Wichita, KS (ICT)	VORTAC	(Lat. 37°44′42.92″ N, long. 097°35′01.79″ W)
Butler, MO (BUM)	VORTAC	(Lat. 38°16′19.49″ N, long. 094°29′17.74″ W)
St Louis, MO (STL)	VORTAC	(Lat. 38°51′38.48″ N, long. 090°28′56.52″ W)
GBEES, IN	FIX	(Lat. 38°41′54.72″ N, long. 085°10′13.03″ W)
BICKS, KY	WP	(Lat. 38°38′29.92″ N, long. 084°25′20.82″ W)
Henderson, WV (HNN)	DME	(Lat. 38°45′14.85″ N, long. 082°01′34.20″ W)
OTTTO, VA	WP	(Lat. 38°51′15.81″ N, long. 078°12′20.01″ W)

* * * * *

* * * * *

V–45 [Amended]

From New Bern, NC; Kinston, NC; Raleigh-Durham, NC; INT Raleigh-Durham 275° and Greensboro, NC, 105° radials; Greensboro; INT Greensboro 334° and Pulaski, VA, 147° radials; Pulaski; Bluefield, WV; to Charleston, WV. From Saginaw, MI; Alpena, MI; to Sault Ste Marie, MI.

* * * * *

V–119 [Amended]

From Parkersburg, WV; INT Parkersburg 067° and Indian Head, PA, 254°radials; Indian Head; to Clarion, PA.

* * * * *

V–174 [Removed]

* * * * *

Issued in Washington, DC, on October 29, 2020.

George Gonzalez,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2020–24288 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0500; Airspace Docket No. 20–AGL–9]

RIN 2120–AA66

Proposed Amendment of V–221 and V–305 in the Vicinity of Bloomington, IN

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Notice of proposed rulemaking (NPRM); withdrawal.

SUMMARY: The FAA is withdrawing the NPRM published in the **Federal Register** on June 26, 2020, proposing to amend VHF Omnidirectional Range (VOR) Federal airways V–221 and V–305 due to the planned decommissioning of the VOR portion of the Hoosier, IN, VOR/Tactical Air Navigation (VORTAC) in support of the FAA's VOR Minimum Operational Network (MON) program. Subsequent to the NPRM, the FAA reviewed the Hoosier VOR decommissioning project and determined additional planning meetings are necessary to ensure a more efficient implementation and integration with other ongoing program activities, and determined that withdrawal of the proposed rule is warranted.

DATES: Effective as of 0901 UTC, November 4, 2020, the proposed rule published June 26, 2020 (85 FR 38343), is withdrawn.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Rules and Regulations, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

The FAA published a NPRM in the **Federal Register** for Docket No. FAA–2020–0500 (85 FR 38343; June 26, 2020). The NPRM proposed to amend VOR Federal airways V–221 and V–305 in the vicinity of Bloomington, IN, due to the planned decommissioning of the VOR portion of the Hoosier, IN, VORTAC navigation aid which provides navigation guidance for portions of the affected airways.

Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

FAA's Conclusions

The FAA has reviewed the Hoosier VOR decommissioning project and determined that additional planning meetings are warranted to ensure a more efficient implementation and integration with other ongoing program activities; therefore, the NPRM is withdrawn.

List of Subjects in 14 CFR part 71

Airspace, Incorporation by reference, Navigation (air).

The Withdrawal

Accordingly, pursuant to the authority delegated to me, the NPRM published in the **Federal Register** on June 26, 2020 (85 FR 38343), FR Doc. 2020–13657, is hereby withdrawn.

Authority: 49 U.S.C. 106(f), 106(g), 40103, 40113, 40120; E.O. 10854; 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

Issued in Washington, DC, on October 29, 2020.

George Gonzalez,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2020–24356 Filed 11–3–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 6

42 CFR Parts 1 and 404

45 CFR Part 6

[Docket No. HHS–OS–2020–0012]

RIN 0991–AC24

Securing Updated and Necessary Statutory Evaluations Timely

AGENCY: Department of Health and Human Services (HHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Regulatory Flexibility Act (RFA) requires agencies to publish plans to conduct periodic reviews of certain of their regulations. Multiple Executive Orders also require agencies to submit plans for periodic reviews of certain regulations. To further comply with the RFA and Executive Orders, and to ensure the Department's regulations have appropriate impacts, the U.S. Department of Health and Human Services (HHS) issues this notice of proposed rulemaking to set expiration dates for its regulations (subject to certain exceptions), unless the Department periodically assesses the regulations to determine if they are subject to the RFA, and if they are, performs a review that satisfies the criteria in the RFA.

DATES: Submit either electronic or written comments on the proposed rule by December 4, 2020, except that electronic or written comments on the portion of the proposed rule amending

42 CFR parts 400–429 and parts 475–499 are due January 4, 2021.

ADDRESSES: You may submit comments, identified by Docket No. HHS–OS–2020–0012, by the following method:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Comments must be identified by RIN *0991–AC24.* Because of staff and resource limitations, all comments must be submitted electronically to *www.regulations.gov.* Follow the ''Submit a comment'' instructions.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the internet and can be retrieved by most internet search engines. No deletions, modifications, or redactions will be made to comments received.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including personally identifiable or confidential business information that is included in a comment. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make. HHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Follow the search instructions on that website to view the public comments.

A public hearing on this proposed rule will be held before the end of the public comment period. A separate notice will be published in the **Federal Register** providing details of this hearing. Subject to consideration of the comments received, the Secretary intends to publish a final regulation.

FOR FURTHER INFORMATION CONTACT: James Lawrence, 200 Independence Avenue SW, Washington, DC 20201; or by email at *reviewnprm@hhs.gov;* or by telephone at 1–877–696–6775.

SUPPLEMENTARY INFORMATION: This notice of proposed rulemaking is organized as follows:

Table of Contents

I. Summary
II. Background
III. Statutory Authority
IV. Provisions of Proposed Rule
V. Request for Comment
VI. Regulatory Impact Analysis

I. Summary

The U.S. Department of Health and Human Services (HHS or the Department) issues this notice of proposed rulemaking to enhance the Department's implementation of section 3(a) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 610, and various executive orders, and improve accountability and the performance of its regulations.[1] The RFA requires federal agencies to publish in the **Federal Register** ''a plan for the periodic review of the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities'' in order ''to determine whether such rules should be continued without change, or should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant impact of the rules upon a substantial number of small entities.'' 5 U.S.C. 610(a). In conducting this retrospective review, agencies must consider a variety of factors, including the continued need for the rule, legal issues, public input, overlap and duplication with other federal or State and local governmental rules, and technological, economic, or other changes. 5 U.S.C. 610(b). Agency compliance with 5 U.S.C. 610 may be subject to judicial review. *See* 5 U.S.C. 611(a).

Several Executive Orders have also directed agencies to submit plans for the periodic review of certain of their regulations. *See, e.g.,* Executive Orders 12866 and 13563.

The Department has tried to carry out the evidence-based approach to regulation prescribed by Congress and the executive orders, but HHS' efforts have met varying levels of success. Several States, as well as jurisdictions outside the United States, have experimented with different ways of ensuring agencies engage in retrospective regulatory reviews so that legal requirements are updated in view of emerging evidence and changed circumstances. Among the lessons that have emerged is that while statutory mandates are helpful, one of the most important factors for ensuring agencies conduct retrospective reviews of their regulations is to provide for the sunset or automatic expiration of certain regulatory requirements after a period of time unless a retrospective review determines that the regulations should be maintained.

Therefore, in order to ensure evidence-based regulation that does not become outdated as conditions change, HHS proposes that, subject to certain exceptions, all regulations issued by the Secretary or his delegates or sub-delegates in Titles 21, 42, and 45 of the CFR shall expire at the end of (1) two calendar years after the year that this proposed rule first becomes effective, (2) ten calendar years after the year of the regulation's promulgation, or (3) ten calendar years after the last year in which the Department Assessed and, if required, Reviewed the regulation, whichever is latest.[2] The RFA and executive orders have only resulted in limited retrospective review by the Department. The Department believes this proposed rule would effectuate the desire for periodic retrospective reviews expressed in the RFA and Executive Orders, as well as ensure the Department's regulations are having appropriate impacts and have not become outdated.

II. Background

A. The Regulatory Flexibility Act

In 1980, Congress enacted the Regulatory Flexibility Act (RFA), Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980). Congress stated that ''the purpose of this Act [is] to establish as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' 94 Stat. at 1165. Consistent with this purpose, section 3(a) of the RFA requires agencies to publish in the **Federal Register** a ''plan for the periodic review of rules which have or will have a significant economic impact upon a substantial number of small entities.'' 5 U.S.C. 610(a). The ''purpose of the review shall be to determine whether such rules should be continued without change, or should be amended or rescinded . . . to minimize any significant economic impact of the rules upon a substantial number of small entities.'' *Id.* In conducting this review,

[1] Unless otherwise indicated, all references to HHS in this proposed rule include HHS' constituent agencies and other components.

[2] As ''Assessed'' and ''Reviewed'' are defined herein.

Congress provided that agencies ''shall consider the following factors'':

(a) The continued need for the rule;

(b) The nature of complaints or comments received concerning the rule from the public;

(c) The complexity of the rule;

(d) The extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and

(e) The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

5 U.S.C. 610(b)(1)–(5). Congress required agencies to conduct an initial review within ten years of the effective date of the RFA, as well as subsequent reviews ''within ten years of the publication of'' future final rules. 5 U.S.C. 610(a).

The retrospective review provided for in 5 U.S.C. 610 is a congressional mandate. Under the plain terms of the Act, having a plan for such reviews is not optional. Congress fashioned a private right of action for small entities to ensure agencies satisfy 5 U.S.C. 610. *See* 5 U.S.C. 611(a)(1) (for ''any rule subject to this chapter, a small entity that is adversely affected or aggrieved by final agency action is entitled to judicial review of agency compliance with the requirements of sections 601, 604, 605(b), 608(b), and 610 in accordance with chapter 7''). Originally, as one commentator explained, the RFA ''contain[ed] an extremely qualified and ambiguous provision for judicial review.'' [3] In 1996, Congress amended the RFA to more clearly provide for judicial review of violations of 5 U.S.C. 610.[4] As one House Committee report explained, the lack of judicial review made ''agencies completely unaccountable for their failure to comply with its requirements,'' a problem the amendment attempted to solve.[5]

B. Executive Orders Directing Agencies To Review Existing Regulations

Other efforts to conduct retrospective regulatory review both predate and have continued after passage of the RFA. In 1978, President Carter issued an executive order on improving federal regulations.[6] The order directed agencies to ''periodically review their existing regulations.'' [7] In determining which existing regulations to review, the order required agencies to consider, among other things, whether ''technology, economic conditions or other factors have changed in the area affected by the regulation.'' [8] The Executive Order considered suggestions from the public that all regulations be reviewed, usually 3–5 years after issuance. But the Carter Administration instead instructed that, due to agency resource limitations, agencies should concentrate their reviews on those regulations which no longer serve their intended purpose, which have caused administrative difficulties, or which have been affected by new developments.[9] The executive order also considered, but rejected, the idea of including a sunset provision in regulations on the ground that agencies cannot entirely eliminate regulations unless the law which authorized the regulations allows it.[10] However, the Department believes that executive order did not consider that the authorizing statutes for many regulations permit those regulations to be rescinded. Moreover, as discussed below, experience since 1978 has shown it is difficult to adequately conduct retrospective regulatory review if regulations do not contain sunset provisions.

Like the Carter Administration, every subsequent administration has directed agencies to engage in retrospective review of existing regulations. In 1981, President Reagan ordered agencies to ''review[ ] existing regulations'' in view of cost-benefit principles and potential alternatives.[11] In 1992, President George H.W. Bush issued a memorandum instructing agencies to conduct a 90-day review ''to evaluate existing regulations and programs and to identify and accelerate action on initiatives that will eliminate any unnecessary regulatory burden or otherwise promote economic growth.'' [12] President Clinton similarly called for review of existing regulations to determine whether they have become ''unjustified or unnecessary as a result of changed circumstances,'' and ''to confirm that regulations are both compatible with each other and [are] not duplicative or inappropriately burdensome in the aggregate.'' [13] Specifically, that Executive Order required agencies to submit to the Office of Information and Regulatory Affairs (OIRA) a program under which the agency ''will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive Order.'' [14] The George W. Bush Administration's Acting OIRA Administrator noted that the Bush Administration was ''in the process of reviewing a variety of existing regulations and regulatory programs in an effort to identify areas where sensible changes will yield greater benefits for the public at lower costs.'' [15]

President Obama also instructed agencies to engage in retrospective regulatory review. In 2011, President Obama issued an executive order ordering agencies ''[t]o facilitate the periodic review of existing significant regulations . . . to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' [16] Similarly, in 2012, President Obama noted that retrospective review has particular relevance ''[d]uring challenging economic times,'' and that agencies should consider whether regulations ''should be modified or streamlined in

---

[3] Paul R. Verkuil, *A Critical Guide to the Regulatory Flexibility Act,* 1982 Duke L.J. 213, 259 (1982).

[4] Contract with America Advancement Act of 1996, Public Law 104–121, 110 Stat. 847, 865–66 (1996).

[5] H.R. Rep. No. 104–500, at 3 (1996).

[6] Exec. Order No. 12044 of Mar. 23, 1978, 43 FR 12661 (Mar. 24, 1978) (revoked by Exec. Order No. 12291 of Feb. 17, 1981, 46 FR 13193 (Feb. 19, 1981)).

[7] 43 FR at 12663.

[8] *Id.*

[9] *Id.* at 12669. As discussed below, the Department is proposing to review a different subset of its regulations than was directed by Exec. Order No. 12044, in part because the RFA's directive to review regulations that have a significant economic impact upon a substantial number of small entities had not yet been enacted at the time of Exec. Order No. 12044. Moreover, Exec. Order No. 12044 was responding to suggestions that the review be performed every three to five years. The Department is proposing that its reviews be performed every ten years (except for regulations that have already been in effect for ten years), which should lessen the burden on the Department's resources.

[10] *Id.* at 12669.

[11] Exec. Order No. 12291 of Feb. 17, 1981, 46 FR 13193, 13193 (Feb. 19, 1981) (revoked by Exec. Order 12866 of Sept. 30, 1993, 58 FR 51735 (Oct. 4, 1993)); *see also* Exec. Order 12498 of Jan. 4, 1985, 50 FR 1036 (Jan. 8, 1985) (creating annual regulatory planning program), revoked by Exec. Order 12866 of Sept. 30, 1993, 58 FR 51735 (Oct. 4, 1993)).

[12] Memorandum on Reducing the Burden of Government Regulation (Jan. 28, 1992).

[13] Exec. Order No. 12866 of Sept. 30, 1993, 58 FR 51735 (Oct. 4, 1993).

[14] *Id.*

[15] Draft Report to Congress on the Costs and Benefits of Federal Regulations Introduction, 66 FR 22041, 22054 (May 2, 2001).

[16] Exec. Order No. 13563 of Jan. 18, 2011, 76 FR 3821, 3822 (Jan. 21, 2011); *see also* Exec. Order No. 13579 of July 11, 2011, 76 FR 41587, 41587 (July 14, 2011) (applying the same requirement to independent regulatory agencies).

light of changed circumstances, including the rise of new technologies.'' [17]

President Trump has attempted to identify existing undue regulatory burdens and facilitate retrospective review of regulations. For example, in January 2017, President Trump issued an executive order requiring agencies to identify at least two regulations to be repealed for every one regulation proposed or otherwise promulgated.[18] Similarly, a 2017 OIRA report to Congress explained, ''Rules should be written and designed to facilitate retrospective analysis of their effects, including consideration of the data that will be needed for future evaluation of the rules' ex post costs and benefits.'' [19] In May 2020, in response to the COVID–19 pandemic, President Trump ordered agencies to ''identify regulatory standards that may inhibit economic recovery'' and to ''consider taking appropriate action, consistent with applicable law,'' including modifying, waiving, or rescinding those regulatory requirements.[20]

In addition to the executive orders, other executive branch actions have sought to spur agencies to conduct the reviews called for by 5 U.S.C. 610. One example was the Regulatory Review and Reform (r3) initiative, which the Small Business Administration launched in part to improve compliance with 5 U.S.C. 610 and further the goals of periodic reviews. The r3 initiative was a long-term project to help agencies pinpoint existing federal rules that warrant review—and to revise those rules if they are found to be ineffective, duplicative, out of date, or otherwise deficient.[21]

Consistent with these actions, HHS has conducted retrospective reviews of some of its regulations. For example, pursuant to Executive Order 13563, HHS published a list of regulations the Department identified as candidates for retrospective review.[22] The Department also took action. For example, HHS, citing Executive Order 13563, eliminated certain restrictions on the use of telemedicine in rural areas.[23]

Nonetheless, the Department has only conducted retrospective review of regulations to a very limited extent. One academic analysis determined that, in response to Executive Order 13563, the Department planned 83 retrospective analyses in 2012 and completed 33 analyses with final action by August 31, 2013.[24] By contrast, the Department issued 247 rules between the date Executive Order 13563 was issued and August 31, 2013.[25] As of July 2016, the Department had 40 planned retrospective analyses and by April 2017 had completed analyses with final action on 19 of them.[26] These findings are consistent with government assessments that the Department's efforts to comply with 5 U.S.C. 610 have at times been lacking.[27]

Scholars have posited reasons why agencies may be reluctant to perform retrospective reviews. One administrative law expert has written:

> [E]ven with sufficient resources, agencies may not be properly incentivized. They are less likely to be found at fault for not conducting rigorous periodic reviews. Many rules, even those with significant effects, are often not on the public's radar once adopted. Challenging agency regulation under the RFA is more difficult than under the Administrative Procedure Act (APA) because there is no comment process and standing is granted to more limited parties. The harm to the public resulting from a cursory analysis is also much less clear. If sufficient interests exist to modify the rule, strong interest groups will directly lobby the agency to modify the rule. But in this case, a brand new rulemaking effort emerges.
>
> There are also political reasons and moral hazard concerns associated with performing retrospective analyses. In most cases, retrospective analyses of existing regulations are routine business matters left to be handled by staff members, rather than political appointees. Political appointees, such as agency heads, tend to come with specific regulatory agendas of their own. By contrast, staff members at regulatory agencies are best viewed as career members who have a vested interest in seeing their agencies continue to exist and thrive. All else equal, they are not inclined to acknowledge that the work of their agency is inefficient or unnecessary, and even less inclined to conduct analyses that may lead to a curtailing of the agency's authority. Whatever the reasons may be, serious ex post reviews are few and far between. A majority of rules, once adopted, will likely persist without significant ex post modification. As to how many agency rules currently implemented may be costing more resources than yielding benefits is anyone's guess.[28]

Thus, the Department proposes that it needs to impose a strong incentive on itself to perform retrospective review, given these countervailing incentives to not perform such reviews and the limited number of retrospective reviews that the Department has performed over the last 40 years. As discussed in more detail in the regulatory impact analysis *infra,* the Department has the resources to periodically review the impacts of its regulations. Only a handful of Department employees are needed to perform the periodic reviews.

