

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 6

Public Health Service

42 CFR Part 1

Centers for Medicare and Medicaid Services

42 CFR Part 404

Office of the Inspector General

42 CFR Part 1000

Office of the Secretary

45 CFR Part 8

Administration for Children and Families

45 CFR Parts 200, 300, 403, 1010, and 1390

[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: Final rule.

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 or the Department) issues this final rule amending its regulations to set expiration dates for the Department's 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: This final rule is effective on March 22, 2021.

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 final rule is organized as follows:

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I. Summary

On November 4, 2020, HHS published in the **Federal Register** a notice of proposed rulemaking titled "Department of Health and Human Services Securing Updated and Necessary Statutory Evaluations Timely" (hereinafter, "proposed rule").¹ On November 23, 2020, the Department held a public hearing on the proposed rule.² For the reasons described herein, after considering public comments on the proposed rule, HHS now finalizes the proposed rule as amended. This final rule will 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.³ 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.⁴

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 finalizes this rule to provide 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) five calendar years after the year that this final rule first becomes effective, (2) ten calendar years after the year of the Section's promulgation, or (3) ten calendar years after the last year in which the Department Assessed and, if required, Reviewed⁵ the Section, whichever is latest. The RFA and executive orders have only resulted in limited retrospective review by the Department. The Department believes this final rule will 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. The literature and the Department's experience suggest that many regulations are having estimated impacts that, over time, differ from what was estimated at the time the regulations were promulgated. This final rule will enhance both (1) the fulfillment of the existing policies that led to the Department's regulations and (2) the Department's longstanding desire

¹ 85 FR 70096 (Nov. 4, 2020).

² The transcript of the public hearing is available on the docket for the proposed rule. *See* <https://beta.regulations.gov/docket/HHS-OS-2020-0012/document>.

³ Unless otherwise indicated, all references to HHS in this proposed rule include HHS' constituent agencies and other components.

⁴ *See, e.g.*, Exec. Order No. 12866 of Sept. 30, 1993, 58 FR 51735 (Oct. 4, 1993), Exec. Order No. 13563 of Jan. 18, 2011, 76 FR 3821 (Jan. 21, 2011).

⁵ "Section," "Assess," and "Review" are capitalized in this preamble where those terms have the definitions ascribed to them in the text of this final rule.

to comply with the RFA and periodically review its regulations.

II. Background

A. The Regulatory Flexibility Act

In 1980, Congress enacted the Regulatory Flexibility Act (RFA), Public Law 96-354, 94 Stat. 1164 (1980) (codified as amended at 5 U.S.C. 601-612). 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, 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.”⁶ In 1996, Congress amended the RFA to more clearly provide for judicial review of violations of 5 U.S.C. 610.⁷ 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.⁸

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.⁹ The order directed agencies to “periodically review their existing regulations.”¹⁰ 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.”¹¹ 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, that have caused administrative difficulties, or that have been affected by new developments.¹² 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 that authorized the regulations allows it.¹³ 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.¹⁴ 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.”¹⁵ 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.”¹⁶ 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.”¹⁷ The George W. Bush Administration’s Acting OIRA Administrator noted that the Bush Administration was “in the

⁶ Paul R. Verkuil, *A Critical Guide to the Regulatory Flexibility Act*, 1982 Duke L.J. 213, 259 (1982).

⁷ Contract with America Advancement Act of 1996, Public Law 104-121, 110 Stat. 847, 865-66 (1996).

⁸ H.R. Rep. No. 104-500, at 3 (1996).

⁹ 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)).

¹⁰ 43 FR at 12663.

¹¹ *Id.*

¹² *Id.* at 12669. As discussed below, the Department is reviewing 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’s reviews will 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.

¹³ *Id.* at 12669.

¹⁴ 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).

¹⁵ Memorandum on Reducing the Burden of Government Regulation (Jan. 28, 1992).

¹⁶ Exec. Order No. 12866 of Sept. 30, 1993, 58 FR 51735 (Oct. 4, 1993).

¹⁷ *Id.*

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.”¹⁸

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.”¹⁹ 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 light of changed circumstances, including the rise of new technologies.”²⁰

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.²¹ 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.”²² 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.²³

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.²⁴

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.²⁵ The Department also took action. For example, HHS, citing Executive Order 13563, eliminated certain restrictions on the use of telemedicine in rural areas.²⁶

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, 2013.²⁷ By contrast, the Department issued 247 rules between the date Executive Order 13563 was issued and August 31, 2013.²⁸ 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.²⁹ 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.³⁰

Commenters on the proposed rule listed the following as examples of regulations that they and/or Congress have requested the Department to review, but that the commenters claimed were not reviewed:

- Regulations mandated for review by the 21st Century Cures Act, Public Law 114–255, sec. 2034, 130 Stat. 1033 (2016). Section 2034 of that Act, according to the commenters, requires the Secretary to lead a review by research funding agencies of all regulations and policies related to the disclosure and reporting of financial conflicts of interest to reduce administrative burden on federally funded researchers. It also calls for the Secretary to harmonize the differences between the Basic HHS Policy for the Protection of Human Research Subjects (45 CFR part 46, subpart A) and the FDA regulations for the protection of human subjects (21 CFR parts 50 and 56). Commenters stated that these regulations are well overdue for assessment and review.

- Regulations covering access to skilled therapy services, which commenters say must be updated to reflect the national settlement in the *Jimmo v. Sebelius* litigation to codify the fact that skilled services are covered for Medicare beneficiaries not just to improve function, but to maintain or prevent deterioration in function.

- The dockets established by FDA’s Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine on Sept. 8, 2017,³¹ in which the Centers requested comments and

²³ Exec. Order No. 13924 of May 19, 2020, 85 FR 31353, 31354 (May 22, 2020).

²⁴ 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.”).

²⁵ See also *Retrospective Review of Existing Rules*, U.S. Dept. of Health & Human Servs., <https://www.hhs.gov/open/retrospective-review/index.html>.

²⁶ 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).

²⁷ 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/>.

²⁸ *Id.*

²⁹ *Id.*

³⁰ See, e.g., Curtis W. Copeland, Cong. Rsch. 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.”).

³¹ E.g., Nonrulemaking Docket FDA–2017–N–5093: Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration, <https://beta.regulations.gov/docket/FDA-2017-N-5093>.

¹⁸ Draft Report to Congress on the Costs and Benefits of Federal Regulations Introduction, 66 FR 22041, 22054 (May 2, 2001).

¹⁹ 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).

²⁰ Exec. Order No. 13610 of May 10, 2012, 77 FR 28469, 28469 (May 14, 2012).

²¹ Exec. Order No. 13771 of Jan. 30, 2017, 82 FR 9339, 9339 (Feb. 3, 2017).

²² 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.”).

information to assist in identifying existing regulations and related paperwork requirements that could be modified, repealed or replaced, consistent with the law, to achieve meaningful burden reduction while allowing FDA to achieve its public health mission and fulfill statutory obligations. The commenters stated these were examples of incomplete regulatory review initiatives.³² Commenters stated that despite submitting extensive comments that detailed numerous regulations that they believe could be modified, repealed or replaced, the agency did not take any further action.

A review conducted for the Department in 2019 (discussed in more detail in Section C) concluded that related good governance stewardship actions were deprioritized and relegated to “rainy day” activities that Department operating divisions would get around to when they could.³³ However, the rainy day in many cases has never arrived.

Scholars have also posited reasons why agencies may be reluctant to perform retrospective reviews. One administrative law expert now at Northwestern University 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.³⁴

Thus, the Department concludes 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.

C. Limitations in Government Projections Counsel in Favor of Widespread 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 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. The literature suggests the need for refinement is widespread, so widespread review would yield greater benefits than review of a handful of regulations. 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.³⁵ OMB considered a pre-regulation estimate to be accurate if the

post-regulation estimate was within ± 25 percent of the pre-regulation estimate.³⁶ 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.³⁷ Agencies overestimated benefits in 19 of 39 sampled regulations, whereas they underestimated benefits in only two of the 39 regulations.³⁸ In two cases, agencies overestimated benefits by a factor of 10.³⁹ 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.⁴⁰ 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.⁴¹

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 the estimated ratios were essentially accurate in only sixteen of the sixty-one cases, though the study found no bias in estimates of benefit-cost ratios.⁴² 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

³⁶ *Id.* at 42.

³⁷ *Id.* at 43–46.

³⁸ *Id.* at 47.

³⁹ *Id.* at 43.

⁴⁰ *Id.* at 47.

⁴¹ *Id.*

⁴² 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 %.

³² See Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration, 82 FR 42506 (Sept. 8, 2017); FDA–2017–N–5093, <https://beta.regulations.gov/docket/FDA-2017-N-5093>.

³³ See *infra* n.68 and accompanying text.

³⁴ Yoon-Ho Alex Lee, *An Options Approach to Agency Rulemaking*, 65 Admin. L. Rev. 881, 895–96 (2013).

³⁵ 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).

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.”⁴³

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.⁴⁴ A regulation was deemed accurate if the regulation’s regulatory impact analysis fell roughly within $\pm 2/-5\%$ of the *ex post* observation.⁴⁵ 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.⁴⁶

These studies all found that in most cases the sampled *ex ante* estimates were not within $\pm 25\%$ of the *ex post* observations. The studies suggest many federal regulations are estimated after the fact to have real-world impacts that differ from the estimated impacts at the time the regulations were promulgated. Although these samples were not necessarily representative, it would not be unreasonable to think that the Department could make major improvements by conducting widespread review of its regulations, rather than merely reviewing the small number of regulations that interested parties ask the Department to consider revising.⁴⁷

⁴³ *Id.* at 34.

⁴⁴ 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.

⁴⁵ *Id.*

⁴⁶ *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)).

⁴⁷ This is not to suggest that prospective regulatory impact analyses are not helpful. To the contrary, they add tremendous value and greatly improve agency rule makings. But as explained elsewhere herein, even when an agency’s cost-benefit analysis uses sound science and the best available information to estimate the costs, benefits or other impacts associated with a rule,

Reasons Regulatory Projections Differ From Regulations’ Real-World Impacts

There are several reasons why regulations’ *ex ante* cost-benefit estimates tend to be inaccurate. First, 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 2019.⁴⁸ A month later, Congress enacted the Patient Protection and Affordable Care Act, Public Law 111–148, 124 Stat. 119 (“ACA”), and the Health Care and Education Reconciliation Act of 2010, Public Law 111–152, 124 Stat. 1029. 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.⁴⁹

Second, 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.⁵⁰ 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

technological innovation or subsequent changes in the law, among other things, can result in an *ex post* assessment of impacts differing from the agency’s estimates at the time it promulgated the rule.

⁴⁸ 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>.

⁴⁹ 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>.

⁵⁰ 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.

requirements with requirements for a single submission in electronic format.⁵¹ Changes in technology had rendered the requirement for multiple copies, whether in electronic format or paper form, no longer necessary.⁵² 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.⁵³ 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, cost estimates per unit can sometimes be reasonably accurate while aggregates are simultaneously overestimated.⁵⁴ (Non-compliance would, of course, also affect the accuracy of benefits estimates.⁵⁵) As such, *ex post* analysis has the potential to inform not just decisions about codified regulatory requirements but also about agency enforcement practices.

Institutionalizing Retrospective Review To Refine Projections That Were Lacking

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.”⁵⁶ Therefore, [a]fter rules are in place, [agencies] should test those speculations, and they should use what they learn when revisiting a regulation

⁵¹ 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).

⁵² *Id.* at 68334.

⁵³ See, e.g., Cass R. Sunstein, *The Regulatory Lookback*, 94 B.U. L. Rev. 579, 599 (2014).

⁵⁴ Winston Harrington, Richard D. Morgenstern and Peter Nelson, *On the Accuracy of Regulatory Cost Estimates*, J. Policy Anal. & Management 2000, 19(2): 297–322.

⁵⁵ 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.

⁵⁶ Cass R. Sunstein, *The Regulatory Lookback*, 94 B.U. L. Rev. 579, 591 (2014).

or issuing a new one.”⁵⁷ 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.”⁵⁸ He has noted that agencies’ failure “until very recently . . . to gather, let alone act on” retrospective reviews is “an astonishing fact.”⁵⁹

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.”⁶⁰ 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.”⁶¹ 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.”⁶²

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.”⁶³

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.”⁶⁴ 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.”⁶⁵

The Need for a Greater Incentive To Institutionalize Retrospective Review

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.⁶⁶ 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 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.⁶⁷ 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.”⁶⁸ Unfortunately, in many cases the Department has for years not gotten around to addressing these issues.

As one observer recently explained:

Retrospective review of existing regulations . . . is a perennial favorite target for advice on how to improve OIRA’s processes. Every administration since President Carter has developed some program to modify, streamline, or expand existing regulations, and there is no shortage of advice on how to make the process run more efficiently. Yet, despite a few notable one-off successes from past retrospective review efforts, no past retrospective review campaign has ever truly succeeded in creating a long-term culture of retrospective review or of prospectively embedding into new regulations a process for data collection and pre-set targets for future lookbacks. Any future efforts around retrospective review, therefore, should be clear-eyed about past failures.⁶⁹

For the reasons discussed in this final rule, the Department believes a stronger

would be the surest way of incorporating ex post learning in rule implementation. This is far from the truth in practice, however.”).

⁶⁷ Regulatory Streamlining & Analysis (Mar. 2019).

⁶⁸ *Id.* at 18

⁶⁹ Jason Schwartz, *Enhancing the Social Benefits of Regulatory Review*, Institute for Policy Integrity, at 30 (Oct. 2020), https://policyintegrity.org/files/publications/Enhancing_the_Social_Benefits_of_Regulatory_Review.pdf. Several weeks after publishing this article, the author submitted a comment opposing the proposed rule. For the reasons discussed in the responses to public comments, the Department did not find those arguments compelling, but believes the quoted passage is a fair description of the problem this final rule aims to solve. The Department is trying to be clear-eyed about past failures, and has concluded that a strong incentive, such as that included in this final rule, is commensurate with the problem to be solved and to more firmly institutionalize retrospective review.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.* at 588.

⁶⁰ 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 Trinidad 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.

⁶¹ 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_Benefit_Report11_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.”).

⁶² Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation*, in *New Perspectives on Regulation* 111, 114 (David Moss & John Cisternino eds., 2009).

⁶³ Cass R. Sunstein, *The Regulatory Lookback*, 94 *B.U. L. Rev.* 579, 589 (2014).

⁶⁴ 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).

⁶⁵ 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).

⁶⁶ 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

incentive is needed to achieve the benefits of retrospective review.⁷⁰ This final rule creates 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

This 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, Missouri, New Jersey, New Mexico, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, and Washington.⁷¹

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).⁷² 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.”⁷³

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.”⁷⁴ On the other hand, one report stated that, despite their initial popularity in the States,⁷⁵ 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.⁷⁶ But that observation is inapplicable to the Department, because this final 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.”⁷⁷

⁷³ Letter from Gov. Ron DeSantis to Florida Agency Heads (Nov. 11, 2019), https://www.floridahasarithtotoknow.myflorida.com/content/download/147113/980326/FINAL_Directive_to_Agencies_11.19.pdf.

⁷⁴ Russell S. Sobel & John A. Dove, *State Regulatory Review: A 50 State Analysis of Effectiveness* 36 (Mercatus Ctr., Working Paper No. 12–18, 2012), <https://www.mercatus.org/system/files/State-Regulatory-Review-50-State-Analysis-Effectiveness.pdf>.

⁷⁵ 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.

⁷⁶ *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”).

⁷⁷ *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

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.”⁷⁸ 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.”⁷⁹ Throughout the 2010 report, the OECD repeatedly noted the value of retrospective regulatory review.⁸⁰

In 2019, the OECD published an additional survey regarding regulatory review practices in the European Union. The OECD again noted the utility of sunset provisions, describing them as a “useful ‘failsafe’ mechanism to ensure the entire stock of subordinate regulation remains fit for purpose over time.”⁸¹ 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.⁸²

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

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.

⁷⁸ OECD, *Better Regulation in Europe: Executive Summaries*, GOV/RPC (2010)13, at 113, <http://www.oecd.org/gov/regulatory-policy/45079126.pdf>.

⁷⁹ *Id.* at 46.

⁸⁰ 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.”).

⁸¹ 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>.

⁸² *Id.* at ch. 4, Table 4.1.

⁷⁰ Regulatory Streamlining & Analysis (Mar. 2019) (it “appears the current set of governance structures, incentives and processes to promulgate regulatory reform need strengthening to be more effective”).

⁷¹ 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; Missouri Rev. Stat., Title XXXVI § 536.175.5; 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.

⁷² 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.

are found to lack feasibility.⁸³ 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.⁸⁴ An OECD report stated that "[g]iven such rationale, the sunset clause is considered as a critical component of efforts in regulatory quality improvement."⁸⁵

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.⁸⁶ That report found evidence that sunset reviews that automatically terminate regulatory boards and agencies absent legislative action assist with "removing unnecessary licensing."⁸⁷ 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."⁸⁸ The report found "[p]eriodic examination of existing rules

is thus helpful in maintaining the quality of occupational regulation."⁸⁹

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.⁹⁰

Professor Greenstone suggested that this review could cause the regulation to be expanded if supported by evidence.⁹¹ According to Professor Greenstone, this would "ensure that ineffective regulations are removed and that society fully benefits from the effective ones."⁹²

⁸³ *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 92, 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 has decided 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).

⁹⁰ Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation*, in *New Perspectives on Regulation* 111, 121 (David Moss & John Cisternino eds., 2009).

⁹¹ *Id.*

⁹² *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 in the proposed rule. 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

This final rule seeks to advance democratic values and apply the lessons learned from States, foreign jurisdictions, and the academic community. This final 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.

E. The Need for Widespread Retrospective Review

The evidence suggests the Department should conduct retrospective review on a broad scale to improve impact estimates and enhance the Department's ability to fulfil the goals motivating its regulations. As explained in Section C, studies of federal regulations consistently find that, in most sampled regulations, the ex ante estimate of costs and benefits is not within +/- 25% of the ex post observation. Although these samples were not necessarily representative, taken together they suggest that many federal regulations are estimated after the fact to have real-world impacts that differ from the estimated impacts at the time the regulations were promulgated. Therefore, HHS believes that review should be done on a broad scale, rather than reviewing a handful of regulations that happen to be brought to the Department's attention.

The artificial intelligence review described in this final rule also suggests that large numbers of Department regulations would benefit from retrospective review. The artificial intelligence review identified that 85% of Department regulations created before 1990 have not been edited; the Department has nearly 300 broken citation references⁹³ in the CFR; and there are more than 50 instances of HHS regulatory requirements to submit paper documents in triplicate or quadruplicate.⁹⁴ This suggests that humans performing a comprehensive review of Department regulations would find large numbers of requirements that

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 Section being Reviewed. 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.

⁹³ As discussed below, HHS has roughly 18,000 regulations total.

⁹⁴ 85 FR 70102.

⁸³ OECD, *Latest Developments on Korea's Regulatory Policy*, at 2, <https://www.oecd.org/gov/regulatory-policy/45347364.pdf>.

⁸⁴ OECD Reviews of Regulatory Reform, *Regulatory Policy in Korea, Toward Better Regulation*, at 86 (2017), https://publicadministration.un.org/unspsa/Portals/0/UNPSA_Submitted_Docs/2019/4cd3e219-c819-40f3-8246-7a024d9a82a9/2020%20UNPSA_the%20Regulatory%20Reform%20Sinnungo_Evaluation%20Report_27112019_032807_e4d166a9-f6ef-4a6c-9aaf-99748fa94284.pdf?ver=2019-11-27-032807-637.

⁸⁵ *Id.*

⁸⁶ *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.

⁸⁷ *Id.* at 48.

⁸⁸ *Id.* at 49.

would benefit from review, and possibly amendment or rescission.

The HHS response to the COVID-19 pandemic also indicates that the Department should perform widespread retrospective reviews. During the COVID-19 pandemic, the Department's response has largely consisted of waiving regulatory requirements or exercising enforcement discretion to not enforce certain regulatory requirements to enhance the Nation's response to the pandemic. Examples include waivers to increase hospital capacity, ease restrictions on services rendered by medical residents, and allowing patients to seek more services via telehealth.⁹⁵ On November 25, 2020, the Department published in the **Federal Register** a non-exhaustive list of 382 enforcement discretion announcements, waivers or changes to regulations, agency guidance materials, or compliance obligations made to respond to the COVID-19 pandemic and its impact on the healthcare industry. See Regulatory Relief to Support Economic Recovery; Request for Information (RFI), 85 FR 75720 (Nov. 25, 2020) at Attachment A. The Department should learn from the pandemic and conduct widespread reviews to determine whether these or other regulatory requirements could hinder the Nation's response to a future emergency, or otherwise should be amended or rescinded. Determining whether the Department's existing 18,000 regulations are having appropriate impacts is a worthwhile enterprise, even if it somewhat reduces the time spent issuing new regulations. Some commenters at the November 23, 2020 public hearing on the proposed rule suggested that the proposed rule was akin to using a missile to kill a mouse. But the literature and the Department's experience indicate the problem is not a mere mouse.

Thus, there is a need for widespread retrospective review, but it is nearly impossible to see how a satisfyingly comprehensive review could occur without a sunset mechanism. The Department recognizes that in many cases the Department had strong reasons for issuing its regulations. Examples of such motivations might include enhancing food safety,⁹⁶ increasing access to health insurance,⁹⁷ or increasing the incentive for Temporary Assistance for Needy Families recipients to work.⁹⁸ These are all

important policy goals that the Department wishes to achieve. This final rule is intended to further these goals, as well as the other goals motivating the Department's regulations. The literature and the Department's experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time the regulations were promulgated. Therefore, the Department needs to conduct periodic reviews of its regulations to determine whether the policy goals behind the regulations are in fact being effected (and if amending those regulations could more effectively further those goals).

This final rule is not a reversal of a prior Department policy, but in fact an effort to enhance both (1) the fulfillment of the existing policies that led to the Department's regulations and (2) the Department's longstanding desire to comply with the RFA and periodically review its regulations. In any event, this final rule provides the reasoned explanation that would be required if it were a change in policy.⁹⁹

F. Operationalization of This Final Rule

In this section, the Department summarizes aspects of how it will operationalize this final rule.

The proposed rule proposed creating a website where the Department would announce when it has commenced Assessments or Reviews. The proposed rule further proposed that the public could comment on regulations and submit comments requesting that the Department Assess or Review a regulation.¹⁰⁰

In light of public comments, the Department is making these procedures more robust. Under this final rule, when the Department commences the process of performing an Assessment or Review, it shall state on a Department-managed website the sections of the Code of Federal Regulations whose Assessment or Review it is commencing. The Department shall also announce once a month in the **Federal Register** those new Assessments or Reviews that it has commenced in the last month. Some comments on the proposed rule said

that announcements should be made in the **Federal Register**, which the public already monitors, rather than a separate website. Therefore, in response to these comments, in this final rule the Department commits to announcing once a month in the **Federal Register** which new Assessments and Reviews it has commenced. The Department will also create a docket on *Regulations.gov* for each Assessment or Review that the Department is conducting. These docket numbers will be referenced in the **Federal Register** announcements. The public will be able to submit comments to the dockets of each rulemaking being Assessed or Reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department Assess or Review a regulation. This addresses the commenters' concern about commenting on a Department website, rather than via the regular **Federal Register** method. The Department anticipates that the process will be similar to that currently used by the EPA.¹⁰¹ The Department also intends to publish the results of the Assessments and Reviews in the dockets for the applicable regulations.

To further aid the public and the Department, the Department is placing at <https://www.hhs.gov/regulations/federal-registry/index.html> a list of Department rule makings; the year they were initially promulgated; the last year the rule making was amended; and the **Federal Register** citation from the time the rule making was amended. This list was generated with artificial intelligence and the Department believes it is accurate, but it is conceivable that some Department regulations are not included. This list includes all Department regulations, including those that may be exempt from this final rule. The Department believes it would be informative to the public to provide a list of all Department regulations, as well as their **Federal Register** citations and promulgation dates. The Department intends to update this list annually with newly-issued regulations.

In addition, the Department intends to create on its website a dashboard that shows its progress on its Assessments and Reviews, including when it commenced those Assessments and Reviews; its progress; and when it expects them to be completed. If they so

⁹⁵ See, e.g., Coronavirus waivers and flexibilities, CMS.gov, <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>.

⁹⁶ E.g., 21 CFR part 112.

⁹⁷ E.g., 45 CFR part 147.

⁹⁸ 45 CFR part 261.

⁹⁹ See *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515–16 (2009) (“[A] reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy,” but the agency “need not demonstrate to a court’s satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates”) (emphasis in original).

¹⁰⁰ See, e.g., 85 FR 70120.

¹⁰¹ See, e.g., Regulatory Flexibility Act Section 610 Review of the Testing and Labeling Regulations Pertaining to Product Certification of Children’s Products, Including Reliance on Component Part Testing, 85 FR 52078 (Aug. 24, 2020).

choose, the public can view this dashboard to see the Department's progress on its Assessments and Reviews of particular regulations. The dashboard will also help to keep the Department on track to timely complete Assessments and Reviews.¹⁰²

Finally, the Department will, within nine months of publication of this final rule, publish in the **Federal Register** its schedule for conducting Assessments and Reviews. The Department's goal is to provide the public with more information on which regulations it intends to Assess or Review in the next 24 months, so that the public can plan ahead for any desired engagement on those regulations. The Department will subsequently publish in the **Federal Register** its schedule for conducting Assessments and Reviews of regulations that the Department does not intend to review in the first 24 months. However, the Department expects that this schedule will be aspirational in nature to ensure Departmental flexibility to depart from the plan if needed to respond to changing circumstances. The Department will update the plan at appropriate intervals based on its progress.

III. Statutory Authority and Legal Basis for This Final Rule

The statutory authorities supporting this final rule are the statutory authorities for the Department's existing regulations.¹⁰³ 85 FR 70103. The Department finalizes herein its proposal to amend its regulations to add expiration dates unless the Department periodically conducts the required Assessment or 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 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.¹⁰⁴ An agency can also provide that its regulations expire when an event occurs or ceases to occur.¹⁰⁵ That is what this final rule does.

Moreover, Agencies can—and often do—issue one rule that applies to many other agency rules, rather than amending or rescinding each affected

regulation individually. To take one example, in 2008 the Department revised the definition of "entity" at 42 CFR 411.351. See 73 FR 48434, 48751 (Aug. 19, 2008). The revised definition had the effect of changing the meaning of "entity" each time it was used in 42 CFR part 411, subpart J. It would be burdensome to specify the meaning of "entity" each time it appears in Subpart J, so the Department issued one definition that broadly applied to all sections of Subpart J.

There are many other examples where an Agency issues a regulation that applies to, amends, rescinds, or supersedes many other regulations.¹⁰⁶ This avoids an unnecessarily cumbersome process. A court ruling that agencies must amend each individual regulation would call into question large numbers of agency regulations and impose substantial burdens on agencies (and the Office of the Federal Register, which would be required to print the same text over and over) when promulgating future regulations.

Moreover, in this rule making the Department considered each individual Department regulation, and, as discussed further, decided to exempt certain regulations. The Department concluded that this final rule should apply to and amend its remaining regulations, because this final rule will enhance both (1) the fulfillment of the existing policies that led to those

¹⁰⁴ 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).

¹⁰⁵ 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"); U.S. Dep't of Transp., Final Regulatory Impact Analysis: Amendment to Federal Motor Vehicle Safety Standard 208 Passenger Car Front Seat Occupant Protection, at XII-35 (July 11, 1984), <http://www-nrd.nhtsa.dot.gov/Pubs/806572.pdf> (explaining that "[i]f mandatory use laws are passed that will cover 67 percent of the population effective September 1, 1989, the rule will be rescinded").

