
7 provides no basis whatsoever for these estimates. *Id.* at 5,743. It is inconceivable to  
8 assume without explanation that the Rule’s estimates are meaningful.

9 87. Based on just this cursory estimate, the Department calculates that it would  
10 take up to 45.6 full-time employees five years to complete the necessary review. *Id.* But  
11 HHS does not explain where the personnel would come from even under that unreasoned  
12 and very conservative estimate or what the effect will be on other Department priorities.  
13 HHS dismissed commenter concerns about diverting resources during the COVID-19  
14 pandemic, stating that it “believes the pandemic will be over by” 2026 when the first round  
15 of mass eliminations is scheduled, *id.* at 5,705, ignoring its own assumption that the task  
16 would take all five years. Nor does the Rule explain how HHS could devote dozens of  
17 employees to full-time retrospective review without compromising the Department’s and  
18 its sub-agencies’ many other crucial tasks, such as protecting the country from future  
19 pandemics, facilitating provision of and access to healthcare, and ensuring food and drug  
20 safety.

21 88. The Department also fails to rationally explain its decision to apply the  
22 “incentive” to nearly all HHS regulations. As discussed above, *supra* ¶ 73, the  
23 Department’s justification relies on its claimed need to implement the RFA. Yet the Rule  
24 schedules the elimination of thousands of regulations HHS “found to not be subject to the  
25 RFA.” *Id.* at 5,742. The Department’s only explanation for why it scheduled automatic  
26 elimination for the 89% of its regulations it assumes are *not* subject to the RFA is that HHS  
27 must do more work to know whether the RFA applies. *See id.* at 5,717, 5,742. However,  
28 instead of doing that work to determine the regulations covered by the RFA—an obvious



1 and far less burdensome alternative—HHS has now required a full Assessment of  
 2 thousands of regulations *not* subject to the RFA in order to avoid their artificial elimination  
 3 deadline.

4 89. Even the sources the Department cites as purported support for regulatory  
 5 expiration provisions in general do not support the assumption that the “incentive” would  
 6 work as intended. For example, HHS relies on the “experience” of certain states like North  
 7 Carolina and Idaho with automatic expiration provisions. *Id.* at 5,700, 5,745. But HHS  
 8 states that the circumstances in Idaho were not comparable, *id.* at 5,745, and notes that  
 9 North Carolina and many other states have repealed their “sunset” laws because they are  
 10 “expensive, cumbersome, and disappointing” *id.* at 5,700 n.76 (internal citation and  
 11 quotation marks omitted). In another example, one of the reports that HHS claims  
 12 illustrates the “benefits of sunset provisions,” *id.* at 5,700, actually concludes that

13 the benefits of sunset laws are largely intangible and likely insignificant  
 14 compared to the costs. Moreover, the burdens of such mandatory reviews  
 15 can draw staff away from performing other vital oversight duties.  
 Generally, sunset requirements produce perfunctory reviews and waste  
 resources.<sup>38</sup>

16 HHS also claims that the Administrative Conference of the United States “called for”  
 17 retrospective review, 86 Fed. Reg. at 5,700, but the cited document only endorses  
 18 retrospective reviews where agencies tailor the “level of rigor of retrospective analysis  
 19 . . . to the circumstances,” and “identify[] regulations that are strong candidates for review”  
 20 based on specific factors that do not include the regulation’s age since promulgation.<sup>39</sup>

21 90. HHS did not conduct any serious review of the harm the Sunset Rule causes  
 22 to the public. It dismissed concerns about harm caused by automatic rescission by  
 23 asserting it “has no intention to rescind regulations that appropriately protect the public  
 24

25 <sup>38</sup> Jason A. Schwartz, Inst. for Policy Integrity, *52 Experiments with Regulatory Review: The Political and Economic Inputs into State Rulemaking* 23-24 (Nov. 2010),  
 26 [https://policyintegrity.org/files/publications/52\\_Experiments\\_with\\_Regulatory\\_Review.pdf](https://policyintegrity.org/files/publications/52_Experiments_with_Regulatory_Review.pdf)  
 27 (footnotes omitted).