C. Limitations in Government Projections Counsel in Favor of Retrospective Regulatory Review

The Congressional and Presidential directives to periodically review existing regulations are sound policy. When the Department first issues a regulation, it makes an educated guess about the regulation's impact. Several years after the regulation is promulgated, the Department has a somewhat greater basis for assessing its real-world impacts and can refine the regulation or agency enforcement practices, as appropriate. This would

[17] Exec. Order No. 13610 of May 10, 2012, 77 FR 28469, 28469 (May 14, 2012).

[18] Exec. Order No. 13771 of Jan. 30, 2017, 82 FR 9339, 9339 (Feb. 3, 2017).

[19] Office of Mgmt. & Budget, 2017 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act at 5 (2017), *https://www.whitehouse.gov/wp-content/uploads/2019/12/2019-CATS-5885-REV_DOC-2017Cost_BenefitReport11_18_2019.docx.pdf; see also id.* at 16 (''[I]t is important to consider retrospective, as opposed to ex ante, estimates of both benefits and costs.'').

[20] Exec. Order No. 13924 of May 19, 2020, 85 FR 31353, 31354 (May 22, 2020).

[21] Testimony of The Hon. Thomas M. Sullivan, Chief Counsel for Advocacy, U.S. SBA, U.S. House of Representatives Comm. on Small Bus. Subcomm. on Reg.'s, Health Care and Trade (July 30, 2008), *https://www.sba.gov/sites/default/files/files/test08_0730.pdf* (''Historically, federal agency compliance with section 610 has been limited.'') (last visited Oct. 19, 2020).

[22] *See also Retrospective Review of Existing Rules,* U.S. Dept. of Health & Human Servs., *https://www.hhs.gov/open/retrospective-review/index.html* (last visited Oct. 19, 2020).

[23] *See* Medicare and Medicaid Programs: Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging, 76 FR 25550 (May 5, 2011); *see also* Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II, 79 FR 27106 (May 12, 2014) (finalizing several rules to remove unnecessary regulatory and reporting requirements previously imposed on hospitals and other health care providers).

[24] Connor Raso, *Assessing regulatory retrospective review under the Obama administration,* Brookings Inst., (Jun. 15, 2017) *https://www.brookings.edu/research/assessing-regulatory-retrospective-review-under-the-obama-administration/.*

[25] *Id.*

[26] *Id.*

[27] *See, e.g.,* Curtis W. Copeland, Cong. Research Serv., RL32801, Reexamining Rules: Section 610 of the Regulatory Flexibility Act 7–8 (2008); U.S. Gov't Accountability Off., GAO/GGD–94–105, Regulatory Flexibility Act: Status of Agencies' Compliance 12 (1994) (quoting a 1983 Small Business Administration report that stated that the Department's section 610 review plan was '' 'very general,' and, as a result, 'it is difficult to measure progress and to make recommendations with respect to future review' ''); *see also* Testimony of The Hon. Thomas M. Sullivan, Chief Counsel for Advocacy, U.S. SBA, U.S. House of Representatives Comm. on Small Bus. Subcomm. on Reg.'s, Health Care and Trade (July 30, 2008), *https://www.sba.gov/sites/default/files/files/test08_0730.pdf* (''Historically, federal agency compliance with section 610 has been limited.'') (last visited Oct. 19, 2020).

[28] Yoon-Ho Alex Lee, *An Options Approach to Agency Rulemaking,* 65 Admin. L. Rev. 881, 895–96 (2013).

further democratic values such as accountability, administrative simplification, transparency, and performance measurement and evaluation.

Indeed, the literature indicates that government projections of regulatory impacts would benefit from refinement based on experience after the regulations are implemented. In 2005, the Office of Management and Budget (OMB) provided an overview of a sample of retrospective analyses based on an examination of forty-seven case studies.[29] OMB considered a pre-regulation estimate to be accurate if the post-regulation estimate was within +/−25 percent of the pre-regulation estimate.[30] This measure of accuracy reveals the difficulty and uncertainty inherent in prospective cost-benefit analysis. OMB found that agencies often inaccurately estimated the benefits of regulations in its sample of regulations, and agencies were more likely to overestimate benefits than to underestimate them, where benefits were estimated.[31] Agencies overestimated benefits in 19 of 39 sampled regulations, whereas they underestimated benefits in only two of the 39 regulations.[32] In two cases, agencies overestimated benefits by a factor of 10.[33] Second, agencies sometimes overestimated the benefit-cost ratio, and in that sense were a bit too optimistic about the consequences of their rules. Agency estimates were accurate in only 11 rules, while the ratio was overestimated in 22 rules and underestimated in 14 rules.[34] Third, agencies also overestimated and, less frequently, underestimated costs in the sampled regulations. Agency cost estimates were accurate for only 12 rules, overestimated for 16 rules, underestimated for 12 rules, and not estimated for seven rules.[35]

Academic studies have also identified inaccuracies in agency estimates, relative to an ex post re-estimation. For example, one study of sixty-one rules for which benefit-cost ratios could be compared before and after the fact (including some not included in the OMB review) found that in only sixteen of the sixty-one cases were the estimated ratios essentially accurate, though the study found no bias in estimates of benefit-cost ratios.[36] In this analysis, Dr. Harrington criticized certain aspects of the OMB analysis. But it is notable that, even though OMB and Dr. Harrington used somewhat differing methods and reviewed samples of regulations that did not completely overlap, they both found ex ante estimates to be in many cases lacking. Dr. Harrington concluded his analysis by noting that ''the results demonstrate the value of *ex post* analysis. It is frustrating that there is so little of it, especially when so many close observers, from all points of view, claim to be in favor of it.'' [37]

A more recent study of a sample of federal regulations found that of the eight regulations for which the author was able to make ex ante and ex post cost comparisons, six regulations involved overestimates of costs, two involved underestimates of costs, and none were deemed accurate.[38] A regulation was deemed accurate if the regulation's regulatory impact analysis fell roughly within +/−25% of the ex post observation.[39] Of the 18 regulatory requirements for which the author was able to compare benefits (also referred to as ''effectiveness'' in the study) estimates on an ex ante and ex post basis, he found that 10 involved overestimates, six were underestimates, and two were relatively accurate.[40]

Inaccurate estimates are not always the result of poor analysis by the agency. Sometimes changes in the legal landscape can cause government projections to become obsolete. For example, in February 2010, officials in the Centers for Medicare and Medicaid Services' Office of the Actuary (OACT) issued health spending and coverage projections through 2019.[41] A month later, Congress enacted the Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119, and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, 124 Stat. 1029 (''ACA''). Largely as a result of the ACA's passage, in October 2010 OACT issued revised projections forecasting that by 2019 the insured share of the population would be 92.7 percent—roughly ten percentage points higher than OACT projected nine months earlier.[42]

Changes in technology can also render projections inaccurate. One study has noted that even when an agency's benefit-cost analysis uses sound science and the best available information to estimate the costs associated with a rule, technological innovation can result in an ex post assessment of costs differing from the agency's cost estimates at the time it promulgated the rule.[43] As an example of technology's impact on regulations, in 2019 the Food and Drug Administration (FDA) issued a rule amending requirements for medical device premarket submissions to remove requirements for paper and multiple copies, and replace these requirements with requirements for a single submission in electronic format.[44] Changes in technology had rendered the requirement for multiple

[29] Office of Mgmt. & Budget, Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, at 46–47 (2005) *http://perma.cc/R8LX–BQMJ* (collecting studies comparing ex ante and ex post analyses of regulations' costs and benefits, including examples where cost and benefit estimates were off by more than a factor of ten).

[30] *Id.* at 42.

[31] *Id.* at 43–46.

[32] *Id.* at 47.

[33] *Id.* at 43.

[34] *Id.* at 47.

[35] *Id.*

[36] Winston Harrington, *Grading Estimates of the Benefits and Costs of Federal Regulation,* Res. for the Future, Discussion Paper 06–39, 2006, at 33, *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=937357.* Dr. Harrington used the same measure of accuracy as OMB. While both OMB and Dr. Harrington noted that using +/−25% as the measure of accuracy could be arbitrary, it is nonetheless informative that in many cases the ex ante estimates in the sampled regulations differed from ex post estimates by more than +/−25%.

[37] *Id.* at 34.

[38] Richard Morgenstern, *Retrospective Analysis of U.S. Federal Environmental Regulation,* 9 J. of Benefit Cost Anal., no. 2, 2018, at 294 *https://www.cambridge.org/core/services/aop-cambridge-core/content/view/891E36D3DBCEB79C969278488E5E1897/S2194588817000173a.pdf/retrospective_analysis_of_us_federal_environmental_regulation.pdf.*

[39] *Id.*

[40] *Id.; see also* Cynthia Morgan & Nathalie B. Simon, *National primary drinking water regulation for arsenic: A retrospective assessment of costs*, 5 J. Benefit Cost Anal. no. 2, 2014, at 259–84 *https://www.cambridge.org/core/services/aop-cambridge-core/content/view/A7B29CE98E650B424E92FF292A8FFC89/S2194588800000774a.pdf/national_primary_drinking_water_regulation_for_arsenic_a_retrospective_assessment_of_costs.pdf* (finding that the EPA methodology overestimated predicted capital costs from its arsenic rule in most studied cases, especially as the size of the system increases (as measured by the design flow rate)).

[41] *See* Truffer CJ, et al. *Health Spending Projections Through 2019: The Recession's Impact Continues,* 29 Health Aff. no. 3, 2010, at 522–29, *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2009.1074.*

[42] *See* Sisko, et al., *National Health Spending Projections: The Estimated Impact Of Reforms Through 2019,* 29 Health Aff. no. 10, at 1936, *https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2010.0788.*

[43] Cynthia Morgan & Nathalie B. Simon, *National primary drinking water regulation for arsenic: A retrospective assessment of costs*, 5 J. Benefit Cost Anal. no. 2, 2014, at 259–84, *https://www.cambridge.org/core/services/aop-cambridge-core/content/view/A7B29CE98E650B424E92FF292A8FFC89/S2194588800000774a.pdf/national_primary_drinking_water_regulation_for_arsenic_a_retrospective_assessment_of_costs.pdf.* One example referred to in this study is that technological innovation or regulatory or technical constraints could result in water systems using different treatment technologies for arsenic removal than assumed by the agency when it promulgated a regulation.

[44] Medical Device Submissions: Amending Premarket Regulations That Require Multiple Copies and Specify Paper Copies To Be Required in Electronic Format, 84 FR 68334 (Dec. 16, 2019).

copies, whether in electronic format or paper form, no longer necessary.[45] Had the Department reviewed more of its regulations, it might have learned of additional instances where technological changes counsel in favor of amendment. In addition, some scholars have suggested that in some cases changes in technology can reduce the costs of complying with regulatory mandates.[46] If retrospective reviews conclude that technology has reduced compliance costs, that can inform the Department's decision about if or how to amend a regulation.

Yet another reason for potential divergence between prospective and retrospective regulatory impact estimates is non-compliance with the regulation being assessed. One study found differing accuracy for prospective per-unit cost estimates and prospective aggregate cost estimates; where there is substantial non-compliance with the regulation being analyzed, the study claimed, cost estimates per unit can sometimes be reasonably accurate while aggregates are simultaneously overestimated.[47] (Non-compliance would, of course, also affect the accuracy of benefits estimates.[48]) As such, ex post analysis has the potential to inform not just decisions about codified regulatory requirements but also about agency enforcement practices.

While the prospective cost-benefit analyses performed in connection with the promulgation of rules are quite useful, former OIRA Administrator Cass Sunstein has explained that '' [w]hen agencies issue rules, they have to speculate about benefits and costs.'' [49] Therefore, ''[a]fter rules are in place, [agencies] should test those speculations, and they should use what they learn when revisiting a regulation or issuing a new one.'' [50] Professor Sunstein described this as ''one of the most important steps imaginable'' for regulatory reform, ''not least because it can reduce cumulative burdens and promote the goal of simplification.'' [51] He has noted that agencies' failure ''until very recently . . . to gather, let alone act on'' retrospective reviews is ''an astonishing fact.'' [52]

Michael Greenstone, who served as Chief Economist on the Council of Economic Advisors between 2009 and 2010, similarly concluded that the ''single greatest problem with the current system is that most regulations are subject to a cost-benefit analysis only in advance of their implementation. This is the point when the least is known and any analysis must rest on many unverifiable and potentially controversial assumptions.'' [53] According to Professor Greenstone, the lack of a regulatory lookback created a system ''largely based on faith, rather than evidence,'' where the agency ''all too frequently takes shots in the dark and we all too infrequently fail to find out if we have hit anything—or even worse, we only find out when things have gone horribly wrong.'' [54] As he explained, ''it is nearly impossible to imagine'' only prospective, and not retrospective, evaluations ''being used in other contexts where people's lives are on the line. For example, I am confident that there would be a deafening uproar of protest if the FDA announced that it would approve drugs without testing them in advance. Yet, this is largely what we do with regulations that affect our health and well-being.'' [55]

If retrospective analysis ''could be firmly institutionalized,'' Professor Sunstein observed, then it ''would count as the most important structural change in regulatory policy since the original requirement of prospective analysis during the Reagan Administration.'' [56]

Other administrative law experts have also urged agencies to more robustly institutionalize retrospective review of regulations. The Administrative Conference of the United States (ACUS) has ''urge[d] agencies to remain mindful of their existing body of regulations and the ever-present possibility that those regulations may need to be modified, strengthened, or eliminated in order to achieve statutory goals while minimizing regulatory burdens.'' [57] More recently, the American Bar Association Section of Administrative Law and Regulatory Practice, has ''*urge[d]* [*the Administration*] *to build on the efforts of previous administration[s] and take steps to institutionalize careful, in-depth retrospective review of existing rules.*'' (Emphasis in original).[58]

Yet, despite these many calls for retrospective review, as noted in section II.B., the Department has had limited success in implementing retrospective review in practice.[59] In 2019, the Department piloted an approach to augment expert policy insights with artificial intelligence-driven data analysis of its regulations, which showed the need to more firmly institutionalize retrospective review. The artificial intelligence review found that 85% of Department regulations created before 1990 have not been

[45] *Id.* at 68334.

[46] *See, e.g.,* Cass R. Sunstein, *The Regulatory Lookback,* 94 B.U. L. Rev. 579, 599 (2014).

[47] Winston Harrington, Richard D. Morgenstern and Peter Nelson, *On the Accuracy of Regulatory Cost Estimates,* J. Policy Anal. & Management 2000, 19(2): 297–322.

[48] *See, e.g.,* Si Kyung Seong and John Mendeloff, *Assessing the Accuracy of OSHA's Projections of the Benefits of New Safety Standards*, Am. J. Industrial Medicine 2004, 45(4): 313–328.

[49] Cass R. Sunstein, *The Regulatory Lookback,* 94 B.U. L. Rev. 579, 591 (2014).

[50] *Id.*

[51] *Id.*

[52] *Id.* at 588.

[53] Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation,* in New Perspectives on Regulation 111, 113 (David Moss & John Cisternino eds., 2009). It should not be inferred, however, that retrospective analysis is free of assumptions (including potentially controversial assumptions) or is generally without challenges, especially with respect to establishing relevant counterfactuals. For discussion and recent examples related to just two of the many areas of Department regulatory activity, see Trinided Beleche *et al., Are Graphic Warning Labels Stopping Millions of Smokers? A Comment on Huang, Chaloupka, and Fong,* 15 Econ Journal Watch 129 (2018) and Aaron Kearsley *et al., A Retrospective and Commentary on FDA's Bar Code Rule,* 9 J. Benefit-Cost Analysis 496 (2018). Moreover, to the extent that retrospective analysis is used to inform policy choices going forward, it becomes, or is at least being used as, prospective analysis and thus relies on assumptions about the future, including as regards technology and the legal and regulatory landscape. But since retrospective analysis is conducted after some real-world experience living under the regulation, it can in many cases be an improvement over earlier prospective analysis.

[54] Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation,* in New Perspectives on Regulation 111, 111–12 (David Moss & John Cisternino eds., 2009); *see also* Office of Mgmt. & Budget, 2017 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act at 5 (2017), *https://www.whitehouse.gov/wp-content/uploads/2019/12/2019-CATS-5885-REV_DOC-2017Cost_BenefitReport11_18_2019.docx.pdf* (''The aim of retrospective analysis is to understand and improve the accuracy of prospective analysis and to provide a basis for potentially modifying rules as a result of *ex post* evaluations.'').

[55] Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation,* in New Perspectives on Regulation 111, 114 (David Moss & John Cisternino eds., 2009).

[56] Cass R. Sunstein, *The Regulatory Lookback,* 94 B.U. L. Rev. 579, 589 (2014).

[57] Administrative Conference of the United States, Recommendation 2014–5, Appendix—Recommendations of the Administrative Conference of the United States, 79 FR 75114, 75114 (Dec. 17, 2014); *see also* ABA Sec. of Admin. Law & Reg. Prac., Improving the Administrative Process: A Report to the President-Elect of the United States (2016), 69 Admin. L. Rev. 205 (2017).

[58] ABA Sec. of Admin. Law & Reg. Prac., *Improving the Administrative Process: A Report to the President-Elect of the United States (2016),* 69 Admin. L. Rev. 205, 219 (2017) (emphasis in original).

[59] *See also* Yoon-Ho Alex Lee, *An Options Approach to Agency Rulemaking,* 65 Admin. L. Rev. 881, 894 (2013), (''one might think that agencies would faithfully take advantage of [] opportunities to conduct rigorous retrospective [cost-benefit analyses] of their existing regulations and test their effectiveness and efficiency. This would be the surest way of incorporating ex post learning in rule implementation. This is far from the truth in practice, however.'').

edited; the Department has nearly 300 broken citation references in the CFR (*i.e.,* CFR sections that reference other CFR sections that no longer exist); more than 50 instances of regulatory requirements to submit paper documents in triplicate or quadruplicate; and 114 parts in the CFR with no regulatory entity listed, 17 of which may be misplaced.[60] The Department concluded that some good governance stewardship recommendations ''were deprioritized and relegated to rainy day activities that [Department operating divisions] would get around to when they could.''[61] Unfortunately, in many cases the Department has for years not gotten around to addressing these issues.

For the reasons discussed in this section, the Department believes a stronger incentive is needed to achieve the benefits of retrospective review.[62] This proposed rule proposes a mechanism to more firmly institutionalize the retrospective reviews that Professors Sunstein and Greenstone, as well as ACUS and others, have called for.