¹⁰⁶ See, e.g., 21 CFR 1.1(b) ("the definitions and interpretations of terms contained in sections 201 and 900 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 and 387) shall be applicable also to such terms when used in regulations promulgated under that act"); 7 CFR 786.113 ("Notwithstanding any other regulation, interest will be due from the date of the disbursement to the producer or other recipient of the funds"); 40 CFR 455.21

("Notwithstanding any other regulation, process wastewater flow for the purposes of this subpart does not include wastewaters from the production of intermediate chemicals"); 45 CFR 611.12 ("All regulations . . . heretofore issued by any officer of the Foundation which impose requirements designed to prohibit any discrimination against individuals on the ground of race, color, or national origin under any program to which this part applies, and which authorize the suspension or termination of or refusal to grant or to continue Federal financial assistance to any applicant for or recipient of such assistance for failure to comply with such requirements, are hereby superseded to the extent that such discrimination is prohibited by this part," with certain exceptions); 7 CFR 3430.1 ("In cases where regulations of this part conflict with existing regulations of NIFA in Title 7 (i.e., 7 CFR parts 3400 through 3499) of the Code of Federal Regulations, regulations of this part shall supersede"); 24 CFR 943.118 ("The participating PHAs must adopt the same fiscal year so that the applicable periods for submission and review of the joint PHA Plan are the same. Notwithstanding any other regulation, PHAs proposing to form consortia may request and HUD may approve changes in PHA fiscal years to make this possible") (emphasis added).

¹⁰² The Department's information technology personnel are currently undertaking a large data migration that had been planned for a long time. Therefore, the dashboard will not be active as of the date this final rule is published. But the Department intends for this dashboard to be active well in advance of 2026, when the first Assessments and Reviews must be completed.

¹⁰³ Including certain ones inadvertently not listed in the proposed rule.

regulations and (2) the Department's longstanding desire to comply with the RFA and periodically review its regulations. There is a need for widespread retrospective review, but it is nearly impossible to see how a satisfyingly comprehensive review could occur without a sunset mechanism. The Department recognizes that in many cases the Department had strong reasons for issuing its regulations. Examples of such motivations might include enhancing food safety,¹⁰⁷ increasing access to health insurance,¹⁰⁸ or increasing the incentive for Temporary Assistance for Needy Families recipients to work.¹⁰⁹ These are all important policy goals that the Department wishes to achieve. This final rule is intended to further these goals, as well as the other goals motivating the Department's regulations. The literature and the Department's experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time the regulations were promulgated. Therefore, the Department needs to conduct periodic reviews of its regulations to determine whether the policy goals behind the regulations are in fact being effected (and if amending those regulations could more effectively further those goals). The Department concluded that the benefits of retrospective review, and need to more strongly incentivize it, justified this course of action. 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 this final rule's pushing mechanism, the Department will not conduct as many retrospective reviews as desired. In addition, the Department will consider each individual Section when conducting Assessments and (if needed) Reviews.

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).

The Department received comments on the statutory authority for the proposed rule. Below the Department

summarizes these comments and responds to them.

IV. Provisions of Proposed Rule and Response to Public Comments¹¹⁰

On November 4, 2020, HHS published in the **Federal Register** the proposed rule.¹¹¹ Part of the proposed rule had a 30-day public comment period, and part of it had a 60-day comment period to comply with 42 U.S.C. 1395hh(b). In response to the publication of that proposed rule, HHS received 486 comments from industry trade organizations, healthcare providers, businesses, legal/policy think tanks, non-profit public interest groups, and members of the U.S. Congress during the initial 30-day public comment period, and 532 comments total throughout the 60-day comment period. Commenters generally opposed the proposed rule, although some commenters supported it. Roughly a quarter of commenters requested that the Department withdraw the proposed rule. Some commenters requested that the Department extend the public comment period.

The Department also held a public hearing on the proposed rule on November 23, 2020. Twenty-one members of the public, all representing either unions, public-interest groups, or industry trade organizations, spoke. The speakers at the public hearing all either expressed concerns about the proposed rule, opposed it, or requested that the Department withdraw it. Both a transcript and recording of the public hearing are available at <https://beta.regulations.gov/docket/HHS-OS-2020-0012/document>.

In the following sections, HHS includes a summary of the provisions of the proposed rule, the public comments received, HHS's responses to the comments, and any changes made to the regulatory text as a result.

General Purpose of the Proposal and General Comments

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 final rule implements Congress's and the President's desires for retrospective

review of regulations. This final rule will lead to the amendment or rescission, where appropriate, of Department regulations that have a significant economic impact upon a substantial number of small entities. This final rule also furthers democratic values such as accountability, administrative simplification, transparency, and performance measurement and evaluation.

General Comments and Responses

Comment: A few commenters stated that the retrospective review of regulations proposed by the rule is an important and necessary tool for improving agency regulation and minimizing unnecessary regulatory burdens. Commenters listed the many benefits of this approach, including the refining of regulations using real-world data and experience, improving government accountability, avoiding the natural tendency of agency officials charged with achieving public benefits to focus on pursuing those benefits and not on reducing the burdens of their regulation to the public, and preventing the continued enforcement of obsolete, outdated, and even unintentionally harmful regulations. Some commenters stated that it is axiomatic that periodic retrospective review is essential to the proper functioning of the executive branch.

Response: The Department agrees, and believes this final rule will achieve these benefits.

Comment: A few commenters stated that beyond simply cutting regulatory burdens, the scheduled assessments and, when necessary, reviews of existing HHS regulations afford HHS the opportunity to keep regulations up to date with modern trends. Commenters noted that not only will this rule establish an opportunity for the Department to terminate obsolete regulations that are no longer fit for purpose or that are judged to be ineffective, but it will also give HHS and the public a reliable framework and a set of tools to continually keep regulations up to date with evolving circumstances.

Response: The Department agrees and emphasizes that the benefits of retrospective review—some of which are cited by these commenters—are substantial. As the proposed rule noted, Professor Cass Sunstein, who served as OIRA Administrator from 2009 to 2012, has observed that “the requirement of retrospective analysis,” if “firmly institutionalized,” “would count as the most important structural change in regulatory policy since the original

¹⁰⁷ E.g., 21 CFR part 112.

¹⁰⁸ E.g., 45 CFR part 147.

¹⁰⁹ 45 CFR part 261.

¹¹⁰ The Department proposed 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 chapters in Titles 21, 42, and 45.

¹¹¹ See 85 FR 70096.

requirement of prospective analysis during the Reagan Administration.”¹¹²

Comment: A large number of commenters stated that the proposed rule will cause an additional burden to the Department and a diversion of the Department’s personnel resources. Some of these commenters suggested that the regulatory review process could adversely affect the Department’s ability to focus on the administration of current programs, to issue new regulations, and to appropriately review current regulations needing modification. Commenters also raised specific concern about the initial review of regulations that are over ten years old within two years after the calendar year in which this rule is finalized. Those commenters expressed concern that HHS would be unable to Assess or Review all 12,400 regulations that the Department estimates will fall under this category because of the high volume of regulations. A number of commenters stated that two years is an arbitrary and inadequate timeline for all 12,400 regulations to be Assessed or Reviewed, and some regulations could expire simply because the Department did not have enough time to conduct an Assessment or Review. Several commenters also stated that they believe the Department’s estimate that 12,400 of its regulations are over ten years old is lower than the actual number, although no commenter provided an independent count of HHS regulations to support this assertion. A few commenters pointed out that after an Assessment or Review occurs, there may be additional need for rulemaking or revision of regulations, which is an additional cost the Department does not contemplate in its estimate. A few commenters stated that it was unclear where HHS plans to obtain the funding and personnel resources needed to implement this regulatory review process.

Response: The Department has considered the public comments, and decided that, for regulations that are more than ten years old on the effective date of this final rule, the Department shall have five years, rather than two as proposed in the proposed rule, to complete the Assessments and (if needed) Reviews. This will spread out the initial burden and provide the opportunity for more robust Assessments and Reviews. The regulatory impact analysis in this final rule explains how HHS has the resources and personnel to perform the Assessments and Reviews called for by this final rule. Moreover, the Regulatory

Flexibility Act already calls for the Department to assess which of its regulations have a significant economic impact upon a substantial number of small entities, and to review those regulations every ten years. Therefore, assuming full compliance with the RFA, this rule does not impose any additional burden on the Department beyond what was already called for in the RFA.

To the extent there are additional burdens resulting from this regulation, HHS believes widespread retrospective review is a worthwhile enterprise. The literature and the Department’s experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time of promulgation. The Department should conduct periodic reviews to determine whether the policy goals behind the regulations are in fact being effected (and if amending those regulations could more effectively further those goals). Thus, it is sensible to periodically review existing regulations, even if it takes some time away from issuing new regulations (many of which, the literature suggests, would have impacts that differ from their estimated impacts at the time of promulgation).

HHS also notes that courts “have no basis for reordering agency priorities. The agency is in a unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way.” *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). For the reasons discussed herein, the Department has done this, and determined that Reviews and Assessments should be a priority.

Lastly, we note that the COVID–19 pandemic imposed a tremendous, unforeseen burden on the Department, yet there has been no material drop in the Department’s ability to promulgate new regulations or enforce existing regulations. This suggests that after the pandemic, the Department will be resourceful enough to perform Assessments and Reviews, as well as promulgate new regulations that need to be promulgated and appropriately enforce existing regulations.

Comment: A few commenters stated that the benefits of this final rule are difficult to fully anticipate, and there are a number of reasons to believe that the benefits of this rulemaking will vastly outweigh the costs. For example, if HHS were to find cost savings worth 0.0025 percent of departmental spending or 0.0007 percent of national spending, the regulation would pay for itself and pass a cost-benefit test at the higher end of cost estimates.

Response: The regulatory impact analysis for this final rule describes what the Department expects to be the primary impacts resulting from this final rule.

Comment: A large number of commenters stated that, as proposed, this rule would divert resources from the Department’s COVID–19 pandemic response efforts. Many of these commenters stated that it is irresponsible for the Department to create a retrospective regulatory review process at a time when it should be devoting all of its resources to combatting COVID–19.

Response: HHS respectfully disagrees with this comment. Due to the changes made from the proposed rule, under this final rule the first Assessments and Reviews need not be completed until the end of 2026. The Department believes the pandemic will be over by then.

In fact, the COVID–19 pandemic has reinforced the need for this final rule. The Department’s response to the pandemic has largely consisted of waiving regulatory requirements or exercising enforcement discretion to not enforce certain regulatory requirements during the pandemic. *See, e.g., Coronavirus waivers and flexibilities, CMS.gov, <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>; Regulatory Relief to Support Economic Recovery; Request for Information (RFI), 85 FR 75720 (Nov. 25, 2020) at Attachment A (non-exhaustive list of enforcement discretion announcements or changes to regulations, agency guidance materials, or compliance obligations made to respond to the COVID–19 pandemic and its impact on the healthcare industry).* The Department should learn from the pandemic and consider whether to retain regulatory requirements that were waived or where flexibility was provided during the Nation’s response to COVID–19, as well as consider the impact its regulations could have on the response to a future pandemic or other emergency.

Comment: A large number of commenters viewed the 30-day comment period (which began on November 4, 2020, the day that the **Federal Register** published the proposed rule and the day after the rule went on public display) as too short. A large number of these commenters stated that the proposed rule should be withdrawn for various reasons, or in the alternative, requested a longer comment period if the proposed rule was not withdrawn. Commenters’ reasons for asking for an extension included lack of

¹¹² Cass R. Sunstein, *The Regulatory Lookback*, 94 B.U. L. Rev. 579, 584 (2014).

advanced notice of the proposed rule, the perceived magnitude of the rule, fewer resources available to commenters due to the COVID-19 pandemic and the Thanksgiving holiday, and the number of topics on which the Department requested comment.

A large number of commenters stated that the 30-day comment period violates the Administrative Procedure Act (“APA”) because it denies meaningful “opportunity to participate in the rule making” required by 5 U.S.C. 553(c).¹¹³ A few commenters specifically mentioned that while there is no established minimum comment period prescribed by the APA, Executive Order 12866 states that the public’s opportunity to comment, “in most cases should include a comment period of not less than 60 days,” although shorter comment periods have been upheld in the face of exigent circumstances.¹¹⁴ Other commenters said the Department should not finalize the rule until the next Administration enters office.

Response: While HHS understands the commenters’ desire for more time, the comment period was adequate. Neither the APA, nor any other statute requires a longer comment period for the proposed rule. Instead, the APA merely requires that “[a]fter notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation.” 5 U.S.C. 553(c). This occurred here. The comment period provided ample time for the submission of 486 comments by a variety of interested parties, including extensive comments by a number of entities just by the end of the 30-day period. Those comments offer a broad array of perspectives on the proposed rule. The number and comprehensiveness of the comments received disprove commenters’ claim that the 30-day comment period was insufficient time for commenters to provide meaningful comment. Accordingly, after reviewing the public comments and the requests for additional time, the Department does not believe that extending the comment period is or was necessary for the public to receive sufficient notice of, and

opportunity to meaningfully comment on, the proposed rule. Nor is there anything that would have required additional outreach outside of the public notice and comment process and the comment period.

Moreover, under this final rule, the public will have a robust opportunity to comment on each regulation during the Assessment or Review process.

HHS respectfully disagrees that Executive Order 12866 requires a 60-day comment period for this rule. Executive Order 12866 repeats the baseline requirement that “each agency should afford the public a meaningful opportunity to comment on any proposed regulation,” which “in most cases should include a comment period of not less than 60 days.”¹¹⁵ Neither Executive Order mandates a 60-day comment period. That is why many HHS, and other agency, regulations are issued with shorter comment periods. No commenter pointed to a court decision vacating a rule based on a failure to comply with an Executive Order’s supposed 60-day comment period requirement. As explained above, the volume of comments received demonstrates that the public has been afforded a meaningful opportunity to comment.¹¹⁶

Moreover, a portion of the proposed rule had a 60-day public comment period because 42 U.S.C. 1395hh(b) requires a 60-day comment period before issuing or amending certain Medicare regulations. The Department did not finalize this rule until after the 60-day comment period closed, and the Department has considered all comments, including those received throughout the 60-day comment period, before finalizing this rule. In all, the Department received 532 comments by the end of the 60-day comment period.

Lastly, past practice has often been to finalize rules that are ready for finalization without waiting for the incoming Administration to take office.¹¹⁷

Comment: A few commenters viewed the 30-day comment period as insufficient because some of the regulations that will be amended by this final rule had a comment period that lasted more than 30 days when they were originally promulgated.

Response: HHS respectfully disagrees with these commenters. Not only did the Department not finalize this rule until after the 60-day comment period closed, but the APA does not specify a required length for comment periods when issuing or amending regulations. The APA has already “established the maximum procedural requirements which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures.” *Vt. Yankee Nuclear Power Corp. v. Natural Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978). Neither courts nor regulated entities may “impose upon [an] agency its own notion of which procedures are ‘best’ or most likely to further some vague, undefined public good.” *Id.* at 549. The number and comprehensiveness of the comments received disprove commenters’ claim that the comment period was insufficient. A portion of the proposed rule had a 60-day public comment period because 42 U.S.C. 1395hh(b) requires a 60-day comment period before issuing or amending certain Medicare regulations. But for many other Department regulations, Congress has enacted no requirement specifying a particular comment period.

Comment: Several commenters stated that they found it unfair that the proposed rule had a 30-day comment period, but parties regulated by CMS have 60 days to comment on the portion of the proposed rule pertaining to certain CMS regulations. Commenters mentioned that they believed this could present a fundamental due process issue.

Response: As stated in the proposed rule, Congress required a 60-day public comment period before issuing or amending certain Medicare regulations. See 42 U.S.C. 1395hh(b); 85 FR at 70104 n.87. No similar statutory requirement applies to most other Department regulations.

Comment: Several commenters stated that seven days’ notice prior to the public hearing on the proposed rule was insufficient time to prepare remarks for the public hearing. The same commenters also stated that holding the public hearing 10 days before the close of the comment period on the rule was insufficient time for commenters to

¹¹³ See *N.C. Growers’ Ass’n, Inc. v. United Farm Workers*, 702 F.3d 755, 770 (4th Cir. 2012) (APA requires “meaningful” opportunity to comment); *Petry v. Block*, 737 F.2d 1193, 1201 (D.C. Cir. 1984) (relying on Administrative Conference of the United States’ view that 30-day comment period is inadequate and 60-day comment period is the reasonable minimum time for comment).

¹¹⁴ Exec. Order No. 12866 of Sept. 30, 1993, 58 FR 190 (Oct. 4, 1993).

¹¹⁵ See also Exec. Order No. 13563 of Jan. 18, 2011, 76 FR 3821 (Jan. 21, 2011) (“To the extent feasible and permitted by law, each agency shall afford the public a meaningful opportunity to comment through the internet on any proposed regulation, with a comment period that should generally be at least 60 days.”).

¹¹⁶ A commenter pointed to 21 CFR 10.40(b)(2) as counseling in favor of a 60-day comment period. But that provision by its terms applies only to the FDA Commissioner. The proposed rule was issued by the Secretary.

¹¹⁷ For example, fifty-six (56) new rules were finalized in the final two (2) full days of the previous Administration. See *Federal Register*, https://www.federalregister.gov/documents/search?conditions%5Bpublication_date%5D%5Bgte%5D=1%2F18%2F2017&conditions%5Bpublication_date%5D%5Blte%5D=1%2F20%2F2017&conditions%5Btype%5D%5B%5D=RULE.

meaningfully incorporate the testimony and learnings from the public hearing into their written comments.

Response: HHS respectfully disagrees. While the specific date of the hearing (November 23, 2020) was published in the **Federal Register** on November 16, 2020, notice that a hearing would be held was provided in the proposed rule itself.¹¹⁸ Thus, commenters were on notice 19 days (November 4, 2020, to November 23, 2020) prior to the hearing and had 19 days to prepare remarks for the hearing. And as these comments themselves show, choosing the date for the public hearing requires a balance between, first, giving the public sufficient time to review the proposed rule, and second, giving the public adequate time to review comments made at the hearing before submitting written comments. Scheduling the hearing on November 23, 2020 reflected an appropriate balance of these considerations.

Comment: Several commenters were supportive of the rule and expressed that the provisions of the Regulatory Flexibility Act should be followed to increase transparency, public participation, and administrative accountability. These commenters appreciated the Department's efforts to ensure recurring attention to the impact of its rules on small and independent businesses, and minimize the regulatory burden it imposes on these entities. These commenters also stated that regulatory review is a laudable goal that administrative agencies should be aiming for.

Several commenters emphasized the importance of periodically reviewing old regulations to determine whether they should be updated to adapt to changing circumstances. For instance, a few commenters stated that the COVID-19 pandemic drew attention to the fact that many of the Health Insurance Portability and Accountability Act (HIPAA) regulations are out-of-date. Some commenters also stated that the process for developing regulatory impact analyses could be improved if, after each regulation is fully implemented, public comments were solicited on the accuracy of the assumptions underlying the original impact analysis. These commenters appreciated the Department's efforts to consider and update its regulatory review process.

Response: HHS agrees with these commenters that the final rule will implement the important goals of the Regulatory Flexibility Act, including transparency, public participation,

administrative accountability, and a more streamlined regulatory structure. The process set out in the proposed rule that is now being finalized will create a structured plan to operationalize the Department's longstanding goals of reviewing and updating its regulations and—where needed—eliminating regulations that no longer serve their intended purpose(s) and unduly burden both small entities or the public at large. Requiring the solicitation of comments on the assumptions in regulatory impact analyses is beyond the scope of this final rule, but the public is welcome to submit such comments to the dockets of regulations being Assessed or Reviewed.

Comment: A few commenters stated that the proposed rule does not provide sufficient examples of how this approach has worked in the past. A few commenters point out that the proposed rule cites an article that indicates that states have adopted and then abandoned similar approaches to adding automatic expirations dates. They also state that HHS dismisses this fact in the proposed rule without providing a compelling reason. Commenters stated that the examples where this approach has been used that the Department cites to in the proposed rule (U.S. states, the European Union, and the Republic of Korea) have no bearing or authority over federal rulemaking in the United States, where Congress through the APA has established procedures and standards for promulgating, updating, and rescinding regulations. They also stated that the executive actions reviewing regulations that are cited to in the proposed rule underscore that the Department does not need this rule to compel periodic regulatory review.

Response: HHS respectfully disagrees. As explained in the proposed rule, 85 FR at 70102 & nn.66–69, to the extent that states abandoned automatic expiration dates, they did so for reasons that are inapplicable to this situation, namely, the provisions' failure to enhance legislative control. As explained in the regulatory impact analysis, at least one state that undid its sunset provision (North Carolina) subsequently reenacted a sunset process for regulations. The article that one commenter referenced¹¹⁹ did not cite any empirical support for the proposition that automatic expirations produce ineffective or inadequate retrospective reviews where sufficient

resources and staff are provided (as is the Department's intent here).¹²⁰

Second, the proposed rule referred to other jurisdictions' sunsets to illustrate that (1) adding sunset provisions does not wreak havoc or cause undue uncertainty and (2) experience shows sunset provisions can be effective in achieving the benefits from robust retrospective review of regulations. The legal framework of federal rulemaking under the APA may differ from other jurisdictions, but that does not detract from the point that other jurisdictions' experience shows that sunset provisions can be effective and do not lead to havoc or tremendous uncertainty. For the reasons explained in the proposed rule and this final rule, this final rule complies with the APA.

The Department also disagrees with the commenters' suggestion that the existence of limited and sporadic instances of retrospective review demonstrate this rule is not necessary. As explained in the proposed rule, the Department has failed to engage in comprehensive retrospective review of its rules notwithstanding the RFA and long-standing Executive Orders calling for such reviews. This history of limited compliance shows that the proposed rule being finalized is appropriate.

Comment: Several commenters stated that the proposed rule was a political effort to cause difficulties for the incoming Biden Administration, which will be tasked with implementing this final rule.

Response: HHS respectfully disagrees with these commenters because the purpose of this final rule is to require the Department to periodically review its regulations. The rule is not politically motivated, but is instead an effort to ensure the Department periodically reviews its regulations that have a significant economic impact upon a substantial number of small entities. In any event, based in part on comments received on the proposed rule, in this final rule the Department has extended the deadline to five calendar years to complete the Assessments and (if necessary) Reviews of regulations that are more than ten years old. Thus, the initial deadline will not occur in the next Presidential term.

Comment: A few commenters stated that this rule is advancing the Trump Administration's conservative agenda at the expense of good regulations that regulate health and safety for patients and consumers. Many of these commenters also indicated that the rule would put the interests of Wall Street ahead of the individual Americans who

¹¹⁹ 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.

¹²⁰ See 85 FR at 70102 n.69.

¹¹⁸ 85 FR at 70097.

are affected by HHS regulations and benefit from the regulatory structures they create.

Response: HHS respectfully disagrees. As emphasized in the proposed rule, (and this final rule) the Department intends to timely Assess and Review all covered regulations. Moreover, this final rule does not favor regulations of any particular ideological bent; it applies to all Department regulations, subject to the exceptions listed herein. Regulations that meet the RFA's criteria will not be modified or rescinded. The focus and anticipated result of the proposed rule is to eliminate or streamline unnecessary regulatory burdens on small entities. Retrospective review enjoys bipartisan support and benefits all Americans. Some regulations may bestow privileges upon narrow constituencies by creating barriers to entry in their industry. Such regulations may also disproportionately burden small businesses, because small businesses may be the new entrants such regulations are intended to keep out. If these regulations do not meet the RFA's criteria and are amended, small businesses and consumers may benefit from increased competition.

Comment: A few commenters stated that regulations issued after this rule is finalized should include the date of promulgation to make it easy for the public to determine how old the regulation is and when it will be reviewed.

Response: Rules already include their date of promulgation. To the extent the commenter requests that amendments to existing rules include the original date of promulgation, the Department may include this date in prospective rulemakings. Moreover, in conjunction with this final rule, the Department is placing at <https://www.hhs.gov/regulations/federal-registry/index.html> a list of Department rulemakings, the year they were initially promulgated, the last year the rules were amended, and the **Federal Register** citation from the time the rule was last amended. This list was generated with artificial intelligence and the Department believes it is accurate, but it is conceivable that some Department regulations are not included. This list includes all Department regulations, including those that may be exempt from this final rule. The Department believes it would be informative to the public to provide a list of all Department regulations, as well as their **Federal Register** citations and promulgation dates. The Department intends to update this list annually with newly-issued regulations.

Comment: One commenter stated that instead of the Department's proposed

schedule of regulatory review, each agency within HHS should include retrospective review compliance into its annual objectives and, perhaps, even into periodic Congressional reports.

Response: The Department thanks the commenter for this suggestion, but experience suggests it would not be adequate to solve the problem. As noted in the proposed rule, the failure to adequately review existing significant regulations has already been well documented to Congress.¹²¹ It is also public knowledge.¹²² Nonetheless, such "public shaming," if that is what the commenter intends, has not resulted in the Department adequately conducting retrospective review.

Comment: A large number of commenters stated that the proposed rule would be unnecessary and duplicative of the Department's existing efforts to review its regulations. These commenters stated that the Department already updates some of its rules annually, and has updated other non-annual rules in the past. Other commenters believe that HHS is already doing a fulsome review as required by the RFA. Several commenters stated that in 2011, the Department posted its final plan for retrospective review of existing regulations, and from 2012–2016 it provided semi-annual updates on its website listing the rules undergoing or scheduled for review. Some commenters suggested that previous executive orders that called for periodic review of existing regulations are a sufficient means of ensuring the Department is conducting these periodic reviews. Commenters suggested that the Department continue to conduct retrospective reviews using its already established process and provide regular updates to the public on its progress. Other commenters stated that the Department does not address why it failed to perform the required regulatory reviews in the past, nor how the process

proposed in the proposed rule will make a difference.

A few commenters noted that even though previous executive orders have prioritized regulatory reviews, most observers to date note that these kinds of reviews have failed to be institutionalized by agencies, including HHS. These commenters cited evidence suggesting that despite efforts to review regulations over the years and to reduce regulatory burdens, the total number of regulatory restrictions that have been issued by HHS continues to grow year after year, except for two brief periods around 1980 and during the mid-1990s (perhaps as part of deregulatory efforts).

Response: The Department respectfully disagrees that this final rule is unnecessary and duplicative. While commenters are correct that HHS annually updates the annual Medicare payment rules, those rules and certain other rules that are updated annually are exempt from this final rule. This final rule also exempts the rules at 42 CFR part 73, since those are periodically reviewed. Regarding the 2011–2016 retrospective review plan and reviews, that effort was helpful but sporadic, not sustained. As explained in the proposed rule, these efforts only resulted in review of a small fraction of rules. See 85 FR at 70099. The failure to institutionalize retrospective review further underscores the need for this final rule and the review process it is implementing. A few instances of the Department taking the initiative to review its regulations cannot reasonably be considered a sufficient regulatory review when thousands of regulations that have been promulgated over the decades have not been touched.¹²³

Comment: Many commenters questioned the Department's plan for personnel resources to conduct the Reviews prescribed by this final rule. These commenters believe that the Department underestimated the number of people who would be needed to conduct the Reviews, and stated that the personnel resources would be better utilized on other projects. For example, some commenters stated that the Department is already too slow in promulgating certain regulations, and should task its employees with carrying out the Department's existing duties.

Response: The regulatory impact analysis for this final rule describes the personnel resources that the Department envisions being used to conduct Assessments and Reviews. The

¹²¹ See, e.g., Curtis W. Copeland, Cong. Rsch. 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).

¹²² See, e.g., 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/>.

¹²³ See, e.g., 85 FR at 70111 (explaining that as of 2019, 85% of Department regulations created before 1990 had not been edited, and the Department had nearly 300 broken citation references in the CFR).

sensitivity analysis therein addresses the possibility that costs could be lower than estimated in the proposed rule. Periodically reviewing regulations with a significant economic impact upon a substantial number of small entities is an existing Department duty. Moreover, as discussed elsewhere herein, retrospective review can yield tremendous benefits. The literature and the Department's experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time the regulations were promulgated. Therefore, the Department should prioritize conducting periodic reviews of its regulations to determine whether the policy goals behind the regulations are in fact being effected (and if amending those regulations could more effectively further those goals).

Comment: A few commenters questioned whether the Department should have employees Assess or Review regulations if those employees are not responsible for implementing them. These commenters stated that if reviewers have not worked on matters connected with the regulations they are Reviewing, those reviewers may not have an adequate understanding of the regulations, which could lead to the expiration of regulations that are essential to the successful operation of the Department's programs.

One commenter also disagreed with the premise of the Department's use of career civil servants to conduct regulatory reviews. This commenter stated that the proposed rule was logically inconsistent because it "maligned" career public servants at the Department for not reviewing the Department's regulations, but also proposes to task these same individuals with carrying out the proposed review process.

Response: Which Department officials Assess or Review particular regulations will be decided on a case-by-case basis, but those conducting Assessments and Reviews will generally be employees who are familiar with those regulations, as well as technical experts, including economists. The Department strongly disagrees with the comment that the proposed rule "maligned" career civil servants. The proposed rule quoted a law professor who was suggesting several reasons why retrospective reviews do not occur as often as desired. The Department believes career civil servants can capably Assess and Review regulations, just as they capably conduct regulatory impact analyses and regulatory flexibility analyses.