28 <sup>39</sup> Administrative Conference of the United States, *Adoption of Recommendations*, 79 Fed. Reg. 75,114, 75,115-17 (Dec. 17, 2014).



1 health or consumers.” 86 Fed. Reg. at 5,725; *see also id.* at 5,708, 5,712. But the Rule  
2 does not codify that intention; the only thing it requires is rescission, which will occur  
3 unless the Department takes separate final agency action to prevent it. And it allows the  
4 Department to abandon any regulation simply by doing nothing, whether or not the public  
5 considers it “appropriate.”

6 91. The Department’s assessment of the cost to the public simply to monitor the  
7 review process and determine which regulations remain in effect is also poorly supported  
8 and irrational. Despite the unprecedented scope of automatic rescission, the “Department  
9 believes the cost of monitoring Assessments will be relatively trivial” because “the  
10 regulated community already monitors Regulations.gov.” *Id.* at 5,744. This conclusion is  
11 inconsistent with the record. It ignores the massive increase to that burden due to the  
12 unprecedented scope of the Rule and the unique nature of the automatic expiration  
13 provisions, as well as the burdens on the *non-regulated* public—all concerns commenters  
14 raised. For example, commenters explained that they do not typically monitor  
15 Regulations.gov to determine whether long-established regulatory schemes will be  
16 automatically rescinded due to Department inaction. And they explained that because they  
17 lack clarity on which regulations are exempted, their monitoring costs will go beyond  
18 merely monitoring a website and now must involve finding out whether regulations never  
19 subjected to Assessments or Reviews have expired or not.

20 92. With respect to Reviews, the Department’s regulatory impact analysis is  
21 based on the broad and unsupported assumption that its pace of Review, and the public’s  
22 interest in Reviews, will match what has occurred in North Carolina, a state that repealed  
23 its automatic expiration provisions as “disappointing” and “expensive.” *Id.* at 5,745, 5,700  
24 n.76, 5,745. HHS “expects it will receive less interest in regulations that are rescinded”  
25 because that is what occurred with respect to unspecified regulations in that state. *Id.* at  
26 5,745. But HHS does not explain how the regulations or circumstances in the state context  
27 are comparable to the extensive regulations covering significant parts of the national  
28 economy (as well as protection of life and well-being) promulgated by HHS. *Id.* The

1 Department's estimate that cost to the public of monitoring is between \$52.2 and \$156.7  
 2 million is similarly grossly underestimated and insufficiently supported. *Id.*

3 93. The Department's justification is based on irrational incentives and  
 4 infeasible factual assumptions and is arbitrary and capricious.

5 **V. The Sunset Rule Harms Plaintiffs and the General Public.**

6 94. Absent any stays, the Sunset Rule will go into effect on March 22, 2021.<sup>40</sup>  
 7 *Id.* at 5,694.

8 95. The Sunset Rule harms all Plaintiffs by scheduling elimination of nearly all  
 9 HHS regulations that structure Plaintiffs' operations and businesses, delineate their  
 10 obligations and rights, or protect their members and the populations they serve. Absent  
 11 further Department action finalizing review of individual regulations, 18,000 regulations  
 12 will expire on a rolling basis, beginning in 2026. Expiration is automatic, and preventing it  
 13 is left to the sole discretion and resource constraints of HHS in finalizing—or not—  
 14 Assessments and/or Reviews of each regulation.

15 96. The Sunset Rule also harms all Plaintiffs by creating substantial confusion  
 16 and uncertainty in every aspect of their work that relates to areas regulated by HHS. While  
 17 some regulations may ultimately remain in place under the Sunset Rule, it is impossible for  
 18 Plaintiffs to know *which* regulations will remain in place because it all depends on whether  
 19 the Department will actually be able, and choose, to complete review on time. Leading up  
 20 to the expiration period, individuals and entities affected by HHS regulations will not  
 21 know whether any particular regulation will continue beyond the expiration date. Even  
 22