D. The Experiences of States and Other Jurisdictions With Automatic Expiration or ''Sunset'' Provisions

The proposed mechanism is based in part on the experiences of States and other jurisdictions. Several States incorporate retrospective regulatory review into their laws. New York, for example, requires retrospective review of regulations ''no later than in the fifth calendar year after the year in which the rule is adopted,'' and requires that rules be ''re-reviewed at five-year intervals'' thereafter. N.Y. A.P.A. Law sec. 207. Similarly, Texas requires State agencies to review rules four years after they go into effect and then subsequently at four-year intervals. Tex. Gov't Code sec. 2001.039. In addition to New York and Texas, State law requires some form of retrospective regulatory review in at least Alabama, Arizona, Illinois, Iowa, Michigan, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, and Washington.[63]

Some States with retrospective review requirements allow regulations to automatically expire or sunset after a period of time, unless reviewed or readopted. In New Jersey, regulations automatically expire ''seven years following the effective date of the rule'' unless extended by the agency. N.J. Stat. Ann. sec. 52:14B–5.1(b).[64] Indiana allows regulations to expire on January 1 following the seven-year anniversary of their effective dates. Ind. Code sec. 4–22–2.5–2. The Governor of Florida recently instructed Florida government agencies to ''include a sunset provision in all proposed or amended rules,'' which ''may not exceed five years unless otherwise required by existing statute.''[65]

Experience in the States suggests that sunset provisions can be an important tool to ensure reviews take place. An analysis of regulation in all 50 States found that for a reduction in both regulatory creation and enforcement, ''[t]he single most important policy in a state is the presence of a sunset provision.''[66] On the other hand, one report stated that, despite their initial popularity in the States,[67] sunset provisions fell out of favor, not because they did not produce more cost-effective, cost-justified regulation, but because sunset requirements did not provide sufficient legislative control over executive agencies.[68] That observation is inapplicable to the Department, because this proposed rule concerns the Department's review of its own regulations. Noting the benefits of sunset provisions, the report added that sunset ''provisions have been responsible for the analysis of thousands of state regulations and, on average, the repeal of twenty to thirty percent of existing regulations and the modification of another forty percent.''[69]

Experience outside the United States also suggests the utility of sunset provisions. The Office for Economic Co-Operation and Development (OECD) analyzed regulatory practices in the European Union. In a 2010 report, the OECD recommended, for ''[t]he management and rationalization of existing regulations,'' that Germany ''[k]eep up the 'spring cleaning' of legislation at regular intervals'' and ''consider the inclusion of a review mechanism in individual draft regulations, or even [include] a sunset clause (beyond which the law automatically expires) where appropriate.''[70] With respect to the United Kingdom's regulatory program, the OECD noted ''sunset clauses are also helpful'' in order ''to remove unnecessary burdens in legislation.''[71] Throughout the 2010 report, the OECD repeatedly noted the value of retrospective regulatory review.[72]

In 2019, the OECD published an additional survey regarding regulatory review practices in the European Union. The OECD again noted the utility of

[60] Regulatory Streamlining & Analysis (Mar. 2019).

[61] *Id.* at 18

[62] *Id.* (it ''appears the current set of governance structures, incentives and processes to promulgate regulatory reform need strengthening to be more effective'').

[63] Ala. Code 41–22–5.2; Ariz. Rev. Stat. 41–1056; 5 Ill. Comp. Stat. Ann. 100/5–130; Iowa Code Ann. 17A.33; Mich. Comp. Laws 10.151; N.J. Stat. Ann. 52:14B–5.1; N.M. Stat. 14–4A–6; N.C. Gen. Stat. 150B–21.3A; N.D. Cent. Code 28–32–18.1; Ohio Rev. Code Ann. 106.03; Okla. Stat. Ann. tit. 75, 307.1; 71 Pa. Stat. Ann. 745.2; R.I. Gen. Laws Ann. tit. 42, ch. 64.13; Tenn. Code Ann. 4–56–102; Wash Rev. Code Ann. 43.70.041, 43.22.052.

[64] Although the New Jersey law permits the Governor, within five days of the expiration of a rule, to restore it, the Department does not include a similar provision in this proposed rule. That is because the RFA contains no such similar provision and the Department is giving itself ten years, as opposed to seven years, to perform Assessments and (when required) Reviews of Regulations.

[65] Letter from Gov. Ron DeSantis to Florida Agency Heads (Nov. 11, 2019) *https://www.floridahasarighttoknow.myflorida.com/content/download/147113/980326/FINAL_Directive_to_Agencies_11.19.pdf.*

[66] Russell S. Sobel & John A. Dove, *State Regulatory Review: A 50 State Analysis of Effectiveness* (Mercatus Ctr., Working Paper No. 12–18, at 36 (2012), *https://www.mercatus.org/system/files/State-Regulatory-Review-50-State-Analysis-Effectiveness.pdf.*

[67] Jason A. Schwartz, *52 Experiments with Regulatory Review: The Political and Economic Inputs into State Rulemakings,* Inst. for Policy Integrity, Rep. No. 6, at 33 (Nov. 2010), *https://policyintegrity.org/files/publications/52_Experiments_with_Regulatory_Review.pdf.*

[68] *See id.* (noting that ''North Carolina was first to repeal its sunset law, and many other states quickly followed suit'' after concluding that ''sunset provisions quickly proved to be an expensive, cumbersome, and disappointing method for enhancing legislative control'').

[69] *Id.* at 23–24. The report added, without citing a great deal of empirical evidence, that ''sunset requirements produce perfunctory reviews and waste resources.'' This appears to be based on a law review article that noted, not that retrospective reviews were per se perfunctory, but that ''unless adequate resources are provided, the reviews *may be* relatively perfunctory and meaningless, wasting whatever resources are expended.'' *See* Neil R. Eisner & Judith S. Kaleta, *Federal Agency Reviews of Existing Regulations,* 48 Admin. L. Rev. 139, 160 (1996) (emphasis added). But this law review article noted that adding ''sunset'' dates to regulations unless they are reviewed was ''likely to ensure that a review is done.'' *Id.* As explained herein, the Department intends to commit adequate resources to its reviews if this proposed rule were to be finalized. The law review article said that sunset provisions should be used only in narrowly focused situations where it is determined that it is necessary to apply some ''pressure'' and only where assessments are made of the available resources and the benefits to be derived from the review. *Id.* But the article was written in 1996. As discussed herein, subsequent experience with efforts short of a forcing mechanism suggest that forcing mechanisms are needed to ensure review of a wide array of Department regulations, and that the benefits from these retrospective reviews would be substantial.

[70] OECD, *Better Regulation in Europe: Executive Summaries,* GOV/RPC(2010)13, at 113 *http://www.oecd.org/gov/regulatory-policy/45079126.pdf.*

[71] *Id.* at 46.

[72] *See, e.g., id.* at 107 (''The *ex post* evaluation of regulations which is provided for in the impact assessment process provides a framework in principle for checking what really happens, and whether regulations have actually achieved the objectives originally set.'').

sunset provisions, describing them as a ''useful 'failsafe' mechanism to ensure the entire stock of subordinate regulation remains fit for purpose over time.'' [73] The report noted as of its 2019 date that sunset provisions are in place for at least some regulations in nine different countries, including the United Kingdom, France, and Germany.[74]

In 2009, the Republic of Korea (ROK) enacted a law under which about 20% of the existing regulations are to be reviewed on a regular basis (about every 3 to 5 years) and become invalid if they are found to lack feasibility.[75] Under the ROK's ''review and sunset,'' there is a duty to carry out a review of a regulation on a specified schedule. This sunset clause was established upon the idea that even a rational regulation needs to be examined periodically to determine its grounds for remaining in force, as its validity may be compromised under any change in circumstances or its characteristics.[76] An OECD report stated that ''[g]iven such rationale, the sunset clause is considered as a critical component of efforts in regulatory quality improvement.'' [77]

These authorities indicate an emerging awareness that sunset provisions are useful in ensuring retrospective regulatory review. This is consistent with the Department's experience over the last 40 years, which suggests that, absent a sunset provision or automatic expiration date, Congressional and Presidential directives to perform periodic retrospective reviews of regulations have limited success.

Indeed, previous Administrations have recognized the benefits of sunset provisions. In a June 2015 report, the Department of Treasury's Office of Economic Policy, the Obama Administration's Council of Economic Advisors, and the Department of Labor discussed sunset provisions as applied to occupational licensing.[78] That report found evidence that sunset reviews that automatically terminate regulatory boards and agencies absent legislative action assist with ''removing unnecessary licensing.'' [79] The report explained that sunset review can be ''useful because, even if licensing was justified when first introduced, technological and economic changes may have rendered it unnecessary or overly restrictive.'' [80] The report found ''[p]eriodic examination of existing rules is thus helpful in maintaining the quality of occupational regulation.'' [81] Professor Greenstone has similarly recommended the automatic repeal of regulations if their benefits and costs are not periodically assessed:

> [Another] step in reforming our regulatory system is to require that all regulations contain rules specifying the date by which the regulatory review board has to assess their costs and benefits. If the regulatory review board fails to meet one of these deadlines, then the regulation should be repealed by default. The purpose of this sunset provision is to ensure that all regulations are evaluated carefully and do not stay on the books just because they have been on the books in the past.[82]

Professor Greenstone suggested that this review could cause the regulation to be expanded if supported by evidence.[83] According to Professor Greenstone, this would ''ensure that ineffective regulations are removed and that society fully benefits from the effective ones.'' [84]

This proposed rule seeks to advance democratic values and apply the lessons learned from States, foreign jurisdictions, and the academic community. This proposed rule would apply the benefits of automatic-expiration-absent-periodic-review to a broader array of regulations than is currently being reviewed by the Department.

III. Statutory Authority

The statutory authorities supporting this rulemaking are the statutory authorities for the Department's existing regulations. The Department proposes herein to amend its regulations to add expiration dates unless the Department periodically conducts the required review of the regulations or an exception applies. Some of the Department's primary rulemaking authorities include:

- Section 701(a) of the Federal Food Drug and Cosmetic Act (FD&C Act), 21 U.S.C. 371(a) which authorizes the Secretary to ''promulgate regulations for the efficient enforcement of [the FD&C Act], except as otherwise provided in this section'';
- Section 1102 of the Social Security Act, 42 U.S.C. 1302, which provides that the Secretary ''shall make and publish such rules and regulations, not inconsistent with this Act, as may be

[73] OECD, *Better Regulation Practices across the European Union,* at ch. 4, Box 4.1 (2019), *https://www.oecd-ilibrary.org/sites/9789264311732-en/1/2/4/index.html?itemId=/content/publication/9789264311732-en&_csp_=07701faff9659027b81a5b5ae2ff041c&itemIGO=oecd&itemContentType=book.*

[74] *Id.* at ch. 4, Table 4.1.

[75] OECD, *Latest Developments on Korea's Regulatory Policy,* at 2, *https://www.oecd.org/gov/regulatory-policy/45347364.pdf.*

[76] OECD Reviews of Regulatory Reform, Regulatory Policy in Korea, Toward Better Regulation, at 86 (2017), *https://publicadministration.un.org/unpsa/Portals/0/UNPSA_Submitted_Docs/2019/4cd3e219-c819-40f3-8246-7a024d9a82a9/2020%20UNPSA_the%20Regulatory%20Reform%20Sinmungo_Evaluation%20Report_27112019_032807_e4d166a9-f6ef-4a6c-9aaf-99748fa94284.pdf?ver=2019-11-27-032807-637.*

[77] *Id.*

[78] *Occupational Licensing: A Framework for Policymakers,* The White House, at 48–50 (July 2015), *https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf.*

[79] *Id.* at 48.

[80] *Id.* at 49.

[81] *Id.* The report also suggests that to strengthen sunset provisions in the States, sunset commissions responsible for conducting the cost-benefit analysis should be provided adequate resources; the cost-benefit review process should be insulated against political interference; a minimum number of votes should be required to overrule the sunrise agency's recommendation; and specialized committees within legislatures be appointed to work with the agency in charge of conducting the review. *See id.* at 42. As discussed herein, the Department believes it has adequate resources to conduct the required reviews. As discussed in footnote 84, it is not clear that a federal agency can legally completely insulate its reviews from supervision by the agency's leadership, but the Department believes that its retrospective reviews will generally be performed by career civil servants. Lastly, the Department cannot require Congress to appoint committees to work with the Department officials performing the retrospective reviews, but the Department would welcome the opportunity to discuss reviews with Congressional staff if Congress so chose. The report also suggested ''sunrise'' reviews can be more effective than sunset reviews. But for already-existing regulations, the Department cannot perform sunrise reviews, so the Department is proposing to take advantage of the benefits of sunset reviews. Moreover, the Department already engages in ''sunrise review'' to some extent when it develops regulatory flexibility analyses, *see* 5 U.S.C. 603, 604, and regulatory impact analyses (notably, such reviews did not occur for regulations that preceded the RFA, many of which still remain in effect).

[82] Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation,* in New Perspectives on Regulation 111, 121 (David Moss & John Cisternino eds., 2009).

[83] *Id.*

[84] *Id.* at 123. Professor Greenstone made a separate suggestion that a regulatory review board be created with the authority to assess the effectiveness of regulations and repeal regulations deemed ineffective. The Department considered this, but has decided not to include this proposal in this notice of proposed rulemaking. First, the Department is concerned that such a board raises legal concerns, since many Department regulations can only be repealed by the Secretary, not by an independent board. Second, Professor Greenstone proposed the independent review board on the grounds that (1) it would remove the board's functions as much as possible from political control, and (2) those most deeply involved in implementing a regulation are likely to see the benefits more clearly than the costs. *Id.* at 119–121. While these concerns are understandable, the Department believes it is capable of performing the Review. As an initial matter, those who conduct the Review would not necessarily be those in the Department who implement the Regulation. Moreover, as described herein, Reviews must be performed in such a manner that they can withstand judicial review under the arbitrary and capricious standard. This would require the Reviews to meet a minimum standard of rigor and require them to consider relevant factors. Moreover, many regulations legally cannot be amended or repealed without authorization by a political appointee.

necessary to the efficient administration of the functions with which [he] is charged under this Act'';

• Section 1871 of the Social Security Act, 42 U.S.C. 1395hh, which provides that ''the Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title''; and

• 5 U.S.C. 301, which provides that ''[t]he head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property. This section does not authorize withholding information from the public or limiting the availability of records to the public.''

It complies with the Administrative Procedure Act (APA) to amend regulations to add dates by which the regulations expire unless a review of the regulation is timely performed. An agency can, through notice-and-comment rulemaking, amend its regulations to provide that they expire at a future date.[85] An agency can also provide that its regulations expire when an event occurs or ceases to occur.[86] That is what the Department is proposing in this proposed rule. This is discussed in more detail in the description of section [XX](c) in Section IV *infra*.

The Department also notes the text of 5 U.S.C. 610 indicates Congress believed agencies had the authority to periodically review at least those regulations that have a significant economic impact upon a substantial number of small entities (and that the agency had the authority to assess which of its regulations have such an impact).

IV. Provisions of Proposed Rule[87]

Section 3(a) of the RFA, 5 U.S.C. 610, and Executive Orders 12866 and 13563 direct agencies to devise plans to periodically review certain of their regulations using certain criteria. By requiring the Department to periodically perform such reviews, this proposed rule would implement Congress' and the President's desires for retrospective review of regulations. This proposed rule would lead to the amendment or rescission, where appropriate, of Department regulations that have a significant economic impact upon a substantial number of small entities. The proposed rule would also further democratic values such as accountability, administrative simplification, transparency, and performance measurement and evaluation. Below the Department discusses each provision of this proposed rule.

Section [XX](a)

Section [XX](a) provides that this section applies to and amends all Regulations issued by the Secretary or his delegates or sub-delegates in this title.

Section [XX](b)

Section [XX](b) defines several terms used in the proposed rule.

Section [XX](b)(1)

Section [XX](b)(1) defines ''Assess''[88] as ''a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.''

5 U.S.C. 610 directs agencies to have plans to periodically review those regulations that have or will have a significant economic impact upon a substantial number of small entities. Accordingly, in order to determine which regulations to periodically review using 5 U.S.C. 610's criteria, the Department must first determine which rules have a significant economic impact upon a substantial number of small entities. When promulgating regulations, the Department is required to determine whether a rule will have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b).[89] The Assessment refers to an essentially identical determination. In making the Assessment, the Department can look to the determination of the regulation's impact on small entities made at the time of promulgation, as well as experience since promulgation.

Section [XX](b)(2)

Section [XX](b)(2) defines ''Review'' as a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether the Regulations that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) 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 Regulations upon a substantial number of small entities. The Department discusses the Reviews in more detail in the discussion of section [XX](d) below.

Section [XX](b)(3)

Section [XX](b)(2) defines ''Regulation'' for purposes of this proposed rule as ''a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Regulation, and 42 CFR 2.14 is another Regulation.'' This definition makes clear that a section of the CFR, as opposed to a part, subpart, or paragraph within a section, is the unit that must be assessed and (if required) reviewed, or will otherwise expire. Defining ''Regulation'' in this objective way makes it easier for the Department and the public to know what exactly has to be reviewed by the dates listed in this proposed rule. Had

[85] *See, e.g.,* Amendment to the Interim Final Regulation for Mental Health Parity, 70 FR 42276, 42277 (July 22, 2005) (amending interim final rule, to provide that ''the requirements of the MHPA interim final regulation apply to group health plans and health insurance issuers offering health insurance coverage in connection with a group health plan during the period commencing August 22, 2005 through December 31, 2005. Under the extended sunset date, MHPA requirements do not apply to benefits for services furnished after December 31, 2005.''); *see generally Clean Air Council* v. *Pruitt,* 862 F.3d 1, 9 (D.C. Cir. 2017) (an agency can amend or revoke a legislative rule through notice-and-comment rulemaking).

[86] *See, e.g.,* Control of Communicable Diseases; Foreign Quarantine, 85 FR 7874, 7874 (Feb. 12, 2020) (providing that, unless extended, interim final rule ''will cease to be in effect on the earlier of (1) the date that is two incubation periods after the last known case of 2019–nCoV, or (2) when the Secretary determines there is no longer a need for this interim final rule''); Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 FR 54820, 54820 (Sept. 2, 2020) (providing that an interim final rule applies ''for the duration of the [public health emergency] for COVID–19'').

[87] The Department proposes to add substantively identical provisions to Titles 21, 42, and 45. For concision, in this section the Department describes these provisions once, rather than repeating the same substantive provisions several times. The Department uses the phrase ''[XX]'' to refer to the fact that substantively identical provisions will be added to Titles 21, 42, and 45. Because certain regulations in Title 42 cannot be amended without a 60-day comment period, *see* 42 U.S.C. 1395hh(b), the Department has written two proposed regulations for Title 42. One applies to the parts of that title that require a 60-day comment period, and the other applies to the remainder of the Department's regulations in Title 42.

[88] ''Assess,'' ''Review,'' and ''Regulation'' are capitalized in this preamble where those terms have the definitions ascribed to them in the text of this proposed rule.

[89] 5 U.S.C. 605(b) refers to rules that have a ''significant economic impact *on* a substantial number of small entities,'' whereas 5 U.S.C. 610 refers to rules that have ''significant economic impact *upon* a substantial number of small entities.'' This does not appear to be a material difference.

the Department used the Administrative Procedure Act's (APA's) definition of ''rule,'' [90] it could be unclear in certain circumstances what precisely needed to be reviewed.