Comment: Several commenters stated that the two-year timeline for review of

all regulations over ten years old was insufficient. A number of commenters suggested that the timeline be extended to five years.

Response: The Department has considered these comments and has decided to revise the rule in light of them. Under this final rule, regulations issued more than ten years prior to the final rule's effective date will not expire if Assessed and (if necessary) Reviewed within five calendar years of the effective date of this final rule. Moreover, under this final rule, if the Secretary makes a written determination that the public interest requires continuation of the Section (as defined in the text of the final rule) in force beyond the date on which the Section otherwise would expire, the Secretary may continue the Section in force one time for a period stated in the determination, which period shall not to exceed one year.

Comment: Several commenters stated that the proposed rule would cause significant regulatory uncertainty in the healthcare industry, which would not know which regulations may or may not expire. Some commenters stated that the proposed rule would cause uncertainty for states, which implement Federal programs and rely on Federal regulations and funding. Potential regulatory changes could create additional compliance and regulatory costs for healthcare providers which may be forced to adapt to a changing regulatory framework. Changes may also trigger regulated entities to forgo future investments because they lack regulatory clarity. For example, some commenters stated that the uncertainty created around the expiration of regulations, including those that guide eligibility for Medicaid, Medicare provider reimbursements, or certification of hospitals and clinics, could disrupt the efficient operation of critical safety-net programs, create regulatory gaps and inconsistent application of the law, and make accessing safety-net services for our most vulnerable populations even more complicated and difficult than it is today. Some commenters said the poor, people of color, and/or the LGBTQ community, would be particularly affected. Additionally, some commenters stated that the proposed rule would make it difficult for them to advise clients on how to comply with the Department's regulations. These commenters stated that if HHS determined that a regulation required modification, it should clearly publicize its intention to exercise enforcement discretion in not enforcing the then-current iteration of the regulation while

the particular regulation is being modified.

Other commenters stated that the regulatory review process set forth in this rule would ensure that HHS reviews regulations as required by the RFA, which means that if HHS were currently complying with the RFA in a satisfactory manner, there would be little additional uncertainty stemming from the proposed rule.

Response: The Department notes that there is always a possibility that regulations could be amended or rescinded, even absent this rule. The Department does not believe uncertainty among the regulated community will add significantly to the costs of this rulemaking for the following reasons. The Department's sporadic use of periodic retrospective review—notwithstanding the RFA and Executive Orders—itself leads to "uncertainty" about how robustly the Department implements directives that make for good policy.¹²⁴ To the extent that the Department can maintain compliance with its obligations, this should build trust in the Department and reduce uncertainty (offsetting some or all of the uncertainty discussed by the commenters, if such uncertainty exists). Further, as noted above, the Department plans to release information about the 18,000 regulations under its authority and when they were adopted, such that any uncertainty surrounding the expiration dates of the Department's various rulemakings will be reduced substantially, if not entirely. Additional measures to mitigate private costs are discussed in the "Operationalization of This Final Rule" section of this final rule. Second, the Department notes that many states and foreign jurisdictions have sunset provisions that are a routine part of their regulatory processes. If the sunset reviews in these other jurisdictions do not create tremendous uncertainty, it stands to reason that neither will this final rule. The regulatory impact analysis for this final rule describes in more detail the sunset provisions from these other jurisdictions.

Under this final rule, the regulated community has five years to adjust to the changes made by this final rule, so any reliance interests are significantly reduced as compared to the proposed rule. Where appropriate, the Department would announce the regulations for

¹²⁴ To the extent this uncertainty has been lessened because the public has seen how the Department has implemented these directives over the course of many years, the same can be said for this final rule once it has been implemented for several years.

which it is exercising enforcement discretion.

Comment: A few commenters stated that the Department should allow reasonable reliance on a regulation while that regulation is under review, and for a reasonable time after a decision to amend, rescind or allow a regulation to expire. These commenters also stated that the final rule should allow the Department to extend a regulation for any period of time reasonably necessary for regulated entities relying on the regulation to adjust their business practices.

Response: HHS appreciates the commenters' concern regarding the reliance interests of regulated entities; however, HHS respectfully disagrees with the premises of these comments. First, HHS does not intend to allow a regulation to simply expire. And as explained in the proposed rule, the public will have the opportunity to provide comments identifying regulations that the public believes need to be Assessed and Reviewed, which mitigates the risk of inadvertent expiration.

Second, with respect to Sections that, after Review, the Department determines should be amended or rescinded, such Sections will be amended or rescinded through a separate notice-and-comment rulemaking process. Considerations about the effective dates of such amendments or rescissions, including the need to allow adequate time for transition, will be taken into account in that separate rulemaking process. Finally, Review under this final rule expressly considers "the continued need for the Section," so regulated entities' reliance interests will be taken into account during Reviews.

Comment: Several commenters stated that the use of artificial intelligence and machine learning technology in regulatory review is a novel and innovative approach, and members of the public should have been afforded notice of the Deloitte research project and the opportunity to comment on the use of this technology. In particular, these commenters wanted to understand if and how the technology would be used by HHS to identify the regulations that will be reviewed. Some commenters asked HHS to provide additional information regarding the methodology used, and the underlying algorithm. A few commenters stated that all code should be posted on a publicly-accessible website, consistent with best practices among academic researchers in data science.

Response: The Department agrees that the use of artificial intelligence machine

learning technology in regulatory review is a novel and innovative approach. The technology discussed in the proposed rule was initially used to perform an internal assessment of Department regulations, which is why the Department did not previously notify the public about this research project. Artificial intelligence will not be used to perform Assessments and Reviews pursuant to this final rule. While artificial intelligence can determine if a regulation has been amended in the last thirty years, it cannot at this time easily determine if a regulation satisfies the criteria listed in 5 U.S.C. 610. The artificial intelligence review was useful, because it suggested that large numbers of Department regulations would benefit from retrospective review. The technology identified that 85% of Department regulations created before 1990 have not been edited; the Department has nearly 300 broken citation references in the CFR; and there are more than 50 instances of HHS regulatory requirements to submit paper documents in triplicate or quadruplicate. This suggests humans performing a comprehensive review of Department regulations would find large numbers of requirements that would benefit from review, and possibly amendment or rescission.

Regarding the technology used to perform the 2019 analysis, the analysis was performed using a tool called RegExplorer. RegExplorer is an "augmented intelligence" tool, meaning it is designed to use artificial intelligence in conjunction with subject matter experts. While RegExplorer is proprietary technology, some of the models deployed within RegExplorer include keyword technology (a structured and iterative approach to process, analyze, and return keyword search results); a clustering algorithm (a cluster is a machine-generated group of regulatory documents that have been algorithmically gathered together based on a set of similar characteristics, such as the relevant sub-agency, placement of text within the regulatory dataset, similarity of text content, and text format and structure); citation extraction and mapping; and similar section analysis.

Comment: A few commenters asked why HHS chose to redact some of the "Regulatory Streamlining & Analysis" published by Deloitte in March 2019 that the Department cites in support of the proposed rule. These commenters pointed out that two of three bullet points in the "executive summary" slide, and all but 25 of the document's 170 pages are redacted. These commenters asked why this information

was not made available to the public, and why HHS did not have a public meeting to discuss the Deloitte findings and solicit feedback on its regulatory reform ideas back in 2019.

Response: The Department was transparent by including the Deloitte analysis in the docket for this rulemaking. The redacted information is information protected by applicable privileges, is confidential information, trade secret information, or not relevant to this rulemaking. As can be seen from the Table of Contents for the analysis, the redacted information does not relate to the machine learning analysis that was conducted to enhance regulatory reform that was discussed in the proposed rule. In November 2020, the Department held a public hearing on the proposed rule, which referred to the Deloitte presentation. The public was able to opine on the analysis at that public hearing. The Department did not have a public meeting to discuss the Deloitte findings and solicit feedback in 2019, because the Department was at the time still undergoing its internal deliberative process.

Comment: A few commenters stated that ideally the systematic evaluation of regulations should be a regular part of the rulemaking process, with the evaluation criteria and timeline embedded within each new rule so that the regulated community has an opportunity to opine on how and when each regulation will be reviewed. Commenters suggested that HHS identify up front what data it will use to track the progress of the regulation, and commit to continually collecting the same kinds of data over time. Such a process would make future evaluation of regulations and programs easier. It would also improve public accountability because the public would have a clearer sense of what the regulation is designed to achieve, and can monitor HHS's progress.

Response: HHS agrees with the commenters' focus on the need to systematically evaluate the effectiveness of agency regulations—indeed, the Department has proposed the instant rule in order to make such evaluations more frequent and comprehensive. The timeline for Review of a given Section is set forth in section [XX](c)(1), and the criteria for Review are set forth in [XX](d). As is current practice, the Department intends to explain in the preambles to future rules what goals the rules are intended to achieve. This will enable the public to know what goals each regulation is designed to achieve. However, the data necessary to evaluate a particular rule will differ from rule to rule, and the Department cannot

generally commit to such collection in advance and in the abstract, although it may be useful to do so in particular cases.

Comment: One commenter suggested that HHS consider performing a cost-savings analysis for regulations receiving a Review under the proposed rule, or for that subset of Assessed regulations that are deemed significant or economically significant. Such analysis could include estimates of the costs, cost savings, and the net cost savings of the regulation.

Response: For purposes of this final rule, the Department has decided to limit the Review criteria to the criteria listed in 5 U.S.C. 610, plus whether the regulation complies with applicable law. These are the criteria that Congress directed the Department to use in its periodic reviews, plus a review for compliance with the law. Determining the regulation's costs, as well as cost savings from amendment or rescission, will often be subsumed in the five criteria listed in 5 U.S.C. 610.

Comment: A large number of commenters stated that the proposed rule would negatively impact programs if review efforts are underfunded, or that the proposed rule was costly and unfunded.

Response: The Department disagrees that regulatory review efforts would be underfunded. As explained in the regulatory impact analysis, this final rule will impose relatively low costs on the Department.

Comment: Several commenters, including Tribal governments and representatives, affiliated groups of Indian Tribes, and the IHS Tribal Self-Governance Advisory Committee, stated that the Department should have consulted with Tribal governments on the rule and failed to notify Tribal leaders and representatives of the proposed rule in violation of HHS's duty as a federal agency to consult with Tribal nations under Exec. Order No. 13175 of Nov. 6, 2000, 65 FR 67249 (Nov. 9, 2000) (E.O. 13175) and the Department's own Tribal consultation policy.

Response: The Department and Indian Tribes share the goal to establish clear policies to further the government-to-government relationship between the Federal Government and Indian Tribes. True and effective consultation shall result in information exchange, mutual understanding, and informed decision-making on behalf of the Tribal governments involved and the Federal Government. The importance of consultation with Indian Tribes was affirmed through Presidential

Memoranda in 1994, 2004 and 2009,¹²⁵ and E.O. 13175. HHS believes that neither the proposed nor the final rule violate the Department's Tribal consultation policy or E.O. 13175. Subject to certain exceptions, the policy and E.O. 13175 require consultation before any action that will significantly affect Indian Tribes, or before promulgating any regulation that has Tribal implications. HHS believes that this final rule does not significantly affect Indian Tribes or have Tribal implications, as those terms are used in the policy and E.O. 13175. This final rule amends existing regulations to provide that the regulations will expire if not Assessed and (if necessary) Reviewed by certain dates. HHS intends that all rules will be Assessed and (if necessary) Reviewed timely. Therefore, this final rule would have no direct impact on Indian Tribes, beyond their costs of participation in the monitoring, Assessment, and Review processes. As explained in this final rule's regulatory impact analysis, the estimated total monitoring costs to the public over ten years is estimated to range from \$52.2 million to \$156.7 million using a 7% discount rate, or \$58.8 million to \$176.3 million over ten years using a 3% discount rate (all figures using \$2020). The U.S. Census estimates that in 2019, 1.7% of the U.S. population was all or partially American Indian or Alaska Native.¹²⁶ 1.7% of the estimated monitoring costs would be roughly \$887,400 to \$2.66 million over ten years using a 7% discount rate, or \$999,600 to roughly \$3 million over ten years using a 3% discount rate (and the cost to Tribes could be less since not every American Indian or Alaska Native is affiliated with a Tribe). Tribes will be able to comment on regulations during the Assessment and Review processes.

Comment: A commenter stated that the rule would allow for the sunset of regulations that merely implement statutory requirements, such as Indian preference. The commenter cited as examples 42 CFR 136.41–43, 42 CFR 121, 42 CFR 136a.41–43, all of which, the commenter stated, are mandated by 25 U.S.C. 5117.

¹²⁵ Presidential Memoranda on Government-to-Government Relations With Native American Tribal Governments, 85 FR 22951 (May 4, 1994), Presidential Memorandum, Government-to-Government Relationship with Tribal Governments, September 23, 2004, <https://www.govinfo.gov/content/pkg/WCPD-2004-09-27/pdf/WCPD-2004-09-27-Pg2106.pdf>, Presidential Memorandum on Tribal Consultation, 74 FR 57879 (Nov. 9, 2009).

¹²⁶ ACS Demographic and Housing Estimates, U.S. Census Bureau, <https://data.census.gov/cedsci/table?q=United%20States&g=0100000US&tid=ACSDP1Y2019.DP05&hidePreview=true>.

Response: The Department respectfully disagrees. This final rule exempts from the Assessment and Review requirement “Sections whose expiration pursuant to this section would violate any other Federal law.” See Section [XX](g). In any event, the Department is not convinced the statutory provision cited by the commenter mandates the cited regulations. There is no obligation imposed on HHS in 25 U.S.C. 5117 to prescribe any particular regulations on Indian preference. Rather, section 5117 provides that “any employee entitled to Indian preference who is within a retention category established under regulations prescribed under such subsection to provide due effect to military preference shall be entitled to be retained in preference to other employees not entitled to Indian preference who are within such retention category.” Neither 25 U.S.C. 5117 nor 25 U.S.C. 5116 (which is referenced in 25 U.S.C. 5117) are cited as statutory authorities for the regulations cited by the commenter.

Comment: A few commenters stated that agencies (including HHS) have long ignored the retrospective review mandate of the RFA and have failed to perform such reviews. One reason for this, according to the commenters, is that the RFA does not create incentives for federal agencies to review their regulations. These commenters stated that this final rule would solve that problem by providing a clear incentive for agencies within HHS to review their regulations to prevent their automatic expiration. Commenters stated that without such a consequence, agencies will continue to fail to conduct retrospective reviews of their regulations.

Response: The Department cannot speak for other federal agencies and would not state that the Department has completely ignored retrospective review. But the Department would agree that it has not performed reviews as often as Congress intended. The Department agrees that this final rule will address this problem by providing an incentive to perform retrospective reviews.

Comment: A few commenters stated that the Department failed to analyze the potential costs of rescinding regulations, and only focuses on the costs of conducting voluntary Assessments and Reviews. A few commenters stated that HHS did not assess the potential forgone benefits of expired regulations.

Response: This is addressed in the regulatory impact analysis for this final rule.

Comment: A few commenters stated that the Department should consider doing a regulatory impact analysis when reviewing rulemakings that predate the Regulatory Flexibility Act and have a significant economic impact upon a substantial number of small entities (“SEISNOSE”). These commenters also noted that conducting additional regulatory impact analyses would impose an additional cost to the Department, which it should account for if it chooses to do additional analysis on Pre-RFA rulemakings.

Response: As explained in the proposed rule, more resources will be required to review regulations that predate the RFA.¹²⁷ The regulatory impact analysis for this final rule accounts for the additional resources required to conduct Reviews of rulemakings that predate the RFA. But the criteria listed in 5 U.S.C. 610 are the criteria that Congress directed the Department to use when reviewing regulations that predate the RFA. Therefore, for rulemakings that predate the RFA and have a SEISNOSE, this final rule requires that the Review consider the factors listed in 5 U.S.C. 610, as well as whether the component Sections within those rulemakings comply with applicable law.

Comment: A few commenters asked for clarification on whether a regulation that is identified for amendment through the regulatory review process set forth in this final rule would be prioritized over new regulations the Department is promulgating.

Response: In the scenario described by commenters, the Department would aim to amend the referenced regulation and also promulgate new regulations that the Department believes should be promulgated. Experience shows the Department is able to amend existing regulations and promulgate new ones at the same time.

Comment: A few commenters asked if regulations that are sunset because they were not Assessed or Reviewed by the deadline would have to go through notice-and-comment rule making to be reissued if they were otherwise unchanged. These commenters also asked how these regulations would be prioritized by the Department.

Response: As explained throughout the proposed rule (and this final rule),

the Department is committed to dedicating adequate resources to timely Assess and Review its regulations. If a regulation did automatically expire, though, the Department would be required to undertake notice-and-comment rule making to reissue the regulation, unless one of the exceptions to notice-and-comment rule making in 5 U.S.C. 553 applies.

Furthermore, allowing for automatic reissuance of an expired regulation threatens to undermine the efficacy of this final rule. If there were no costs or obstacles to simply resurrecting an expired regulation in its original, pre-expiration form, then there would be no compelling incentive to timely Assess and Review Department regulations.

It is impossible to say at this point how the Department might “prioritize” re-issuance of expired regulations, without knowing which regulation is at issue and what other competing priorities the Department might have at the time. That said, the Department anticipates it will prioritize re-issuance of expired regulations in line with the public need for such regulation, balancing the same considerations it always does in allocating its policy-making resources. As noted above, the risk that important, “priority” regulations—those that meaningfully impact regulated entities—will expire is mitigated by the fact that interested members of the public can alert the Department to a needed Assessment or Review. Commenters have also flagged regulations to review during the public comment process on this rule.

Comment: A few commenters stated that the Department should clarify how it will reconcile or update applicable guidance documents associated with rescinded regulations. If guidance documents remain in existence or are not updated to account for the regulatory changes resulting from the process established in this final rule, it could lead to confusion for regulated entities. A few commenters asked for clarification on whether the Department is considered to have Reviewed a regulation if the Department issues a guidance document on that particular regulation.

Response: The Department may not issue any guidance document that establishes a legal obligation that is not reflected in a duly enacted statute or in a regulation lawfully promulgated under a statute. The Department may not use any guidance document for purposes of requiring a person or entity outside the Department to take any action, or refrain from taking any action, beyond what is required by the terms of an applicable

statute or regulation.¹²⁸ Therefore, any guidance document based on an expired regulation has no effect. If a guidance document addresses expired regulations as well as regulations still in effect, the Department would seek to expeditiously revise the guidance document.

The Department is not considered to have Reviewed a Section simply because the Department issues a guidance document concerning that particular Section. The Department is only considered to have Reviewed a Section if, with respect to the Section, the Department has followed the procedures specified in section [XX](f) of this final rule. The Department must publish the results of the Review, 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), in the **Federal Register**.

Comment: A few commenters asked how other enforcement agencies, such as the Office of the Inspector General or the Department of Justice, and federal healthcare program contractors, would be affected by the proposed rule. Commenters stated that a lack of coordination between agencies and other entities with equities in an expired regulation could lead to different and possibly contrary conclusions about how to proceed. These commenters also stated that this could lead to conflicting requirements, resulting in different rules in different jurisdictions. Commenters asked the Department to clarify how corporate compliance programs should advise their organizations if a regulation expires.

Response: This final rule applies to the HHS Office of Inspector General (OIG), which is a component of HHS, although certain regulations for which OIG has enforcement responsibility are exempt, such as 42 CFR 1001.952. 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). In addition, when Assessing or Reviewing regulations that require review and approval by the Attorney General under Exec. Order No. 12250 of

¹²⁷ See 85 FR 70115 (“Of the 273 rulemakings subject to Reviews in the first two years, the Department estimates roughly 16%, 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”).

¹²⁸ Department of Health and Human Services Good Guidance Practices, 85 FR 78785 (Dec. 7, 2020).

Nov. 2, 1980, 45 FR 72995 (Nov. 4, 1980), 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 DOJ can review and approve prior to the publication of the findings. If an HHS regulation is amended, rescinded, or expires, no other governmental body may take a different view of the regulation's legal effect.

Regarding how corporate compliance programs should advise their organizations if a regulation expires, an HHS regulation that expires no longer has legal effect and cannot be enforced by any governmental body against a regulated entity.

Comment: One commenter stated that HHS observes that the proposed rule's review requirements "do not impose new burdens . . . if incomplete compliance [with the Regulatory Flexibility Act] is not accounted for in the regulatory baseline."¹²⁹ But HHS's entire rationale for the proposed rule, according to the commenter, is that incomplete compliance with existing review requirements is and will continue to be a problem under the regulatory baseline (*i.e.*, absent the proposed rule).

Response: HHS maintains that the proposed rule, as well as this final rule, does not impose new burdens if incomplete compliance with the RFA is not accounted for in the regulatory baseline. HHS recognizes that, after implementation of this final rule, the Department's Assessments and Reviews will likely result in an additional resource expenditure beyond what would occur absent promulgation of this final rule. This was analyzed in the Regulatory Impact Analysis of the proposed rule and in more detail (largely due to comments received) in the Regulatory Impact Analysis of this final rule. It is worth noting, though, that the burdens resulting from this final rule are burdens that Congress already intended for the Department to bear.

Comment: A few commenters stated that the Department does not cite any reason why a regulatory review should be triggered by the age of a regulation or why ten years should be the trigger. Some commenters stated that a regulatory review could also be based on the subject matter of the regulation, its economic impact, or the number of people it affects. Other commenters pointed out that the Department also could have used a different time period other than ten years to conduct its reviews. Commenters point to the

Department's citation to a number of foreign and sub-national entities that mandate the reviews of regulations after five or seven years. These commenters stated that since there are other options for the frequency of regulatory review, the proposal to have such rules automatically expire after ten years is arbitrary and capricious.

Response: HHS respectfully disagrees. The proposed rule explained why the Department chose ten years:

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,¹³⁰ while at least one state uses a ten-year time period.¹³¹ 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.¹³²

This rationale still holds. In this final rule, the Department decides to Review rules that have a SEISNOSE, because those are the rules that the RFA directed HHS to review.

Comment: A few commenters stated that the proposed rule interferes with the RFA's procedure for regulatory review. 5 U.S.C. 610–611. These commenters note that those sections require agencies to publish plans for regulatory review, provide a schedule for revision that varies by agency, give agency heads the right to delay review for one-year periods, up to a maximum of five years, identify multiple factors that must be considered in reviewing each rule, prescribe the terms of public notice via the **Federal Register**, and specify judicial appeal procedures and criteria, including standing rights and remedies. These commenters also stated that the Department's proposed rule would scrap that process and replace it with a default of across-the-board regulatory repeal in case of inaction, without recourse, using a completely different system of judicial review premised on the underlying APA, rather than the RFA. Commenters stated that this would be a usurpation of Congress's role, and would raise constitutional questions involving balance of power between the branches. According to

commenters, the Department must address this issue or else promulgating this final rule would be arbitrary and capricious.

Response: HHS respectfully disagrees. This final rule is consistent with the RFA's requirement to publish a plan for periodic review—it *is* such a plan, and the RFA does not prohibit the Department from including expiration dates in its regulations. The Review process considers the five factors enumerated in the RFA. *See* 5 U.S.C. 610(b). This final rule requires publication in the **Federal Register** of the results of Assessments and Reviews under section [XX](f). This final rule does not supplant or purport to foreclose any available judicial review under 5 U.S.C. 611. And with respect to section 610 compliance, the RFA's judicial-review provisions expressly cross-reference the broader APA judicial-review provisions. *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.*") (emphasis added). Because this rule is consistent with the RFA, it does not usurp Congress's role or raise constitutional separation-of-power concerns. To the contrary, it implements Congressional intent for periodic review of regulations. Section II.F of this final rule further addresses the commenters' concerns in discussing how the Department will operationalize this final rule.

Comment: Several commenters stated that the proposed rule violates the RFA's intent as expressed by Congress. In passing the RFA, Congress expressly made the following finding: "the practice of treating all regulated businesses, organizations, and governmental jurisdictions as equivalent may lead to inefficient use of regulatory agency resources, enforcement problems and, in some cases, to actions inconsistent with the legislative intent of health, safety, environmental and economic welfare legislation."¹³³ These commenters stated that the proposed rule departs from the Congressional intent in passing the RFA because the proposed rule would subject every regulation to mandatory review as well as repeal by default. In this way, the proposed rule "treats all regulated businesses, organizations, and governmental jurisdictions as equivalent" by terminating all

¹³⁰ *See, e.g.*, N.J. Admin. Code § 1:30–6.4 (2020) (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).

¹³¹ N.C. Gen. Stat. 150B–21.3A.

¹³² 85 FR at 70106.

¹³³ Public Law 96–354, 94 Stat. 1164, 1164 (1980) (as amended 1996).

regulations, without considering the unique set of stakeholders affected by each regulation.

Response: HHS respectfully disagrees with these comments because these commenters fundamentally misunderstand the operation of this final rule, as well as the Congressional finding they quote. This final rule does not repeal regulations by default. As explained in this final rule, the Department intends to timely complete the necessary Assessments and Reviews and has built in safeguards to mitigate the risk of inadvertent expiration. Under this final rule, the Department must Assess which of its rule makings have a significant economic impact upon a substantial number of small entities, and then perform the more robust Reviews on those rule makings. Therefore, the Department is paying special attention to those regulations which have a significant economic impact upon a substantial number of small entities. As explained in the proposed rule, the Department cannot know which regulations currently have a SEISNOSE without Assessing its regulations.¹³⁴ This process is consistent with the RFA, which instructs agencies to review “the rules issued by the agency which have or will have a significant economic impact upon a substantial number of small entities.”

Reviews consider the five factors expressly included within the RFA, as well as an additional factor that is indisputably beneficial and appropriate: “Whether the rulemaking complies with applicable law.” See Section [XX](d). Subjecting regulations with a SEISNOSE to Review does *not* “treat all regulated businesses, organizations, and governmental jurisdictions as equivalent” because the findings of the Review will be tailored to the regulation.¹³⁵

The commenters also quote the language from the Congressional findings and declaration of purpose out of context. Congress was clearly focused on agencies ignoring the distinction between “large scale entities” and small entities.¹³⁶ Given that this rule closely

tracks the RFA’s goal of minimizing undue burden on small entities, it aligns with the Congressional intent behind the RFA.

Comment: A commenter stated that automatic expiration of Department regulations could frustrate the RFA’s purpose by inappropriately sunseting rules that increase economic benefits for small entities. This commenter stated that the proposed rule does not sufficiently address this concern. This commenter also stated that the proposed rule undermines congressional intent because the proposed rule does not consider that the Department may be impeding its ability to conduct reviews under the RFA by instituting added procedural requirements and broadly applicable regulatory sunsets. This commenter further stated that expiration dates are particularly contrary to effectuating RFA compliance because the Department will need to prioritize assessing rules without any impact on small entities simply due to their imminent expiration, rather than using Department resources efficiently to focus on rules requiring the Department’s review under the RFA.

Response: The Department respectfully disagrees. The RFA calls on the Department to periodically review regulations that have a significant economic impact upon a substantial number of small entities. This final rule intends to increase the number of such reviews that occur, and directs the Department to review using the criteria specified in 5 U.S.C. 610(b) (plus whether the rule making complies with applicable law). As for Assessing regulations not previously determined to have a SEISNOSE, implicit in 5 U.S.C. 610 is the requirement to determine which regulations have a SEISNOSE.¹³⁷ 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.¹³⁸ The Department does not intend for any regulations to inadvertently sunset, and it is unlikely that any regulations with significant benefits would slip through

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.”).

¹³⁷ 85 FR 70112.

¹³⁸ 85 FR 70107.

the cracks. The regulatory impact analysis addresses this in more detail.

Comment: A few commenters stated that beyond simply cutting regulatory burdens, the scheduled regulatory review of existing HHS regulations will afford HHS the opportunity to keep regulations up to date with modern trends. These commenters noted that not only will this rule establish an opportunity for the Department to terminate obsolete regulations that are no longer fit for purpose or that are judged to be ineffective, but it will also give HHS and the public a reliable framework and a set of tools to continually keep regulations up to date with evolving circumstances.