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23 <sup>40</sup> President Biden's Chief of Staff issued a memorandum to all agency heads on January  
 24 20, 2021, instructing them to consider, for rules that have been published in the Federal  
 25 Register but have not taken effect, postponing the rules' effective dates for 60 days from  
 26 the date of the memorandum, consistent with applicable law and certain specified  
 27 exceptions, "for the purpose of reviewing any questions of fact, law, and policy the rules  
 28 may raise." Memorandum from Ronald A. Klain, Assistant to the President and Chief of  
 Staff, to the Heads of Exec. Dep'ts & Agencies, Regulatory Freeze Pending Review (Jan.  
 20, 2021), [https://www.whitehouse.gov/briefing-room/presidential-  
 actions/2021/01/20/regulatory-freeze-pending-review/](https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review/). As of the filing of this Complaint,  
 HHS has not issued a stay in response to this memorandum.

1 where HHS undertakes an Assessment or Review, Plaintiffs will have no assurance that  
2 review will be completed before expiration. And for the regulations potentially subject to  
3 the exception for “Sections prescribed by Federal law” the Rule creates significant  
4 uncertainty because HHS has not published a list of which regulations are excepted.  
5 Plaintiffs cannot know whether HHS considers any particular regulation to be “prescribed  
6 by Federal law such that the Department exercises no discretion as to whether to  
7 promulgate the Section and as to what is prescribed by the Section” or one “whose  
8 expiration pursuant to this section would violate any other Federal law.” *See* 86 Fed Reg.  
9 at 5,764. The scope of this uncertainty affects many (and for some, nearly every) aspect of  
10 Plaintiffs’ missions.

11       97. The Sunset Rule will also harm Plaintiffs and their members by forcing  
12 them to divert significant time and finite resources to amass evidence concerning the  
13 benefits of regulations that most affect them even before review occurs so that they can  
14 adequately ensure that necessary regulations remain in place. HHS expects that the public  
15 will “remind the Department” to conduct a Review “if the Review deadline is nearing and  
16 the Department has not commenced the Review,” monitor its progress to help “safeguard  
17 against accidental expirations,” gather facts and cost-benefit information, and comment in  
18 support of relevant regulations. 85 Fed. Reg. at 70,117; 86 Fed. Reg. at 5,748. Plaintiffs  
19 such as the County of Santa Clara simply cannot devote all the resources that would be  
20 necessary to undertake this intensive process for the hundreds to thousands of relevant  
21 HHS regulations subject to the Rule.

22       98. The Rule will also force Plaintiffs to divert significant time and resources to  
23 track each relevant regulation’s progress, educate the public on the patchwork of  
24 obligations and protections at risk of expiration, and revise their advocacy strategies to  
25 ensure that essential regulations remain in place and combat the ill effects of expiration.  
26 HHS explicitly envisioned that the public would incur between \$52.2 million and \$176.3  
27 million in costs to monitor the regulations and participate in the review process. This  
28

1 estimate, while implausibly low, clearly confirms that the Sunset Rule places a substantial  
2 financial burden on Plaintiffs and other entities.

3       99. The Sunset Rule will also harm members of the general public, including  
4 the elderly, children, doctors and other healthcare workers, tribal members, and anyone  
5 who needs medical care, is affected by pandemics or disasters, or simply eats food. These  
6 individuals will suffer worse outcomes in terms of health and well-being if they lose  
7 protections under HHS programs. This, too, will increase the economic costs to Plaintiffs,  
8 who will need to devote more time, energy, and resources to finding ways to assist  
9 individuals absent these protections from the federal government.

10           **a. County of Santa Clara**

11       100. Thousands of HHS regulations that the County of Santa Clara relies on to  
12 operate the County's Hospitals and Clinics, Social Services Agency, Public Health  
13 Department, Behavioral Health Services Department, Valley Health Plan, and Emergency  
14 Medical Services Agency are scheduled to be automatically rescinded under the Sunset  
15 Rule. Indeed, the Rule sets expiration dates for more regulations governing more  
16 significant issue areas than the County can currently identify and count. Yet even the  
17 expiration of a single regulation—such as 45 C.F.R. § 164.512(b)(1)(i), the HIPAA  
18 exemption that permits healthcare providers to share information for public health response  
19 purposes—will cause colossal chaos and harm to the County and the communities and  
20 patients that it serves.