Section [XX](b)(4)

Third, this proposed rule defines ''Year of the Regulation's Promulgation'' to mean the calendar year the Regulation first became effective, irrespective of whether it was subsequently amended. The purpose of this definition is to provide clarity to the Department and the public. If a Regulation were amended, questions could arise whether the clock for re-reviewing a Regulation begins on the date the Regulation was first promulgated; the date it was last amended; or whether the clock for reviewing the amended portion begins on a different date than the portion that was initially enacted. This definition creates simplicity for the Department and the public, because this definition, in conjunction with section [XX](c), makes clear that the clock starts for the retrospective review of an entire Regulation on the date that the Regulation was first promulgated, even if it is subsequently amended.

If, for example, the Department issues a Regulation and amends it nine years later, the Department may wish to conduct the Review at the time of amendment, particularly since the Department is presumably already performing a regulatory impact analysis with regard to the amendment. Since the Department is already conducting a regulatory impact analysis, performing the Review at that time may save Department resources and spare the Department from having to perform the Review on the Regulation the next year. In fact, any time the Department amends a Regulation, it could perform the Review of the Regulation at that time, thereby restarting the Regulation's ten-year clock.

Section [XX](b)(5)

Section [XX](b)(5) provides that ''[s]ignificant economic impact upon a substantial number of small entities'' shall have the meaning ascribed to that term in the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996).

Section [XX](c)

Section [XX](c) provides that unless a Regulation contains an earlier expiration date or is rescinded earlier, all Regulations issued by the Secretary or his delegates or sub-delegates in this title shall expire at the end of either (1) two calendar years after the year that this proposed rule first becomes effective, (2) ten calendar years after the Year of the Regulation's Promulgation, or (3) ten calendar years after the last year in which the Department Assessed and (if Review of the Regulation is required pursuant to paragraph (d)) Reviewed the Regulation, whichever is latest. The last year in which the Department Assessed and (if Review of the Regulation is required) Reviewed the Regulation shall be the year during which the findings of the Assessment and, if required, the Review of the Regulation are published in the **Federal Register** pursuant to paragraph (f) of this section.

In other words, the Department must Review all its Regulations (subject to the exceptions listed below) that have a significant economic impact upon a substantial number of small entities every ten years, or such Regulations shall expire. To determine which Regulations have a significant economic impact upon a substantial number of small entities, the Department must Assess all its Regulations (subject to the exceptions listed below) every ten years, or such Regulations shall expire if not Assessed. For Regulations that have already been in effect at the time this proposed rule goes into effect, the Department would have two years from this proposed rule's effective date, or ten years from the Regulation's promulgation, whichever is later, to conduct the Assessment and, if required, the Review. The Department believes all of its Regulations (subject to the exceptions listed below) should be Assessed and, if they have a significant economic impact upon a substantial number of small entities, Reviewed. Assessments and Reviews should not be performed only on those Regulations issued after this proposed rule goes into effect. After all, it is likely that some Regulations promulgated decades ago may have become outdated.[91]

Section [XX](c) makes clear that Department Regulations (subject to the exceptions listed below) shall expire if the Assessment and (if required) the Review are not timely performed on them. Both section 3(a) of the RFA and executive orders by multiple presidents over several decades direct the Department to devise plans to periodically review many of its regulations.[92] Although the Department retrospectively reviewed a very limited number of its regulations, it has not reviewed many of its regulations, notwithstanding that observers have over the decades noted that the Department has not always performed retrospective review to a satisfactory extent. Therefore, the Department has concluded that it is appropriate to impose on itself a stronger incentive to ensure it complies with the purposes animating the RFA and the executive orders, as well as to ensure its regulations are not unduly burdening the public. As a CRS report put it, ''[w]ithout some type of enforcement of the review requirement, agencies are unlikely to conduct many more reviews than have occurred pursuant to Section 610.'' [93] This is one reason why analyses

[90] 5 U.S.C. 551(4) (providing that '' 'rule' means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing'').

[91] *See, e.g.,* Office of Mgmt. & Budget, Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities, at 46–47 (2005) *http://perma.cc/R8LX-BQMJ;* Cynthia Morgan and Nathalie B. & Nathalie B. Simon, *National primary drinking water regulation for arsenic: A retrospective assessment of costs,* 5 J. Benefit Cost Anal. no. 2, 2014, at 259–84 *https://www.cambridge.org/core/services/aop-cambridge-core/content/view/A7B29CE98E650B424E92FF292A8FFC89/S2194588800000774a.pdf/national_primary_drinking_water_regulation_for_arsenic_a_retrospective_assessment_of_costs.pdf.*

[92] The RFA and the Executive Orders direct agencies to review overlapping, but not identical, sets of regulations. The RFA directs agencies to have plans to review regulations that have a ''significant economic impact upon a substantial number of small entities.'' 5 U.S.C. 610. By contrast, Executive Order 12866 directed agencies to submit to OIRA programs to periodically review ''significant regulations.'' Exec. Order 12866, sec. 5(a). ''Significant regulations'' are not necessarily those that have a ''significant economic impact upon a substantial number of small entities.'' *Id.* at sec. 3(f) (defining ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.''). Executive Order 13563 also directed agencies to review ''significant regulations.'' Exec. Order. 13563, sec. 6. The Department has proposed to Review those regulations that satisfy the RFA criteria, since those are the regulations that Congress directed agencies to have plans to review. The Department requests comment on whether additional regulations, such as significant regulations, should also be Reviewed.

[93] Curtis W. Copeland, Cong. Research Serv., RL32801, Reexamining Rules: Section 610 of the

Continued

have found that sunset provisions are an effective way to improve governance and reduce undue regulatory burdens.[94] States have imposed similar expiration dates for many of their regulations unless they are reviewed or readopted.

It complies with the APA to amend Regulations to add dates by which Regulations expire unless the Assessment and/or Review is timely performed. An agency can, through notice-and-comment rulemaking, amend its regulations to provide that they expire at a future date.[95] An agency can also provide that its regulations expire upon the occurrence of a condition.[96] That is what the Department is proposing in this proposed rule. To be sure, an agency generally must ''articulate a satisfactory explanation'' for its action, ''including a rational connection between the facts found and the choice made,'' and cannot ''entirely fail[] to consider an important aspect of the problem.'' [97] The Department anticipates that if a Regulation expires because the Department does not timely Review it, a litigant might object to the expiration on the grounds that the Department by definition did not ''articulate a satisfactory explanation'' or ''failed to consider an important factor,'' because in not performing a Review, the Department failed to consider any factors. The Department rejects such arguments. In this rulemaking, the Department is considering the important factors. It issues this notice of proposed rulemaking because, for the reasons described herein, the Department believes the benefits of retrospective review, and the need to strongly incentivize it, are so great that the risk of a Regulation inadvertently expiring is outweighed by the benefit of institutionalizing retrospective review in this manner. Forty years of experience since the RFA's enactment; the decades since relevant Executive Orders were enacted; and other Federal government efforts to spur the Department to conduct more retrospective reviews indicate that, absent such a forcing mechanism, the Department will not conduct as many retrospective reviews as desired.

The Department believes that the benefits of retrospective review also outweigh the burden from any additional work that the Department would be required to perform. The Department intends to timely Assess all its Regulations (and timely Review those it must Review), but has considered that there is some risk that a Regulation could expire because the Department failed to timely Assess or Review it. The Department proposes to mitigate this risk by setting up a website where, if the deadline for publishing an Assessment or Review is nearing and the Department has not yet announced that it has commenced the Assessment or Review, the public can submit a comment requesting that the Department begin the Assessment or Review. This requirement is described in more detail in the discussion of proposed Section [XX](g). Therefore, in this rulemaking process, which amends Department regulations through the notice-and-comment process, the Department is considering the important factors.

The Department proposes to perform the Assessment and (if required) the Review on each Regulation every ten years. Some states provide that, unless readopted or re-reviewed, their regulations expire in seven years,[98] while at least one state uses a ten-year time period.[99] The Department proposes to perform the Assessment and (if required) the Review every ten years, because ten years is the period listed in 5 U.S.C. 610. The Department has many Regulations, some of which are complex, so having to perform the Assessment and Review more than once every ten years could unduly burden the Department and increase the likelihood that a Regulation inadvertently expires because it is not Assessed or Reviewed.

The proposed rule would provide that Regulations promulgated more than ten years ago will expire at the end of two calendar years from the date this proposed rule, if finalized, becomes effective, unless the Assessment and (if required) the Review is performed on those Regulations. The Department believes that two years is a sufficient amount of time to conduct the initial Assessments and (if required) Reviews of those Regulations. The Assessments will be similar to, but not as burdensome as, the determinations made during rulemaking about whether a rule has a significant economic impact upon a substantial number of small entities. Assessments will be less burdensome because those performing the Assessments can in many instances benefit from the work already performed when the Regulation is initially promulgated. Likewise, the Reviews will be similar to the section 610 reviews that agencies currently perform. The Reviews will be less burdensome than regulatory impact analyses or regulatory flexibility analyses, because they are limited to assessing the five factors listed in 5 U.S.C. 610 and certain legal considerations. The regulatory flexibility analyses and regulatory impact analyses for HHS' rulemakings are typically performed in far less than two years. Therefore, even if this proposed rule increases substantially the volume of Assessments and Reviews to perform,[100] two years should be a sufficient amount of time to perform the Reviews that need to be performed during that time frame. This is discussed in more detail in the regulatory impact analysis below. The Department believes Regulations promulgated more than ten years ago should be Assessed and, if needed, Reviewed in fairly short order, since they are presumably generally the ones most likely to have become obsolete. The Department is interested in public

Regulatory Flexibility Act 11 (2008); *see also* Yoon-Ho Alex Lee, *An Options Approach to Agency Rulemaking,* 65 Admin. L. Rev. 881, 895–96 (2013) (setting forth possible reasons why agencies, even when they have adequate resources, may be reluctant to perform retrospective reviews).

[94] Russell S. Sobel & John A. Dove, *State Regulatory Review: A 50 State Analysis of Effectiveness* (Mercatus Ctr., Working Paper No. 12–18 (2012), at 36); *Occupational Licensing: A Framework for Policymakers,* at 48–50 (July 2015).

[95] *See, e.g.,* Amendment to the Interim Final Regulation for Mental Health Parity, 70 FR 42276 (July 22, 2005) (amending interim final rule, to provide that ''the requirements of the MHPA interim final regulation apply to group health plans and health insurance issuers offering health insurance coverage in connection with a group health plan during the period commencing August 22, 2005 through December 31, 2005. Under the extended sunset date, MHPA requirements do not apply to benefits for services furnished after December 31, 2005.''); *see generally Clean Air Council,* 862 F.3d at 9 (an agency can amend or revoke a legislative rule through notice-and-comment rulemaking).

[96] *See, e.g.,* Control of Communicable Diseases; Foreign Quarantine 85 FR 7874, 7874 (Feb. 12, 2020 (providing that, unless extended, interim final rule ''will cease to be in effect on the earlier of (1) the date that is two incubation periods after the last known case of 2019–nCoV, or (2) when the Secretary determines there is no longer a need for this interim final rule''); Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 85 FR 54820, 54820 (Sept. 2, 2020) (providing that an interim final rule applies ''for the duration of the [public health emergency] for COVID–19'').

[97] *Little Sisters of the Poor Saints Peter and Paul Home* v. *Pennsylvania,* 140 S. Ct. 2367, 2383–84 (2020) (quoting *Motor Vehicle Mfrs. Assn. of United States, Inc.* v. *State Farm Mut. Automobile Ins. Co.,* 463 U.S. 29, 43 (1983)).

[98] *See, e.g.,* N.J.A.C 1:30–6.4 (regulations expire every seven years unless readopted, subject to certain exceptions); Ind. Code 4–22–2.5–2 (imposing seven-year expiration date on regulations unless readopted).

[99] N.C. Gen. Stat. 150B–21.3A.

[100] The Department has roughly 12,400 regulations that were promulgated more than ten years ago. *See* Enhancing Regulatory Reform Through Advanced Machine Learning Findings (internal HHS slide). Since many of these regulations were promulgated as part of the same rulemakings, the numbers of Reviews to be performed in two years is roughly a fifth this number.

comment on whether two years is an appropriate time period to Assess and (if required) Review Regulations promulgated more than ten years ago.

The Department has decided that all of its Regulations (subject to the exceptions listed below) should be periodically assessed to determine whether they have a significant economic impact upon a substantial number of small entities. Without performing the Assessment, the Department may not know which regulations have or will have a significant economic impact upon a substantial number of small entities. Due to changed circumstances, a regulation that did not have such an impact at the time it was promulgated may now have such an impact. The Department is also aware of literature suggesting that agencies have not been consistent in deciding which rules have a significant economic impact on a substantial number of small entities, or have avoided such a finding in order to avoid complying with the RFA's requirements.[101] By Assessing all of its Regulations (subject to the exceptions described herein) and publishing the results of the Assessments, the Department can avoid concern that the Department is failing to Assess or Review Regulations that have a significant economic impact on a substantial number of small entities.

The Department should in many cases perform a single Assessment (and, where required, a single Review) that considers all Regulations issued as part of the same rulemaking. That would generally make sense from an economic perspective, for the same reasons as why the Department in many cases does a single regulatory impact analysis on all Regulations that are issued as part of the same rulemaking. Such an approach is not only permissible, but is encouraged, under this proposed rule. It would in some cases be nonsensical to Assess or Review a Regulation in isolation from the other Regulations promulgated as part of the same or a related rulemaking. Indeed, 5 U.S.C. 605(c) provides that ''[i]n order to avoid duplicative action, an agency may consider a series of closely related rules as one rule for the purposes of sections 602, 603, 604 and 610 of this title.'' Moreover, if a series of Regulations were issued as part of the same rulemaking and one of those Regulations was subsequently amended, the Department would in many cases take the view that the series of Regulations could be Assessed or Reviewed together for purposes of this proposed rule.

For Regulations that were issued in coordination with another Agency, that function in concert with another Agency's regulations, or that have a specific, direct impact on regulations issued by another Federal agency, the Department shall consult with that other Agency when undertaking the Assessment or Review, and consider the other Agency's views when considering the factors described in section [XX](d). An example of Regulations that have a specific, direct impact on regulations issued by another Federal agency are the Department's ACA regulations concerning the operation of Exchanges that affect eligibility for the advance premium tax credit. Such regulations have a specific, direct impact on Department of the Treasury regulations.[102]

The Department's understanding is that the decisions based upon Reviews, including the amendment, repeal, or affirmation of Regulations, will constitute final agency action. First, the decisions will mark the consummation of the agency's decisionmaking process with respect to whether a Regulation satisfies the criteria described in section [XX](d). Second, the decisions constitute action by which rights or obligations have been determined, or from which legal consequences will flow. This is because if the Review is not performed, the Regulation would expire.[103] Therefore, because the decisions based upon Reviews constitute final agency action, they must be performed in such a manner that they would withstand judicial review under the arbitrary and capricious standard.[104]

Similarly, if an Assessment concludes that a Regulation does not have a significant economic impact upon a substantial number of small entities, that would mark the consummation of the Department's decisionmaking process with respect to whether a Review must be performed on the Regulation. Such an Assessment's findings would also constitute action by which rights or obligations have been determined, or from which legal consequences will flow, because if the Assessment is not performed, the Regulation would expire. Therefore, Assessments must also be performed in such a manner that they would withstand judicial review under the arbitrary and capricious standard.

Section [XX](d)

Section [XX](d) provides that the Department is required to Review those Regulations that the Department Assesses have a significant economic impact upon a substantial number of small entities. In reviewing Regulations to minimize any significant economic impact of the Regulation on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's Review shall consider (1) the continued need for the Regulation, consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules; (2) the nature of complaints or comments received concerning the Regulation from the public; (3) the complexity of the Regulation; (4) the extent to which the Regulation overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation since the Regulation was promulgated or the last time the Regulation was Reviewed by the Department; (6) whether the Regulation complies with applicable law; and (7) other considerations as required by relevant executive orders and laws.

This largely mirrors the review described in 5 U.S.C. 610. It is also consistent with ACUS' recommendation that agencies ''consider whether the [existing] regulations are accomplishing their intended purpose or whether they might, to the extent permitted by law, be modified, strengthened or eliminated in order to achieve statutory goals more faithfully, minimize compliance burdens on regulated entities, or more effectively confer regulatory

[101] *See, e.g.,* Connor Raso, *Agency Avoidance of Rulemaking Procedures,* 67 Admin. L. Rev. 65, 93–95, 99–101 (2015); Michael R. See, *Willful Blindness: Federal Agencies' Failure to Comply with the Regulatory Flexibility Act's Periodic Review Requirement—And Current Proposals to Reinvigorate the Act,* 33 Fordham Urb. L. J. 1199, 1222–25 (2006).

[102] *See, e.g.,* 45 CFR 155.340 (regarding administration of advance payments of the premium tax credit and cost-sharing reductions and requiring the Exchange to comply with Treasury regulations).

[103] *See U.S. Army Corps of Engineers* v. *Hawkes Co., Inc.,* 136 S. Ct. 1807, 1813 (2016) (to have final agency action, ''First, the action must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow'' (quoting *Bennett* v. *Spear,* 520 U.S. 154, 177–78 (1997)).

[104] *See* 5 U.S.C. 704 (final agency action is reviewable); 5 U.S.C. 706 (a reviewing court shall hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law).

benefits.'' [105] Prior to finalization, OIRA may review Reviews, including to coordinate inter-agency participation in the Review process where there are significant inter-agency equities or as otherwise appropriate.[106] For example, when Assessing or Reviewing Regulations that require Executive Order 12250 review and approval by the Attorney General, the Department will consult with the Department of Justice (DOJ) and provide a draft of the findings to DOJ well in advance of the Assessment or Review deadline, so that DOJ can review and approve prior to the publication of the findings. It may be appropriate for OIRA to coordinate this process.

Section [XX](d) provides that the Department shall consider the continued need for the Regulation, ''consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules.'' The quoted phrase is not found in 5 U.S.C. 610, but the Department includes it to clarify that determining the continued need for the Regulation includes determining the extent to which it defines terms or sets standards used in or otherwise applicable to other Federal rules. However, this is not meant to be the only factor the Department should consider when determining the continued need for the Regulation. The Department shall consider any factors that, for the particular Regulation, are relevant to determining whether there is a continued need for the Regulation.

In addition to this phrase, two factors listed in section [XX](d) are not found in 5 U.S.C. 610. The first is that section [XX](d) states that the Review should take into account ''whether the Regulation complies with applicable law.'' Since applicable law may have changed since the Regulation was promulgated, the Department wants to ensure that its Regulations are regularly reviewed to ensure that they comply with applicable law. Second, section [XX](d) states that the Review should take into account ''other considerations as required by relevant executive orders and laws.'' To the extent Executive Orders or laws enacted since section 610 require the Department to consider additional factors when performing retrospective review of particular regulations, the Department wishes to comply with those Executive Orders and laws. A recent Department of Transportation rule similarly required that agency, when periodically reviewing its regulations, to consider ''[o]ther considerations as required by relevant executive orders and laws.'' *See* 49 CFR 5.13(d)(2)(vi).