Response: The Department agrees with these comments and emphasizes that the benefits of retrospective review—some of which are cited by these commenters—are substantial. As the proposed rule noted, Professor Cass Sunstein, who served as OIRA Administrator from 2009 to 2012, has observed that “the requirement of retrospective analysis,” if “firmly institutionalized,” “would count as the most important structural change in regulatory policy since the original requirement of prospective analysis during the Reagan Administration.”¹³⁹

Comment: A few commenters stated that regulatory review does not create as much benefit to regulated entities as the proposed rule suggests, because many of the costs of regulatory compliance have already been factored into the cost of doing business, and are essentially evanescent over time.

Response: While some costs of regulatory compliance may have been factored into the cost of doing business, this comment overlooks many of the benefits of retrospective review. For example, economic, technological, or legal changes can make a regulation obsolete over time. Retrospective review is widely acknowledged to be beneficial by scholars across the ideological spectrum, many of whom are cited in the proposed and this final rule.

Comment: A commenter asked for greater detail on the Assessment and Review process, especially planning of what is to be included and excluded in the retrospective review process. The commenter also asked for greater explanation of how the Department will provide notification of what rules have been Assessed. The commenter also asked what would happen if a part of a rule was reviewed but not other parts of it.

¹³⁹ Cass R. Sunstein, *The Regulatory Lookback*, 94 B.U. L. Rev. 579, 584 (2014).

¹³⁴ See 85 FR 70107.

¹³⁵ Under the commenters’ argument, the fact that the RFA sets forth five factors to be considered (see 5 U.S.C. 610(b)) would also supposedly be inconsistent with Congressional intent.

¹³⁶ See Public Law 96–354, 94 Stat. 1164, 1164 (1980) (as amended 1996), Sec. 2(a)(2) (“laws and regulations designed for application to large scale entities have been applied uniformly to small businesses, small organizations, and small governmental jurisdictions even though the problems that gave rise to government action may not have been caused by those smaller entities”); Sec. 2(b) (“It is the purpose of this Act to establish

Response: Section II.F of this final rule's preamble provides greater detail on the Assessment and Review process and the Department's planning for Assessments and Reviews. Examples of Section 610 reviews conducted by the EPA are instructive on how the Department anticipates the five factors set forth in 5 U.S.C. 610(b) will be analyzed.¹⁴⁰ The results of all Assessments and Reviews conducted in a calendar year will be published in a single document in the **Federal Register** during that calendar year. The Department also intends to place the results of an Assessment or Review in the docket for the rule on *Regulations.gov*. Lastly, this final rule defines "Assess" as a determination as to whether the "Sections 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. This final rule defines "Review" as a process the purpose of which is to determine whether "Sections 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, amended, or rescinded. Thus, while Sections are what expire if they are not timely Assessed or Reviewed, the Department should be Assessing or Reviewing all Sections that were part of the same rulemaking (and any amendments or additions that may have been issued thereafter), not just some of them.

Comment: One commenter stated that it previously advocated for the review and modernization of some of the Department's regulations covering Medicare health and safety standards. For example, according to the commenter, the Medicare Conditions of Participation regulations for psychiatric hospitals do not align their requirements with modern psychiatric care. However, the commenter stated that no substantive revisions to the

provisions have occurred since the requirements for psychiatric hospitals were first implemented, meaning that a comprehensive review of these regulations has not occurred for at least 40 years, when psychiatric care was delivered much differently. This commenter stated that this is a clear example of why regular regulatory reviews are necessary.

Response: The Department thanks the commenter for identifying these regulations. The Department intends to timely Assess and (if necessary) Review these regulations. If the Assessments and Reviews suggest these regulations should be amended or rescinded, the Department will commence rulemaking to amend or rescind them.

Comment: A few commenters applauded the Department for continuing the bipartisan work on regulatory review to ensure federal agencies are continually held accountable to taxpayers and that regulations remain relevant and updated to innovation and changes in market conditions. The commenters also asked when the planning and drafting of the proposed rule began, any recent regulatory actions that would demonstrate the effects that regulatory reviews, suspensions, or updates can have on the health care industry, or the economy more broadly, and a list of Department regulations suspended during the pandemic.

Response: The Department thanks the commenters for the first part of this comment. Second, for a non-exhaustive list of 382 enforcement discretion announcements, waivers or changes to regulations, agency guidance materials, or compliance obligations made to respond to the COVID-19 pandemic and its impact on the healthcare industry, see Regulatory Relief to Support Economic Recovery; Request for Information (RFI), 85 FR 75720 (Nov. 25, 2020) at Attachment A. The planning and drafting of the proposed rule is subject to the deliberative process privilege, but evolved out of the 2019 regulatory streamlining analysis discussed in the proposed rule.

Technical Legal Comments

Comment: A large number of commenters stated that the proposed rule would violate the Administrative Procedure Act (APA), because it would allow the Department to revise or rescind thousands of regulations at one time instead of conducting notice and comment rulemaking on each existing individual rule it chooses to repeal. Some of these commenters also mentioned that the APA requires agencies to use substantially the same

process to repeal a rule as they used to promulgate a rule, so a process that allows for automatic expiration of a rule would not meet this statutory requirement. A commenter stated that "Revocation constitutes a reversal of the agency's former views as to the proper course" and "[w]hile the agency is entitled to change its view on [a matter], it is obligated to explain its reasons for doing so. . . . [A]n agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change" and "[g]enerally, one aspect of that explanation would be a justification for rescinding the regulation. . . ." (quoting *Motor Vehicles Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41, 42, 52, 56 (1983)). Commenters stated that this rule would be arbitrary and capricious on these grounds. One commenter stated that if the Department does not perform an affirmative action to prevent expiration of a regulation, the Department would fail to articulate a satisfactory explanation for its expiration, making the agency action arbitrary and capricious.

Response: This final rule complies with the APA. The APA generally requires, with certain exceptions, notice and comment prior to finalizing a "rule making," 5 U.S.C. 553, which is defined as "formulating, amending, or repealing a rule." 551(5). See *Motor Vehicles Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41 (1983) ("We believe that the recession or modification of an [agency rule] is subject to the same test."). The APA has already "established the maximum procedural requirements which Congress was willing to have the courts impose upon agencies in conducting rulemaking procedures." *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978). Neither courts nor regulated entities may "impose upon [an] agency its own notion of which procedures are 'best' or most likely to further some vague, undefined public good." *Id.* at 549.

The Department agrees with commenters who stated the APA generally requires agencies to use substantially the same process to amend or repeal a rule as they used to promulgate a rule. The Department is complying with this requirement. See *Clean Air Council v. Pruitt*, 862 F.3d 1, 9 (2017) (an agency can amend or revoke a legislative rule through notice-and-comment rulemaking). In this rule making, the Department has gone through notice-and-comment rule making to amend its regulations by establishing conditions under which the regulations will either be Assessed and/

¹⁴⁰ See Results of EPA's Section 610 Review of the Final Rule for Control of Emissions of Air Pollution from Nonroad Diesel Engines and Fuel, EPA Off. of Transp. & Quality (Sept. 2014), <https://www.regulations.gov/document?D=EPA-HQ-OAR-2013-0642-0003>; Regulatory Flexibility Act Section 610 Review of the National Pollutant Discharge Elimination System (NPDES) Permit Regulation and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFOs), EPA Off. of Water (June 3, 2014), <https://www.regulations.gov/document?D=EPA-HQ-OW-2012-0813-0216>; Results of EPA's Section 610 Review of the Final Rule for Lead; Renovation, Repair, and Painting Program, EPA Off. of Pollution Prevention and Toxics (Apr. (April 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0126-0019>.

or Reviewed or expire. This is permissible. The Department is going through notice-and-comment rule making to amend its regulations to apply expiration dates unless certain conditions are satisfied. Agencies already promulgate regulations that expire upon the satisfaction of a future event or non-event.¹⁴¹ Nothing in the APA forecloses agencies from including conditional expirations dates in regulations. It would call into question many rules—and be extremely disruptive—if courts held that conditional expiration dates violate the APA.

The Department also rejects the argument that it cannot revise many regulations in one rule making, but instead must conduct notice-and-comment rule making on each individual regulation it seeks to amend or rescind. The APA does not include such a requirement. When 5 U.S.C. 551(5) defines “rule making” as an “agency process for formulating, amending, or repealing a rule” (emphasis added), that includes formulating, amending, or repealing “rules.” See 1 U.S.C. 1 (“In determining the meaning of any Act of Congress, unless the context indicates otherwise—words importing the singular include and apply to several persons, parties, or things”). Agencies can—and often do—issue one rule that applies to many other agency rules, rather than amending or rescinding each affected regulation individually. To take one example, in 2008 the Department revised the definition of “entity” at 42 CFR 411.351. See 73 FR 48434, 48751 (Aug. 19, 2008). The revised definition had the effect of changing the meaning of “entity” each time it was used in 42 CFR part 411, subpart J. It would be burdensome to specify the meaning of “entity” each time it appears in subpart

J, so the Department issued one definition that broadly applied to all sections of subpart J. There are many other examples where an Agency issues a regulation that applies to, amends, rescinds, or supersedes many other regulations.¹⁴² This avoids an unnecessarily cumbersome process. A court ruling that Agencies must amend each individual regulation would call into question large numbers of Agency regulations and impose substantial burdens on agencies (and the Office of the Federal Register, which would be required to print the same text over and over) when promulgating future regulations. In addition, the Department will consider each individual regulation when conducting Assessments and (if needed) Reviews.

Moreover, in this rule making the Department considered each individual Department regulation, and, as discussed further, decided to exempt certain regulations from this final rule. The Department concluded that the benefits of retrospective review, and need to more strongly incentivize it, justified applying this final rule to the Department’s remaining regulations. In this rule making, the Department is considering the important factors. It issues this final rule 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 justified 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 pushing mechanism, the Department will not conduct as many retrospective reviews as desired. Indeed, this final rule, rather than being a revocation of prior regulations, will enhance the fulfillment of the existing policies that led to the Department’s regulations subject to this final rule.

Comment: Many commenters stated that the proposed rule could create legal uncertainty regarding the validity and enforceability of regulations that the Department, after conducting a Review, determines should be amended or rescinded. Commenters stated this could have negative effects on the HHS programs, the healthcare industry, and states which administer Medicaid and CHIP. Some of these commenters stated that HHS admits that enforcing a Regulation deemed to require amendment or rescission in some cases could raise concerns about whether such enforcement is arbitrary and capricious. Continuing to enforce the regulation (or portions thereof) could arguably run counter to the evidence before the agency. However, these commenters stated that, HHS provides no insight or explanation on how it would address this conundrum.

Response: The Department respectfully disagrees. The commenters’ concerns only apply where the Department has announced, after Review, that a regulation should be amended or rescinded. Where that is the case, the announced results will suggest what portions of the regulation may need revision and the Department anticipates that commenters will generally be able to participate in subsequent rule making regarding amending or rescinding the regulation. The basis for amendment or rescission will suggest the extent to which continued enforcement in the interim is appropriate. That is why the proposed rule states the Department would exercise enforcement discretion “on a case-by-case basis as appropriate.”¹⁴³ Consistent with Department practice, the Department would announce if it is exercising enforcement discretion to not enforce a regulation.

Comment: Several commenters stated that if Congress’s intent was to effectuate results similar to those in the proposed rule, it could have included sunset provisions in its statutes. By not including sunsets in its statutes, Congress must not have perceived a need for Congressionally-directed

¹⁴¹ 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”); U.S. Dep’t of Transp., Final Regulatory Impact Analysis: Amendment to Federal Motor Vehicle Safety Standard 208 Passenger Car Front Seat Occupant Protection, at XII-35 (July 11, 1984), <http://www-nrd.nhtsa.dot.gov/Pubs/806572.pdf> (explaining that “[i]f mandatory use laws are passed that will cover 67 percent of the population effective September 1, 1989, the rule will be rescinded”).

¹⁴² See, e.g., 21 CFR 1.1(b) (“the definitions and interpretations of terms contained in sections 201 and 900 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 and 387) shall be applicable also to such terms when used in regulations promulgated under that act.”); 7 CFR 786.113 (“Notwithstanding any other regulation, interest will be due from the date of the disbursement to the producer or other recipient of the funds”); 40 CFR 455.21 (“Notwithstanding any other regulation, process wastewater flow for the purposes of this subpart does not include wastewaters from the production of intermediate chemicals”); 7 CFR 3430.1 (“In cases where regulations of this part conflict with existing regulations of NIFA in Title 7 (i.e., 7 CFR parts 3400 through 3499) of the Code of Federal Regulations, regulations of this part shall supersede”); 45 CFR 611.12 (“All regulations . . . heretofore issued by any officer of the Foundation which impose requirements designed to prohibit any discrimination against individuals on the ground of race, color, or national origin under any program to which this part applies, and which authorize the suspension or termination of or refusal to grant or to continue Federal financial assistance to any applicant for or recipient of such assistance for failure to comply with such requirements, are hereby superseded to the extent that such discrimination is prohibited by this part,” with certain exceptions).

¹⁴³ 85 FR 70108.

rulemaking to expire in the foreseeable future, or at least not automatically.

Response: HHS disagrees that Congress's choice to not include automatic sunset provisions in its statutes undercuts or forecloses the proposed rule. The RFA requires the Department to develop "a plan for the periodic review of the rules issued by the agency which have or will have a" SEISNOSE, but leaves the details of said plan to the Department. 5 U.S.C. 610(a). The RFA demonstrates Congress's intent that agencies conduct retrospective review, and the Department has determined, for the reasons explained in the proposed rule, that sunset provisions are a practical and effective way to ensure that Congressional intent is honored. The commenters' position suggests it is improper to take steps to effectuate Congressional intent if Congress itself has not expressly legislated such steps—but, of course, agencies frequently fill in the details of a statutory regime implemented by Congress.

Comment: One commenter stated that the proposed rule is misleading, which thwarts public comment and violates the APA. This commenter stated that it was misleading and irrational for HHS to suggest that it is hypothetical whether any regulation would sunset under the rule, because every regulation would sunset unless a timely Assessment or Review occurs. This commenter suggested that the rule's description is inadequate to meet the notice standard required by the APA. This commenter reasoned that the Department's explanation of the proposed rule and its reasoning did not provide the public with a meaningful opportunity to participate in rulemaking through the submission of comments, which violates the notice and comment requirement of the APA. 5 U.S.C. 553.

Response: HHS respectfully disagrees. "The APA requires that the notice of proposed rulemaking contain 'reference to the legal authority under which the rule is proposed' and 'either the terms or substance of the proposed rule or a description of the subjects and issues involved.'" *Little Sisters of the Poor Saints Peter and Paul Home v. Pa.*, 140 S. Ct. 2367, 2384 (2020) (quoting 5 U.S.C. 553(b)(2)–(3)). The notice of proposed rulemaking, which spanned 29 pages of the **Federal Register**, did just that. The adequacy of the notice is demonstrated by the fact that the agency received 532 comments—both critical and in support of the proposed rule—that raised general issues as well as commented on specific provisions of the proposed rule. The volume of comments also demonstrates that the public had

ample, meaningful opportunity to participate in this rulemaking. There is nothing misleading in the Department's statement that it intends to timely Assess and (where required) Review its Sections. The proposed rule and this final rule adequately explain the basis for this final rule.

Comment: One commenter stated that the proposed rule is arbitrary and capricious because the stated rationale of incentivizing retrospective regulatory review is implausible. This commenter stated that it is wrong to think that the Department is incentivized to Assess or Review its regulations, because the Department may want its regulations to expire. The commenter said that the penalty for failure to review regulations actually falls on the regulated industry, not the Department. The commenter stated that HHS unlawfully ignored the predictable effects of the proposed rule on third parties.

Response: HHS respectfully disagrees. The proposed rule amply explained the benefits of retrospective review. It also explained why sunset deadlines were necessary to incentivize retrospective review (including, for example, the Department's experience with underutilization of retrospective review). This rationale is not implausible because of the speculative possibility that the Department will intentionally forego Assessments and Reviews. If the Department wanted its regulations to expire, it would have conducted rulemakings to rescind its regulations. The proposed rule and this final rule demonstrate the Department's commitment to timely Assess and (where necessary) Review its regulations. For example, the proposed rule and final rule include (among other things) a clear-eyed analysis of the resources and staff time required to conduct Assessments and Reviews, and provide a mechanism for the public to request the Department to conduct Assessments and Reviews on certain regulations.

Comment: A few commenters stated that the proposed regulatory review process is arbitrary and capricious, because it elevates the need to undertake RFA reviews above any other purpose served by the Department's regulations, which commenters state is disproportionate to the problem at hand. These commenters state that since HHS estimates that only 11% of its regulations have a SEISNOSE and would be subject to the RFA, it is arbitrary and capricious to subject the other 89% of regulations to possible rescission.

Response: HHS respectfully disagrees. As explained in the proposed rule and

this final rule's preamble, there is a need for widespread retrospective regulatory review. It is nearly impossible to see how a satisfyingly comprehensive review could occur without a sunset mechanism. The Department recognizes that in many cases the Department had strong reasons for issuing its regulations. Those regulations were motivated by important policy goals that the Department wishes to achieve. This final rule will further these goals. The literature and the Department's experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time the regulations were promulgated. Therefore, the Department needs to conduct periodic reviews of its regulations to determine whether the policy goals behind the regulations are in fact being effected (and if amending those regulations could more effectively further those goals). Therefore, this final rule is in fact an effort to enhance both (1) the fulfillment of the existing policies that led to the Department's regulations and (2) the Department's longstanding desire to comply with the RFA and periodically review its regulations.

As for conducting Assessments on many regulations, and not just Reviewing those regulations previously determined to have a SEISNOSE, the proposed rule explained that "[w]ithout 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."¹⁴⁴

Comment: One commenter stated that the Department may not finalize the proposed rule without conducting a review under the National Environmental Policy Act (NEPA) or considering how the proposed rule is consistent with Executive Orders 13045 or 12898.

This commenter stated that HHS violated its obligations under NEPA because commenters believe the rule is a major federal action. According to the commenter, the proposed rule stated that it "will not have a significant impact on the environment" without providing additional explanation.¹⁴⁵ The commenter stated that the FDA's own NEPA regulations require it to conduct *at least* an environmental assessment before promulgating certain

¹⁴⁴ 85 FR 70107.

¹⁴⁵ 85 FR 70118.

regulations, and FDA cannot rescind those regulations without conducting NEPA review. See 21 CFR 25.20.

This commenter also stated that the proposed rule does not adequately consider Executive Orders 13045 or 12898. Executive Order 13045 imposes requirements on agencies to protect children from environmental health risks and safety risks.¹⁴⁶ The commenter stated that because the Department did not mention Executive Order 13045 in its proposed rule, it must have failed to consider it. Executive Order 12898 directs federal agencies to make environmental justice part of their mission, and to identify and address the disproportionate environmental and health effects of their activities.¹⁴⁷ This commenter expressed that HHS did not consider whether the proposed sunset rule will cause “disproportionately high and adverse human health or environmental effects . . . on minority populations and low-income populations”¹⁴⁸ even though the commenter believes there is every reason to think that the sunset rule will cause such adverse effects.

Response: HHS respectfully disagrees that further analysis under NEPA, E.O. 12898 (“Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations”), and/or E.O. 13045 (“Protection of Children From Environmental Health Risks and Safety Risks”), is required. The commenter’s position is based on a fundamental misunderstanding of how the final rule functions. As explained in the notice of proposed rulemaking, this rule does not in and of itself rescind any regulations; it provides that certain regulations will expire if not Assessed and (if required) Reviewed by certain dates.

Thus, there is no basis to say that this final rule itself “significantly affect[s] the quality of the human environment,” 42 U.S.C. 4332(C); may cause “disproportionately high and adverse human health or environmental effects . . . on minority populations and low-income populations,” E.O. 12898, Sec. 1–101; or “concern[s] an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children,” E.O. 13045 Sec. 2–202(b).¹⁴⁹

The commenter says an environmental assessment may be

necessary, including consideration of alternatives as required by section 102(2)(E) of NEPA, 40 CFR 1501.5(c)(2), if it is unclear whether the rule will significantly affect the environment. But it is clear that this rule alone does not have a significant environmental impact. Any rescissions or amendments pursuant to Assessments and Reviews will be effected through notice-and-comment rulemaking independent of this rule and include any required environmental (and other) analyses. In any event, the Department adequately explained the alternatives it considered in its proposed rule,¹⁵⁰ as well as in the regulatory impact analysis for this final rule.

Comment: A few commenters stated that HHS mistakenly exempts the proposed rule from the regulatory review process it creates. The proposed rule states that it “cannot, absent other actions, directly impose on the public costs that exceed benefits . . . [o]nly the failure to perform an Assessment or Review in the future could theoretically impose on the public costs that exceed benefits.”¹⁵¹ These commenters stated that it was a mistake for HHS to assume that the proposed rule will not “directly impose on the public costs that exceed benefits” because costs would be imposed on the public unless Assessment or Review of Regulations take place. These commenters took the position that the Department’s regulations would expire by default, and that expiration would impose a cost that would exceed benefits.

Response: HHS respectfully disagrees. This final rule would not become obsolete due to economic, technological, or legal changes the way that many other rules can. For the reasons discussed herein, the Department believes the process set forth in this final rule will enable the Department to Assess and (where required) Review its regulations. It is a mistake, and bereft of evidence, to assume that the Department’s regulations would expire by default.

Comment: Several commenters stated that the Department did not adequately explain its reasoning for the proposed rule. Some of these commenters stated that HHS did not acknowledge the facts and circumstances that motivated the initial promulgation of its regulations, nor did HHS discuss in the proposed rule the serious reliance interests that have been created by some of these regulations. Commenters asserted that the Department claims that it “is considering the important factors”—

without articulating what those factors are—and asserts that it “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.”¹⁵² A few commenters asked HHS to identify the regulations that are vulnerable to rescission under the rule, and to describe the nature and magnitude of the harm that might result from their expiration.

Response: The Department believes the proposed rule adequately explained the facts and circumstances that motivated issuing the proposed rule, and adequately showed that the Department considered the relevant factors. The same is true for the preamble to this final rule, which provides additional explanation for why the Department is issuing this final rule and the factors it considered. The Department recognizes that in many cases the Department had strong reasons for issuing its regulations. Examples of such motivations might include enhancing food safety,¹⁵³ increasing access to health insurance,¹⁵⁴ or increasing the incentive for Temporary Assistance for Needy Families recipients to work.¹⁵⁵ These are all important policy goals that the Department wishes to achieve. This final rule is intended to further these goals, as well as the other goals motivating the Department’s regulations. The literature and the Department’s experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time the regulations were promulgated. Therefore, the Department needs to conduct periodic reviews of its regulations to determine whether the policy goals behind the regulations are in fact being effected (and if amending those regulations could more effectively further those goals). Outside of the exempted regulations, no particular regulations are more “vulnerable to rescission” than others under this final rule. This final rule is agnostic as to all Department regulations. They must all be Assessed and, if they have a SEISNOSE, Reviewed using the criteria specified in section [XXI](d).

¹⁴⁶ Exec. Order No. 13045 of Apr. 21, 1997, 62 FR 19885 (Apr. 23, 1997) (E.O. 13045).

¹⁴⁷ Exec. Order No. 12898 of Feb. 11, 1994, 59 FR 7629 (Feb. 16, 1994) (E.O. 12898).

¹⁴⁸ *Id.*

¹⁴⁹ See also 85 FR 70118 (“HHS has determined that the proposed rule will not have a significant impact on the environment.”).

¹⁵⁰ See 85 FR 70116–17.

¹⁵¹ 85 FR 70109.

¹⁵² 85 FR 70106.

¹⁵³ *E.g.*, 21 CFR part 112.

¹⁵⁴ *E.g.*, 45 CFR part 147.

¹⁵⁵ 45 CFR part 261.

Comments on the Statutory Authority for This Final Rule

Comment: Several commenters stated that the Department does not have the authority to propose automatic expiration of its regulations. Some commenters stated that HHS fails to explain how Congress's grants of authority to the Department to "promulgate," 21 U.S.C. 371(a), to "make and publish," 42 U.S.C. 1302(a), or to "prescribe," 42 U.S.C. 1395hh(a), regulations also give it the authority to rescind those regulations, with that rescission subject to future reversal at the Department's discretion. Other commenters stated that the proposed rule not only falls outside these grants of rulemaking authority, but squarely contradicts Congress's instructions that HHS "shall" promulgate certain regulations. *E.g.*, 21 U.S.C. 371, 42 U.S.C. 1395hh(a). Some commenters cited to section 1102 of the Social Security Act, which directs the Secretary of HHS to issue regulations "not inconsistent with this Act" to implement the Medicaid and CHIP programs but does not provide specific statutory authority for the Secretary to write automatic expiration dates into regulations.

Response: The Department respectfully disagrees. As explained in the proposed rule, the statutory authorities supporting this rule making are the statutory authorities for the Department's existing regulations.¹⁵⁶ Moreover, the Department believes that the relevant portions of the proposed rule, as finalized herein, are fully consistent with 42 U.S.C. 1302(a). Indeed, it specifically cited this provision as one source of statutory authority for promulgating the proposed rule (85 FR at 70103), and does so in this final rule. The commenters' position is incorrect for multiple reasons. First, the commenters' assertion seems to suggest that *any* action by the Department to repeal or amend Medicaid or CHIP regulations, by the mere act of amendment or rescission, is "inconsistent" with those programs. That position is untenable.¹⁵⁷ In fact,

this final rule is the promulgation of a regulation that will contribute to "the efficient administration of" the Department's functions under the Social Security Act, because the Reviews called for by this final rule will take into account both the continued need for particular regulations, as well as whether the burden of those regulations on small entities can be minimized (among several other factors that will enhance efficiency, such as the complexity of the Regulation or whether it is duplicative). For the same reasons, this final rule is the promulgation of a regulation for "the efficient enforcement" of the Federal Food Drug, and Cosmetic Act and necessary to carry out the administration of the Medicare program. *See* 21 U.S.C. 371(a); 42 U.S.C. 1395hh(a)(1). This final rule will enhance the fulfillment of the policies that motivated the regulations issued pursuant to 42 U.S.C. 1302, 42 U.S.C. 1395hh, and 21 U.S.C. 371.

Comment: Several commenters stated that the proposed rule exceeds the statutory authority of the RFA, because the RFA only affects regulations that "have a significant economic impact upon a substantial number of small entities." 5 U.S.C. 602, 604, 605. However, according to the commenters, the proposed rule does not limit its reach to those regulations covered by the RFA because it adds expiration dates to *all* HHS regulations, not just those that "have a significant economic impact upon a substantial number of small entities."¹⁵⁸ These commenters added that the RFA also does not mandate the automatic expiration of regulations that have not undergone agency review.

Response: The primary statutory authorities for this final rule are the statutory authorities for the Department's existing regulations. The Department also notes, though, that the text of 5 U.S.C. 610 indicates Congress believed agencies have the authority to periodically review at least those regulations that have a significant economic impact upon a substantial number of small entities (and that agencies have the authority to assess which of their regulations have such an impact). *See* 5 U.S.C. 610(a)–(b). The commenters are correct that the RFA does not mandate the automatic expiration of rules; however, the RFA also does not foreclose this final rule's approach. As explained throughout the

statutory authority for amending and removing regulatory text).

¹⁵⁸ *See* 85 FR 70123; *id.* at 70104–05 (defining "Regulations" as "a section of the Code of Federal Regulations").

proposed rule and in this final rule, decades of experience, empirical evidence, and scholarly commentary all support the Department's view that this final rule will enhance compliance with the RFA's directive to periodically review regulations with a SEISNOSE.

Comment: A few commenters stated that the proposed rule does not cite the RFA (5 U.S.C. 610) as a source of its statutory authority. These commenters stated that they believe the Department omitted the RFA in its list of statutory authority because the rule is contrary to the statute.

Response: The proposed rule cited 5 U.S.C. 610 as one of the statutory bases for the proposed rule.¹⁵⁹ The statutory bases for this rulemaking also include the existing statutory authorities for the Department's regulations. This final rule is consistent with the RFA, because it sets forth a plan for the periodic review of the regulations issued by the Department which have or will have a significant economic impact upon a substantial number of small entities. *See* 5 U.S.C. 610(a). Moreover, this final rule requires such review to consider the factors set forth in 5 U.S.C. 610(b). The text of 5 U.S.C. 610 indicates Congress believed agencies have the authority to periodically review at least those regulations that have a significant economic impact upon a substantial number of small entities (and that agencies have the authority to assess which of their regulations have such an impact). *See* 5 U.S.C. 610(a)–(b).