21       101. If the Rule takes effect, it will require significant additional administrative,  
22 logistical, and operational contingency planning by the County, and make it harder for the  
23 County to embark on new plans and activities. The potential expiration of thousands of  
24 regulations that HHS has maintained for years fundamentally destabilizes the County's  
25 reasonably settled expectations, which it relies upon to budget and plan. The Rule will  
26 force the County to roll back new planned services and support to its community because  
27 of the substantial risk that federal funding that the County depends upon will diminish or  
28 disappear. It will disrupt its ability to make new long-term commitments in physical

1 infrastructure, budgets, programming, human capital, research, services, outreach, public  
2 education, electronic systems, and much more.

3 102. The Rule also requires the County to prepare to offer healthcare services  
4 with lower or no reimbursements because payments and requirements under federal  
5 programs are scheduled to expire while the County's existing obligations—many of which  
6 are the subject of highly negotiated, long-term, multi-entity, complex contracts that cannot  
7 be amended without substantial lead time—remain the same. The County may be forced  
8 to rent or own facilities that are no longer certified, purchase goods and services that  
9 cannot be used, run programs for which no one is eligible, employ a healthcare workforce  
10 that is suddenly uncredentialed, and fill in the costs from missing federal funding on which  
11 it depends. The uncertainty and harms will be all the more profound because of the  
12 immense technical complexity of the industries that HHS oversees, the substantive statutes  
13 that it administers, and the regulations that the Rule subjects to impending expiration.

14 **b. California Tribal Families Coalition**

15 103. CTFC's member tribes are affected by many of the HHS regulations  
16 scheduled to be automatically rescinded under the Sunset Rule. CTFC's member tribes are  
17 independent governments that administer programs related to foster care, child welfare,  
18 healthcare, and public health. They receive mandatory funding to operate programs under  
19 HHS regulations. Automatic rescission of any, or all, of these regulations will harm  
20 CTFC's member tribes and their tribal members by eliminating protections and funding  
21 that they are entitled to under the Indian Self-Determination and Education Assistance Act.

22 104. CTFC's member tribes are also affected by HHS regulations governing the  
23 distribution of emergency supplies to tribes and tribal health clinics. For example, under  
24 "Project TRANSAM," a cooperative program between the Indian Health Service and the  
25 Department of Defense, tribes are entitled to receive medical supplies and other assets  
26 from closed military bases.<sup>41</sup> HHS regulations governing this program address

27 \_\_\_\_\_  
28 <sup>41</sup> *About Project TRANSAM*, Indian Health Service,  
<https://www.ihs.gov/transam/abouttransam/> (last visited Mar. 8, 2021).

1 maintenance of asset integrity through proper storage, security, inventory management and  
2 reports, coordination between HHS and tribes, and issues related to emergency response  
3 requirements. Without this regulatory framework, equipment, supplies, and assets may not  
4 be deployed at all, much less in a safe and orderly manner.

5 105. CTFC's member tribes will suffer immediate and substantial harm if the  
6 Sunset Rule takes effect because of the extreme and unprecedented uncertainty it creates,  
7 particularly with respect to funding. The Sunset Rule's scheme—and its vague  
8 exemptions—make it impossible for the tribes to know which regulations that they rely  
9 upon for funding and supplies will soon disappear. The regulatory foundation of their  
10 healthcare and social program funding will be destabilized, making it difficult for the tribes  
11 to budget, hire staff, enter into contracts, or develop programs to protect tribal members.  
12 The funding uncertainty will also have a trickle-down effect on other tribal programs, such  
13 as social service programs that work with the tribal courts to protect vulnerable tribal  
14 members.

15 106. This level of uncertainty is the antithesis of the goals of the Department's  
16 Tribal Consultation Policy and would not exist if HHS had consulted with CTFC's  
17 member tribes. Consultation would have given CTFC's member tribes the opportunity to  
18 determine the degree of harm to their government operations and propose feasible means  
19 to avoid or mitigate them.