The Department anticipates that the Reviews would be similar to the section 610 analyses currently performed by agencies. The Reviews would benefit from real-world data and information gathered since the Regulation was promulgated to potentially discern the impact of the Regulation on small entities and on society more generally.

Section [XX](d) requires only that regulations that have a significant economic impact upon a substantial number of small entities be Reviewed, because those are the regulations that 5 U.S.C. 610 requires agencies have a plan to periodically review.

Section [XX](e)

Section [XX](e) provides that if the Review concludes that a Regulation should be amended or rescinded, the Department shall have two years from the date that the findings of the Review are published in the **Federal Register** pursuant to paragraph (f) to amend or rescind the Regulation. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time for a total of not more than five years.

The Department includes this provision, because if the Review concludes that a Regulation should be amended or rescinded, the Regulation should in fact be amended or rescinded. The Department believes that two years will generally be an adequate amount of time to amend or rescind a Regulation, since the Department has already conducted a Review of the Regulation. In circumstances where amendment is not feasible within that time period, the Secretary can so certify in a statement published in the **Federal Register** and extend the completion date by one year at a time for a total of not more than five years.

When the Review determines that a Regulation should be amended or rescinded, the Department would, on a case-by-case basis as appropriate, use enforcement discretion to not enforce the Regulation or a portion of the Regulation until it is amended or rescinded. This is because in many cases the Department would not want to enforce Regulations (or portions of Regulations) that it determines should be amended or rescinded. The Department notes that enforcing a Regulation deemed to require amendment or rescission in some cases raises concerns about whether such enforcement is arbitrary and capricious. Continuing to enforce the Regulation (or portions thereof) would arguably ''run[ ] counter to the evidence before the agency.'' [107]

Section [XX](f)

Next, section [XX](f) provides that the results of all Assessments and Reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which Assessments and Reviews were conducted during that calendar year. The document shall also specify the year by which the next Assessment (and, if required, the next Review) of the Regulation shall be completed.

The Department includes this requirement so that both the Department and the public can readily know which Regulations were Assessed and Reviewed each year. If Assessments and Reviews were published in disparate places throughout the year, it could become extraordinarily difficult for both the Department and the public to know which Regulations were Assessed and Reviewed each year. Section [XX](f) will enable both the Department and the public to look in one place to know which Assessments and Reviews were conducted each calendar year, and know the findings of those Assessments and Reviews.

When publishing the findings of an Assessment or Review, the Department should include the full underlying analyses and data used to support the results, subject to any applicable privilege, protections for confidential business information, or explicit prohibition on disclosure. This will increase transparency and permit the public to see how the Department reached its conclusion. By requiring publication of the Reviews and the underlying analyses and data, the Department also incorporates ACUS' suggestion that ''[a]gencies should

[105] Administrative Conference of the United States, Recommendation 2014–5, 79 Fed. App'x—Recommendations of the Administrative Conference of the United States, 79 FR 75114, 75117 (Dec. 17, 2014).

[106] OIRA may also coordinate inter-agency participation in the Assessment process where there are significant inter-agency equities or as otherwise appropriate.

[107] *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983).

disclose relevant data concerning their retrospective analyses'' so as to ''allow private parties to recreate the agency's work and to run additional analyses concerning existing rules' effectiveness.'' [108]

The Department does not believe that the deliberative process privilege would generally bar disclosing the final underlying analyses and data referred to in section [XX](f).[109]

Section [XX](f) also provides that the document published in the **Federal Register** shall specify the year by which the next Assessment (and, if required, the next Review) of the Regulation shall be completed. This can be particularly helpful if the Department conducts an Assessment or Review of a Regulation prior to the deadline year.

Section [XX](g)

Section [XX](g) provides that paragraph (c) of the proposed rule shall not apply to Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. For such Regulations that are adopted after the effective date of this section, the Federal law described shall be cited in the notice of adoption. Section [XX](g) also provides that paragraph (c) of the proposed rule shall not apply to (1) Regulations whose expiration pursuant to this section would violate any other Federal law; (2) this section; (3) Regulations that involve a military or foreign affairs function of the United States; (4) Regulations addressed solely to internal agency management or personnel matters; (5) Regulations related solely to Federal Government procurement; and (6) Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

Section [XX](g)(1) excepts Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. This is only the case in rare circumstances. Because the Department lacks discretion over what is contained in these Regulations and cannot rescind them, they are exempted from section [XX](c). For such Regulations that are promulgated after the effective date of this proposed rule, the Department shall describe in the Regulation's notice of adoption the Federal law that results in the Department having no discretion as to whether to promulgate the Regulation and what is prescribed by the Regulation. The proposed rule includes this requirement so the public has notice that such Regulations are exempt from section [XX](c).

Section [XX](g) likewise also exempts from section [XX](c) any Regulation whose expiration pursuant to this section would violate any other Federal law. The exceptions listed in sections [XX](g)(1) and [XX](g)(2) are not satisfied simply because the statutory authority for the Regulation provides that the Secretary ''shall'' prescribe regulations. For example, section 804(b) of the Federal Food Drug & Cosmetic Act, 21 U.S.C. 384(b), provides that the ''Secretary, after consultation with the United States Trade Representative and the Commissioner of U.S. Customs and Border Protection, *shall* promulgate regulations permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States'' (emphasis added). However, although the statute was enacted in 2003, as of January 1, 2020 the Department had not issued any regulations implementing it, indicating the Department's view that section 804(b) did not require the Department to issue regulations. Similarly, Section 1102 of the Social Security Act, 42 U.S.C. 1302, provides that the Secretary ''*shall* make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which [he] is charged under this Act'' (emphasis added). But the Department does not believe every regulation promulgated pursuant to section 1102 is required to have been issued, or that it would violate Federal law to rescind such regulations.

Section [XX](g) also exempts this proposed rule from section [XX](c). Assuming that no rules expire due to lack of Assessment or Review, this proposed rule cannot, absent other actions, directly impose on the public costs that exceed benefits, since this proposed rule merely requires the Department to periodically Assess and, in some cases, Review its Regulations. Only the failure to perform an Assessment or Review in the future could theoretically impose on the public costs that exceed benefits (assuming expired Regulations were on balance benefiting the public). This proposed rule would improve the Department's Regulations by requiring the Department to evaluate the impact of its Regulations and amend or rescind those Regulations with a significant economic impact upon a substantial number of small entities that the Department determines should be amended or rescinded. Therefore, the rationale for periodic review does not apply to this proposed rule to the extent it applies to other Department regulations. The Department realizes that certain members of the regulated community might rely on particular regulations, but the Department will take that into account when performing Assessments and Reviews. The Department would only determine that a Regulation should be amended or rescinded if the Regulation's burdens outweigh these reliance interests and the other benefits of the Regulation or if other factors, such as a change in law, might compel amendment or rescission. The Department does not intend to avoid Assessing or, if required, Reviewing any Regulation and does not anticipate that an important Regulation would expire due to failure to Assess or Review it. Moreover, the Department anticipates that the public would remind the Department to perform the Assessment or Review if the deadline is nearing and the Department has not yet commenced the Assessment or Review.[110] Accordingly, the Department proposes to exempt this proposed rule from Section [XX](c).

Section [XX](g) also exempts Regulations that involve a military or foreign affairs function of the United States. For purposes of this proposed rule, ''a military or foreign affairs function of the United States'' shall have the same meaning as that phrase has under 5 U.S.C. 553(a). Regulations that involve a military or foreign affairs function of the United States are exempted from this proposed rule for the same reasons that Congress exempted them from the requirements of 5 U.S.C. 553.

Section [XX](g) also exempts Regulations addressed solely to internal agency management or personnel matters and Regulations related solely to

[108] 79 FR 75114, 75117 (Dec. 17, 2014); *see also* Exec. Order 13563, sec. 6(a) (Jan. 18, 2011) (''retrospective analyses, including supporting data, should be released online whenever possible''). Although this proposed rule incorporates several ACUS' recommendations, it does not incorporate all of them. This proposed rule does not set forth a prioritization scheme. That is in part because it is difficult to determine which regulations should be prioritized without having performed Reviews. HHS also invites public comment on how best to integrate retrospective review into new rulemakings, which was another ACUS recommendation.

[109] *See, e.g., Coastal States Gas Corp.* v. *Dep't of Energy,* 617 F.2d 854, 866 (D.C. Cir. 1980) (''[E]ven if the document is predecisional at the time it is prepared, it can lose that status if it is adopted, formally or informally, as the agency position on an issue or is used by the agency in its dealings with the public.'').

[110] *See* the discussion of section [XX](h) *infra.*

Federal Government procurement. Because such Regulations do not directly impact the public, the rationale for retrospective review is weaker with respect to these Regulations.[111]

Section [XX](g) also exempts any Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency. This is because the Department cannot on its own rescind or amend a Regulation issued jointly with another Federal agency. An example of a regulation issued in consultation with other agencies because of a legal requirement to consult with that other agency is section 104 of the Health Insurance Portability and Accountability Act, which directs the Secretaries of HHS, Labor and the Treasury to ensure that regulations issued pursuant to provisions where the Secretaries share interpretive jurisdiction (which includes many of the provisions in Title XXVII of the Public Health Service (PHS) Act) are administered to have the same effect at all times.[112]

The Department considered excepting additional Regulations, but wanted to limit the exceptions to Regulations that legally cannot be rescinded, are otherwise being periodically reviewed by the Department, do not substantially impact the public, or have a very strong countervailing policy. The exceptions listed herein are the only ones the Department tentatively believes satisfy these criteria. The Department seeks comment on whether to retain all these exceptions in a final rule or whether to add additional exceptions.

Section [XX](h)

Section [XX](h) provides that when the Department commences the process of performing an Assessment or Review, it shall state on a Department-managed website the Regulation(s) whose Assessment or Review it is commencing. The public will be able to submit comments regarding these Regulation(s) in the manner specified on this website. Members of the public can also submit comments in the manner specified on the website requesting that the Department begin the Assessment or Review of a Regulation, particularly if they are concerned that the deadline is nearing and the Department has not stated that it has commenced the Assessment or Review.

The Department includes this provision so that, when the Department is Assessing or Reviewing a Regulation, the public can submit comments for the Department's consideration. The Department believes this will maximize transparency, public participation, and the Department's knowledge of the real-world impacts of its Regulations.

The Department also proposes in this provision to allow the public to submit a comment on the website requesting that the Department begin the Assessment or Review of a Regulation. The Department has considered the risk that a Regulation could expire because the Department inadvertently did not Assess or Review it. The Department proposes to mitigate this risk by allowing members of the public to submit comments requesting that the Department commence the Assessment or Review of a Regulation. If a person is concerned that the Department has not announced the Assessment or Review of a Regulation and the deadline is nearing, the person can remind the Department to conduct the Assessment or Review.

The Department intends to timely Assess and, where required, Review all its Regulations. The Department notes, however, that if it has not announced that it is Assessing or Reviewing a Regulation, and the deadline is nearing, those who rely on the Regulation are on notice that it might expire, just as the public is on notice that a regulation might be rescinded when an agency issues a notice of proposed rulemaking to rescind the regulation.

Section [XX](i)

Lastly, this proposed rule includes a severability clause. The Department believes this proposed rule fully complies with applicable law, but does not wish to see the entire proposed rule vacated in the event that a portion of it is vacated. For example, the Department does not wish to see this entire proposed rule vacated because one of the exceptions listed in section [XX](g) is invalidated. However, the Department requests comment on whether the amendments to add expiration dates should be severable from other portions of the proposed rule, including the requirements to perform Assessments and Reviews. It is not clear that this proposed rule could properly function without the expiration dates, so the Department requests comment on this.

V. Request for Comment

HHS requests comment on all aspects of this notice of proposed rulemaking, including its likely costs and benefits. HHS is particularly interested in comments on:

- Whether the exceptions listed in section [XX](g) should be retained in the final rule.
- Whether the exceptions listed in section [XX](g), if worded as they currently are, will lead to uncertainty and litigation and, if so, how they should be revised.
- Whether additional exceptions should be included in section [XX](g).
- Regulations of particular importance that HHS needs to ensure are Assessed or Reviewed so they do not expire.
- Whether the Review should consider, in addition to the factors listed in 5 U.S.C. 610, whether the Regulation remains cost-effective and/or cost-justified. If so, how should the Department determine if a Regulation is cost-effective and/or cost-justified?
- When the Department performs a Review and determines that a Regulation should be amended or rescinded, what course of conduct should the Department take during the interim period before the Regulation is amended or rescinded? For example, should the final rule mandate that such a regulation cannot be enforced prior to amendment or rescission; should the Department determine whether to exercise enforcement discretion on a case-by-case basis; should the Department continue to enforce the Regulation in the same manner as prior to the Review; or should the Department follow a different course of conduct?
- If, when the Review concludes that a Regulation should be amended or

[111] The portion of the proposed rule applying to Title 42 also exempts 42 CFR 1001.952 from expiration. 42 CFR 1001.952 provides a safe harbor for various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute. The Department exempts this regulation because it is concerned that certain otherwise permissible behavior could become criminal simply because the Department did not Review this Regulation. The portion of the proposed rule applying to Title 42 also exempts 42 CFR part 73. 42 U.S.C. 262a provides that, with respect to Part 73, the ''Secretary shall review and republish [a list of certain biological agents and toxins] biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.'' Since those regulations are already being reviewed biennially, there is no need for this proposed rule to apply to 42 CFR part 73. Similarly, the portion of the proposed rule applying to Title 42 also exempts the annual Medicare Part A and Part B payment methodology update rules. Since these are amended annually, it does not make sense to Review them every ten years. Lastly, the portion of the proposed applying to Title 42 also exempts 42 CFR 100.3, since the statutory basis for this regulation provides that it cannot be amended unless (1) a proposed regulation is provided to the Advisory Committee on Childhood Vaccines (ACCV) and the ACCV is provided at least 90 days to make recommendations and comments, and (2) there is subsequently a 180-day public comment period. *See* 42 U.S.C. 300aa–14(c).

[112] *See* Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, 110 Stat. 1978.

rescinded, should the Secretary be allowed to extend the completion date for amendment or rescission beyond two years? If extensions are permitted, should the Secretary be allowed to extend the completion date by one year at a time for a total of not more than five years, or should he be permitted to extend for a shorter or longer period of time?

- Whether the Department should Review a different set of regulations than those that have a significant economic impact upon a substantial number of small entities (*i.e.,* whether it should Review all Department regulations; those that were, upon issuance, designated significant under Executive Order 12866; those that have a significant adverse economic impact upon a substantial number of small entities; or some other group). If the Department reviews a different set of regulations, should it review them using the criteria described in 5 U.S.C. 610(b) or different criteria, such as the criteria described in section 5(a) of Executive Order 12866?
- How best to integrate plans for retrospective review into new rulemakings.
- What timeframe to use when Assessing or Reviewing Regulations, and whether the timeframe should vary based on how old the Regulation is.
- What the baseline should be when Assessing or Reviewing Regulations, and what factors to consider when determining the baseline.
- Any other factors that would improve the rigor or methodology of the Assessments or Reviews.
- The regulatory impact of this proposed rule.
- The impact of this proposed rule on small entities, as that term is defined in the RFA.
- How this proposed rule, if finalized, should be designated under Executive Order 13771.

VI. Regulatory Impact Analysis

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary and not prohibited by statute, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a regulation (1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. OMB has designated this rule as economically significant for the purposes of Executive Orders 12866 and 13563. This proposed rule's designation under Executive Order 13771 will be informed by comments received.

Section 5 of Executive Order 12866 requires agencies to submit to the Office of Information and Regulatory Affairs (OIRA) a plan to periodically review their existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and principles. Section 6 of Executive Order 13563 similarly requires agencies to submit to OIRA a plan to periodically review their existing significant regulations to determine whether any such regulations should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.

This proposed rule would require the Department to assess whether its regulations have a significant economic impact upon a substantial number of small entities, and periodically review the impacts of such regulations using the criteria listed in section 3(a) of the RFA (as well as determine whether such regulations comply with applicable law).

The need for a Department-wide regulatory review process is also supported by the Department's regulatory reform project, which piloted an approach to augment expert policy insights with AI-driven data analysis. Machine learning surfaced a number of potential reform opportunities, identifying over 1,200 CFR section citations that merited consideration for reform and 159 CFR sections that could benefit from regulatory streamlining based on their similarities to other sections.[113] The project also uncovered that 85% of Department regulations created before 1990 have not been edited, and the Department has nearly 300 broken citation references in the CFR (*i.e.,* CFR sections that reference other CFR sections that no longer exist). Without a clear process for periodically reviewing these regulations, there is no guarantee that regulations will be reviewed and revised (if needed) to align with technological, economic, and other developments. (*Supra* Section II.)

This proposed rule would result in the Department assessing which of its regulations have a significant economic impact upon a substantial number of small entities, and Reviewing those regulations to determine whether they should be continued without change, amended, or rescinded. Where the Review determines that the Department's Regulations should be continued without change, those Regulations will be maintained in their current form. Where the Review determines that, based upon current data and information, the Regulation should be amended or rescinded, the Department will begin rulemaking to amend or rescind the Regulation. Thus, Regulations that have become outmoded will be amended or rescinded, whereas those Regulations that satisfy the Review criteria will be maintained. The Department believes it can complete Reviews for all Regulations that are more than ten years old in the proposed two-year timeframe. However, the Department recognizes that there is a risk that a Regulation whose benefits outweigh its costs could expire because the Department failed to Assess or Review it. The Department believes that risk may be lowered by members of the public reminding the Department if the Assessment or Review deadline is nearing and the Department has not commenced the Assessment or Review of a Regulation.

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. Moreover, in assessing the burdens of this proposed rule on the Department, it is important to note that the Department

[113] Regulatory Streamlining & Analysis, at 11 (Mar. 2019).

is already required to periodically review its regulations that have a significant economic impact upon a substantial number of small entities. *See* 5 U.S.C. 610. Implicit in 5 U.S.C. 610 is the requirement to determine which regulations have a significant economic impact upon a substantial number of small entities. Therefore, the Review requirements in the proposed rule do not impose new burdens not already imposed on the Department, if incomplete compliance is not accounted for in the regulatory baseline. If the Department believes a Regulation is important enough to justify imposing its requirements on the public, the Department should be able to prioritize periodically assessing the Regulation's impact.