Specific Provisions of the Proposed Rule and Final Rule

Section [XX](a)

In the proposed rule, HHS proposed to add Section [XX](a), which provided that the proposed rule would apply to and amend all Regulations issued by the Secretary or his delegates or sub-delegates in this title. HHS received no comments specific to Section [XX](a). However, in this final rule HHS replaces "this title" with "this chapter," and amends the relevant chapters of Titles 21, 42, and 45, rather than amending all regulations that were issued by the Secretary (or his delegates or sub-delegates) in the titles. HHS makes this change to increase clarity and precision. For example, certain chapters in Title 21 contain Drug Enforcement Administration, not HHS or FDA regulations. Although the proposed rule's use of the language "Regulations issued by the Secretary or his delegates or sub-delegates in this title" addressed this by limiting the scope of the

¹⁵⁶ 85 FR 70103.

¹⁵⁷ *See, e.g.*, Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II, 79 FR 27106, 27153 (May 12, 2014) (citing 42 U.S.C. 1302 as statutory authority for the removal of certain regulatory text); Medicare Program; Amendment to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011 76 FR 1366, 1367 (Jan. 10, 2011) (relying on 42 U.S.C. 1302 and 42 U.S.C. 1395hh, among other statutory provisions, to amend or remove regulatory text); Color Additives; D&C Green No. 6; Uniform Specifications, 51 FR 37908, 37909 (Oct. 27, 1986) (citing 21 U.S.C. 371 as

¹⁵⁹ *See* 85 FR 70119, 70120, 70121, 70123.

proposed rule to regulations issued by the HHS Secretary or his delegates or sub-delegates, HHS in this final rule amends the chapters belonging to HHS, rather than the entirety of the titles. This is not a substantive change and does not cause the application of the final rule or the rights and obligations it creates to differ from the proposed rule.¹⁶⁰

Similarly, HHS clarifies that it is amending its other regulations through the provisions in this final rule by generally applying an expiration date to those regulations, if certain conditions are not met, rather than asking the Office of the Federal Register to literally amend each other regulation, which would be unnecessarily burdensome and resource intensive. Accordingly, this final rule states that it applies to and “shall be deemed to amend” all regulations issued by the Secretary or his delegates or sub-delegates in the applicable chapters. This is not a substantive change and does not affect the application of the final rule or the rights and obligations it creates.

HHS received no comments specific to section [XX](a) of the proposed rule.

Accordingly, HHS finalizes section [XX](a) to read, “[t]his section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.”

Section [XX](b)

HHS proposed to add section [XX](b), which defined several terms used in the proposed rule.

i. Section [XX](b)(1)

HHS proposed to define “Assess” 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).¹⁶¹ 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.

Comments on Section [XX](b)(1)

HHS received the following comment on the proposed definition of “Assess.”

Comment: A few commenters stated that HHS should clarify that periodic Assessments *must* look to the determination of the regulation’s impact on small entities made at the time of promulgations, *as well as* experience since promulgation.¹⁶² These commenters stated that HHS should clarify that any Assessment that only contemplates the former and ignores the latter will be deficient.

Response: Assessments must analyze the regulation’s impact on small entities at the time the regulation is being Assessed. The Department believes this is clear from the text of the proposed rule, which defined “Assess” 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” (emphasis added). Accordingly, the Department adopts in this final rule the definition of “Assess” from the proposed rule, except that the term “Regulations” in the proposed rule is changed to “Sections” in this final rule. The determination made at the time of promulgation about whether a rulemaking had a SEISNOSE may be a useful data point in assessing

the regulation’s current impact on small entities.

Accordingly, HHS is finalizing the definition of “Assess” as proposed, with the technical amendment just mentioned.

ii. Section [XX](b)(2)

HHS proposed to define “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.

HHS received no comments specific to the proposed definition of “Review.”

Accordingly, HHS is finalizing the definition of “Review” as proposed, except that it replaces the term “Regulations” with “Sections,” to conform this provision to the rest of this final rule.

iii. Section [XX](b)(3)

HHS proposed to define “Regulation” 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 was proposed to make 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 Assessed or Reviewed by the dates listed in the proposed rule. Had the Department used the Administrative Procedure Act’s (APA’s) definition of “rule,”¹⁶³ it could be unclear in certain circumstances what precisely needed to be reviewed.

In the final rule, HHS changes the term “Regulation” to “Section” for the reasons previously discussed.

¹⁶⁰ In addition, whereas the proposed rule added certain regulatory text to Title 45, Part 6, this final rule adds the text to Title 45, Part 8. This is not a substantive change. Since the Department anticipates that, for good governance and streamlining reasons, Part 6 soon may soon be subsumed into Part 5, the Department in this final rule adds the relevant text to Part 8.

¹⁶¹ 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.

¹⁶² *See A Guide for Government Agencies: How To Comply With The Regulatory Flexibility Act*, U.S. SBA Off. of Advoc., at 80–81 (2017), <https://cdn.advocacy.sba.gov/wp-content/uploads/2019/06/21110349/How-to-Comply-with-the-RFA.pdf>, (“If Congress meant to limit periodic reviews, it would have simply required agencies to review rules that originally had a significant impact, rather than rules that now have a significant impact.”).

¹⁶³ 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”).

Comments on Section [XX](b)(3)

HHS received the following comments on the proposed definition of “Regulation.”

Comment: A few commenters stated that HHS arbitrarily chose to reject the APA’s definition of “Regulation” and adopted its own definition of “Regulation” for the purposes of this rule, defining regulation as “a section of the Code of Federal Regulations.” Some commenters stated that using a different definition in this rule from the definition in the APA (and incorporated in Executive Order 12866 and Executive Order 13771) is confusing. Commenters stated that the Department’s explanation that it used a special definition of “Regulation” to avoid confusion that could be created by using the APA’s definition was insufficient and lacked statutory basis.

Response: To avoid any confusion, HHS uses “Section,” rather than “Regulation,” in this final rule to refer to a section of the Code of Federal Regulations. It is crucial to the proper function of this final rule that the Department and public clearly understand the scope and timing of the Assessment and Review process. Such understanding is made easier with a bright-line definition of the agency issuances that are subject to Assessment and Review. The Department’s use of “Section” endeavors to provide such clarity by using a readily available and well-established system of organization, the Code of Federal Regulations. It is clear when a section of the Code of Federal Regulations was first promulgated.

The use of “Section,” rather than “Regulation,” in this final rule is not a substantive change from the proposed rule. Rather, it is an attempt to bring additional clarity by using “Section” to refer to a section of the Code of Federal Regulations, rather than using the term “Regulation.”

Comment: One commenter expressed concern over the proposed rule’s definition of “Regulation,” stating that the definition is too narrow. This commenter stated that under the proposed rule, each Regulation would be Assessed or Reviewed without the context of the preamble language that was included in the rulemaking.

Response: HHS respectfully disagrees. “Assessment” and “Review” are defined in this final rule as determinations with respect to “Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter).” In the proposed rule, “Regulation” was defined as a section of

the Code of Federal Regulations so the Department and public can know what units would expire absent Assessment or (if needed) Review. But the text of the final rule makes clear that a single Assessment or Review should be performed on all Sections that were issued as part of the same rulemaking (and any amendments or additions that may have been issued thereafter). The Department disagrees with the commenters who stated that, under the proposed rule, each Regulation would be Assessed or Reviewed without the context of the preamble language that was included in the rulemaking. Under this final rule, the Department may consider this information when conducting Assessments and Reviews.

Accordingly, HHS is finalizing the definition proposed, except that it defines the term “Section” rather than “Regulation.”

iv. Section [XX](b)(4)

HHS proposed to define “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 proposed definition was to provide clarity to the Department and the public. If a regulation were amended, questions could arise whether the clock for re-reviewing the rule making in which the regulation was first promulgated begins on the date the rule making 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. The proposed definition is more clear for the Department and the public, because this definition, in conjunction with section [XX](c) of the proposed rule, makes clear that the clock starts for the retrospective review of a regulation on the date that the rule making from which the regulation originates was first promulgated, even if it is subsequently amended.

If, for example, the Department issues a regulation as a part of a rule making and amends it nine years later, the Department may wish to conduct the regulatory review of the entire rule making at the time of amendment of a specific regulation initially promulgated in that rule making, 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 regulatory 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 regulatory review at that time, thereby conserving Department resources.

HHS received no comments specific to the proposed definition of “Year of the Regulation’s Promulgation.”

Accordingly, HHS is finalizing the definition of “Year of the Regulation’s Promulgation” as proposed, except that it changes the term “Regulation” to “Section.”

v. Section [XX](b)(5)

HHS proposed to define “[s]ignificant economic impact upon a substantial number of small entities” as having the meaning ascribed to that term in the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996).

HHS received the following comments on the proposed definition of “Significant economic impact upon a substantial number of small entities.”

Comment: A few commenters stated that neither the proposed rule, nor the RFA gives a clear definition of “significant impact” or of “small entity,” and asked that HHS clarify the definition of these terms in the final rule.

Response: HHS declines to add definitions of these terms within this final rule. “Significant economic impact” and “small entity” are terms within the RFA, which has been in existence for over forty years. These terms have been applied by the Department and other agencies since the RFA’s enactment. Definitions pertinent to “small entity” appear at 5 U.S.C. 601. As explained in the proposed rule, the Department has considered 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.¹⁶⁴

Comment: One commenter stated that the citation in the definition of “Significant economic impact upon a substantial number of small entities” found at 21 CFR 6.1(b)(5), 42 CFR 1.1(b)(5), 42 CFR 404.1(b)(5), and 45 CFR 6.1(b)(5) was incorrect. The proposed rule cited the Regulatory Flexibility Act, Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (as amended 1996). This commenter stated that because the definition in the RFA appears in section 610 of title 5 of the U.S. Code, the correct citation is to the code. This commenter also stated that the definition of “Significant economic impact upon a substantial number of

¹⁶⁴ See 85 FR at 70117.

small entities” shall be defined to have the meaning “of” that term in 5 U.S.C. 610, rather than the meaning “ascribed to” that term in 5 U.S.C. 610.

Response: HHS appreciates the comments and agrees that citation to the Code is proper. This final rule incorporates this suggestion, and replaces the citation in the proposed rule with “5 U.S.C. 610.” It also incorporates the comment to use “of” instead of “ascribed to.” This revised definition may provide increased clarity.

Accordingly, in this final rule HHS is finalizing the definition of “[s]ignificant economic impact upon a substantial number of small entities” to provide that this term shall have the meaning of that term in section 610 of title 5 of the United States Code.

Section [XX](c)

i. Section [XX](c)(1)–(2)

In the proposed rule, HHS proposed 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 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, under the proposed rule 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 proposed rule stated that the Department must Assess all its regulations (subject to the exceptions listed below) every ten years, or such regulations shall expire if not Assessed. The Department believes all of its regulations (subject to the exceptions) should be Assessed and, if they have a significant economic impact upon a substantial number of small entities,

Reviewed. The proposed rule stated that Assessments and Reviews should not be performed only on those regulations issued after the proposed rule goes into effect. After all, it is likely that some regulations promulgated decades ago may have become outdated.¹⁶⁵

Section [XX](c) of the proposed rule made clear that Department regulations (subject to the exceptions listed below) shall expire if their Assessment and (if required) Review are not timely performed. Both 5 U.S.C. 610 and executive orders by multiple presidents over several decades direct the Department to devise plans to periodically review many of its regulations.¹⁶⁶ Although the Department retrospectively reviewed a very limited number of its regulations, observers have over the decades noted that the Department has not always performed retrospective review to a satisfactory extent, and many of its regulations have not been reviewed. Therefore, the Department concluded in the proposed rule that it was appropriate to impose

¹⁶⁵ 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 & 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/S219458880000774a.pdf/national_primary_drinking_water_regulation_for_arsenic_a_retrospective_assessment_of_costs.pdf.

¹⁶⁶ 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 requested comment on whether additional regulations, such as significant regulations, should also be Reviewed.

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.”¹⁶⁷ This is one reason why analyses have found that sunset provisions are an effective way to improve governance and reduce undue regulatory burdens.¹⁶⁸ 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 specify 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.¹⁶⁹ An agency can also provide that its regulations expire upon the occurrence of a condition.¹⁷⁰ That is what the Department proposed

¹⁶⁷ Curtis W. Copeland, Cong. Rsch. Serv., RL32801, Reexamining Rules: Section 610 of the 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).

¹⁶⁸ Russell S. Sobel & John A. Dove, *State Regulatory Review: A 50 State Analysis of Effectiveness* 36 (Mercatus Ctr., Working Paper No. 12–18, 2012), <https://www.mercatus.org/system/files/State-Regulatory-Review-50-State-Analysis-Effectiveness.pdf>; *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.

¹⁶⁹ 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*, 862 F.3d at 9 (an agency can amend or revoke a legislative rule through notice-and-comment rulemaking).

¹⁷⁰ 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”).

in the 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.”¹⁷¹ The Department anticipates that if a regulation expires because the Department does not timely complete its regulatory review, 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 an Assessment or Review, the Department failed to consider any factors. The Department rejects such arguments. In this rulemaking, the Department is considering the important factors. For the reasons described in the proposed rule and in this final rule, 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 justified 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 will mitigate this risk by setting up two web pages on the Department’s website by the date this final rule is published; one that lists the dates of promulgation of all of its rulemakings, and a second that lists the rulemakings that contain regulations (called “Sections” in this final rule) that the Department has decided to Assess or Review. The Department will regularly update the web page listing the rulemakings containing Sections that it has decided to Assess or Review with all additional rulemakings containing Sections that it begins to Assess or Review. The Department will also create a docket on *Regulations.gov*, to which the public may direct any comments requesting that the Department begin the Assessment or Review of regulations. This requirement is described in more detail in the discussion of section [XX](h).

Therefore, in this rulemaking process, which amends Department regulations through the notice-and-comment process, the Department is considering the important factors. In addition, the Department intends to create on its website a dashboard that shows its progress on its Assessments and Reviews, including when it commenced those Assessments and Reviews, its progress, and when it expects them to be completed. The Department also intends to create a dashboard showing its progress on conducting Assessments and Reviews. See Section II.F. for more detail on the dashboard.

The Department proposed 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,¹⁷² while at least one state uses a ten-year time period.¹⁷³ The Department proposed 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 proposed rule provided that regulations promulgated more than ten years ago will expire at the end of two calendar years from the date the proposed rule, if finalized, became effective, unless an Assessment and (if required) the Review is performed on them. In the proposed rule, the Department requested public 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.¹⁷⁴ 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 upon 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 that the Department in many cases does a single regulatory impact analysis on all regulations that are issued as part of the same rulemaking. That is why the proposed rule and this final rule define “Assess” and “Review” as determinations regarding “Regulations issued as part of the same rulemaking (and any amendments or additions that may have been added thereafter)” (except that the term “Regulations” is replaced with “Sections” in this final rule). 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.” Thus, 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 final rule.

The same is true for the converse. Consider, for example, the 2015 rulemaking Preventive Controls for Human Food that established 21 CFR part 117 and also amended or revised individual regulations in Parts 1, 106, 110, 114, 120, 123, 129, 179, and 211 that were originally issued before 2015.¹⁷⁵ If the Department so chose, when the deadline approaches for Assessing and (if required) Reviewing the amended regulations in 21 CFR part

¹⁷⁴ 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 Reinvent the Act*, 33 Fordham Urb. L. J. 1199, 1222–25 (2006).

¹⁷⁵ Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food, 80 FR 55,907 (Sept. 17, 2015). <https://www.federalregister.gov/documents/2015/09/17/2015-21920/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-human>.

¹⁷¹ *Little Sisters of the Poor Saints Peter and Paul Home v. Pa.*, 140 S. Ct. 2367, 2383–84 (2020) (quoting *Motor Vehicle Mfrs. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

¹⁷² See, e.g., N.J. Admin. Code § 1:30–6.4 (2020) (regulations expire every seven years unless readopted, subject to certain exceptions); Ind. Code 4–22–2.5–2 (2020) (imposing seven-year expiration date on regulations unless readopted).

¹⁷³ N.C. Gen. Stat. 150B–21.3A (2020).

106, the Department could, as part of the same Assessment or Review, also assess or review the other regulations that were amended in this rulemaking.

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 proposed rule proposed that the Department would 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.¹⁷⁶

The Department's understanding is that the decisions based upon Reviews, including the amendment, repeal, or continuance of regulations without change, 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.¹⁷⁷ 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.¹⁷⁸

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.

The Department proposed 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,¹⁷⁹ while at least one state uses a ten-year time period.¹⁸⁰ The Department proposed 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.

Comments and Responses Regarding Section [XX](c)

HHS received the following comments on Section [XX](c) of the proposed rule.

Comment: Several commenters asked the Department to extend, from two years to five years, the timeframe for Assessment or Review of regulations that are over ten years old.

Response: The Department considered this comment, and has decided to make this change. Under this final rule, regulations that are more than ten years old when this final rule becomes effective shall expire if not Assessed and (if needed) Reviewed within five calendar years of the year that this final rule becomes effective. This will spread out the initial burden on the Department and provide the opportunity for more robust Assessments and Reviews. It also reduces any harm to reliance interests, since the public will now be on notice further in advance of the initial Assessment and Review deadlines.

Comment: Several commenters stated that the final rule should provide the Secretary with the authority to make

one-time, case-by-case exceptions to the automatic expiration of a rule.

Response: HHS appreciates this comment and has decided to include within this final rule a provision that allows the Secretary—on a non-delegable basis—to extend on a one-time, case-by-case basis the automatic expiration date of a Section by one year. The Department shall promptly publish in the **Federal Register** any such determination by the Secretary to extend the expiration date.

Comment: A large number of commenters stated that the process established in the proposed rule could result in important regulations slipping through the cracks and expiring, which could have implications for other rules. These commenters stated that the Assessment and Review process established in the proposed rule would be complicated and time-consuming to put into practice, which could result in the automatic expiration of some regulations. A large number of commenters specifically mentioned regulations at 42 CFR 435.603, on which multiple insurance affordability programs, including Medicaid and CHIP, rely to determine financial eligibility using Modified Adjusted Gross Income (MAGI) methodologies. According to the commenters, the expiration of that regulation would allow programs to redefine MAGI household and income counting rules, with no standards, consistency, or accountability, which commenters fear could wreak havoc in HHS programs. Another commenter stated that if some critical regulations, such as the Medicare health and safety standards which provide a baseline for patient safety sunset, this could threaten patient safety. A large number of commenters suggested that safeguards be put in place to ensure that regulations that are critical to the operation of safety net providers do not simply expire because an Assessment or Review was not completed in time.

Response: HHS appreciates the theoretical possibility raised by these commenters that important regulations (such as MAGI methodologies or Medicare health and safety standards) could expire inadvertently. But as explained throughout the proposed rule and in this final rule, the Department intends to timely complete the required Assessments and Reviews. As noted in the proposed rule, as an additional safeguard, in the unlikely event it appears HHS has overlooked an impending deadline, interested members of the public can raise the need to Assess or Review specific regulation through public comment. As

¹⁷⁶ 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).

¹⁷⁷ 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))).

¹⁷⁸ 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).

¹⁷⁹ 85 FR 70,105.

¹⁸⁰ *Id.*

an additional safeguard, the Department adds in this final rule that if, prior to the expiration of a Section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under this final rule, the Secretary may continue the Section in force one time for a period stated in the determination, which period shall not exceed one year.

Comment: Several commenters expressed concern about the precedent created by an automatic expiration date, which they believe could allow future administrations to reject regulations by simply letting them lapse. These commenters stated that this scenario would allow the Department to bypass the regulatory process and deprive the American people of the opportunity for comment and input.

Response: HHS respectfully disagrees that this is a significant enough risk to outweigh the tremendous benefits from retrospective review. The commenters' concerns assume a lack of good faith by future administrations. There would also likely be a tremendous public outcry if many beneficial regulations were permitted to expire.

This final rule does not bypass the regulatory process or deprive the American people of the opportunity for comment and input. In this rulemaking, the Department is going through the APA's ordinary notice-and-comment process. This final rule reflects that the Department accepted and considered over 500 public comments on the proposed rule. The Department also held a public hearing on the proposed rule and considered the comments made there in promulgating this final rule. In addition, this final rule institutionalizes an ongoing opportunity for public comment during this regulatory review process.

Comment: Several commenters stated that public harm could result from removing regulations that protect the public health and consumers. A few commenters suggested that the Assessments and Reviews conducted by the Department should specifically consider consumer protection.

Response: For the reasons explained in the preamble and regulatory impact analysis for this final rule, this final rule implements a process by which the Department will Assess and Review its regulations. HHS intends to undertake a careful Assessment, and (if necessary) Review of each regulation subject to this final rule to determine if the regulation should be continued without change, amended, or rescinded. HHS has no intention to rescind regulations that

appropriately protect the public health or consumers. Reviews will consider the factors described in 5 U.S.C. 610(b) (as well as whether the regulation complies with applicable law). These are the factors that Congress directed the Department to consider when periodically reviewing regulations that have a SEISNOSE. Considerations with respect to consumer protection will often be subsumed in this analysis.

Comment: A few commenters suggested that instead of the proposed timeframe for review, the Department should instead Review regulations on a rolling basis but not less than 10 years from the date of first promulgation or substantial amendment.

Response: HHS respectfully disagrees. Clear and specific deadlines are needed to ensure the efficacy of this rule and to secure robust retrospective review of agency regulations. Moreover, the commenters' suggestion that review occur no less than 10 years from the date of promulgation or substantial amendment is, in the Department's view, an undue time lapse. It threatens to leave long outdated and burdensome regulations in place for too long.

Comment: One commenter stated that the proposed timeline for reviewing regulations is inconsistent with the proposed rule's goal of reviewing regulations based on the likelihood of their obsolescence. This commenter stated that the proposed rule assumes that the passage of time increases the likelihood of regulatory obsolescence, but the proposed rule defines a Regulation's age based on the date on which it was originally promulgated, regardless of subsequent amendments. Therefore, some regulations that have been subsequently amended could reach their time for review earlier than regulations that were promulgated and never amended. For example, a Medicaid regulation first adopted in 1968 but revised repeatedly and as recently as 2020 would need to be Assessed, possibly Reviewed, and possibly revised again even though it was just amended.

This commenter said this timing is also incongruent with specific provisions in the RFA. The RFA defines a "rule" to include "any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b)," which explicitly includes regulatory amendments. See 5 U.S.C. 553(b) and 551(5). The commenter stated that this statutory provision requires the proposed rule's "clock" for 10-year review to be reset based on the most recent regulatory amendment that went through APA notice and comment procedures.

Response: HHS respectfully disagrees. As an initial matter, 5 U.S.C. 610 refers to review "within" ten years; it does not foreclose reviewing regulations sooner. Second, this rule seeks to balance the desire to review older regulations first, while also specifying clear, easily-ascertainable deadlines for Assessments and Reviews. It would be harder for the Department and the public to determine the Assessment and Review deadlines if the deadlines changed each time a regulation were amended. Providing that the "clock" begins to run from the year a Section was first promulgated is a reasonable way to balance these considerations. Tying deadlines to the amendments of Sections threatens to make the rule completely unwieldy—leaving an open question of when certain parts of a rule are up for Assessment and Review.

Also, as explained in the proposed rule, if the Department is amending a regulation close in time to its ten-year Assessment or Review date, then the Department can conduct Assessment and Review alongside the amendment, thereby restarting the ten-year clock if it publishes the findings in the **Federal Register** in the manner specified in this final rule.¹⁸¹

Amendments to Section [XX](c)

After considering the public comments on the two year time period to Assess and (if required) Review regulations that are more than ten years old, the Department has decided to extend this time period to five calendar years after the year that this section first becomes effective. Furthermore, in this final rule the Department amends section [XX](c) to read "this chapter," rather than "this title," as was used in the proposed rule. The Department makes this change to conform to the fact that this final rule amends certain chapters, rather than entire titles. The Department finalizes sections [XX](c)(1)–(2) as amended.

ii. Section [XX](c)(3)

After considering the public comments received on the proposed rule, the Department decided to add a new Section [XX](c)(3) to this final rule.

Section [XX](c)(3) states that if, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time

¹⁸¹ 85 FR 70105.

for a period stated in the determination, which shall not exceed one calendar year. This final rule requires the Department to promptly publish any such written determination in the **Federal Register**. The authority of the Secretary to make this written determination is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law. This provision, like other provisions of this final rule, is severable.

The Department adds this provision so that, if a pandemic, emergency, or other development arises that prevents the Department from timely Assessing or Reviewing certain Sections and the public interest requires their continuation, the Department can have additional time to Assess and (if needed) Review those Sections.

A. Section [XX](d)

HHS proposed in Section [XX](d) of the proposed rule that the Department would be 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 proposed rule stated that 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 benefits."¹⁸² 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.¹⁸³ 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.

Proposed section [XX](d) of the proposed rule provided 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 included it in the proposed rule to clarify that determining the continued need for a regulation includes determining the extent to which it defines terms or sets standards used in or otherwise applicable to other Federal rules. However, this was not meant to be the only factor the Department should consider when determining the continued need for a regulation. Under the proposed rule, the Department shall consider any factors that, for a 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) of the proposed rule were not found in 5 U.S.C. 610. The first is that section [XX](d) of the proposed rule stated that the Review should take into account "whether the Regulation complies with applicable

law." Since applicable law may have changed since a 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) of the proposed rule stated that the Review should take into account "other considerations as required by relevant executive orders and laws." The proposed rule stated that to the extent Executive Orders or laws enacted since the RFA 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). Upon further consideration, the Department has decided not to finalize this seventh factor. First, this factor is not included in the RFA.¹⁸⁴ Second, this factor is potentially unclear and could be open to multiple interpretations. Third, this final rule already requires the Department to consider whether the rulemaking complies with applicable law. Thus, the seventh factor is not only susceptible to multiple interpretations, but seems largely (if not entirely) subsumed by other factors in this final rule.

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 regulations were promulgated to potentially discern the impact of the regulation on small entities and on society more generally.

Section [XX](d) of the proposed rule requires that only 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.

Comments on Section [XX](d)

HHS received the following comments on Section [XX](d) of the proposed rule.

Comment: Several commenters suggested that HHS consult with trade

¹⁸² 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).

¹⁸³ OIRA may also coordinate inter-agency participation in the Assessment process where there are significant inter-agency equities or as otherwise appropriate.

¹⁸⁴ The RFA also does not include "whether the Regulation complies with applicable law" as a factor. But it seems uncontroversial to require the Department to consider whether its regulations comply with applicable law, and this phrase has a clear meaning.

groups and other specialty societies to consider the policy recommendations of providers and others in the healthcare industry to understand the implications of modifying or rescinding existing regulations. Some of these commenters brought up certain regulations for which they care deeply and would like to see rescinded or maintained.

Response: HHS appreciates these comments and wishes for the public to have the opportunity to provide meaningful feedback on regulatory changes that the Department may consider as it conducts its Assessments and Reviews. To achieve that goal, the proposed rule, as finalized, includes a process of soliciting robust public comments and feedback, which HHS will consider and incorporate into its Assessment and Review decisions. As stated in [XX](d)(2), “[t]he nature of complaints or comments received concerning the Regulation from the public” is one of the factors that the Department is required to consider under this rule when it conducts its Assessments and Reviews. HHS is committed to ensuring that the public has ample opportunity to opine on its regulations, and looks forward to thoughtfully considering public comments during the regulatory review process resulting from this final rule.

Comment: A few commenters stated that the Department’s process for reviewing regulations that have a SEISNOSE was unclear from the proposed rule. These commenters asked that the Department provide at least one example of how factors would be considered and how HHS would conduct its decision-making process.

Response: Based in part on these comments, in this final rule the Department removes the final factor specified in the proposed rule (“other considerations as required by relevant executive orders and laws”). The Department does so because this factor’s meaning could be unclear, it is not in the RFA, and it adds little beyond what is already more clearly stated in other factors, such as whether the rulemaking complies with applicable law. Beyond removing this factor, HHS respectfully declines to provide additional clarity within this final rule as to the exact contours of the Review process. As explained in the proposed rule, the Review takes into account factors that already exist under 5 U.S.C. 610(b), along with a consideration of whether the rulemaking complies with applicable law, a factor whose meaning is clear and uncontroversial. It is anticipated that the Review process will track the Department’s and other agencies’ past practice with respect to

Section 610 analyses. In particular, examples of Section 610 reviews conducted by the EPA are instructive on how the Department anticipates the five factors set forth in 5 U.S.C. 610(b) will be analyzed.¹⁸⁵ The Review decision-making process will be implemented in a manner appropriate for the regulation in question, including but not limited to input from subject-matter experts within the Department and the public.