20 107. CTFC is also directly harmed by the Sunset Rule. CTFC must now expend  
21 significant resources to monitor thousands of existing regulations to determine whether  
22 they are amended by the Rule and whether HHS will choose to Assess and Review them.  
23 This will divert significant resources from CTFC's primary goal of advocating for the  
24 inclusion of tribal concerns in regulations to promoting the retention and possibly re-  
25 issuance of the complex regulatory schemes the tribes already rely upon. CTFC will need  
26 to spend more resources than ever before to be able to advise tribes on their funding  
27 eligibility, the regulations they must abide by, and the programs available to them. This  
28 harm to CTFC is exacerbated because member tribes have their own regulations and

1 programs that may differ in how they interact with HHS; CTFC will have to advise  
2 different members differently and advocate to HHS on multiple fronts at the same time. It  
3 will be impossible for CTFC to adequately advocate for all member tribes with respect to  
4 all HHS regulations that are amended by the Sunset Rule.

5 **c. National Association of Pediatric Nurse Practitioners**

6 108. Thousands of HHS regulations that govern the businesses and operations of  
7 NAPNAP's members are scheduled to be automatically rescinded under the Sunset Rule.  
8 Federal protections that govern NAPNAP's pediatric advanced practice registered nurses  
9 and protect children's health are wide ranging. They include regulations that ensure access  
10 to vaccines and other critical preventive services, ensure safe and effective pediatric  
11 medicines and therapies, protect children from the harms of tobacco, and allow children to  
12 access high-quality, affordable health care coverage. By HHS's own estimate, the Sunset  
13 Rule schedules rescission of thousands of regulations under Medicaid and the Children's  
14 Health Insurance Program alone. These include, for example, Medicaid's Early and  
15 Periodic Screening, Diagnostic and Treatment benefits, which defines the standard of  
16 pediatric care and covers an array of services like developmental, dental, vision and  
17 hearing screenings, and early diagnosis and treatment of health problems. In addition,  
18 regulations governing Home and Community-Based Services waivers, which thousands of  
19 children and youth with special health care needs depend on, are subject to automatic  
20 elimination under the Rule.

21 109. The Rule also imperils regulations that directly protect child health, such as  
22 regulations under the 2009 Family Smoking Prevention and Tobacco Control Act that  
23 regulate tobacco products to protect children and adolescents from the harmful effects of  
24 tobacco and e-cigarette use. Another example is regulations under the Vaccines for  
25 Children Program, which plays a key role in protecting America's children from vaccine-  
26 preventable diseases. These and many other regulations germane to NAPNAP's mission  
27 are now subject to automatic rescission provisions.



110. The Sunset Rule will create regulatory chaos and confusion that will burden NAPNAP's members and other pediatric providers with an uncertain and unpredictable practice environment. Critically important children's health regulations could expire en masse, while underlying statutes remain. The result is that states, health plans, and other stakeholders will lack clear guidance on how to follow the law and implement important programs, making it virtually impossible for NAPNAP's members to provide care with the assurance that they are complying with the law.

111. The Sunset Rule will also harm NAPNAP directly. As a professional membership association, NAPNAP has an obligation to provide its members with comprehensive, accurate information to help them provide evidence-based, high-quality care for their patients. If the rule takes effect, NAPNAP will have to expend significant additional resources to monitor, review, and provide expert comments on thousands of regulations affecting its members' ability to practice. This effort would force the association to reallocate resources, which are already stretched by loss of conference revenue and other activities during the COVID-19 pandemic. It would thus reduce its ability to meet its members' need for educational and professional clinical resources. This degree of burden is directly caused by the Rule.