To obtain additional insight into the potential benefits, costs, and burdens of this proposed rule, the Department performed several analyses. First, it examined recently-completed actions that occurred as a result of the relatively rare section 610 reviews that the Department has performed:

TABLE—RECENTLY-COMPLETED ACTIONS AS A RESULT OF SECTION 610 REVIEWS

Name of rulemaking	CFR citation and RIN	Year	Regulatory changes made as a result of section 610 reviews
Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care.	42 CFR Parts 403, 416, 418, 441, 460, 482, 483, 484, 485, 486, 488, 491, and 494. RIN 0938–AT23	2019 (Final Rule)	Reformed Medicare regulations that were identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, and increased the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert resources away from furnishing high quality patient care. Updated fire safety standards for Medicare and Medicaid participating End-Stage Renal Disease (ESRD) facilities by adopting the 2012 edition of the Life Safety Code and the 2012 edition of the Health Care Facilities Code, and updated the requirements that hospitals and Critical Access Hospitals must meet to participate in the Medicare and Medicaid programs. Requirements were intended to conform to current standards of practice and support improvements in quality of care, reduce barriers to care, and reduce some issues that may exacerbate workforce shortage concerns.
Medicare and Medicaid Programs; Conditions of Participation for Home Health Agencies.	42 CFR Parts 409, 410, 418, 440, 484, 485 and 488. RIN 0938–AG81	2017 (Final Rule)	Revised the conditions of participation that home health agencies (HHAs) must meet in order to participate in the Medicare and Medicaid programs. The new requirements focus on the care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements.
Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities.	42 CFR Parts 405, 431, 447, 482, 483, 485, 488, and 489. RIN 0938–AR61	2016 (Final Rule)	Revised the requirements that Long-Term Care facilities must meet to participate in the Medicare and Medicaid programs. These changes are necessary to reflect the substantial advances that have been made over the past several years in the theory and practice of service delivery and safety.

These results suggest that, if the Department performs additional Reviews, additional benefits will be achieved from revising and streamlining certain regulatory requirements.

The Department also performed the following analysis to estimate the costs and burdens to the Department from (1) assessing which Department regulations have a significant economic impact upon a substantial number of small entities, and (2) Reviewing those regulations.[114] The Department has roughly 18,000 regulations, the vast majority of which it believes would need to be Assessed.[115] Roughly 12,400 of these regulations are over ten years old.[116] The vast majority of these would need to be Assessed within two years if this proposed rule were finalized. But because the Department estimates that roughly five regulations on average are part of the same rulemaking, the number of Assessments to perform in the first two years is estimated to be roughly 2,480.

To help estimate the impact of this proposed rule, the Department conducted a random sample [117] of its regulations and assessed whether the sampled regulations would be exempt from this proposed rule and whether, at the time of issuance, the regulations were: Economically significant; found to have a significant economic impact upon a substantial number of small entities (SEISNOSE); or subject to the

[114] The Department is generally already required to undertake reviews under 5 U.S.C. 610. The Department includes this analysis because it may be informative for the public to see an estimate of the costs and burdens of assessing which regulations have a significant economic impact upon a substantial number of small entities, and Reviewing the Regulations that have such an impact.

[115] *See* Enhancing Regulatory Reform Through Advanced Machine Learning Findings (internal HHS slide) (the sum of the numbers listed in the table under the column denoted ''#'' is 17,890 Department regulations).

[116] *See id.* (adding the figures listed in the ''#'' columns for the 1950s, 1960s, 1970s, 1980s, 1990s, and 2000s yields 12,383 regulations).

[117] With the aid of a random number generator, the Department selected Department regulations in the Code of Federal Regulations. The Department then reviewed the relevant rulemaking associated with the specific regulation selected and analyzed those rulemakings in view of the categories listed in the table.

Unfunded Mandates Reform Act of 1995. Also included in the table is the estimated impact of the regulations when they were first promulgated. The findings of this sample are below:

Title	Rulemaking	Citation	Exempt from this proposed rule?	Economically significant?	SEISNOSE?	Subject to UMRA?	Impact estimates at issuance
21	Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products.	73 FR 63886	No	No	No	No	"[O]ne-time costs will range from approximately $38.0 million to $49.6 million and annual costs will range from $12.4 million to $46.3 million."[118]
21	Unique Device Identification System.	78 FR 58786	No	Yes	Yes	Yes	"Over 10 years, the estimated present value of the total domestic costs is $642.2 million using a 7 percent discount rate and $737.7 million using a 3 percent rate, and the annualized costs are $85.7 million using a 7 percent discount rate and $84.1 million using a 3 percent discount rate."[119]
21	Requirements for Foreign and Domestic Establishment Registration And Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs.	81 FR 60170	No	No	No	No	"We estimate one-time total costs of $59.7 million and recurring costs of $0.5 million. These costs represent total annualized costs of $9 million when calculated at a 7-percent discount rate over 10 years, and $7.5 million when calculated using a 3-percent discount rate. The largest cost elements will be for registrants reading and understanding the final rule and making changes to their standard operating procedures."[120]
21	Human Tissue Intended for Transplantation.	62 FR 40429	No	No	No	No	FDA confirmed "that the only economic impact of the rule would be related to recordkeeping burdens" that already existed.[121]
42	Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care.	70 FR 57368	No	Yes	No	No	"The Congress provided $142,000,000 for the loan program effective July 1, 2004 through September 30, 2008, and not more than $2,000,000 may be used for the administration of the loan program for each of the fiscal years (that is, 2004 through 2008)."[122]

Title	Rulemaking	Citation	Exempt from this proposed rule?	Economically significant?	SEISNOSE?	Subject to UMRA?	Impact estimates at issuance
42	Organ Procurement and Transplantation Network.	63 FR 16296	No	Yes	No	No	Although incremental effects attributable to the rule were not estimated, impact categories would have included life-years saved by non-renal organ transplants, quality of life improvements for kidney recipients, and the admittedly expensive costs of transplantation.[123]
42	Medicare Program; Hospital Insurance Entitlement and Supplementary Medical Insurance Enrollment and Entitlement.	53 FR 47199	No	No	No	N/A (rule issued prior to UMRA being enacted).	N/A: "We have determined that a regulatory impact analysis is not required for these rules because they would not have an annual impact of $100 million or more." [124]
45	Cooperation in Identifying and Providing Information To Assist States in Pursuing Third Party Health Coverage.	56 FR 8926	No	No	No	N/A (rule issued prior to UMRA being enacted).	"[T]he cost of implementation is expected to be insignificant." [125]
45	Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors.	76 FR 53256	No	No	No	No	Estimated annual cost of $23,236,238.[126]
45	Rate Increase Disclosure and Review.	76 FR 29964	No	No	No	No	"CMS estimates that issuers will incur approximately $10 million to $15 million in one-time administrative costs, and $0.6 million to $5.5 million in annual ongoing administrative costs related to complying with the requirements of this final rule from 2011 through 2013. In addition, States will incur very small additional costs for reporting the results of their reviews to the Federal government, and the Federal government will incur approximately $0.7 million to $5.9 million in annual costs to conduct reviews of justifications filed by issuers in States that do not perform effective reviews." [127]

None of the sampled regulations would be exempt from this proposed rule. At the time the ten sampled regulations were promulgated, the Department believed that one of the ten had a significant economic impact upon a substantial number of small entities. If the Assessments' findings mirror the findings from the time of issuance, one of the ten sampled regulations would need to be Reviewed. Similarly, an academic study that found 11.1% of Department final rules issued in 1993 had a significant economic impact upon a substantial number of small entities.[128] A more recent study found that agencies exempted over 92% of their rules from the RFA.[129] If the Department has roughly 2,480 rulemakings that are more than ten years old, and roughly 11% have a significant economic impact upon a substantial number of small entities, the Department would need to perform roughly 273 Reviews [130] in the two years after this proposed rule is finalized. If the Department has roughly 3,600 total rulemakings and roughly 11% [131] have a significant economic impact upon a substantial number of small entities, the Department would have to perform roughly 396 Reviews in the ten years after this proposed rule is finalized.[132]

Of the 273 rulemakings subject to Reviews in the first two years, the Department estimates roughly 16%,[133] or 44, of those rulemakings were promulgated prior to the requirement for prospective regulatory flexibility analyses. As described further below, those 44 Reviews will require more Department resources than the estimated 229 Reviews of rulemakings promulgated after the prospective analysis requirement went into effect.

A. Costs Related to Section 610 Reviews of Regulations More Than Ten Years Old

The Department estimates that a total of between 20,160 and 44,900 hours will be spent on Reviews outside the Assessment process during the first two years, which will clear the backlog of section 610 reviews for regulations ten years old or older. The Department assumes 40 to 100 hours per Review for the estimated 229 Reviews for which an initial prospective analysis was performed. The Department assumes 250 to 500 hours per Review for the estimated 44 Reviews where no such initial prospective analysis was performed.

HHS estimates that the fully-loaded cost per hour to the Department to employ a person to conduct a Review or Assessment is $244.98 per hour (referred to as ''*LaborCost*'').[134] Accordingly, multiplying the 20,160 to 44,900 estimated hours by *LaborCost* yields an estimated cost of between roughly $4,938,797 to $10,999,602, or approximately 17.4 to 38.7 FTEs working at *LaborCost,* to initiate and conduct Reviews in the first two years if this proposed rule were finalized. Thus, the average cost per year in the first two years would be between roughly $2,469,399 and $5,499,801.

B. Costs Related to Rulemakings That ''Age In'' to Section 610 Review

For years three through ten after this proposed rule were finalized, the Department estimates it will require between 4,920 to 12,300 hours to Review the estimated 123 rulemakings that ''age in'' [135] to the section 610 review during that time period. The Department assumes those 123 Reviews would take between 40 to 100 hours per Review, as each of those rulemakings were promulgated after prospective regulatory analysis was required. Multiplying the estimated 4,920 to 12,300 estimated hours by *LaborCost* yields total costs of between roughly $1,205,302 and $3,013,254, or approximately 4.2 to 10.6 FTEs working at *LaborCost,* to conduct 123 Reviews in the eight years following the first two years if the proposed rule were finalized, *i.e.,* years 3 to 10.

C. Costs Related to Assessments

In addition to performing Reviews of rulemakings already deemed to have a SEISNOSE, the Department will allocate resources to conducting Assessments of its rulemakings to determine whether a Review is required. The Department believes each Assessment will require between three and 10 hours to perform. The Department estimates that it will have to conduct roughly 2,207 [136] Assessments in the first two years if this proposed rule were finalized, and an additional roughly 997 [137] Assessments in the subsequent eight years, for a total of 3,204 Assessments across ten years. As such, the Department believes 6,621 to 22,070 hours will be spent on Assessments in the first two years and 2,991 to 9,970 hours over the next eight years. Multiplying those hour estimates by *LaborCost* yields roughly $1,622,013 to $5,406,709, or approximately 5.7 to 19.0 FTEs working at *LaborCost,* to conduct 2,207 Assessments in the first two years, and roughly $732,735 to $2,442,451, or approximately 2.6 to 8.6 GS–15 FTEs working at *LaborCost,* to conduct 997 Assessments in the

[118] Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products, 73 FR 63886, 63892 (Oct. 28, 2008).

[119] Unique Device Identification System, 78 FR 58786, 58811 (Sept. 24, 2013).

[120] Requirements for Foreign and Domestic Establishment Registration And Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs, 81 FR 60170, 60171 (Aug. 31, 2016).

[121] Human Tissue Intended for Transplantation, 62 FR 40429, 40442 (Jul. 29, 1997).

[122] Medicare Program; Health Care Infrastructure Improvement Program; Selection Criteria of Loan Program for Qualifying Hospitals Engaged in Cancer-Related Health Care, 70 FR 57368, 57372 (Sept. 30, 2005).

[123] Organ Procurement and Transplantation Network, 63 FR 16296, 16321–29 (Apr. 2, 1998).

[124] Medicare Program; Hospital Insurance Entitlement and Supplementary Medical Insurance Enrollment and Entitlement, 53 FR 47199, 47201 (Nov. 22, 1988).

[125] Cooperation in Identifying and Providing Information To Assist States in Pursuing Third Party Health Coverage, 56 FR 8926, 8929 (Mar. 4, 1991).

[126] Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, 76 FR 53256, 53280 (Aug. 25, 2011).

[127] Rate Increase Disclosure and Review, 76 FR 29964, 29978 (May 23, 2011).

[128] Michael R. See, *Willful Blindness: Federal Agencies' Failure to Comply with the Regulatory Flexibility Act's Periodic Review Requirement—And Current Proposals to Reinvigorate the Act,* 33 Fordham Urb. L. J. 1199, 1218 (2006).

[129] Connor Raso, *Agency Avoidance of Rulemaking Procedures,* 67 Admin. L. Rev. 65, 69 (2015).

[130] This figure is a bit high, since some of these regulations will be exempt from this proposed rule.

[131] The Department chooses 11%, rather than 8% or 10%, to err on the side of assuming a larger burden to the Department and because the study that found 11.1% of Department regulations had a significant economic impact upon a substantial number of small entities was focused solely on the Department's regulations.

[132] Roughly 273 of these would be performed in the first two years after this proposed rule were finalized, and the other 123 Reviews would occur in years 3–10. For purposes of this analysis, the Department assumes it will have to Review all Department regulations that the Department previously found had a SEISNOSE. If some of those regulations are determined to no longer have a SEISNOSE, the cost and burden to the Department would be less than estimated in this proposed rule.

[133] 16% is the percentage of Department regulations that are more than ten years old that were promulgated prior to 1980, when Congress passed the RFA.

[134] Here, the Department uses the reported ''FY 2021 average fully supported cost to [FDA of] $284,174 per FTE,'' divided by 1,160 ''Net Supported Direct FDA Work Hours Available for Assignments'' per year to arrive at $244.98 per hour. Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2021, 85 FR 46669, 46670 (Aug. 3, 2020).

[135] ''Age in,'' meaning that the rules become ten years old during years three through ten.

[136] 2,207 is derived from 2,480 Department rulemakings that are at least 10 years old minus the 273 rulemakings reviewed in years 1 and 2.

[137] 3,600 total rulemakings minus the 2,480 rulemakings that are over 10 years old yields 1,120 rulemakings that are left to be assessed during years 3–10. 123 of these rulemakings will be reviewed in years 3–10, leaving 997 rulemakings to be assessed (1,120 less 123 equals 997).

following eight years. Therefore, the Department estimates $2,354,748 to $7,849,160 will be incurred on Assessments in the first ten years if the proposed rule were finalized.

D. Costs Related to Review of Rulemakings Found to Have a SEISNOSE

Depending on the outcome of the Assessments, the Department may have to Review additional rulemakings. The Department estimates roughly 5% of Assessments of Regulations not initially found to have a SEISNOSE will conclude that a Review is required. The Department believes this is a reasonable estimate, because the 5% rate is roughly half of the percentage of all Department regulations the Department currently believes have a SEISNOSE. Accordingly, the Department estimates 110 [138] Reviews will be required in the first two years, and 50 [139] Reviews will be required in the subsequent eight years, for a total of 160 Reviews. During the first two years, the Department estimates the 110 Reviews will require 4,400 to 11,000 hours,[140] and that the 50 Reviews will require 2,000 to 5,000 hours in the subsequent eight years. Multiplying these hour estimates by *LaborCost* yields an estimated roughly $1,077,912 to $2,694,780, or 3.8 to 9.5 FTEs for post-Assessment Reviews in the first two years, and roughly $489,960 to $1,224,900, or 1.7 to 4.3 FTEs for post-Assessment Reviews in the subsequent eight years, for a total cost of $1,567,872 to $3,919,680 over ten years for post-Assessment Reviews.

E. Total Estimated Costs to the Department From Implementing This Rulemaking

In sum, the Department estimates a total cost of between roughly $10,066,719 to $25,781,696, or approximately 35.4 to 90.7 FTEs working at *LaborCost,* over ten years in order to do the following: (a) Clear the backlog of section 610 reviews for Department rulemakings more than ten years old that have never been subject to retrospective review in years 1 to 2, (b) conduct section 610 reviews of rulemakings that ''age in'' to section 610 review in years 3 to 10, (c) conduct Assessments of 3,204 rulemakings in years 1 to 10, and (d) conduct section 610 reviews of an estimated 160 rulemakings deemed to be subject to Review following an Assessment in years 1 to 10.[141] The cost in the first two years is estimated to be roughly $7,638,722 to $19,101,091, and roughly $2,427,997 to $6,680,605 in the following eight years. If the proposed rule were finalized, the Department estimates a total investment of 26.9 to 67.2 FTEs in the first two years, and 8.5 to 23.5 FTEs in the subsequent eight years, each FTE working at *LaborCost.* The Department estimates the annual cost of conducting Assessments and Reviews of between roughly $1,006,672 to $2,578,170 per year over ten years.

As noted above, the Department estimates one Review will take between 40 and 100 hours on average to perform. A full initial Regulatory Flexibility Act (RFA) analysis requires 250 to 500 hours to complete, because federal agencies must analyze the impact of their regulatory actions on small entities (small businesses, small non-profit organizations and small jurisdictions of government) and, where the regulatory impact is likely to be ''significant,'' affecting a ''substantial number'' of these small entities, seek less burdensome alternatives for them. This involves defining the market and determining costs for each small entity. The section 610 review is a more streamlined analysis because the regulatory flexibility analysis is the starting point, and it will focus on, in addition to certain legal considerations, 5 areas of analysis: (1) Whether there is a continued need for the rule, (2) whether there is duplication, (3) the number and nature of complaints, (4) the complexity of the regulation, and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule. As such, the Department estimates that a Review will require significantly less time than a full RFA analysis.

The Department recognizes that some regulations were promulgated prior to when the requirement for prospective regulatory analysis went into effect, and that section 610 review of such rulemakings may be more time-intensive. The Department estimates 203 rulemakings will be subject to section 610 review where some prospective analysis has been performed, in which case such reviews will take 40 to 100 hours. HHS estimates it will undertake section 610 reviews of 39 rules for which no prospective regulatory review was performed. HHS assumes that between 250 to 500 hours may be required for these reviews, even though the section 610 review is more circumscribed than a full regulatory flexibility analysis and will therefore generally take less time to perform.

The Department also notes that there could be costs associated with publishing the notices of Assessments and Reviews to the Department's website for public comment, but that such costs will be minimal and would not require the hiring of additional personnel.

Alternatives Considered

The Department considered alternatives, including not issuing this proposed rule. But the RFA and certain Executive Orders direct the Department to periodically review certain Department regulations. Moreover, the literature suggests that in some cases the actual impacts of regulations differ from the projected impacts at the time of promulgation, so regulations should be periodically reviewed. The Department's experience over the last forty years suggests that, absent a strong incentive such as the potential expiration of a regulation, the Department will not review an adequate number of its regulations. The Department considered Reviewing all of its Regulations, but determined that that might be too burdensome. It also considered only Reviewing those regulations that, at the time of promulgation, the Department determined had a significant economic impact upon a substantial number of small entities. But such determinations were not made for regulations that precede the RFA, and some post-RFA regulations that did not have such an impact at the time of promulgation might have such an impact today. In addition, the Department is aware of literature suggesting that agencies have not been consistent in deciding which rules have a significant economic impact on a substantial number of small entities, or have avoided such a finding in order to avoid complying with the RFA's requirements.[142] Therefore, the Department proposes to Assess all of its Regulations (subject to the exceptions listed herein) to determine which have a significant economic impact upon a substantial number of small entities, and Review those Regulations using the criteria listed in 5 U.S.C. 610. The Department also considered reviewing

[138] Which is 5% of the 2,207 assessments done in years 1–2.