Comment: A few commenters asked for clarification regarding the Department’s decision-making process as to whether a regulation would be identified as requiring a rescission or amendment based on the factors provided. For example, if HHS were to identify overlap or duplication between a regulation under Review and other Federal regulations, how would HHS assess the factors to make a decision to rescind or amend? These commenters also asked for clarification on how the Department would determine that a regulation is duplicative.

Response: The factors specified in the final rule will be balanced, and a determination as to whether to amend or rescind a Section will be made on a case-by-case basis. No one factor by itself is dispositive (unless the Section does not comply with applicable law). The balancing of a series of considerations, sometimes complex and wide-ranging, is inherent in the Department’s policy-making functions, even beyond the context of the Review process set out in this final rule. In the prior comment, the Department provided examples of how the Reviews will consider the relevant factors. The concept of regulatory duplication, which has been in the RFA, 5 U.S.C. 610(b)(4) for over forty years, is largely self-explanatory. A regulation may be considered duplicative, if, for instance, it serves the same function or overlaps with another regulation.¹⁸⁶ Amending or rescinding duplicative regulations

can reduce complexity and regulatory burden.

Comment: Some commenters asked HHS to clarify how it would consider public comments about a regulation, and whether there would be numerical or content benchmarks that HHS would use to guide its decision-making regarding the public feedback it receives.

Response: The Department will create dockets on *Regulations.gov* for its Assessments and Reviews, and the public may submit comments to those dockets in the same manner as it can submit comments on notices of proposed rulemaking. The Department’s Reviews will be holistic and consider the five factors specified in 5 U.S.C. 610(b), as well as compliance with applicable law. No one factor by itself is dispositive (unless the Section does not comply with applicable law). The weight that the Department gives to comments will be a case-by-case determination. For example, fifty complaints about a major rule that also had 500 supportive comments might not counsel in favor of amending or rescinding the rule. But fifty complaints about a rule that had no comments supporting it might weigh in favor of amendment or rescission, particularly if the other section 610 factors do not counsel strongly in favor of continuing the regulation without change. The public-comment process, and how much weight to give to various comments, is familiar to the Department and the public from the many instances of public comment on Department policymaking actions. A similar standard will be applied here.

Accordingly, the Department finalizes section [XX](d) of the proposed rule as proposed, except that it removes (d)(7), which proposed that Reviews consider “[o]ther considerations as required by relevant executive orders and laws.” Moreover, in the finalized section [XX](d), the Department replaces the term “Regulation” with “rulemaking.” This is in response to comments previously discussed expressing concern about potential ambiguity caused by the use of the term “Regulation.” This change is also made to conform section [XX](d) to the fact that “Reviews” are defined as determinations as to “whether Sections¹⁸⁷ 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, amended, or rescinded. Reviews are therefore not of individuals sections but of the sections

¹⁸⁵ See *Results of EPA’s Section 610 Review of the Final Rule for Control of Emissions of Air Pollution from Nonroad Diesel Engines and Fuel*, EPA Off. of Transp. & Quality (Sept. 2014), <https://www.regulations.gov/document?D=EPA-HQ-OAR-2013-0642-0003>; *Regulatory Flexibility Act Section 610 Review of the National Pollutant Discharge Elimination System (NPDES) Permit Regulation and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFOs)*, EPA Off. of Water (June 3, 2014), <https://www.regulations.gov/document?D=EPA-HQ-OW-2012-0813-0216>; *Results of EPA’s Section 610 Review of the Final Rule for Lead; Renovation, Repair, and Painting Program*, EPA Off. of Pollution Prevention and Toxics (Apr. (April 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0126-0019>.

¹⁸⁶ *Duplicative*, Black’s Law Dictionary (11th ed. 2019) (defining “duplicative” as “Having or characterized by having overlapping content, intentions, or effect”).

¹⁸⁷ “Regulations” in the proposed rule.

issued as part of the same rulemaking. Thus, this revision to section [XX](d) is made for clarity but is not a substantive change from the proposed rule.

Section [XX](e)

In the proposed rule, HHS proposed 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. The proposed rule further stated that 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 included this provision in the proposed rule 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 will have already conducted a Review of the Regulation. In circumstances where amendment is not feasible within that time period, the proposed rule stated that the Secretary could 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.

As stated in the proposed rule, 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 noted 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.”¹⁸⁸

Comments on Section [XX](e)

HHS received the following comments on Section [XX](e) of the proposed rule.

Comment: Some commenters stated that the Department should limit the length of time for amending or rescinding a Regulation from two years with three one-year extensions for a total of not more than five years to two years with the possibility to extend for one year (for a total of not more than three years). One commenter also stated that the current text is ambiguous as to whether it is a maximum of five years (two years plus three one-year extensions) or a maximum of seven years (two years plus five one-year extensions).

Response: HHS appreciates these comments and, in this final rule, modifies the rule’s text to clarify that, if a Review concludes that a Section should be amended or rescinded, the maximum time for amending or rescinding the Section (including all possible extensions) is five years. That is, there is a two-year period to amend or rescind, which can be extended no more than three times for one year each time.

The Department believes the two-year default period is appropriate and declines to further limit the number of possible extensions. If the Department concludes that a regulation should be amended or rescinded, it does not want to unduly delay doing so. The Department believes that two years will generally be an adequate amount of time to amend or rescind such regulations, since the Department has already Reviewed them. However, given the complexity of some Department regulations and competing priorities, in some circumstances it may not be feasible to amend or rescind a regulation within two years. In circumstances where amendment or rescission 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 no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

Accordingly, after considering the public comments, the Department chose to clarify the language in section [XX](e) of the proposed rule with respect to the time period for extension of the completion of an amendment or rescission. Where the proposed rule stated that the Secretary “may extend the completion date by one year at a time for a total of not more than five years,” the final rule clarifies that the Secretary “may extend the completion

date by one year at a time, *no more than three times*, for a total of not more than five years (*inclusive of the initial two-year period*)” (emphasis added). This change does not alter the time period for extending the completion date of an amendment or rescission, but HHS believes that this language clarifies the length of time that the completion may be extended. The Department finalizes Section [XX](e) of the proposed rule, with this clarifying language.

Section [XX](f)

Section [XX](f) of the proposed rule provided 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 proposed rule stated that 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. It further proposed that 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 included this requirement in the proposed rule so that both the Department and the public could 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) was proposed to 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.

The proposed rule stated that 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 incorporated ACUS’

¹⁸⁸ *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

suggestion that “[a]gencies should 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.”¹⁸⁹ 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).¹⁹⁰

Section [XX](f) of the proposed rule 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.

Comments on Section [XX](f)

HHS received the following comments on Section [XX](f) of the proposed rule.

Comment: A few commenters suggested that the results of each Assessment and Review should be published separately in the **Federal Register** as they are completed, with a title clearly identifying the affected regulation and the Department’s responses to the public comments received.

Response: HHS respectfully disagrees that the results should be published on a rolling basis. Announcing the results of all Assessments and Reviews within a single document makes it easier for the public (and the Department) to determine (1) which Sections were Assessed and Reviewed, (2) the dates by which they were Assessed and Reviewed, and (3) when they next need to be Assessed and (if needed) Reviewed. Interested parties need only refer to a single source of information for a given year. Publishing all Assessments and Reviews for a given year in a single document also reduces the risk that a Section will inadvertently expire.

The commenters’ concerns about the Reviews including the Department’s responses to public comments was already addressed in the proposed rule. Section [XX](d) of the proposed rule directed the agency to consider, as part of Reviews, “the nature of complaints or comments received concerning the Regulation from the public.” And the document published in the **Federal Register** shall include 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.” Section [XX](d)’s requirement to consider the nature of complaints or comments only applies to Reviews, not Assessments. Assessments are preliminary determinations that only focus on whether a rule making has a SEISNOSE, and do not require as extensive an analysis as Reviews. If the Department receives comments during the Assessment process, it would endeavor to take them into account in determining whether a rule making has a SEISNOSE. Moreover, as the proposed rule proposed,¹⁹¹ the document published in the **Federal Register** will be organized in a manner that enables both the Department and the public to readily determine which Assessments and Reviews were conducted during each calendar year.

Comment: Some commenters stated that the Department should commit to publishing results of Reviews as they are completed, or on no less than a monthly basis, so that the interested public can truly contemplate each regulation now in question.

Response: The Department intends to publish the results of the Assessments and Reviews in the dockets for the applicable regulations. However, as compared to publishing Assessments and Reviews in the **Federal Register** on a rolling basis, announcing the results of all Assessments and Reviews within a single document makes it easier for the public (and the Department) to determine (1) which Sections were Assessed and Reviewed, (2) the dates by which they were Assessed and Reviewed, and (3) when they next need to be Assessed and (if needed) Reviewed. Interested parties need only refer to a single source of information for a given year. Publishing all Assessments and Reviews for a given year in a single document also reduces the risk that a Section will inadvertently expire. The Department will announce on a periodic basis when it has

commenced the process of performing an Assessment or Review.

Comment: A few commenters asked what role the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB) would have in reviewing the reports, and any proposed revisions to standing regulations.

Response: As noted in the proposed rule, “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.”¹⁹²

Accordingly, after considering the public comments, HHS finalizes section [XX](f) as proposed.

Section [XX](g)

HHS proposed in Section [XX](g) of the proposed rule that paragraph (c) of the proposed rule would 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 proposed rule stated that the Federal law described shall be cited in the notice of adoption. Section [XX](g) of the proposed rule also provided that paragraph (c) of the proposed rule would 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) of the proposed rule excepted 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 final rule, the Department shall describe in the Regulation’s notice of adoption the Federal law that results in

¹⁸⁹ 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 final rule incorporates several ACUS’ recommendations, it does not incorporate all of them. This final rule does not set forth a prioritization scheme, although the Department intends to subsequently set forth a schedule for conducting Assessments and Reviews.

¹⁹⁰ 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.”).

¹⁹¹ See, e.g., 85 FR 70121.

¹⁹² 85 FR 70108.

the Department having no discretion as to whether to promulgate the Regulation and what is prescribed by the Regulation. The proposed rule included this requirement so the public has notice that such Regulations are exempt from section [XX](c).

Section [XX](g) of the proposed rule likewise also exempted 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) of the proposed rule 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) of the proposed rule also exempted the proposed rule from section [XX](c). Assuming that no rules expire due to lack of Assessment or Review, the proposed rule stated that this rule cannot, absent other actions, directly impose on the public costs that exceed benefits, since the proposed rule merely would require 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). The proposed rule stated that it 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 would not apply to the 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 proposed that it would take that into account when performing Assessments and Reviews. The Department proposed that it 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 stated in the proposed rule that it 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. Accordingly, the Department proposed to exempt the proposed rule from Section [XX](c).

The Department also proposed in Section [XX](g) of the proposed rule to exempt Regulations that involve a military or foreign affairs function of the United States. For purposes of the proposed rule (as well as in this final rule), “a military or foreign affairs function of the United States” has 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 were exempted from the proposed rule for the same reasons that Congress exempted them from the requirements of 5 U.S.C. 553.

Section [XX](g) of the proposed rule also exempted Regulations addressed solely to internal agency management or personnel matters and Regulations related solely to Federal Government procurement. Because such Regulations do not directly impact the public, the rationale for retrospective review is weaker with respect to these Regulations.

The portion of the proposed rule applying to Title 42 also exempted 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 proposed to exempt this regulation because it was 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 exempted 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 was no need for the proposed rule to apply to 42 CFR part 73. Similarly, the portion of the proposed rule applying to Title 42 also exempted the annual Medicare Part A and Part B payment methodology update rules. Since these rules are amended annually, it does not make sense to Review them every ten years. Lastly, the portion of the proposed rule applying to Title 42 also exempted 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). For these reasons, these regulations are also exempted from this final rule.

Section [XX](g) of the proposed rule also exempted 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 regulations issued with other agencies because of a legal requirement to consult with those other agencies are the regulations issued jointly by the Department and the Departments of Labor and the Treasury in accordance with section 104 of the Health Insurance Portability and Accountability Act (HIPAA). This provision 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.¹⁹³ An example of jointly-issued regulations are regulations governing State innovation waivers under section 1332 of the

¹⁹³ *See* Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, 110 Stat. 1936 (1996).

Patient Protection and the Affordable Care Act.¹⁹⁴

The Department retains these exemptions for the reasons discussed in the proposed rule. For the reasons discussed below, this final rule also exempts certain other regulations from this final rule.

Comments on Section [XX](g)

HHS received the following comments on Section [XX](g) of the proposed rule.

Comment: Several commenters asked for further clarity on the proposed exemptions from the proposed rule. These commenters stated that it is unclear how the public would know which regulations are eligible for an exemption under the proposed rule. They suggested that the Department may be interpreting “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 in the Regulation” very narrowly, because the proposed rule stated that it is “rare” that the Department has “no discretion as to whether to promulgate [a] regulation and what is prescribed by the regulation.”¹⁹⁵ These commenters stated that the examples given in the proposed rule were insufficient and open to interpretation, and members of the public should not be expected to be able to conduct their own statutory analysis. Some commenters specifically asked for at least one example of a regulation that would be exempted under this rule. Commenters also asked for examples of regulations that “were issued in consultation with other agencies because of a legal requirement to consult with that other agency.”

Response: The Department thanks these commenters for their comments. Regulations that “involve a military or foreign affairs function of the United States” are regulations that would satisfy that standard under 5 U.S.C. 553(a)(1). “Regulations addressed solely to internal agency management or personnel matters” refers to regulations that would satisfy the “matter relating to agency management or personnel” standard under 5 U.S.C. 553(a)(2).¹⁹⁶

An example of regulations issued with other agencies because of a legal

requirement to consult with those other agencies are the regulations issued jointly by the Department and the Departments of Labor and the Treasury in accordance with section 104 of HIPAA. This provision 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 PHS Act) are administered to have the same effect at all times.¹⁹⁷ Such regulations constitute a small percentage of the Department’s overall number of regulations (although they may have an outsize impact), and the Department is not aware of many regulations outside those promulgated pursuant to the relevant HIPAA provisions that would satisfy this exception. 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 in the regulation is also a very small category.

Comment: A few commenters stated that it was disingenuous for HHS to specifically decide to exempt this rule from the assessment and review process. These commenters stated that this decision is at best disingenuous or at worst an attempt to permanently impose a rigid review structure.

Response: HHS respectfully disagrees. This final rule does not permanently impose a rigid review structure, because this rule can be amended or rescinded under the APA. As explained in the notice of proposed rulemaking, the nature of this rule means that “the rationale for periodic review does not apply to this proposed rule to the extent it applies to other Department regulations.”¹⁹⁸ This final rule would not become obsolete due to economic, technological, or legal changes the way that many other rules can.

Comment: Several commenters stated that they do not want the annual Notice of Benefits and Payment Parameters (NBPP) rule to be subject to this rule.

Response: The Department agrees and has decided to exempt the annual Notice of Benefit and Payment Parameters update rules. Just as the proposed rule exempted the annual Medicare payment rules, this final rule need not apply to NBPP rules that are already reviewed and updated annually. The 2021 NBPP annual rules can be found at 85 FR 29164 (May 14, 2020).

These and the equivalents for other years are exempt from this final rule.

Final Section [XX](g)

Based in part on comments, the Department has decided in the portion of the final rule applying to Title 21, Chapter I to also exempt the following provisions from this final rule:

- 21 CFR parts 131, 133, 135–137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163–166, 168, 169.
- 21 CFR parts 331–333, 335–336, 338, 340–341, 343–344, 346–350, 352, 355, 357, 358.
- 21 CFR parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, 892, 895, 898.

Based in part on comments, the Department decided in the portion of the file rule applying to Title 45, Subchapter A, to also exempt the annual Notice of Benefit and Payment Parameters update rules.

The first three bullets encompass FDA’s food standard, device-specific, and over-the-counter drug regulations that specify characteristics of certain foods, devices, and over-the-counter drugs. These are regulations that specify the characteristics of particular foods, devices, and over-the-counter drugs. Many of the device regulations are already required to be reviewed in some way every five years.¹⁹⁹ Similarly, FDA is already undergoing a process to establish a set of general principles for food standards for FDA to use when considering whether to establish, revise, or eliminate a food standard.²⁰⁰ Thus, there is less need to review these regulations every ten years, since these are being reviewed, or new processes for reviewing these regulations are being established. In addition, the exempt food standard, device, and OTC drug regulations simply create product identities.

As explained *supra*, the annual Notice of Benefit and Payment Parameters update rules are also now being exempt because those are already updated

¹⁹⁹ See, e.g., 21 U.S.C. 360(l) (providing that “at least once every 5 years thereafter, as the Secretary determines appropriate, the Secretary shall identify, through publication in the **Federal Register**, any type of class I device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness”; 21 U.S.C.(m) (providing that the Secretary, “at least once every 5 years thereafter, as the Secretary determines appropriate [] publish in the **Federal Register** a notice that contains a list of each type of class II device that the Secretary determines no longer requires a report under subsection (k) to provide reasonable assurance of safety and effectiveness”).

²⁰⁰ See <https://www.federalregister.gov/documents/2020/04/20/2020-08182/food-standards-general-principles-and-food-standards-modernization-extension-of-comment-period>.

¹⁹⁴ See, e.g., 77 FR 11700 (Feb. 27, 2012).

¹⁹⁵ 85 FR 70109.

¹⁹⁶ See, e.g., regulations amended in Update of Organizational References, 50 FR 8993 (Mar. 6, 1985) (“Because these amendments related to internal agency management and personnel and because the amendments are not substantive, the rule is exempt from the notice and comment and delayed effective date requirements of section 553(b) and (d)(3) of the Administrative Procedure Act”).

¹⁹⁷ See Health Insurance Portability and Accountability Act of 1996, Public Law 104–191, 110 Stat. 1936 (1996). See also 85 FR 70110.

¹⁹⁸ 85 FR at 70109.

annually. Thus, there is no need to Assess or Review them every ten years.

In addition, whereas the proposed rule exempted in Title 42 the “annual Medicare Part A and Part B payment methodology update rules,” this final rule exempts the “annual Medicare payment update rules.” All annual Medicare payment update rules are revised annually, so there is no need to require Assessment or Review of them every ten years.

Other than adding or revising these exemptions and changing the term “Regulation” to “Section,” the Department finalizes Section [XX](g) as proposed.

Section [XX](h)

HHS proposed in Section [XX](h) of the proposed rule 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. As proposed, the public would be able to submit comments regarding these Regulation(s) in the manner specified on this website. HHS proposed that members of the public could 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 included this provision in the proposed rule so that, when the Department is Assessing or Reviewing a regulation, the public can submit comments for the Department’s consideration. The Department stated in the proposed rule that it believes this will maximize transparency, public participation, and the Department’s knowledge of the real-world impacts of its regulations.

The Department also proposed in this provision to allow the public to submit comments on the Department website requesting that the Department begin the Assessment or Review of a regulation. The Department stated that it considered the risk that a regulation could expire because the Department inadvertently did not Assess or Review it. The Department proposed 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 request that the Department to conduct the Assessment or Review.

The Department stated in the proposed rule that it intends to timely Assess and, where required, Review all its regulations. The Department noted, 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.

Comments on Section [XX](h)

HHS received the following comments on section [XX](h) of the proposed rule.

Comment: Several commenters questioned the adequacy of the proposed process for soliciting comments on the regulations that are reaching their time for Assessment or Review. Some of these commenters stated that the public should be given ample notice of upcoming Assessments and Reviews, and a clear and adequate timeframe for providing comments. Other commenters expressed concern about the process of posting information regarding Assessments and Reviews to a Department-managed website. Some commenters stated that instead of providing notice of Assessments and Reviews and instructions on how to submit public comments exclusively on a Department-managed website, the Department should also put this information on the **Federal Register**.

Several commenters stated that members of the public should not be responsible for monitoring an HHS website to see if Assessment or Review of a particular regulation is commencing. Some commenters cited the added expense on the regulated industry that would be created if an additional review process is created by this rule, which would disproportionately fall on small businesses. One commenter even suggested this was a purposeful decision by the Department to create a system that favors well-funded special interests that can afford lawyers and lobbyists to advocate for their favored policies. Commenters stated that although HHS proposes to create a website to enable the public to comment and request a review when the deadline for assessing a rule is approaching, this website would not be governed by APA rules and the Department would not be required to meaningfully respond to those comments. Commenters stated that, as a result, rules that govern the administration of Medicaid and CHIP

and affect access to care for millions of beneficiaries could automatically expire without public comment.

A potential solution suggested by one commenter is that the Department could include in the final rule a requirement that it include a notice of all regulations scheduled for review during the next 12 months in its semi-annual regulatory agendas published in the **Federal Register**. This commenter also suggested that HHS publish semi-annually in the **Federal Register** a list of regulations that are scheduled to expire in the next 12 months if they are not Assessed and Reviewed.

Other commenters requested clarification on how HHS will treat the comments it receives. For example, some commenters asked whether the comments would be included as a part of the public record. Other commenters mentioned that the proposed rule does not clarify whether HHS will be required to respond to all comments made by the public. These commenters asked the Department to ensure that it publicly display the comments it receives.

Response: The Department appreciates these comments and seeks to minimize costs for the public. Accordingly, this final rule makes some revisions in response to these comments. Under this final rule, when the Department commences the process of performing an Assessment or Review, it shall state on a Department-managed website the Section(s) whose assessment or Review it is commencing. It shall also announce once a month in the **Federal Register** those new Assessments or Reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each Assessment or Review that the Department is conducting. These docket numbers will be referenced in the **Federal Register** announcements. The public will be able to submit comments to the dockets of each rule making being Assessed or Reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department Assess or Review a regulation. These changes address the concern about putting the information on a Department website, rather than in the **Federal Register**. The Department anticipates that the process will be similar to that currently used by the EPA.²⁰¹ The Department also intends to

²⁰¹ See, e.g., Regulatory Flexibility Act Section 610 Review of the Testing and Labeling Regulations Pertaining to Product Certification of Children’s

publish the results of the Assessments and Reviews in the dockets for the applicable regulations.

Separately, in conjunction with this final rule, the Department is placing at <https://www.hhs.gov/regulations/federal-registry/index.html> a list of Department rule makings, the year they were initially promulgated, the last year the rule making was amended, and the **Federal Register** citation from the time the rule making was last amended. This list was generated with artificial intelligence and the Department believes it is accurate, but it is conceivable that some Department regulations are not included. This list includes all Department regulations, including those that may be exempt from this final rule. The Department believes it would be informative to the public to provide a list of all Department regulations, as well as their **Federal Register** citations and promulgation dates. The Department intends to update this list annually with newly-issued regulations. The schedule for Assessment and Review is discussed in Section II.F.

HHS disagrees that this final rule is for the benefit of well-financed special interests. As the Department observed in the proposed rule, empirical evidence confirms that, due to the inherent advantage from economies of scale, large, well-capitalized entities are better positioned to absorb compliance costs than small entities.²⁰² By announcing Assessments and Reviews on *Regulations.gov*, and putting the dockets for Assessments and Reviews on *Regulations.gov*, this final rule reduces the costs associated with having to monitor two separate websites. The regulatory impact analysis for this final rule addresses the estimated impacts for this final rule, including monitoring and comment costs.

Comment: A few commenters suggested that instead of the process set forth in the proposed rule, HHS should provide a means of soliciting public comment at least every ten years on the Department's existing rules, which the Department would then be required to consider.

Response: The Department is incorporating aspects of this suggestion. This final rule makes the nature of complaints or comments on a regulation one of the factors to be considered when performing Reviews. But the commenters' suggestion by itself would not be adequate to address the problem. The Department's rules have always

been open for public comment under 5 U.S.C. 553(e), yet only limited retrospective review has taken place, contrary to Congressional intent. The suggestion that the Department take a passive role in retrospective review is inconsistent with the RFA, which intends for HHS to engage in this analysis on its own initiative.

Comment: Several commenters stated that, according to the process set forth in the proposed rule, it would be difficult, if not impossible, for the public to accurately determine whether a regulation is subject to an Assessment, and if so, the deadline for informing the agency and commenting. These commenters surmise that there could be scenarios where a regulation was not Assessed, but it is unclear whether it has expired or was exempt from the regulatory review process and is still in place. This could leave regulated entities subject to the regulation without guidance on what is expected of them, or could result in regulations being inadvertently removed with negative impacts on beneficiaries, consumers, and the public in general.

Response: The Department respectfully disagrees. Again, as stated above, the Department intends to timely Assess and (if needed) Review its regulations. This final rule provides that un-Reviewed and un-Assessed Sections expire based on the time elapsed since the Year of the Section's promulgation. To aid the public, in conjunction with this final rule the Department is placing at <https://www.hhs.gov/regulations/federal-registry/index.html> a list of Department rule makings, the year they were initially promulgated, the last year the rule making was amended, and the **Federal Register** citation from the time the rule making was last amended. This list was generated with artificial intelligence and the Department believes it is accurate, but it is conceivable that some Department regulations are not included. This list is meant to be an aid to the public and the Department, but the **Federal Register** and Code of Federal Regulations are what have legal force and determine the dates of promulgation. Moreover, a regulated entity can use the **Federal Register** and Code of Federal Regulations to determine the year in which a Section was promulgated. From there, the regulated entity can determine the year by which a Section must be Assessed and (if needed) Reviewed. The regulated entity can consult the **Federal Register** document containing the findings of the Department's Assessments and Reviews from that year to determine if the Section was timely Assessed and (if needed) Reviewed.

This is less burdensome than many legal research activities that regulated entities need to do to determine whether they are in compliance with the law. Regulated entities frequently must determine whether a particular statute or regulation is still in effect, has been amended, or whether there is a proposed change to the statute or regulation before Congress or in front of an agency.

Comment: Several commenters had comments related to APA petitions. A commenter stated that the APA also includes a process for the public to petition for retrospective review of existing rules. See 5 U.S.C. 553(e). Other commenters noted the APA does not specify the process for receiving petitions. As a result, according to the commenters, how petitions are received and treated varies across—and even within—agencies. These commenters stated that to date, HHS has not adopted any particular regulations concerning the form that petitions under section 553(e) must take. Nor has HHS adopted recommendations by the Administrative Conference of the United States for receiving, processing, and responding to petitions. A few commenters noted that they had submitted petitions but no action had been taken to date on their request. For example, one commenter stated that it filed citizen petitions in August 2016 and February 2017 asking the agency to remove outdated recordkeeping requirements. Another commenter stated that in February 2018 it commented to the Food and Drug Administration Center for Veterinary Medicine (CVM) on regulations that the commenter claimed are outdated or needing improvement.

Response: The Department respectfully disagrees with the commenters' suggestion that the petition mechanism in 5 U.S.C. 553(e) somehow undercuts or forecloses this final rule. Indeed, the substantive point of these comments—that the agency should retrospectively review its rules to determine whether amendment or rescission is necessary, especially where pressed to do so by the public—is fully consistent with this final rule. The commenters who stated they petitioned the Department to amend or rescind regulations, yet the Department took no action, further supports why this final rule is needed (although the Department takes no position in this final rule on whether any particular commenters' petition had merit).²⁰³ The comments

Products, Including Reliance on Component Part Testing, 85 FR 52078 (Aug. 24, 2020).

²⁰² 85 FR 70118 & n.145.

²⁰³ See also Maeve P. Carey, Cong. Rsch. Serv., R46190, Petitions for Rulemaking: An Overview 1 (2020) (describing § 553(e) as “arguably

suggest the Department is not examining its existing regulations as often as is desired. Moreover, 5 U.S.C. 553(e)'s petition process does not make this final rule unnecessary, because there is reason to believe that even some rules that have not been the subject of any petitions would benefit from amendment or rescission.²⁰⁴ The literature and the Department's experience suggest that large numbers of regulations are having impacts that, over time, differ from what was estimated at the time of promulgation.

Some HHS components have regulations governing petitions.²⁰⁵ But whether the Department should have additional or different petition procedures is outside the scope of this final rule, which, like 5 U.S.C. 610, operates independently of 5 U.S.C. 553(e)'s petition process.

Comment: Some commenters stated that it was arbitrary for HHS to not meaningfully consider other "strong incentives" to revisit its own rules besides the process it proposes. For example, commenters suggested that HHS could have explored creating a petition process whereby parties could request review of certain rules, or could have convened a Federal Advisory Committee to advise the Department on which rules merit review. In both these scenarios, HHS could incentivize itself to act by giving parties a right of judicial review if the Department failed to respond to a petition or a Committee recommendation.