#### **d. American Lung Association**

112. Thousands of HHS regulations across multiple sub-agencies germane to ALA's healthcare mission are scheduled to be automatically rescinded under the Sunset Rule. Medicaid and the Children's Health Insurance Program, two critical programs that provide healthcare for millions of individuals with or at risk of lung disease, are administered based on thousands of regulations subject to the Rule. Regulations establishing health insurance marketplaces—the sole place where individuals can access federal financial assistance—and market reforms governing individual and group market coverage are now at risk of disappearing all at once. Without further HHS action to prevent expiration, key regulations implementing the ACA will expire, including regulations that guarantee issuance and renewal of insurance coverage, protections for



1 people with preexisting conditions, and requirements for comprehensive treatment.  
2 Individuals with or at risk of lung disease, the population that ALA supports and  
3 represents, rely on these and many other HHS regulations for the provision and assurance  
4 of quality, affordable healthcare. Without these regulations, the health and access of these  
5 individuals will suffer.

6 113. Regulations germane to ALA's lung disease prevention mission are also  
7 scheduled to be automatically rescinded under the Rule. For example, in 2016, the FDA  
8 finalized a regulation asserting its authority over e-cigarettes, cigars, hookah, pipe,  
9 dissolvable, and other forms of tobacco products. 81 Fed. Reg. 28,973 (May 10, 2016).  
10 Such products are used by millions of people, including youth and young adults. If this  
11 regulation expires, as is required under the Sunset Rule unless HHS takes further action,  
12 these products will become unregulated and millions of people will be at new risk of  
13 becoming addicted to tobacco. ALA's smoking cessation programs will become much  
14 more costly and difficult to operate, forcing ALA to divert resources from its other  
15 activities. More importantly, it would lead to more disease and death and billions of  
16 increased healthcare costs. And because of the nature of the regulation, automatic  
17 rescission could trigger a domino effect of undermining regulations that rely on the  
18 authority asserted in the 2016 regulation.

19 114. If it takes effect, the Sunset Rule will cause immediate and irreparable harm  
20 to ALA. ALA will need to divert its resources from advocating for more protections for  
21 the population it serves to simply trying to ensure that existing protections are not lost. It  
22 will need to expend significant time and resources to monitor the progress of relevant  
23 regulations through the retrospective review process and to discern which regulations are  
24 subject to the Rule's exemptions. Its ability to advise its target population on available  
25 protections and its ability to promote the health of its target population will be severely  
26 hampered. It will need to expend additional resources through its programs, including its  
27 Lung Helpline, to help new users end their addictions.

1 **e. Center for Science in the Public Interest**

2 115. The Sunset Rule conflicts with, impairs, and frustrates CSPI's mission and  
3 activities. CSPI will be forced to divert substantial resources from other organizational  
4 priorities to ensuring that thousands of regulations do not expire or otherwise change in a  
5 way that jeopardizes CSPI's mission and the health and safety of millions of Americans.

6 116. Approximately 2,000 FDA regulations germane to CSPI's mission are  
7 scheduled to be automatically rescinded under the Sunset Rule. More than 800 of these  
8 regulations determine the conditions, if any, under which certain additives may be safely  
9 added to food. For example, 21 C.F.R. § 172.345 mandates that certain grain cereals be  
10 enriched with folic acid and is widely credited with preventing approximately 1,000 neural  
11 tube birth defects each year.<sup>42</sup> Another example is the 2015 FDA ban on the addition of  
12 artificial trans fats, a regulation issued after a 25-year CSPI public health campaign.<sup>43</sup> See  
13 80 Fed. Reg. 34,650 (June 17, 2015). Other regulations subject to the Sunset Rule govern  
14 food labeling and transparency and food safety. For example, regulations under the Food  
15 Safety Modernization Act require companies to take specific actions to prevent food  
16 contamination. Such regulations give consumers confidence that they can purchase food  
17 without contracting a deadly foodborne disease.

18 117. Under the Rule, CSPI must now divert significant time to, among other  
19 things: (1) confirming whether and when Assessments are scheduled; (2) tracking the  
20 relevant regulations' progress through the Assessment process; (3) drafting comments  
21 during the regulations' Assessments to explain why Review is not required;  
22 (4) encouraging the Department to complete Assessments on time to avoid the dire  
23

24 <sup>42</sup> Jennifer Williams *et al.*, *Updated Estimates of Neural Tube Defects Prevented by*  
25 *Mandatory Folic Acid Fortification — United States, 1995–2011*, CDC Morbidity and  
26 Mortality Weekly Report (Jan. 16, 2015),  
<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6401a2.htm>.