[139] Which is 5% of the 997 assessments done in years 3–10.

[140] Each review will take 40–100 hours to assess.

[141] In reality, the total cost will likely be less, since this analysis does not account for certain Regulations being exempt from the Assessment and Review requirements.

[142] *See, e.g.,* Connor Raso, *Agency Avoidance of Rulemaking Procedures,* 67 Admin. L. Rev. 65, 93–95, 99–101 (2015); Michael R. See, *Willful Blindness: Federal Agencies' Failure to Comply with the Regulatory Flexibility Act's Periodic Review Requirement—And Current Proposals to Reinvigorate the Act,* 33 Fordham Urb. L. J. 1199, 1222–25 (2006).

all significant regulations, as that term is defined in Executive Order 12866. The Department is proposing to Review those regulations that have a significant economic impact upon a substantial number of small entities, in order to hew closely to the RFA. But the Department requests comment on whether to also review additional regulations, such as those that are significant under Executive Order 12866.

The Department also considered including in the proposed rule an opportunity for the Department to extend the ten-year deadline to Assess or Review Regulations in certain circumstances. However, the Department decided against including such a provision. First, the RFA does not permit such an extension for rules issued after the RFA's enactment, even though it allows the Department to extend the time to complete the review of rules existing at the time of the RFA's enactment. *See* 5 U.S.C. 610(a). Second, ten years is a long time and the Department believes it affords adequate time to perform the Assessments and (where required) Reviews. The Department is concerned that if it granted itself extensions, that would cause the Department to have more work to do in future years and therefore require it to grant extensions to Assess or Review Regulations whose expiration dates are in subsequent years. This could become a vicious cycle.[143]

Regulatory Flexibility Act

The Department has examined the economic implications of this proposed rule as required by the RFA (5 U.S.C. 601–612). The RFA generally requires that when an agency issues a proposed rule, or a final rule pursuant to section 553(b) of the APA or another law, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the **Federal Register**. 5 U.S.C. 603, 604. Specifically, the RFA normally requires agencies to describe the impact of a rulemaking on small entities by providing a regulatory impact analysis. Such analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. The RFA defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. 5 U.S.C. 601(3)–(6). Except for such small government jurisdictions, neither State nor local governments are ''small entities.'' Similarly, for purposes of the RFA, individual persons are not small entities. The requirement to conduct a regulatory impact analysis does not apply if the head of the agency ''certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' 5 U.S.C. 605(b). The agency must, however, publish the certification in the **Federal Register** at the time of publication of the rule, ''along with a statement providing the factual basis for such certification.'' *Id.* If the agency head has not waived the requirements for a regulatory flexibility analysis in accordance with the RFA's waiver provision, and no other RFA exception applies, the agency must prepare the regulatory flexibility analysis and publish it in the **Federal Register** at the time of promulgation or, if the rule is promulgated in response to an emergency that makes timely compliance impracticable, within 180 days of publication of the final rule. 5 U.S.C. 604(a), 608(b).

The Department considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue on at least five percent of small entities. Department regulations impact at least NAICS industry sectors 11, 31–33, 42, 44–45, 48–49, 52, 54, 62, 81, and 92.

This proposed rule would require the Department to review its existing regulations (subject to certain exceptions) that have a significant economic impact upon a substantial number of small entities using the criteria described in the RFA. To the extent that the review determines that the criteria described in section 3(a) of the RFA favor rescinding or amending a regulation, HHS would do so. Thus, this proposed rule is not expected to impose direct burdens on small entities, as defined in the RFA. In the event that the Department does not announce that it has commenced an Assessment or Review, there may be some burden on small entities associated with requesting that the Department perform an Assessment or Review. The Department assumes that regulated entities would already be familiar with any regulations that they would not want to expire, and thus the burden associated with the request to perform an Assessment or Review would be minimal. The Department seeks comment on this assumption. Any other burdens on small entities would result from future actions independent of this proposed rule (*i.e.* the determination that a regulation should be amended or rescinded based on the RFA review criteria and other legal considerations).

The indirect costs and benefits from this proposed rule cannot be fully determined until the Department performs the Reviews of its Regulations and determines their present-day impacts. However, the Department believes that the benefits to small entities from this proposed rule will outweigh its costs to them. When the Department first promulgates regulations, it often has to speculate about the economic impact of the regulations on small entities. After a regulation has been in place for years, however, the Department will be able to learn from the real-world impacts of its regulations and minimize any significant economic impact of the regulations on a substantial number of small entities and promote simplification. To the extent this proposed rule resulted in amendment or rescission of a Regulation, the Department would be doing so to minimize any significant economic impact upon a substantial number of small entities. Moreover, the Department anticipates that any amendment or rescission undertaken by the Department in response to the reviews would be conducted in a manner that complies with the RFA. For the same reasons, this proposed rule would minimize any significant economic impact on a substantial number of small rural hospitals.

The Department recognizes that there is a risk that small entities could be adversely impacted if a Regulation that has a positive economic impact on small entities expires because the Department failed to Review it. But the Department believes that risk is low, particularly since members of the public will remind the Department if the Review deadline is nearing and the Department has not commenced the Review of a Regulation that the public believes is important or beneficial.[144] Even if a Regulation with

[143] Section [XX](c) proposes to allow the Department to extend the deadline to amend or rescind Regulations that the Department concludes should be amended or rescinded. The Department does so in part because the vicious cycle concern does not apply with equal force to such circumstances. That is because the Department expects that only a subset of its Regulations will need to be amended, whereas the Review Assessment must be performed on nearly all of the Department's Regulations. In addition, the universe of Regulations to be Reviewed will presumably be larger than the universe of Regulations to amend or rescind.

[144] While the Department does not anticipate that every small entity will closely monitor the Department-managed website, the Department believes that for Regulations that have a truly significant impact on small entities, at least one

Continued

a positive economic impact on small entities somehow expired because the Department did not Review it, the Department believes such costs are far outweighed by the benefits achieved by periodically Reviewing Regulations and amending or rescinding those determined to no longer be appropriate based on current data and information. In addition, both the hearings that spurred passage of the RFA and subsequent data suggest that regulations tend to disproportionately burden small entities.[145] To the extent this is the case, any rescission could very well benefit small entities. Moreover, the opportunity for small entities to comment on Regulations during the Review process will enable the Department to better assess the economic impacts of its Regulations on small entities and minimize any significant economic impacts that its Regulations are having upon a substantial number of small entities. The Department realizes that this proposed rule, if finalized, could result in some uncertainty for small entities in that there is a possibility that a regulation could expire. However, small entities will be on notice that a regulation could expire if the Review deadline is nearing and the Department has not announced that it has commenced the Review of the regulation. Moreover, there is always some risk that any particular regulation could be rescinded.

Therefore, the Department believes the benefits from the widespread retrospective reviews to minimize the substantial economic impact upon a significant number of small entities that would result from this proposed rule would far outweigh the costs from any uncertainty resulting from this proposed rule. Small entities may incur additional costs if the regulatory environment turns out to be different than anticipated.

As a result, the Department has determined, and the Secretary certifies, that this proposed rule will not have a significant impact on the operations of a substantial number of small entities.

The Department seeks comment on this analysis of the impact of the proposed rule on small entities and small rural hospitals, and the assumptions that underlie this analysis.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires that covered agencies prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $154 million. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The Department has preliminarily determined that this proposed rule is not expected to result in expenditures by State, local, and tribal governments, or by the private sector, of $154 million or more in any one year. The Department seeks comment on this determination. This proposed rule would establish a requirement for the Department to periodically assess and, in some cases, review its regulations. Accordingly, the Department has not prepared a budgetary impact statement. The Department has nonetheless in this proposed rule addressed regulatory alternatives that it considered.

National Environmental Policy Act (NEPA)

HHS has determined that the proposed rule will not have a significant impact on the environment.

Executive Order 12988: Civil Justice Reform

HHS has reviewed this rule under Executive Order 12988 on Civil Justice Reform and has determined that this proposed rule complies with this Executive Order.

Executive Order 13132: Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct costs on State and local governments or has federalism implications. The Department has determined that this proposed rule does not impose substantial direct costs on State and local governments or have federalism implications as defined in Executive Order 13132. The proposed rule requires the Department to periodically review certain of its regulations, and provides that if the regulations are not reviewed by a certain date, they will expire. Any rescission of a regulation would only occur because of acts independent of this proposed rule—either the findings of a Review determining a regulation should be amended, or a failure to perform an Assessment or Review. Thus, this proposed rule would impose no substantial direct costs on State and local governments.

The Department notes, though, that the proposed rule might, if finalized, indirectly have beneficial federalism implications. Among other things, the Reviews called for by this proposed rule require the Department to determine if its regulations overlap, duplicate or conflict with State and local government rules and, if so, to consider that when determining whether to amend or rescind the regulations. If a Review conducted pursuant to this proposed rule were to find that a Department regulation should be amended or rescinded, the Department would comply with Executive Order 13132 in amending or rescinding the regulation.

The Department requests comment on this analysis.

Plain Writing Act of 2010

Under the Plain Writing Act of 2010 (Pub. L. 111–274, October 13, 2010), executive departments and agencies are required to use plain language in documents that explain to the public how to comply with a requirement the federal government administers or enforces. The Department has attempted to use plain language in promulgating this proposed rule, consistent with the Federal Plain Writing Act guidelines.

Assessment of Federal Regulation and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999, Public Law 105–277, sec. 654, 112 Stat. 2681 (1998) requires Federal departments and agencies to determine whether a policy or regulation could affect family well-being. Section 601 (note) required agencies to assess whether a regulatory action (1) impacted the stability or safety of the family, particularly in

affected small entity, or small entity trade association(s), would.

[145] *See, e.g., Regulatory Reform: Hearings on S. 104, S. 262, S. 755, S. 1291 Before the Subcomm. on Admin. Practice & Procedure of the Comm. on the Judiciary,* 96th Cong. 3–4 (1979) (statement of Peter J. Petkas, Director, The Regulatory Council) (describing the disproportionate impact on small businesses and uncertainty about benefits resulting from burdensome regulations); 142 Cong. Rec. 3881 (1996) (statement of Sen. Bond) (''The SBA chief counsel for advocacy released a report that said that small businesses bear a disproportionate share of the regulatory burden.''); Nicole V. Crain & W. Mark Crain, *The Impact of Regulatory Costs on Small Firms,* (U.S. Small Bus. Admin., Office of Advocacy, Washington, DC), at 55, 57 (2010) (finding that ''regulations cost small firms an estimated $10,585 per employee. Regulations cost medium-sized firms $7,454 per employee, and large firms $7,755 per employee,'' and that in the health care sector, the cost per employee is 45 percent higher in small firms than in medium-sized firms, and 28 percent higher in small firms than in large firms).

terms of marital commitment; (2) impacted the authority of parents in the education, nurturing, and supervision of their children; (3) helped the family perform its functions; (4) affected disposable income or poverty of families and children; (5) was justified if it financially impacted families; (6) was carried out by State or local government or by the family; and (7) established a policy concerning the relationship between the behavior and personal responsibility of youth and the norms of society.

This proposed rule would amend Department Regulations to add dates by which they would expire unless the Department periodically reviews the Regulations using certain criteria. Standing alone, absent the failure to perform a Review, this proposed rule would have no direct impact, other than resulting in the Department amending or rescinding Regulations that it determines do not satisfy the Review criteria.

If the family well-being determination requirement were still in force, the Department assumes that the benefits to the public, including families, that flow from periodic Reviews of Regulations far outweigh any potential adverse impact on family well-being that might result from a Regulation expiring because the Department did not Review it. The Department believes that impacted families benefit greatly when a regulatory body considers the real-world impacts of its regulations, and whether changes in technology, the economy, or the legal landscape counsel in favor of amending or rescinding regulations. It is conceivable that a Regulation affecting the disposable income or poverty of families or children could expire. It is also possible that the expiration of a Regulation that the Department does not Review could have beneficial impacts on family well-being.

Paperwork Reduction Act of 1995

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR 1320 Appendix A.1), HHS has reviewed this proposed rule and has determined that there are no new collections of information contained therein.

List of Subjects

21 CFR Part 6

Administrative practice and procedure.

42 CFR Part 1

Administrative practice and procedure.

42 CFR Part 404

Administrative practice and procedure.

45 CFR Part 6

Administrative practice and procedure.

For the reasons set forth in the preamble, the Department amends 21 CFR, chapter I, 42 CFR chapters I and IV and 45 CFR subtitle A as follows:

Title 21—Food and Drugs

■ 1. Add 21 CFR part 6 to read as follows:

PART 6—REVIEW OF REGULATIONS

Sec.

1.1 Retrospective Review of Existing Regulations.
1.2 through 1.5 [Reserved]

Authority: 5 U.S.C. 301; 15 U.S.C. 402, 409, 1261–1276, 1333, 1451–1461, 4402; 18 U.S.C. 1905; 19 U.S.C. 1490–1491, 2531–2582; 21 U.S.C. 321–394, 679, 802, 811–812, 821–831, 842, 875, 877, 951–958, 965, 971, 1034; 28 U.S.C. 2112; 35 U.S.C. 156; 42 U.S.C. 201–263, 263a, 263b–264, 265, 300aa–28, 300u through 300u–5, 300aa–1, 300aa–28, 4321, 7671 *et seq.;* Pub. L. 113–54; Pub. L. 111–353, 124 Stat. 3885, 3889; Pub. L. 111–31, 123 Stat. 1776; Pub. L. 108–155; Pub. L. 107–188, 116 Stat. 594, 688–690; Pub. L. 107–109; Pub. L. 105–115, 111 Stat. 2322, 5 U.S.C. 610.

§ 6.1 Retrospective review of existing regulations.

(a) This section applies to and amends all Regulations issued by the Secretary or his delegates or sub-delegates in this title.

(b) For purposes of this section:

(1) ''Assess'' shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) ''Review'' shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Regulations that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) 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 Regulations upon a substantial number of small entities.

(3) ''Regulation'' shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Regulation, and 42 CFR 2.14 is another Regulation.

(4) ''Year of the Regulation's promulgation'' shall mean the year the Regulation first became effective, irrespective of whether it was subsequently amended.

(5) ''Significant economic impact upon a substantial number of small entities'' shall have the meaning ascribed to that term in the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996).

(c)(1) Unless a Regulation contains an earlier expiration date or is rescinded earlier, all Regulations issued by the Secretary or his delegates or sub-delegates in this title shall expire at the end of:

(i) Two calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Regulation's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Regulation is required pursuant to paragraph (d)) reviewed the Regulation, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Regulation is required) reviewed the Regulation shall be the year during which the findings of the assessment and (if required) the review of a Regulation are published in the **Federal Register** pursuant to paragraph (f) of this section.

(d) The Department is required to review those Regulations that the Department Assesses have a significant economic impact upon a substantial number of small entities. In reviewing Regulations to minimize any significant economic impact of the Regulation on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's Review shall consider the following factors—

(1) The continued need for the Regulation, consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the Regulation from the public;

(3) The complexity of the Regulation;

(4) The extent to which the Regulation overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the Regulation since the Regulation was promulgated or the last time the Regulation was reviewed by the Department;

(6) Whether the Regulation complies with applicable law; and

(7) Other considerations as required by relevant executive orders and laws.

(e) If the review concludes the Regulation should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) to amend or rescind the Regulation. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time for a total of not more than five years.

(f) The results of all assessments and eviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Regulation shall be completed.

(g) Paragraph (c) of this section shall not apply to

(1) Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. For Regulations described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Regulations whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Regulations that involve a military or foreign affairs function of the United States.

(5) Regulations addressed solely to internal agency management or personnel matters.

(6) Regulations related solely to Federal Government procurement.

(7) Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Regulation(s) whose assessment or review it is commencing. The public will be able to submit comments regarding the Regulation(s) in the manner specified on this website. The public can also submit comments in the manner specified on the website requesting that the Department assess or review a Regulation.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§§ 6.2 through 6.5 [Reserved].

Title 42—Public Health

■ 2. Add 42 CFR part 1 to read as follows:

PART 1—REVIEW OF REGULATIONS

Sec.

1.1 Retrospective Review of Existing Regulations
1.2 through 1.5 [Reserved]

Authority: 5 U.S.C. 301, 42 U.S.C. 216, 42 U.S.C. 300a–4, 42 U.S.C. 10801, 42 U.S.C. 1302, 42 U.S.C. 702(a), 42 U.S.C. 702(b)(1)(A), 42 U.S.C. 706(a)(3), 42 U.S.C. 247b, 247c, 31 U.S.C. 1243 note, 42 U.S.C. 254c, 42 U.S.C. 262a, 42 U.S.C. 264–271, 42 U.S.C. 290aa(m), 42 U.S.C. 284g, 42 U.S.C. 285a–6(c)(1)(E), 42 U.S.C. 285a–7(c)(1)(G), 42 U.S.C. 285b–4, 42 U.S.C. 285c–5, 42 U.S.C. 285c–8, 42 U.S.C. 285d–6, 42 U.S.C. 285e–2, 42 U.S.C. 285e–3, 42 U.S.C. 285e–10a, 42 U.S.C. 285f–1, 42 U.S.C. 285g–5, 42 U.S.C. 285g–7, 42 U.S.C. 285g–9, 42 U.S.C. 285m–3, 42 U.S.C. 285o–2, 42 U.S.C. 286a–7(c)(1)(G), 42 U.S.C. 287c–32(c), 42 U.S.C. 288, 42 U.S.C. 300cc–16, 42 U.S.C. 1302, 5 U.S.C. 610.

§ 1.1 Retrospective review of existing regulations.

(a) This section applies to and amends all Regulations issued by the Secretary or his delegates or sub-delegates in this title (other than those Regulations in parts 400–429 and parts 475–499).

(b) For purposes of this section,

(1) ''Assess'' shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) ''Review'' shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Regulations that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) 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 Regulations upon a substantial number of small entities.

(3) ''Regulation'' shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Regulation, and 42 CFR 2.14 is another Regulation.

(4) ''Year of the Regulation's promulgation'' shall mean the year the Regulation first became effective, irrespective of whether it was subsequently amended.

(5) ''Significant economic impact upon a substantial number of small entities'' shall have the meaning ascribed to that term in the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996).

(c)(1) Unless a Regulation contains an earlier expiration date or is rescinded earlier, all Regulations issued by the Secretary or his delegates or sub-delegates in this title (other than those Regulations in parts 400–429 and parts 475–499) shall expire at the end of:

(i) Two calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Regulation's promulgation; or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Regulation is required pursuant to paragraph (d)) reviewed the Regulation, whichever is latest.

(2) The last year in which the Department Assessed and (if review of the Regulation is required) reviewed the Regulation shall be the year during which the findings of the assessment and (if required) the review of a Regulation are published in the **Federal Register** pursuant to paragraph (f) of this section.

(d) The Department is required to review those Regulations that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing Regulations to minimize any significant economic impact of the Regulation on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors—

(1) The continued need for the Regulation, consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the Regulation from the public;

(3) The complexity of the Regulation;

(4) The extent to which the Regulation overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the Regulation since the Regulation was promulgated or the last time the Regulation was reviewed by the Department;

(6) Whether the Regulation complies with applicable law; and

(7) Other considerations as required by relevant executive orders and laws.