Response: HHS respectfully disagrees. The APA itself already affords a process for petitioning for review of rules. 5 U.S.C. 553(e) ("Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule."). And denials of such petitions may be subject to the APA's judicial review procedures.²⁰⁶ Notwithstanding the existence of section 553(e), comprehensive retrospective review of agency rules has not taken hold. The literature suggests large numbers of Department regulations are having impacts that differ from their estimated impacts. It is unlikely that a Federal Advisory

Committee could undertake the scale of review needed to comprehensively advise on which regulations merit review.

Comment: Some commenters stated that the Department should provide clear notice to the public of when a Regulation may be about to expire, and provide actual notice of rescissions.

Response: The Department reiterates its previous response to a similar comment. The Department intends to timely Assess and, where required, Review all its regulations. However, if the Department has not announced that it is Assessing or Reviewing a regulation, and the deadline is nearing, the public is 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.²⁰⁷ Moreover, section [XX](f) requires that the Department, in announcing the results of Assessments and Reviews, "shall also specify the year by which the next assessment (and, if required, the next review) of the Section shall be completed."

The Department plans to periodically announce in the **Federal Register** regulations that have expired, and have the Code of Federal Regulations revised accordingly.

Final Section [XX](h)

Accordingly, based on public comments, HHS finalizes section [XX](h) to provide that when the Department commences the process of performing an Assessment or Review, it shall state on a Department-managed website the Section(s) whose Assessment or Review it is commencing. It shall also announce once a month in the **Federal Register** those new Assessments or Reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each Assessment or Review that the Department is conducting. The public will be able to submit comments to the dockets of each rule making being Assessed or Reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

Section [XX](i)

Lastly, the proposed rule included a severability clause. The Department stated in the proposed rule that it believes the 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 the entire final rule vacated because one of the exceptions listed in section [XX](g) is invalidated. However, the Department requested comment in the proposed rule 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. The Department stated that it was requesting comments on this because it is not clear that the proposed rule could properly function without the expiration dates.

HHS received no comments specific to Section [XX](i) of the proposed rule.

Accordingly, for the reasons stated in the proposed rule, HHS finalizes the provisions of Section [XX](i) as proposed.

Additional Comments on Particular Regulations

Comment: Commenters identified certain regulations that they would not want to expire under the proposed rule. These regulations include, but are not limited to:

- Regulations implementing Medicare, Medicaid, CHIP, and other large programs that HHS administers.
- Regulations implementing the Affordable Care Act (ACA).
- Regulations that operate Temporary Assistance for Needy Families (TANF) program, the Child Care and Development Fund (CCDF) program, Head Start and Early Head Start Programs, and the Family Violence Prevention and Services (FVPSA) Program.
- FDA Regulations at 21 CFR Chapter 1.
- Provisions at 42 CFR 435.603 which determine financial eligibility using the Modified Adjusted Gross Income (MAGI) methodologies.
- Regulations implementing Income and Eligibility Verification requirements at 42 CFR 435.940–435.965.
- 42 CFR 435.907, related to Medicaid application requirements.
- Medicaid cost-sharing regulations.
- Regulations governing Medicaid waivers, including Section 1115 and Section 1332 waivers and Home & Community-Based Services (HCBS) waivers.
- Fair Hearings for Applicants and Beneficiaries requirements in 42 CFR 431 Subpart E.
- Confidentiality regulations in 42 CFR part 431 Subpart F.
- Regulations relating to comparability or services for groups of

underused"); ACUS, "Adoption of Recommendations," 79 FR 75114, 75117–18 (describing long-standing problems in agencies' handling of § 553(e) petitions).

²⁰⁴ See Section II, *supra*.

²⁰⁵ See, e.g., 21 CFR 10.20, 10.30, 10.33.

²⁰⁶ See, e.g., *Am. Horse Protection Assoc. v. Lyng*, 812 F.2d 1 (D.C. Cir. 1987). Case law also suggests that an agency's failure to respond may also be subject to judicial redress. See Jason A. Schwartz and Richard L. Revesz, "Petitions for Rulemaking—Final Report to the Administrative Conference of the United States" at 13 & n.55, 28–29 (Nov. 5, 2014).

²⁰⁷ 85 FR 70110.

beneficiaries and sufficiency of amount, duration, and scope of Medicaid services, found at 42 CFR 440.230–440.250.

- The Medicaid balanced billing regulation at 42 CFR 447.15.
- Regulations that shape children's access to care in a wide range of areas, including but not limited to: 42 CFR 438.1–438.930—Medicaid Managed Care; 42 CFR 447.56—Limitations on premiums and cost sharing; 42 CFR 447.203—Documentation of access to care and service payment rates; 42 CFR 447.204—Medicaid provider participation and public process to inform access to care; 42 CFR 447.400—Payments for Primary Care Services Furnished by Physicians; 42 CFR 410.78—Telehealth services; 45 CFR 156.10–156.1256—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges.
- Regulations concerning infant formula, including: 21 CFR 101: Food Labeling; 21 CFR 105.65: Infant Foods; 21 CFR 106: Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control; Procedures, Quality Factors, Records and Reports, and Notifications; 21 CFR 107: Infant Formula; and 21 CFR 312: Investigational New Drug Application.
- Regulations implementing the Vaccines for Children Program at 42 CFR 441.600–441.615 and Grants for Childhood Immunization Programs at 42 CFR 51b.201–51b.206.
- Regulations implementing title IV–E programs that HHS administers, which provide funds for States and Tribes to provide foster care, transitional independent living programs for children, guardianship assistance, and adoption assistance for children with special needs at 45 CFR part 1356.
- Regulations that pertain to maternal and child health project grants administered by the Health Resources and Services Administration's Maternal and Child Health Bureau at 42 CFR 51a.1–42 CFR 51a.8.
- Medicaid regulations that outline the mandatory and optional benefits that States commonly use to finance home visiting services, such as: Extended pregnancy services (42 CFR 440.210, 42 CFR 440.220); Targeted case management (42 CFR 440.169(b)); Medical or other remedial care by licensed practitioners (42 CFR 440.60); Early and Periodic Screening, Diagnostic and Treatment (42 CFR 440.40(b)); Medicaid Administrative Claiming (42 CFR 433.15); and Managed care (42 CFR part 438).

- Regulations in 45 CFR Subchapter B that require insurance coverage of essential health benefits (EHBs) such as preventive health services, prohibit preexisting condition exclusions, and establish fair practices in setting health insurance premiums and mental health parity, among other protections.

- Regulations in 42 CFR part 441, which sets forth State Medicaid plan requirements and Federal Financial Participation for specific services. Commenters specifically mentioned Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) regulations found throughout Part 441, which provide essential comprehensive and preventive services to children who are covered by Medicaid.

- Regulations that protect nursing home patients by requiring reasonable promptness for medical assistance fair hearing obligations (42 CFR 435.930(a), 42 CFR 431.10(c)(3); 435.1200(b).

- Regulations found in 42 CFR part 483 protecting long term care facility residents, and specifically Subpart G, which protects children in psychiatric residential treatment facilities (PRTFs) from restraint and seclusion used as a means of “coercion, discipline, convenience or retaliation.”

- Regulations found in 42 CFR part 460, implementing Programs of All-Inclusive Care for the Elderly (PACE).

- Regulations implementing the Medicare Low Income Subsidy program under 42 CFR part 423.

- Regulations at 42 CFR part 438 which implement Medicaid Managed Care.

- Regulations related to food ingredients, including color additives (21 CFR parts 70–82), Generally Recognized as Safe (GRAS) regulations, and procedural regulations governing the agency's premarket review functions, among others.

- Regulations implementing the Food Safety Modernization Act (FSMA), Good Manufacturing Practices (GMPs), low acid canned foods/acidified foods (LACF/AF), Hazard Analysis and Critical Control Point (HACCP) regulations for juice and seafood, Dietary Supplement GMPs, import/export requirements, and infant formula, among others).

- Nutrition labeling regulations.
- Regulations implementing Food Standards of Identity and Quality (e.g., dairy standards, bottled water (21 CFR 165.110), cacao products, and other food categories).

- Regulations implementing the Family Smoking Prevention and Tobacco Control Act (the “TCA”).

- Regulations governing the Indian health system, the Indian Health

Service's (IHS) Tribal Self-Governance program, and Indian specific provisions in the Medicaid, Medicare CHIP and Marketplace regulations.

- Regulations implementing the Indian Child Welfare Act, which impacts all Indian Health Service regulations (42 CFR parts 136 and 136a) and the Department's Tribal Self-Governance regulations (42 CFR part 137).

- Regulations implementing the Mental Health Parity and Addiction Equity Act (MHPAEA), which requires that mental health and substance use disorder coverage be comparable to general medical coverage.

- Regulations that implement programs authorized by the Developmental Disabilities Assistance and Bill of Rights Act that help ensure people with intellectual or developmental disabilities and their families have access to needed community services and individualized supports, and other programs that are important to people with disabilities, such as the Independent Living programs and critical safety net programs such as Medicaid.

- 42 CFR 457.520, relating to cost sharing for well-baby and well-child care services.

- Regulations in 42 CFR part 407 relating to Hospital Insurance Entitlement and Supplementary Medical Insurance Enrollment and Entitlement, Part B enrollment including so-called state buy-in plans would harm seniors, and retroactive liability for Part B premiums when a beneficiary loses eligibility for a buy-in plan.

- Provisions found at 45 CFR 146.136 that apply the federal law requiring parity between private health insurance coverage for physical ailments and for mental illness and substance use disorders would be at risk.

- Regulations that implement the Title X Family Planning Program.

- Regulations guiding the practice of social work.

- Regulations implementing the Health Insurance Portability and Accountability Act of 1996 (HIPAA), found in 45 CFR parts 160, 162, and 164, particularly 45 CFR 164.502, which clarifies and strengthens privacy protections people with HIV.

- Preadmission Screening and Resident Review (PASRR) regulations found at 483.100 through 483.138.

- Regulations protecting the confidentiality of Substance Use Disorder (SUD) patient records, found at 42 CFR part 2.

- Regulations that prohibit insurance plans and issuers from imposing

financial requirements or treatment limitations on mental health and SUD benefits that are more restrictive than those that apply to medical/surgical benefits.

- Office of Human Research Protections (OHRP) regulations in 45 CFR part 46, and FDA regulations at 21 CFR part 50, which protect human research subjects.

- Regulations in 45 CFR part 96, which govern block grants.

- 42 CFR 489.24, related to the special responsibilities of Medicare hospitals in emergency cases.

- Regulations concerning Section 1557 of the Affordable Care Act, which prevents discrimination on the basis of race, sex, sexual orientation, and gender identity in healthcare settings.

- Regulations implementing the Ryan White Program

- Regulations governing Medicare's Six Protected Classes.

- Regulations related to the Congregate and Home-Delivered Nutrition Programs.

- Regulations related to over-the-counter medicine products.

- Regulations at 42 CFR 425.612 identify the circumstances under which specific payment regulations are waived under the accountable care organization (ACO) program.

- Regulations related to non-emergency medical transportation (NEMT).

- Regulations affecting the domestic and global seafood industry.

- Regulations affecting the pet food industry.

- Regulations implementing the Medicare Modernization Act, such as 42 CFR 422.2268, which establishes standards for marketing by MA plans.

- Regulations requiring CMS programs to include an extraordinary circumstances exception (ECE) policy for natural disasters and other circumstances (*see* 42 CFR 412.140(c)(2) for the inpatient quality reporting (IQR) program and 42 CFR 412.160(c)(1)–(4) for the value-based purchasing program).

- Regulations at 42 CFR 441.62, which require, according to the commenters, that states assure transportation for periodic screening and treatment for Medicaid eligible children, and regulations at 42 CFR 440.170(a), which provide the definition for what constitutes transportation, *e.g.*, ambulance, taxicab, common carrier or other appropriate means, as well as meals and lodging for both the child and necessary attendant.

- 42 CFR 440.230(b)–(d), which requires that services be “sufficient in amount, duration, and scope to

reasonably achieve their purpose,” directs states not to “arbitrarily deny or reduce the amount, duration, or scope of such services to an otherwise eligible individual solely because of the diagnosis, type of illness, or condition,” and permits states to place appropriate limits on a service based on such criteria as “medical necessity” or on utilization review criteria.

- 42 CFR 435.831, which establishes the standards for determining eligibility for the “medically needy”—an optional category that may enable aged, blind and disabled persons in certain states who have “excess income” above the Medicaid limits to qualify for Medicaid, if they incur certain medical expenses.

- 42 CFR 415.174 Exception: Evaluation and management services furnished in certain centers.

- 42 CFR 457.496—Parity in mental health and substance use disorder benefits.

- 42 CFR 457.410—Health benefits coverage options.

- What commenters characterized as many highly important and sensitive Medicare provisions in Title 42, CFR parts 400–499 that directly impact beneficiaries and health care providers. Some of these provisions include beneficiary and provider appeal rights (Part 405); Part A eligibility and entitlement provisions (Part 406); Part B enrollment and entitlement provisions (Part 407); provisions that outline the scope of Part A Benefits, including hospital and skilled nursing facility coverage (Part 409); Medicare Advantage coverage rules and enrollee protections (Part 422); and, Part D prescription drug parameters (Part 423).

Response: The Department thanks the commenters for identifying these regulations. The Department intends to timely Assess and (if necessary) Review these regulations.

Comment: Commenters identified certain regulations for which they would like the Department to prioritize amendment through its proposed retrospective regulatory review process. These regulations include, but are not limited to:

- Regulations mandated for review by the 21st Century Cures Act, Public Law 114–255, sec. 2034, 130 Stat. 1033 (2016). Section 2034 of that Act requires the Secretary to lead a review by research funding agencies of all regulations and policies related to the disclosure and reporting of financial conflicts of interest to reduce administrative burden on federally funded researchers. It also calls for the Secretary to harmonize the differences between the Basic HHS Policy for the Protection of Human Research Subjects

(45 CFR part 46, subpart A) and the FDA regulations for the protection of human subjects (21 CFR parts 50 and 56). Commenters stated that these regulations are well overdue for assessment and review.

- Regulations covering access to skilled therapy services, which commenters say must be updated to reflect the national settlement in the *Jimmo v. Sebelius* litigation to codify the fact that skilled services are covered for Medicare beneficiaries not just to improve function, but to maintain or prevent deterioration in function.

- The dockets established by FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine on Sept. 8, 2017,²⁰⁸ in which the Centers requested comments and information to assist in identifying existing regulations and related paperwork requirements that could be modified, repealed or replaced, consistent with the law, to achieve meaningful burden reduction while allowing FDA to achieve its public health mission and fulfill statutory obligations are examples of incomplete regulatory review initiatives.²⁰⁹ Commenters stated that despite submitting extensive comments that detailed numerous regulations that they believe could be modified, repealed or replaced, the agency did not take any further action.

Response: The Department thanks the commenters for identifying these regulations. The Department intends to timely Assess and (if necessary) Review these regulations. If the Assessments and Reviews suggest these regulations should be amended or rescinded, the Department will commence rulemaking to amend or rescind them.

Comment: Commenters identified certain regulations that they would want amended or rescinded. These regulations include, but are not limited to:

- What the commenters characterized as unnecessary burdens in post-acute care (PAC) regulations.

- What the commenters characterized as the outdated and inappropriate “in the home” requirement for coverage of durable medical equipment (DME), which commenters believe significantly limits the mobility devices available to beneficiaries with mobility disabilities.

²⁰⁸ *E.g.*, Nonrulemaking Docket FDA-2017-N-5093: Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration, <https://beta.regulations.gov/docket/FDA-2017-N-5093>.

²⁰⁹ *See* Review of Existing General Regulatory and Information Collection Requirements of the Food and Drug Administration, 82 FR 42506 (Sept. 8, 2017); FDA-2017-N-5093, <https://beta.regulations.gov/docket/FDA-2017-N-5093>.

Response: The Department thanks the commenters for identifying these regulations. The Department intends to timely Assess and (if necessary) Review these regulations. If the Assessments and Reviews suggest these regulations should be amended or rescinded, the Department will commence rulemaking to amend or rescind them.

Comment: Some commenters provided feedback on what baseline the Department could use when conducting an analysis of an existing regulation. Commenters suggested that HHS could simply conduct an ex ante analysis of how the regulation is likely to perform going forward compared with the baseline scenario of what would happen if the regulation were allowed to expire. The benefits of this approach, according to the commenters, are that HHS already produces ex ante analyses (so this approach would not be departing from present practices), the analysis could still include a backward-looking component to the extent that data on past performance could be used to forecast the regulation's future performance, and the regulation's future performance is what should ultimately determine whether the regulation should continue as-is or be amended or rescinded. Another option, according to commenters, is that the Department could perform a retrospective cost-benefit analysis that looks at how the regulation performed relative to the baseline of what would have happened in the absence of the regulation, or relative to the regulation as it stood before it was last significantly amended.

Response: The Department appreciates this comment. The comments suggest different approaches may make sense for different regulations. Accordingly, the Department declines to adopt in this final rule a single method for conducting retrospective reviews. Reviews must be conducted in a manner that is not arbitrary and capricious under the APA, so that will provide a minimum level of rigor that all Reviews will have to meet, though different methodologies may be appropriate in different cases. The Department intends to take into account these comments when conducting Reviews pursuant to this final rule.

V. Regulatory Impact Analysis (Executive Orders 12866, 13563, 13771)

A. Executive Order 12866 Determination

Executive Order 12866 directs agencies to assess the 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. 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"). OMB has designated this rule as economically significant for the purposes of Executive Order 12866. This regulatory impact analysis fulfills analytical obligations under section 3(f) of Executive Order 12866 for economically significant rulemakings.²¹⁰

B. Need for Regulation

The first principle of regulation, according to Executive Order 12866, is that "Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem." The regulation being finalized by the Department addresses lax compliance with periodic review requirements under the Regulatory Flexibility Act (RFA) of 1980 and the need to periodically review existing regulations to determine if they are having their intended impacts. Section 610 of the RFA calls upon the Department to have a plan to conduct periodic reviews of its regulations that have or will have a significant economic impact upon a substantial number of small entities (SEISNOSE). The RFA directs agencies to consider the following factors as part of those reviews: (1) The continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of

the rule; (4) the extent to which the rule overlaps, duplicates or conflicts with other rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

A review of department semi-annual agenda reports over the last ten years, as well as a review of specific rules identified in those agendas as completed rulemakings resulting from section 610 reviews, indicated three completed final rulemakings that emanated from section 610 reviews since 2011.²¹¹ (These rules are presented in table 1 below). To put this in context, the Department estimates it has roughly 18,000 regulations under its purview and that five regulations on average are part of the same rulemaking. Further, (as discussed in more detail below) the Department estimates approximately 11% of its regulations have a SEISNOSE, which suggests that approximately 396 Department rulemakings have a SEISNOSE. The three rules in table 1 amend approximately 130 sections of the CFR. (If an average rulemaking contains five sections, 130 sections correspond to the number of sections on average in approximately 26 rulemakings.) Given that Section 610 of the RFA sets a 10-year schedule for review of rulemakings, one might expect that roughly ten percent of regulations with a SEISNOSE would be reviewed each year, which would be approximately 40 rulemakings every year.²¹² Moreover, many of these regulations should likely be updated to reflect evolving circumstances. However, this does not appear to be occurring.²¹³

²¹¹ Note that some rules labeled as 610 reviews in Department semi-annual agendas were not, in actuality, a result of section 610 reviews.

²¹² There are roughly 3,600 rulemakings (18,000 divided by 5). 11% of this figure is 396. Ten percent of 396 is roughly 40.

²¹³ A review of Department semiannual regulatory agendas issued between June of 2016 and August of 2020 confirms the three rules listed in table 1 are the only three final rulemakings to be completed in the last five years that are also associated with section 610 reviews. One rule, 0938-AT23, was merged with another rule, 0938-AS21. See Dept. Health & Human Servs., Semiannual Regulatory Agenda, 81 FR 37,294 (Jun. 9, 2016); 81 FR 94742 (Dec. 23, 2016); 82 FR 40278 (Aug. 24, 2017); 83 FR 27126 (Jun. 11, 2018); 83 FR 58020 (Nov. 16, 2018); 84 FR 29624 (Jun. 24, 2019); 84 FR 71130 (Dec. 26, 2019); and 85 FR 52704 (Aug. 26, 2020).

²¹⁰ This analysis was informed by public comments and also by work of Dr. James Broughel.

TABLE 1—FINAL ACTIONS AS A RESULT OF SECTION 610 REVIEWS SINCE 2011

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.

The Department's limited success in performing retrospective regulatory review is further supported by a regulatory reform project the Department piloted, which utilized AI-driven data analysis. Machine-learning algorithms identified 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.²¹⁴ That project uncovered that 85% of Department regulations created before 1990 have not been edited, and that the Department has nearly 300 broken citation references in the CFR (*i.e.*, CFR sections that reference other CFR sections that no longer exist).²¹⁵ These findings are consistent with a 2018 study by the same consulting firm that estimated that 68 percent of federal regulations have never been updated.²¹⁶

These findings suggest regulations are not being updated to reflect evolving economic conditions and technology, even though this is a goal of the RFA.

Machine-learning tools also demonstrate the complexity of Department rules—and reducing complexity is another goal of the RFA. *See, e.g.*, 5 U.S.C. 610(b)(3). Data from the Mercatus Center show that the Department's regulations in 2019 received a Shannon entropy score of 8.2. Shannon Entropy is a measure of complexity based on the amount of information contained in text. It can be thought of as measuring the number of new ideas that are introduced in a document, or, alternatively, how much computational effort would be required to understand a document. To put the Shannon entropy score into context, a typical Shakespeare play receives a Shannon entropy score of 8.0. The complexity of Department regulations is

not entirely surprising given that regulations often involve science, engineering, or other highly technical material. However, having regulations that are more complex than a typical Shakespeare play would seem to be at odds with various directives that fall on the Department for regulations to be simple, easy to understand, and written in plain language.²¹⁷

TABLE 2—2019 SHANNON ENTROPY SCORE FOR HHS REGULATIONS

Department	Shannon entropy score
Department of Health and Human Services	8.2

Source: *Quantgov.org*.

Without a consistent process for periodically reviewing regulations, there is no guarantee that regulations will be

²¹⁴ Regulatory Streamlining & Analysis, at 11 (Mar. 2019).

²¹⁵ *Id.*

²¹⁶ William D. Eggers & Mike Turley, *The Future of Regulation: Principles for Regulating Emerging*

Technologies, Deloitte Ctr. for Gov't Insights (2018), <https://www2.deloitte.com/content/dam/Deloitte/lu/Documents/risk/lu-future-of-regulation.pdf>.

²¹⁷ *See, e.g.*, Exec. Order No. 12866; Exec. Order 13563, sec. 1; and various presidential memoranda and guidance on plain language.

reviewed and revised to align with technological, economic, and other developments. 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 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 regulatory objectives.

However, existing executive orders have not institutionalized a process for retrospective review and periodic updating of regulations, as evidenced by the fact that relatively few Department regulations are updated. Furthermore, every president since Jimmy Carter, including all those elected after enactment of 5 U.S.C. 610, has ordered some form of retrospective review of regulations,²¹⁸ with mixed effects. This suggests that stronger incentives and forcing mechanisms are needed to ensure retrospective review occurs to an appropriate extent.

Some commenters suggested that a review of existing regulations does not make sense during a pandemic, but this misses the broader point that the Department has waived, suspended, or exercised enforcement discretion not to enforce many regulations in order to respond to the pandemic.²¹⁹ Had the Department not done so, this may have hampered the Department's ability to respond nimbly, flexibly and quickly to the emergency.²²⁰ For example, the

Department has issued waivers or exemptions, or exercised enforcement discretion with respect to, certain Medicare, Medicaid, CHIP, and HIPAA restrictions, including waivers to increase hospital capacity, ease restrictions on services rendered by medical residents, and allow patients to seek more services via telehealth. Meanwhile, other regulations that may have facilitated pandemic response have remained in place.

The Department's position is that retrospective review would require some change from the status quo, and unless there is a strong incentive to change, continuing business as usual is the path of least resistance.²²¹ Thus, the status quo is maintained. Moreover, rescinding a regulation that has already been promulgated is likely to meet greater resistance than resistance to foregoing promulgating a regulation not yet enacted. This reflects a phenomenon known as loss aversion.²²²

The Department's determination is that this final rule will address these issues by changing the choice architecture facing the Department by enacting a new default rule when the Department fails to conduct retrospective reviews. Sunset provisions change the default from rules staying on the books indefinitely to rules being eliminated after some predetermined amount of time unless evidence is presented for why rules should continue. When a default rule is changed, the choice architecture confronting decision makers is altered and can spur changes in behavior. A consistent finding in the literature on behavioral anomalies is that choice architecture and default rules have an important influence on decision making.²²³ Changes in the Department's choice architecture can ultimately result in changes in public wellbeing.

To conclude, this final rule is intended to address a failure to periodically review regulations as often as desired in line with the RFA and other directives for retrospective review. The Department believes that this final rule, by changing the default for regulations from continued existence to expiration unless periodic review is conducted, will result in more widespread retrospective review of

regulations. Requiring the expiration of rules that have not been assessed or reviewed in accordance with section 610 of the RFA should result in more regulations being updated to reflect evolving circumstances.

C. Alternatives Considered

The Department considered several alternatives to the proposed regulation. First, it considered not issuing this final rule. However, the RFA and certain Executive Orders direct the Department to periodically review certain Department regulations. Moreover, the literature and the Department's experience suggest that large numbers of regulations are having estimated impacts that, over time, differ from what was estimated at the time the regulations were promulgated, so many regulations should be periodically reviewed.²²⁴ The Department's experience over the last forty years is that, absent a strong incentive such as the potential expiration of a regulation, the Department will not review an adequate number of its regulations.

Next, the Department considered seeking to perform the reviews called for by the RFA without implementing a new forcing mechanism. Given past experience, however, it seems unrealistic to assume this would bring about meaningful change. First, the fact that these reviews are not already occurring is evidence they are unlikely to occur in the future. Second, as discussed above, there is a strong bias towards the status quo in governmental action, and this may stand in the way of behavior changes. Third, the literature suggests that enforcement mechanisms are needed to spur more periodic reviews, and specifically that sunset provisions are a useful enforcement mechanism.²²⁵ Moreover,

²²⁴ 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); Winston Harrington, *Grading Estimates of the Benefits and Costs of Federal Regulation* 33 (Res. for the Future, Discussion Paper 06–39, 2006), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=937357; Richard Morgenstern, *Retrospective Analysis of U.S. Federal Environmental Regulation*, J. of Benefit Cost Anal. 9 no. 2, 2018, at 285.

²²⁵ Curtis W. Copeland, Cong. Rsch. Serv., RL32801, Reexamining Rules: Section 610 of the Regulatory Flexibility Act (2008); Michael Greenstone, *Toward a Culture of Persistent Regulatory Experimentation and Evaluation*, in *New Perspectives on Regulation* 111, 113 (David Moss & John Cisternino eds., 2009); Australian Gov't Att'y Gen.'s Dep't, Guide to Managing the Sunset of Legislative Instruments, at 3 (July

Continued

²¹⁸ See Exec. Order No. 12044 of Mar. 23, 1978, 43 FR 12661 (Mar. 24, 1978) (President Carter) (revoked by Exec. Order No. 12291 of Feb. 17, 1981, 46 FR 13193 (Feb. 19, 1981) (President Reagan)); Memorandum on Reducing the Burden of Government Regulation (Jan. 28, 1992) (President H.W. Bush); Exec. Order No. 12866 of Sept. 30, 1993, 58 FR 190 (Oct. 4, 1993) (President Clinton); Exec. Order No. 13563 of Jan. 18, 2011, 76 FR 3821 (Jan. 21, 2011) (President Obama); Exec. Order No. 13771 of Jan. 30, 2017, 82 FR 9339 (Feb. 3, 2017) (President Trump).

²¹⁹ See Regulatory Relief to Support Economic Recovery; Request for Information (RFI), 85 FR 75720, at Attachment A (Nov. 25, 2020).

²²⁰ See, for example, Alec Stapp, "Timeline: The Regulations—and Regulators—That Delayed Coronavirus Testing," *The Dispatch* (March 20, 2020).

²²¹ See also Yoon-Ho Alex Lee, *An Options Approach to Agency Rulemaking*, 65 Admin. L. Rev. 881, 895–96 (2013) (positing reasons why agencies may be reluctant to perform retrospective reviews).

²²² Daniel Kahneman et al., *Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias*, 5 J. Econ. Persp. 193 (1991).