27 <sup>43</sup> *A Final Farewell to Artificial Trans Fat: Partially Hydrogenated Oil Increasingly Hard*  
28 *to Find as Companies Face Monday Deadline to Eliminate It*, CSPI (June 13, 2018),  
<https://bit.ly/2MV54Hp>.

1 consequences of expiration; (5) drafting comments for regulations undergoing Review to  
2 explain their benefits; (6) encouraging the Department to complete Reviews on time to  
3 avoid automatic expiration; (7) drafting comments for any such regulations the Department  
4 proposes to rescind or amend; and (8) petitioning for re-issuance of any such regulations  
5 that expire under the Rule.

6 118. Each such comment or petition will require substantial research, drafting  
7 time, and internal review, in addition to efforts to mobilize members and other partner  
8 organizations. In its cost analysis, HHS estimates that it will take between 5 to 15 hours to  
9 write a comment. 86 Fed. Reg. at 5,745. In CSPI's experience, that is a tremendous  
10 underestimate. CSPI routinely spends at least 40 hours drafting and finalizing a comment.  
11 On complex rules, CSPI can spend 100 hours or more on a comment.

12 **f. Natural Resources Defense Council**

13 119. Dozens of regulations germane to NRDC's public health mission are  
14 scheduled to "expire" under the Sunset Rule. These include regulations governing the use  
15 of antibiotics in animal agriculture, food additives, bottled water safety, and the protection  
16 of human subjects in scientific research.

17 120. NRDC devotes considerable resources to advocating for these and other  
18 health-protective regulations at HHS, and to educating its members and the public about  
19 these regulations. For example, NRDC has successfully advocated for regulations limiting  
20 the presence of arsenic and other contaminants in bottled water, 21 C.F.R. § 165.110, and  
21 has worked to ensure the effectiveness of regulations governing the safety of chemicals in  
22 food packaging, *e.g.*, 21 C.F.R. Part 170 Subpart B. These regulations and others  
23 safeguard the health of NRDC members and the public. NRDC is also actively advocating  
24 for new regulations and improved oversight on a wide range of public health issues. For  
25 example, NRDC petitioned HHS to withdraw its approval of the preventative use of  
26 livestock antibiotics.

27 121. Under the Rule, NRDC will be forced to divert its limited resources from  
28 these advocacy efforts to rehash issues that have already been addressed by HHS. Among

1 other things, to prevent the regulations that protect its members from expiring, NRDC will  
2 now have to (1) compile a list of HHS regulations it does not wish to see expire; (2)  
3 calculate when those regulations will turn ten years old; (3) interpret the Sunset Rule's  
4 confusing exemptions to confirm that a particular regulation is subject to termination; (4)  
5 monitor the Department's Assessments and Reviews to know whether a certain regulation  
6 is under review; and (5) at some undefined time when the expiration date is nearing,  
7 submit a reminder to HHS that the regulation is due to expire. If HHS chooses to undertake  
8 an Assessment and/or Review of one of these regulations, NRDC will have to divert  
9 resources to submit comments, engage its members and activists, and otherwise ensure that  
10 health-protective regulations remain on the books. And if HHS instead does nothing and  
11 allows a regulation to expire, NRDC will have to divert resources to educate its members  
12 about the new risks to their health caused by this expiration and to petitioning HHS to re-  
13 promulgate that expired regulation. This will in turn force NRDC to divert significant  
14 resources from its advocacy and public education efforts in order to ensure that HHS does  
15 not allow health-protective regulations to expire.

16 122. The Sunset Rule also harms NRDC's members. Absent further voluntary  
17 action by HHS, many regulations protecting NRDC members' health will expire,  
18 increasing NRDC members' and their families' risk of harm from, for example, consuming  
19 contaminated food, being inadvertently exposed to food allergens, or using unregulated  
20 hand and body wash products.