(e) If the review concludes the Regulation should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) to amend or rescind the Regulation. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time for a total of not more than five years.

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next Review) of the Regulation shall be completed.

(g) Paragraph (c) of this section shall not apply to

(1) Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. For Regulations described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Regulations whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Regulations that involve a military or foreign affairs function of the United States.

(5) Regulations addressed solely to internal agency management or personnel matters.

(6) Regulations related solely to Federal Government procurement.

(7) Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(8) 42 CFR part 73.

(9) 42 CFR 1001.952.

(10) 42 CFR 100.3.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Regulation(s) whose assessment or review it is commencing. The public will be able to submit comments regarding the Regulation(s) in the manner specified on this website. The public can also submit comments in the manner specified on the website requesting that the Department assess or review a Regulation.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§§ 1.2 through 1.5 [Reserved].

■ 3. Add 42 CFR part 404 to read as follows:

PART 404—REVIEW OF REGULATIONS

Sec.

404.1 Retrospective Review of Existing Regulations
404.2 through 404.5 [Reserved]

Authority: 5 U.S.C. 301, 42 U.S.C. 216, 42 U.S.C. 300a–4, 42 U.S.C. 10801, 42 U.S.C. 1302, 42 U.S.C. 702(a), 42 U.S.C. 702(b)(1)(A), 42 U.S.C. 706(a)(3), 42 U.S.C. 247b, 247c, 31 U.S.C. 1243 note, 42 U.S.C. 254c, 42 U.S.C. 262a, 42 U.S.C. 264–271, 42 U.S.C. 290aa(m), 42 U.S.C. 284g, 42 U.S.C. 285a–6(c)(1)(E), 42 U.S.C. 285a–7(c)(1)(G), 42 U.S.C. 285b–4, 42 U.S.C. 285c–5, 42 U.S.C. 285c–8, 42 U.S.C. 285d–6, 42 U.S.C. 285e–2, 42 U.S.C. 285e–3, 42 U.S.C. 285e–10a, 42 U.S.C. 285f–1, 42 U.S.C. 285g–5, 42 U.S.C. 285g–7, 42 U.S.C. 285g–9, 42 U.S.C. 285m–3, 42 U.S.C. 285o–2, 42 U.S.C. 286a–7(c)(1)(G), 42 U.S.C. 287c–32(c), 42 U.S.C. 288, 42 U.S.C. 300cc–16, 42 U.S.C. 1302, 42 U.S.C. 1395hh, 5 U.S.C. 610.

§ 404.1 Retrospective review of existing regulations.

(a) This section applies to and amends all Regulations issued by the Secretary or his delegates or sub-delegates in parts 400–429 and parts 475–499 of this title.

(b) For purposes of this section,

(1) ''Assess'' shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) ''Review'' shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Regulations that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) 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 Regulations upon a substantial number of small entities.

(3) ''Regulation'' shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Regulation, and 42 CFR 2.14 is another Regulation.

(4) ''Year of the Regulation's promulgation'' shall mean the year the Regulation first became effective, irrespective of whether it was subsequently amended.

(5) ''Significant economic impact upon a substantial number of small entities'' shall have the meaning ascribed to that term in the Regulatory

Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996).

(c)(1) Unless a Regulation contains an earlier expiration date or is rescinded earlier, all Regulations issued by the Secretary or his delegates or sub-delegates in parts 400–429 and parts 475–499 of this title shall expire at the end of:

(i) Two calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Regulation's promulgation; or

(3) Ten calendar years after the last year in which the Department assessed and (if review of the Regulation is required pursuant to paragraph (d)) reviewed the Regulation, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Regulation is required) reviewed the Regulation shall be the year during which the findings of the assessment and (if required) the review of a Regulation are published in the **Federal Register** pursuant to paragraph (f) of this section.

(d) The Department is required to review those Regulations that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing Regulations to minimize any significant economic impact of the Regulation on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors—

(1) The continued need for the Regulation, consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the Regulation from the public;

(3) The complexity of the Regulation;

(4) The extent to which the Regulation overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the Regulation since the Regulation was promulgated or the last time the Regulation was Reviewed by the Department;

(6) Whether the Regulation complies with applicable law; and

(7) Other considerations as required by relevant executive orders and laws.

(e) If the review concludes the Regulation should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) to amend or rescind the Regulation. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time for a total of not more than five years.

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Regulation shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. For Regulations described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Regulations whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Regulations that involve a military or foreign affairs function of the United States.

(5) Regulations addressed solely to internal agency management or personnel matters.

(6) Regulations related solely to Federal Government procurement.

(7) Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(8) The annual Medicare Part A and Part B payment methodology update rules.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Regulation(s) whose assessment or review it is commencing. The public will be able to submit comments regarding the Regulation(s) in the manner specified on this website. The public can also submit comments in the manner specified on the website requesting that the Department assess or review a Regulation.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§§ 404.2 through 404.5 [Reserved].

Title 45—Public Welfare

■ 4. Add 45 CFR part 6 to read as follows:

PART 6—REVIEW OF REGULATIONS

Sec.

6.1 Retrospective Review of Existing Regulations

6.2 through 6.5 [Reserved]

Authority: 5 U.S.C. 301, 504, 552, 552a, 552b, 553, 3401–3408, 5514, 7301; 5 U.S.C. App. 1, App. 8G(a)(2); 6 U.S.C. 279; 8 U.S.C. 1103(a)(3), 1182, 1232, 1255a, 1522 and note; 10 U.S.C. 4594; 16 U.S.C. 2401 *et seq.;* 18 U.S.C. 207, 506, 701, 1017, 1905; 20 U.S.C. 91, 959, 971–977, 1405, 1501 *et seq.,* 1681–1688, 2001–2012, 4501 *et seq.;* 21 U.S.C. 853a, 1174; 21 U.S.C. 853a, 1174; 22 U.S.C. 1621(a)(2), 1622, 2151b(f), 2451 *et seq.,* 7631; 24 U.S.C. 321–329; 25 U.S.C. 1603(12), 1621e; 28 U.S.C. 1746, 2461 and note, 2672; 29 U.S.C. 669(a)(5), 709, 791 *et seq.,* 2996e(d)(5), 3343; 31 U.S.C. 200–212, 1243 note, 1352, 3701–3720A, 3720D, 3721, 3801–3812, 6505–6506, 7501–7507, 9701; 35 U.S.C. 200–212; 36 U.S.C. 124; 39 U.S.C. 3220; 40 U.S.C. 72, 104, 106, 121, 318–318d, 484, 486, 1001; 41 U.S.C. 701 *et seq.;* 42 U.S.C. 216, 217b, 238n, 263a(f)(1)(E), 280g–1(d), 289(a), 289b–1, 290bb–36(f), 290dd–2, 299c–4, 300a–7, 300v–1(b), 300w *et seq.,* 300x *et seq.,* 300y *et seq.,* 300aa–11, 300gg through 300gg–63, 300gg–91, 300gg–92, 300gg–94, 300jj–11, 300jj–14, 300jj–52, 303, 601 and note, 602 and note, 603, 604, 605, 606, 607, 608, 608, 609, 610, 611, 612, 613(i), 616, 618, 619, 620 *et seq.,* 651 through 658, 658a, 659a, 660, 663, 664, 666 through 669A, 670 *et seq.,* 701 *et seq.,* 862a, 1202, 1203, 1301, 1301, 1302, 1302, 1306, 1308, 1308, 1310, 1313, 1315, 1315a, 1316, 1320a–1, 1320a–7e, 1320c–11, 1320d through 1320d–9, 1337, 1352, 1353, 1382 note, 1383 note, 1395b–4, 1395cc(f), 1395i–3, 1395i–5, 1395w–22(j)(3)(B), 1395w–26, 1395w–27, 1395x, 1396a, 1396b, 1396f,

1396k, 1396r, 1396r–2, 1396s(c)(2)(B)(ii), 1396u–2(b)(3)(B), 1397 *et seq.,* 1397j–1(b), 1870, 1871, 1973gg–5, 1975, 1975a, 1975b, 2000d to 2000d–7, 2991 *et seq.,* 2996(5), 2996(b)(2), 2996c(g), 2996d(b)(2), 2996e, 2996f, 2996g, 3001 *et seq.,* 3121, 3334, 3505, 3515e, 3535(d), 4950 *et seq.,* 4321, 4371 *et seq.,* 4601 note, 4633, 4950 *et seq.,* 4951 *et seq.,* 5024, 5043, 5044(a), 5052, 5057, 5059, 5060, 5065, 5106i(a), 5701, 6101–6107, 7609, 8621 *et seq.,* 9801 *et seq.,* 9858, 9901 *et seq.,* 10401 *et seq.,* 11101–11152, 11302, 11411, 11461–11464, 11472, 12501 *et seq.,* 12521–12529, 12541–12547, 12561, 12571–12595, 12601–12606, 12631–12638, 12645g, 12651b through 12651d, 12653, 12653o, 12657, 14406, 15001 *et seq.,* 15607(d), 18021–18024, 18031–18032, 18041–18042, 18044, 18051, 18054, 18061, 18063, 18071, 18081–18083, 18113, 18116; 44 U.S.C. 2104(a); 48 U.S.C. 1469a; 49 U.S.C. 794; 50 U.S.C. App. 2001, App. 2061–2171; Pub. L. 115–245, div. B, secs. 209, 507(d), 132 Stat. 2981; Pub. L. 114–328, sec. 1705(a)(2), 130 Stat. 2644; Pub. L. 114–74, sec. 701, 129 Stat. 584; Pub. L. 112–96, sec. 4004, 126 Stat. 197; Pub. L. 111–5, secs. 13400–13424, 123 Stat. at 258–279; Pub. L. 111–148, secs. 1019, 1104, 1311, 1312, 1334, 1411, 1412, 124 Stat. 119; Pub. L. 111–13, sec. 1612, 123 Stat. 1459; Pub. L. 109–171, sec. 7102, 120 Stat. 135; Pub. L. 105–277, 112 Stat. 2681; Pub. L. 105–119, tit. V, secs. 501(b) and (c), 502, 503, 504, and 505, 111 Stat. 2440, 2510–12; Pub. L. 104–208, 110 Stat. 3009; Pub. L. 104–134, tit. V, secs. 503(f), 504, 509(c), 110 Stat. 1321, 1321–53, 1321–59; Pub. L. 102–325, sec. 471(a), 106 Stat. 606; Pub. L. 101–426, sec. 6(h)(2), 104 Stat. 925; Pub. L. 101–410, 104 Stat. 890; Pub. L. 101–392, sec. 501(c), 104 Stat. 831; Pub. L. 101–239, sec. 10405, 103 Stat. 2489; Pub. L. 101–201, sec. 1(a), 103 Stat. 1795; Pub. L. 101–121, 103 Stat. 701; Pub. L. 100–707, sec. 105(i), 102 Stat. 4693; Pub. L. 100–383, secs. 105(f) and 206(d), 102 Stat. at 908, 914; Pub. L. 100–259, 102 Stat. 28; Pub. L. 100–241, sec. 15, 101 Stat. 1812; Pub. L. 100–77, sec. 501, 101 Stat. 509–10; Pub. L. 99–603, 100 Stat. 3359; Pub. L. 99–514, sec. 1883, 100 Stat. 2916; Pub. L. 98–64, sec. 2, 97 Stat. 365; Pub. L. 97–458, sec. 4, 96 Stat. 2513; Pub. L. 97–248, 96 Stat. 324; Pub. L. 95–437, 92 Stat. 1055; Pub. L. 94–114, sec. 6, 89 Stat. 579; Pub. L. 93–579, 88 Stat. 1896; Pub. L. 93–113, secs. 402(14), 417, 420, 87 Stat. 398, 407, and 414; Pub. L. 93–113, 87 Stat. 394; Pub. L. 89–506, sec. 1(a), 80 Stat. 306; Pub. L. 87–293, sec. 5(a), 75 Stat. 613; Pub. L. 86–571, secs. 1–11, 74 Stat. 308–310; Pub. L. 81–808, 64 Stat. 903; Pub. L. 81–152, sec. 203, 63 Stat. 377, 385; Reorganization Plan No. 1 of 1953, secs. 1, 5, 6, and 7, 67 Stat. 631; 5 U.S.C. 610.

§ 6.1 Retrospective Review of Existing Regulations.

(a) This section applies to and amends all Regulations issued by the Secretary or his delegates or sub-delegates in this title.

(b) For purposes of this section,

(1) ''Assess'' shall refer to a determination by the Department, in consultation with other Federal agencies as appropriate, as to whether the Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter) currently have a significant economic impact upon a substantial number of small entities.

(2) ''Review'' shall refer to a process conducted by the Department, in consultation with other Federal agencies as appropriate, the purpose of which shall be to determine whether Regulations that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter) 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 Regulations upon a substantial number of small entities.

(3) ''Regulation'' shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Regulation, and 42 CFR 2.14 is another Regulation.

(4) ''Year of the Regulation's promulgation'' shall mean the year the Regulation first became effective, irrespective of whether it was subsequently amended.

(5) ''Significant economic impact upon a substantial number of small entities'' shall have the meaning ascribed to that term in the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996).

(c)(1) Unless a Regulation contains an earlier expiration date or is rescinded earlier, all Regulations issued by the Secretary or his delegates or sub-delegates in this title shall expire at the end of:

(i) Two calendar years after the year that this section first becomes effective;

(ii) Ten calendar years after the year of the Regulation's promulgation, or

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Regulation is required pursuant to paragraph (d)) reviewed the Regulation, whichever is latest.

(2) The last year in which the Department assessed and (if review of the Regulation is required) reviewed the Regulation shall be the year during which the findings of the assessment and (if required) the review of a Regulation are published in the **Federal Register** pursuant to paragraph (f) of this section.

(d) The Department is required to review those Regulations that the Department assesses have a significant economic impact upon a substantial number of small entities. In Reviewing Regulations to minimize any significant economic impact of the Regulation on a substantial number of small entities in a manner consistent with the stated objectives of applicable statutes, the Department's review shall consider the following factors—

(1) The continued need for the Regulation, consideration of which shall include but not be limited to the extent to which the Regulation defines terms or sets standards used in or otherwise applicable to other Federal rules;

(2) The nature of complaints or comments received concerning the Regulation from the public;

(3) The complexity of the Regulation;

(4) The extent to which the Regulation overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules;

(5) The degree to which technology, economic conditions, or other factors have changed in the area affected by the Regulation since the Regulation was promulgated or the last time the Regulation was reviewed by the Department;

(6) Whether the Regulation complies with applicable law; and

(7) Other considerations as required by relevant executive orders and laws.

(e) If the review concludes the Regulation should be amended or rescinded, the Department shall have two years from the date that the findings of the review are published in the **Federal Register** pursuant to paragraph (f) to amend or rescind the Regulation. If the Secretary determines that completion of the amendment or rescission is not feasible by the established date, he shall so certify in a statement published in the **Federal Register** and may extend the completion date by one year at a time for a total of not more than five years.

(f) The results of all assessments and reviews conducted in a calendar year, including the full underlying analyses and data used to support the results (subject to any applicable privilege, protections for confidential business information, or explicit legal prohibition on disclosure), shall be published in a single document in the **Federal Register** during that calendar year. The document shall be organized in a manner that enables both the Department and the public to readily determine which assessments and reviews were conducted during that calendar year. The document shall also specify the year by which the next assessment (and, if required, the next review) of the Regulation shall be completed.

(g) Paragraph (c) of this section shall not apply to:

(1) Regulations that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation. For Regulations described in this paragraph (g)(1) that are adopted after the effective date of this section, the Federal law described in this paragraph (g)(1) shall be cited in the notice of adoption.

(2) Regulations whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

(4) Regulations that involve a military or foreign affairs function of the United States.

(5) Regulations addressed solely to internal agency management or personnel matters.

(6) Regulations related solely to Federal Government procurement.

(7) Regulations that were issued jointly with other Federal agencies, or that were issued in consultation with other agencies because of a legal requirement to consult with that other agency.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Regulation(s) whose assessment or review it is commencing. The public will be able to submit comments regarding the Regulation(s) in the manner specified on this website. The public can also submit comments in the manner specified on the website requesting that the Department assess or review a Regulation.

(i) Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 6.2 through 6.5 [Reserved].

Dated: October 21, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–23888 Filed 11–3–20; 4:15 pm]

BILLING CODE 4150–26–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 192 and 195

[Docket No. PHMSA–2019–0199]

Pipeline Safety: Midstream Facilities Frequently Asked Questions

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notification and request for comments.

SUMMARY: PHMSA is making available for comment a set of draft frequently asked questions (FAQs) regarding federal oversight of midstream processing facilities. Specifically, this guidance will delineate where PHMSA and the Occupational Safety and Health Administration (OSHA) will each perform inspection and enforcement activities for midstream processing facilities where there is overlapping authority. The proposed guidance consists of a set of seven FAQs that were developed by the Midstream Processing Working Group (Working Group) established by the Technical Pipeline Safety Standards Committee, also known as the Gas Pipeline Advisory Committee (GPAC), and the Technical Hazardous Liquid Pipeline Safety Standards Committee, also known as the Liquid Pipeline Advisory Committee (LPAC).

DATES: Persons interested in submitting comments on the draft FAQs must do so by January 4, 2021.

ADDRESSES: You may submit comments, which should be identified by docket number PHMSA–2019–0199, by any of the following methods:

- *Federal eRulemaking Portal:* Comments may be submitted to *http://www.regulations.gov.* Please follow the online instructions to submit comments.
- *Mail:* Comments may be submitted by mailing them to the Dockets Management System, U.S. Department of Transportation, Dockets Operations, M–30, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* Comments may be submitted by hand-delivering them to 1200 New Jersey Avenue SE, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001. Comments may be delivered between 9 a.m. and 5 p.m. ET, Monday through Friday, except for Federal holidays.
- *Fax:* Comments may be faxed to 202–493–2251.
- *Instructions:* Identify docket number PHMSA–2019–0199 at the beginning of your comments. If you submit your comments by mail, you must submit two copies. If you wish to receive confirmation that PHMSA received your comments, you must include a self-addressed stamped postcard. Internet users should submit comments at *http://www.regulations.gov.*
- *Privacy Act:* DOT may solicit comments from the public regarding certain general notices. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*
- *Confidential Business Information:* Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this document contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this document, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 CFR 190.343, you may ask PHMSA to give confidential treatment to information you give to the agency by taking the following steps: (1) Mark each page of the original document submission containing CBI as ''Confidential''; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under FOIA, and they will not be placed in the public docket of this notification. Submissions containing CBI should be sent to Sayler Palabrica at *sayler.palabrica@dot.gov.* Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.
- *Docket:* The docket containing background documents and received comments is available at *http://www.regulations.gov.* Once on this site, please follow the online instructions for accessing the dockets. Alternatively, you may review these documents in person at the street address listed above.