21 ///

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CLAIMS FOR RELIEF

COUNT ONE

(on behalf of all Plaintiffs)

**The Sunset Rule Is *Ultra Vires* and Issued in Excess of Statutory Authority, in Violation of 5 U.S.C. § 706(2)(C), and Contrary to Law, in Violation of 5 U.S.C. § 706(2)(A).**

123. Plaintiffs repeat and incorporate by reference each of the preceding paragraphs.

124. Under 5 U.S.C. § 706(2)(C), courts shall hold unlawful and set aside agency action that is taken in excess of statutory jurisdiction, authority, or limitations.

125. Under 5 U.S.C. § 706(2)(A), courts shall hold unlawful and set aside agency action that is not in accordance with law.

126. As a federal agency, HHS has no power to act unless Congress confers that power, and actions that are unauthorized by Congress or inconsistent with congressional discretion are *ultra vires*.

127. The Sunset Rule is *ultra vires* and issued in excess of HHS's authority because it modifies and schedules rescission of approximately 18,000 regulations, in reliance on the RFA, without the process required by the RFA.

128. The Sunset Rule is *ultra vires* and issued in excess of HHS's authority because it modifies and schedules rescission of regulations whose review is not authorized by the RFA.

129. The Sunset Rule is contrary to law because it schedules the automatic elimination of regulations that are required by statute, including, among other things, regulations issued under 42 U.S.C. § 1396a, 42 U.S.C. § 655(f), 42 U.S.C. § 289, and 21 U.S.C. § 343(q)(5)(H).

130. The Sunset Rule is further contrary to law because it modifies and adds expiration dates to approximately 18,000 regulations without providing the same level of process provided for the original regulations, including, among other things, assessing the impact of the change to each regulation being amended, the underlying statutory

1 requirements for each regulation, and the impacts of the regulatory uncertainty created by  
2 the amendments.

3 **COUNT TWO**  
4 *(on behalf of all Plaintiffs)*

5 **The Sunset Rule Is Arbitrary and Capricious in Violation of 5 U.S.C. § 706(2)(A).**

6 131. Plaintiffs repeat and incorporate by reference each of the preceding  
7 paragraphs.

8 132. Under 5 U.S.C. § 706(2)(A), courts shall hold unlawful and set aside  
9 agency action that is arbitrary or capricious.

10 133. The Sunset Rule is arbitrary and capricious and lacks a rational basis  
11 because, among other reasons, it (a) eliminates public health regulations as a purported  
12 incentive for the Department to conduct RFA reviews; (b) assumes that HHS will conduct  
13 RFA reviews at an implausible pace it has not shown that it can achieve; (c) does not  
14 consider the extreme degree of regulatory uncertainty the Rule creates; (d) underestimates  
15 the burden imposed on Plaintiffs for monitoring HHS regulations to ensure they do not  
16 expire; (e) fails to consider the specific regulations being amended to automatically expire;  
17 (f) does not clearly identify which regulations have been amended and does not consider  
18 the impact of that ambiguity; (g) amends regulations not subject to RFA retrospective  
19 review requirements while exempting the Sunset Rule itself because it is not subject to the  
20 RFA; (h) fails to respond meaningfully to significant comments; and (i) fails to address  
21 alternatives proposed by commenters.

22 **COUNT THREE**  
23 *(on behalf of all Plaintiffs)*

24 **The Sunset Rule Violates the APA's Requirements for Notice-and-Comment  
25 Rulemaking under 5 U.S.C. §§ 553 and 706(2)(D).**

26 134. Plaintiffs repeat and incorporate by reference each of the preceding  
27 paragraphs.

28 135. The APA requires this Court to hold unlawful and set aside any agency  
action taken "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).



11            144.    The Department’s refusal to consult with tribes was also arbitrary and  
12 capricious because it relied on the assumption that regulations affecting tribes will not be  
13 allowed to expire when that assumption is speculative and wholly infeasible. Indeed, by  
14 its terms, the Rule allows regulations to expire automatically and thus without  
15 consultation.

17 WHEREFORE, Plaintiffs pray that this Court:

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d) grant all other relief this Court deems appropriate.

Dated: March 9, 2021

Respectfully submitted,

By: /s/ Lorraine Van Kirk

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*\*Pro hac vice application forthcoming*