²²³ Richard H. Thaler et al., *Choice Architecture*, in *The Behavioral Foundations of Public Policy* 428, (Eldar Shafir ed., 2012).

even if the Department conducted the reviews called for by the RFA absent a new forcing mechanism, there might be benefits to this final rule, albeit ones that are hard to quantify. For example, this final rule could guard against a decrease in the frequency of Department retrospective reviews in future years.

Another alternative the Department considered is conducting in-depth Reviews of all of its Regulations (absent those that are exempt from this rulemaking), not just those designated as having a SEISNOSE. The Department sees value in conducting such widespread Reviews. However, the Department has opted not to require a complete Review of all Department regulations at the present time, although it leaves open the option to require such Reviews in the future.

The Department also considered conducting Reviews of significant regulations, as that term is defined in Executive Order 12866. The Department is choosing to Review those regulations that have a SEISNOSE, in order to maintain a close connection between this final rule and the RFA. The Department sought comment on whether to Review additional regulations, such as those that are significant under Executive Order 12866. Given limited responses to this request, the Department will not Review other regulations at this time beyond those designated as having a SEISNOSE. However, the Department leaves open the possibility to conduct Reviews of other regulations in the future.

The Department considered only Reviewing those regulations that, at the time of promulgation, the Department determined had a SEISNOSE. However, such determinations were not made for regulations that were promulgated prior to the passage of the RFA,²²⁶ and some post-RFA regulations that did not have such a SEISNOSE at the time of promulgation might have such a SEISNOSE today. One commenter suggested that an alternative to the proposed rule would be to attach sunset dates only prospectively for regulations finalized after the effective date of this rule. The same commenter suggested requiring retrospective reviews only for those regulations specifically identified by stakeholders as problematic. But as a general matter, the Department believes that older regulations are more likely to be obsolete. As a result, the Department

believes that this final rule should apply to them. Moreover, only reviewing regulations identified by stakeholders is unlikely to suffice. Regulations are known to create entry barriers into industries and these barriers often affect small businesses disproportionately.²²⁷ Therefore, the Department believes stakeholder input cannot be the only source of information to spur reviews. Concentrated interest groups will lobby to protect regulations that have been specifically constructed for their benefit. Meanwhile, consumers, small businesses, and the public more generally often experience dispersed costs that are not taken into account by these stakeholders. The work of political scientist Mancur Olson explains why these groups that comprise broader society, because they are larger, face collective action problems and often find it costly to organize and lobby on behalf of their own interests.²²⁸ Meanwhile, more narrow, concentrated interests find it relatively easier to organize and lobby for their own interests. Thus, stakeholders may not identify to the Department many regulations that are unduly burdensome to the public at large.²²⁹

The Department is also aware of literature suggesting that agencies have not been consistent in deciding which rules have a SEISNOSE or have avoided such a finding in order to avoid the RFA's requirements.²³⁰ Moreover, 5

²²⁷ 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. S1637 (daily ed. Mar. 7, 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).

²²⁸ Mancur Olson, *The Logic of Collective Action* (Harv. U. Press 1971).

²²⁹ The Department welcomes comments from all members of the public on (1) regulations being Assessed or Reviewed pursuant to this final and (2) future notices of proposed rulemaking. The Department will consider comments received from all members of the public. We merely make this observation to explain why relying solely on stakeholders may not enable the Department to identify certain regulations that should be amended or rescinded.

²³⁰ See, e.g., Connor Raso, *Agency Avoidance of Rulemaking Procedures*, 67 Admin. L. Rev. 65, 93–95, 99–101 (2015); Michael R. See, *Willful*

U.S.C. 610 presupposes the agency will make a determination about which regulations have or will have a SEISNOSE. This suggests there is good reason to Assess most of the Department's regulations. For these reasons, the Department has chosen to Assess all of its Regulations (subject to the exceptions listed herein) to determine which have a SEISNOSE and to Review those Regulations that have a SEISNOSE using the criteria listed in 5 U.S.C. 610 (as well as whether they comply with applicable law).

Finally, some commenters suggested that the Department include a provision granting the Secretary the authority to extend the expiration date in certain circumstances. Other commenters suggested that the proposed rule's two-year Assessment and Review period affecting some of the Department's older regulations was too short. In response, the Department has made several modifications to the final rule from its proposed form. First, regulations older than ten years will expire after five years, as opposed to expiring after two years, if these Regulations are not Assessed and (when necessary) Reviewed. Second, this final rule grants the Secretary a one-time option to push back this expiration date by one year for a given Regulation. Both of these modifications have the effect of lowering some costs of this final rule as compared to the proposed rule, because these changes lengthen the expected Assessment and Review period, pushing some costs into the future. This reduces the present value of these costs.

D. Cost Analysis

5 U.S.C. 610 already directs the Department to undertake periodic reviews of its regulations. Nevertheless, because the Department believes this final rule will stimulate a behavior change at the Department and among the public, the regulation has some costs associated with it. Therefore, the Department performed the following analysis to estimate the costs and burdens to the Department and the public from (1) Assessing which Department regulations have a SEISNOSE, and (2) Reviewing those regulations.

The Department has roughly 18,000 regulations, the vast majority of which it believes would need to be Assessed.²³¹ Roughly 12,400 of these

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).

²³¹ See Enhancing Regulatory Reform Through Advanced Machine Learning Findings (internal

2020), <https://www.ag.gov.au/sites/default/files/2020-07/Guide%20to%20Managing%20Sunsetting%20of%20Legislative%20Instruments.pdf>.

²²⁶ The Department estimates that 16% of its regulations that are more than ten years old were promulgated prior to 1980, when Congress passed the RFA.

regulations are over ten years old, and roughly 17,200 are more than five years old.²³² The vast majority of these would need to be Assessed within five years of this final rule's effective date (or six years if the optional extension is exercised by the Secretary). The Department estimates that roughly five regulations on average are part of the same rulemaking due to the number of unique **Federal Register** citations associated with its regulations. This would suggest the Department would have to perform roughly 3,440 Assessments in the first five years (or six for certain of these regulations if the

extension is exercised by the Secretary, and 3,600 Assessments in total.

However, some of these rulemakings are exempt from this final rule. The Department estimates that approximately 66 parts of the CFR that the Department actively updates contain the vast majority of the regulations that are exempt from this final rule. According to analysis from the Mercatus Center, however, the Department has approximately 8,574 active parts of the CFR.²³³ 66 parts are therefore less than 1% of the Department's active parts. As a result, the Department does not believe the exemptions will

significantly alter the costs of this final rule.²³⁴

To help estimate the impact of this final rule, the Department conducted a limited randomized sampling²³⁵ of its regulations and assessed whether the sampled regulations would be exempt from this final rule and whether, at the time of issuance, the regulations were: Economically significant; found to have a SEISNOSE; or subject to the Unfunded Mandates Reform Act (UMRA) of 1995. This information is included in table 3. Also included in table 3 is the estimated impact of the regulations when they were first promulgated.

TABLE 3—SAMPLED DEPARTMENT REGULATIONS

Title	Rulemaking	Citation	Exempt from this Final 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." ²³⁶
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." ²³⁷
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." ²³⁸
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 record-keeping burdens" that already existed. ²³⁹
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)." ²⁴⁰

HHS slide) (the sum of the numbers listed in the table under the column denoted "#") is 17,890 Department regulations).

²³² See *id.* (adding the figures listed in the "#" columns for the 1950s, 1960s, 1970s, 1980s, 1990s, and 2000s yields 12,383 regulations. 17,200 regulations are estimated to have been issued by the end of 2016).

²³³ These data are available at *Quantgov.org*.

²³⁴ The exempt parts may on average have more Sections than other parts. But even still, it seems

unlikely the exemptions would significantly alter the costs of this final rule. If the Department were incorrect about this assumption, costs from this final rule would likely be lower than estimated herein. Similarly, the Department does not have enough information at present to determine whether the CFR sections that could potentially benefit from regulatory streamlining based on their similarities to, overlap with, or duplicativeness of other Sections will lead to a reduction in Department costs of Assessments and Reviews, due

to duplication of work. The initial Assessment of all non-exempt regulations would determine whether this is the case.

²³⁵ With the aid of a random number generator, the Department selected Department regulations in each of its three main titles (21, 42, and 45) of the Code of Federal Regulations. The random number generator was used to identify the relevant part of each title of the CFR to assess.

TABLE 3—SAMPLED DEPARTMENT REGULATIONS—Continued

Title	Rulemaking	Citation	Exempt from this Final 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. ²⁴¹
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." ²⁴²
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." ²⁴³
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. ²⁴⁴
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." ²⁴⁵

None of the sampled regulations would be exempt from this final rule,

²³⁶ Toll-Free Number for Reporting Adverse Events on Labeling for Human Drug Products, 73 FR 63,886, 63,892 (Oct. 28, 2008).

²³⁷ Unique Device Identification System, 78 FR 58786, 58811 (Sept. 24, 2013).

²³⁸ 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).

²³⁹ Human Tissue Intended for Transplantation, 62 FR 40429, 40442 (Jul. 29, 1997).

²⁴⁰ 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).

²⁴¹ Organ Procurement and Transplantation Network, 63 FR 16296, 16321–29 (Apr. 2, 1998).

²⁴² Medicare Program; Hospital Insurance Entitlement and Supplementary Medical Insurance Enrollment and Entitlement, 53 FR 47199, 47201 (Nov. 22, 1988).

²⁴³ Cooperation in Identifying and Providing Information To Assist States in Pursuing Third Party Health Coverage, 56 FR 8926, 8929 (Mar. 4, 1991).

²⁴⁴ 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).

meaning all sampled rules would need to be Assessed. This is consistent with the assumption that few enough regulations would be exempt from this final rule to significantly affect the cost estimates presented here. At the time the ten sampled regulations were promulgated, the Department believed that one of the ten had a SEISNOSE. 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 found 11.1% of Department final rules issued in 1993 had a SEISNOSE.²⁴⁶ A more recent study found that 92% of agency rules were found to not be subject to the RFA, suggesting agencies believe roughly 8%

²⁴⁵ Rate Increase Disclosure and Review, 76 FR 29964, 29978 (May 23, 2011).

²⁴⁶ 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, 1217 (2006).

of their regulations have a SEISNOSE.²⁴⁷

Assuming the Department has roughly 3,600 total rulemakings that are subject to this final rule; 3,440 of these are more than five years old (*i.e.* would be ten years old by the end of 2026); and that roughly 11%²⁴⁸ have a SEISNOSE, then the Department might have to perform roughly 396 Reviews in total, of which 378 would have to be completed in the five years after this rule is finalized. However, some of these rulemakings might be reviewed as part of section 610 reviews even in absence of this final rule (*i.e.*, in the baseline scenario). As noted above, the Department estimates that the three completed rulemakings emanating from section 610 reviews over the last decade amend approximately 130 sections of the CFR.

²⁴⁷ Connor Raso, *Agency Avoidance of Rulemaking Procedures*, 67 Admin. L. Rev. 65, 69 (2015).

²⁴⁸ The Department chooses 11%, rather than 8% or 10%, 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.

If the decade following implementation of this final rule is similar to the previous decade, then the Department can expect to review and amend 130 sections of the CFR, which is equivalent to 26 average rulemakings if 5 regulations correspond with one rulemaking on average. These 26 rulemakings are assumed to be what would be Reviewed in the baseline scenario. Therefore, the Department expects to conduct 370 Reviews in total, of which 353 would have to be completed in the five years after this rule is finalized.²⁴⁹

Of the 353 rulemakings subject to Reviews in the first five years (or six years if the Secretary exercises the one-year extension authority), the Department estimates roughly 44 rulemakings were promulgated prior to the requirement for prospective regulatory flexibility analyses. Those 44 Reviews will require more Department resources than the estimated 309 Reviews of rulemakings promulgated after the prospective analysis requirement went into effect.

Therefore, as a result of this final rule, the Department expects to have to conduct 370 Reviews in total. These include approximately 44 rulemakings that were promulgated prior to the requirement for prospective regulatory flexibility analyses, and 326 Reviews of rulemakings promulgated after the prospective analysis requirement went into effect. Of these 326, the Department assumes most Reviews will occur earlier in the coming ten years such that 309 Reviews are conducted in the first five calendar years following implementation of this final rule and 17 of the Reviews occur in the second five calendar years. This is consistent with the fact that the vast majority, roughly 95 percent, of Department regulations are older than five years (and therefore will be more than ten years old by the end of 2026).

1. Costs Related to Section 610 Reviews of Regulations More Than Five Years Old

The majority of the Reviews conducted in response to this regulation will have to be conducted in the first five calendar years following implementation of this regulation, because the vast majority of the Department's regulations were finalized before the end of 2016. 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" and 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. The section 610 review focuses on five areas of analysis: (1) Whether there is a continued need for the rule, (2) the number and nature of complaints, (3) the complexity of the regulation, (4) whether there is duplication, and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule, as well as whether the Regulation complies with applicable law. 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 a section 610 review of such rulemakings may be more time intensive. The Department estimates 309 rulemakings from 2016 or earlier 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. The Department estimates it will undertake section 610 reviews of 44 rules for which no prospective regulatory analysis was performed. The Department 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 and the **Federal Register** for public comment, but that such costs will be minimal and would not require the hiring of additional personnel.

Therefore, the Department estimates that a total of between 23,360 and 52,900 hours will be spent on Reviews outside the Assessment process during the first five years (the number of hours may ultimately be slightly less if the Secretary exercises the optional one-year extension with respect to some regulations), which will clear the

backlog of section 610 reviews for regulations at least five years old. The Department assumes 40 to 100 hours per Review for the estimated 309 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.

The Department 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*").²⁵⁰ Assuming the 23,360 to 52,900 estimated hours are spread evenly across the first five years following implementation of this final rule, and assuming a 7 percent discount rate, the present value of these costs ranges from \$4.7 to \$10.6 million in total. Without discounting, this is equal to 20.1 to 45.6 full-time equivalents (FTEs) working at *LaborCost* to initiate and conduct Reviews of regulations in the first 5 years.

2. Costs Related to Rulemakings That "Age In" To Section 610 Review

The Department estimates 17 rulemakings would "age in"²⁵¹ to the section 610 review requirement during years six through ten after this rule is finalized. The Department estimates it will require between 680 to 1,700 hours to Review these rules, because the Department assumes those 17 Reviews would take between 40 to 100 hours per Review, as each of those rulemakings were promulgated after prospective regulatory analysis was required. Assuming hours reviewing these rulemakings are spread equally across years six through ten, the Department estimates the present value of the cost of Reviewing 17 rulemakings in years six through ten to be between \$0.1 million and \$0.3 million at a seven percent discount rate. Without discounting, this represents 0.6 to 1.5 FTEs working at *LaborCost* to conduct 17 Reviews of rules that age into the Review requirement during the decade following implementation of this regulation.

²⁵⁰ 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).

²⁵¹ "Age in," meaning that the rules become ten years old during years six through ten.

²⁴⁹ Since approximately 95 percent of Department rules were finalized before 2016, this analysis assumes 25 Reviews in the baseline scenario would occur in the first five years following implementation of this final rule, and one Review would occur in the subsequent five years.

3. Costs Related to Assessments

In addition to conducting Reviews of rulemakings that have a SEISNOSE, the Department will allocate resources towards conducting Assessments of its rulemakings to determine whether a Review is required. At the time of promulgation, regulations are evaluated as to whether they had a SEISNOSE under the RFA. However, some regulations were promulgated prior to the RFA, while others were certified exempt from having to produce a regulatory flexibility analysis because they were certified as not having a SEISNOSE. This final rule will require the Department to make a determination as to whether covered rulemakings currently have a SEISNOSE and, if so, to Review those regulations. Because circumstances could change over time, the designation that a regulation has a SEISNOSE is likely to change for some rules. As a result, this final rule requires the Department to timely Assess all of its regulations (subject to the exceptions in this final rule) to determine whether they have a SEISNOSE, otherwise the regulations would expire. As discussed above, some rulemakings may overlap with or be duplicative of one another, reducing the number of Reviews that will be eventually required. However, the Department believes an initial Assessment of all rulemakings (subject to this final rule's exceptions) will likely be required first to determine the extent of such overlap or duplication.

The Department believes each Assessment will require between three and 10 hours to perform. The Department estimates that it will have to conduct roughly 3,062 Assessments in the first five years after this rule is finalized, and an additional 142 Assessments in the subsequent five years, for a total of 3,204 Assessments across ten years.²⁵²

As such, the Department believes 9,186 to 30,620 hours will be spent on Assessments in the first five years. The Department believes 426 to 1,420 hours will be spent on Assessments in the following five years. Assuming these hours are spread evenly across their respective ranges of years, the present value of costs associated with these Assessments ranges from \$1.9 to \$6.4 million at a 7 percent discount rate. Without discounting, this represents 8.3 to 27.6 FTEs working on a total of 3,204

Assessments over ten years. If, as seems plausible, Assessments of regulations more than ten years old will disproportionately occur in the latter half of the 2021–2026 time period, the present value of the cost of Assessments will be slightly less than estimated herein.

4. Costs Related to Review of Additional 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 that the Department currently believes have a SEISNOSE. Accordingly, the Department estimates 153 Reviews will be required in the first five years,²⁵³ and seven Reviews will be required in the subsequent five years,²⁵⁴ for a total of 160 additional Reviews. The Department estimates the 153 Reviews will require 6,120 to 15,300 hours,²⁵⁵ and that the seven Reviews will require 280 to 700 hours in the subsequent five years.

Assuming these hours are spread evenly across the corresponding time frames, multiplying these hour estimates by *LaborCost* and discounting at a seven percent discount rate yields an estimated \$1.3 to \$3.2 million over ten years, which corresponds with 5.5 to 13.8 FTEs for additional post-Assessment Reviews over ten years (without discounting). If, as seems plausible, Reviews of regulations in this category will not be spread evenly across the corresponding time frames but will disproportionately occur in the latter half of the time frames, the present value of the cost of these Reviews will be slightly less than estimated herein.

5. Monitoring Costs

Some commenters argued that the proposed rule's regulatory impact analysis underestimated the costs of this rulemaking, because it did not consider the costs to the regulated community of: Monitoring which regulations may expire; commenting either during the Assessment and Review process or to request that the Department conduct an Assessment or Review; and, when necessary, writing and submitting comments on regulations amended as a

result of retrospective reviews conducted pursuant to this final rule.

The Department believes the cost of monitoring Assessments will be relatively trivial. This final rule requires the Department to announce on its website, as well as on *Regulations.gov*, when it has commenced Reviews and Assessments. Making the announcement on *Regulations.gov* (as opposed to only on the Department's website, as proposed) will reduce the monitoring costs raised by the commenters, because the regulated community already monitors *Regulations.gov*.

Moreover, in conjunction with this final rule, the Department is placing at <https://www.hhs.gov/regulations/federal-registry/index.html> a list of Department regulations, the year they were initially promulgated, the last year the rule was amended, and the **Federal Register** citation from the time the rule was initially promulgated. This list was generated with artificial intelligence and the Department believes it is accurate, but it is conceivable that some Department regulations are not included. This list can be used to easily create a schedule of expiration dates, so that the monitoring public does not need to identify these dates itself. Announcements of this kind conform to Organisation for Economic Co-operation and Development guidelines that recommended creating a predetermined schedule for when regulations are due for assessment and review.²⁵⁶ This type of "programmed review" would give both the Department and the public ample time to prepare for the Review and to submit comments as needed. It would also reduce the time and effort required of the public to track those regulations that are set to expire or be revised. As such, the monitoring public should not bear any significant expense keeping track of when regulations are set to expire or reminding the Department of when regulations are set to expire. Additionally, monitoring costs associated with Assessments are likely to not be significant because Assessments are unlikely to result in amendments of regulations, absent a subsequent Review also occurring. This final rule only mandates amendment or rescission of certain regulations that have been Reviewed.

In addition, the Department intends to create on its website a dashboard that shows its progress on its Assessments and Reviews, including when it commenced those Assessments and Reviews, its progress, and when it

²⁵² 3,062 is 3,440 total Department rulemakings older than 2016, minus 25 rulemakings Reviewed in the baseline scenario, minus the 353 rulemakings Reviewed in the first five years. 142 is 160 rulemakings affected by this final rule in the second five years, minus one rulemaking Reviewed in the baseline scenario, minus the 17 rulemakings expected to be Reviewed in the second five years.

²⁵³ 5% of 3,062 is 153.

²⁵⁴ 5% of 142 is 7.

²⁵⁵ Each review will take 40–100 hours.

²⁵⁶ Organisation for Economic Co-operation and Development, "Reviewing the Stock of Regulation" (2020).

expects them to be completed. If they so choose, the public can view this dashboard to see the Department's progress on its Assessments and Reviews of particular regulations. The dashboard will also help to keep the Department on track to timely complete Assessments and Reviews.

Based on the experience of North Carolina,²⁵⁷ the Department estimates that approximately 10 percent of Reviewed rulemakings will be rescinded and 30 percent of Reviewed rulemakings will be amended in some way. Since 530 rulemakings are expected to be Reviewed in total,²⁵⁸ this suggests 53 regulations will be rescinded and 159 will be updated.

To estimate how much interest these expiring and amended regulations are likely to generate, the Department notes that it received 486 comments on the proposed rule as of the close of the 30-day public comment period. A typical commenter is likely to be someone with a legal background. According to the Bureau of Labor Statistics,²⁵⁹ the mean hourly wage of a lawyer is \$71.60 (2020\$). Assuming base salary constitutes one half of fully-loaded wages,²⁶⁰ this suggests the fully loaded cost per hour of writing comments is \$143.20.

If a typical comment takes 5 to 15 hours to write, and if the 486 comments the Department received on the proposed rule is a good proxy for the interest the Department will receive on the 159 rulemakings expected to be amended as a result of this final rule over the next decade, then the total (undiscounted) monitoring cost related to writing comments on those 159 regulations is \$55.3 to \$166.0 million.²⁶¹ However, rulemakings are not likely to all be amended at the same time. Further, if the Secretary determines that completion of an amendment or a

rescission is not feasible by the required date, he or she can certify this in a statement published in the **Federal Register** and may extend the completion date by one year at a time, no more than three times.

Assuming the Secretary does not extend the completion date (this assumption is relaxed in the sensitivity analysis below), the Department expects 152 of the amended rulemakings will be Reviewed in the first five years and seven regulations Reviewed in the second five years. Assuming monitoring costs are spread equally across these timeframes (with the understanding that this may overestimate costs somewhat since rulemakings are likely to be amended after they are Reviewed, which would push amendment to the later end of the timeframe) the present value of these monitoring costs ranges from \$44.8 to \$134.3 million at a seven percent discount rate.

The Department expects it will receive less interest in regulations that are rescinded after being Reviewed, given that many regulations that are sunset in states often face little resistance from the public, perhaps because their rescission is uncontroversial. For example, the state of Idaho underwent a sunset review process for its entire regulatory code in 2019. As a result of the review, 19 percent of rule chapters, 10 percent of pages, and more than 19,000 regulatory restrictions were rescinded when the code was rewritten in the summer of 2019.²⁶² This occurred with little controversy, suggesting many regulations that were rescinded were obviously outdated or counterproductive, such that their removal was uncontroversial.²⁶³

The North Carolina experience, which has been ongoing for several years, may be a better representation of what the

Department can expect from its reviews, since the circumstances in Idaho were somewhat unique. Nonetheless, the 10 percent of reviewed rules being rescinded in North Carolina is comparable to the 10 percent of pages of rules repealed during Idaho's mid-2019 review. The Department assumes rescinded regulations will receive half as many comments as amended regulations. In that case, 53 rescinded regulations, of which 51 are expected in the first five years, should generate costs of \$7.5 to \$22.4 million (discounted at a 7 percent discount rate, assuming rescinded regulations are spread across corresponding timeframes in a manner consistent with the amended regulations described above). Thus, the total cost of monitoring is likely to range from \$52.2 to \$156.7 million (at a seven percent discount rate).

6. Total Estimated Costs From Implementing This Rulemaking

The Department estimates a total cost of between \$60.2 to \$199.3 million over ten years in order to do the following: (a) Conduct section 610 Reviews for Department rulemakings from 2016 or earlier in years 1 to 5, (b) conduct section 610 Reviews of rulemakings that "age in" to section 610 review in years 6 to 10, (c) conduct Assessments of rulemakings in years 1 to 10, and (d) conduct section 610 Reviews of rulemakings deemed to be subject to Review following an Assessment in years 1 to 10. The total number of Department employees required to conduct these activities is estimated to be 34.5 to 88.5 FTEs over ten years. The Department has also estimated the cost of increased monitoring falling on regulated entities. Results are presented in table 4 below, which also includes cost estimates discounted at a 3 percent discount rate for sensitivity purposes.²⁶⁴

TABLE 4—PRESENT VALUE OF ESTIMATED COST OF ASSESSING AND REVIEWING DEPARTMENT REGULATIONS OVER TEN YEARS (MILLIONS OF 2020\$), AT 3 AND 7 PERCENT DISCOUNT RATES

Type of cost	Cost (7%)	Cost (3%)	FTEs
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Department Costs:

²⁵⁷ Jon Sanders, *Rule removal under periodic review has slowed down, but a new law tightens the process*, The John Locke Found.: The Locker Room (July 22, 2019), <https://lockerroom.johnlocke.org/2019/07/22/rule-removal-under-periodic-review-has-slowed-down-but-a-new-law-tightens-the-process/>.

²⁵⁸ This is 370 Reviews from rules that were initially identified as having a SEISNOSE plus the 160 Reviews from Assessments determining that additional rulemakings have a SEISNOSE.

²⁵⁹ See Bureau of Labor Statistics, Occupational Employment Statistics, 23–1011 Lawyers. <https://www.bls.gov/oes/current/oes231011.htm>.

²⁶⁰ This assumption is in line with Department guidelines on regulatory analysis. See U.S. Dep't of Health & Hum. Servs., Guidelines for Regulatory Impact Analysis, at 28 (2016).

²⁶¹ This is 159 rulemakings × 486 commenters × \$143.20 per hour × 5 to 15 hours per comment.

²⁶² Office of Gov. Brad Little, Idaho's Historic Regulatory Cuts (July 2019).

²⁶³ The fact that there seemed to be little controversy surrounding rescinded rules may imply some of those rescissions were fairly trivial in some cases. While data on the extent to which rescissions were trivial or nontrivial are unavailable, news

stories provide some basis for this belief. Note that rescinded rules being relatively trivial is not evidence that amended rules were trivial. See, e.g., Editorial, *Idaho Quits Worrying About Snails*, Wall St. J., June 28, 2019, <https://www.wsj.com/articles/idaho-quits-worrying-about-snails-11561763217>.

²⁶⁴ The Office of Management and Budget recommends a 7 percent base-case default discount rate be used in regulatory impact analysis. OMB also recommends a 3 percent consumption rate of interest be used as an alternative. See Office of Mgmt. & Budget, Circular A–4, Regulatory Analysis (Sept. 17, 2003).

TABLE 4—PRESENT VALUE OF ESTIMATED COST OF ASSESSING AND REVIEWING DEPARTMENT REGULATIONS OVER TEN YEARS (MILLIONS OF 2020\$), AT 3 AND 7 PERCENT DISCOUNT RATES—Continued

Type of cost	Cost (7%)	Cost (3%)	FTEs
A. Costs Related to Section 610 Reviews of Regulations More Than Five Years Old.	\$4.7 to \$10.6 million.	\$5.2 to \$11.9	20.1 to 45.6.
B. Costs Related to Rulemakings That “Age In” to Section 610 Review	\$0.1 to \$0.3	\$0.2 to \$0.4	0.6 to 1.5.
C. Costs Related to Assessments	\$1.9 to \$6.4	\$2.1 to \$7.1	8.3 to 27.6.
D. Costs Related to Review of Additional Rulemakings Found to Have a SEISNOSE.	\$1.3 to \$3.2	\$1.4 to \$3.6	5.5 to 13.8.
Private Costs:			
E. Cost to Monitoring Public	\$52.2 to \$156.7	\$58.8 to \$176.3	N/A.
Total	\$60.2 to \$177.2	\$67.7 to \$199.3	34.5 to 88.5.

These figures can also be presented on an annualized basis, calculations of which are presented in table 5 below. Annualized costs are estimated to range from \$7.9 million to \$25.2 million per year over the decade following implementation of this final rule.

TABLE 5—ACCOUNTING STATEMENT: ANNUALIZED COSTS OF FINAL RULES

Present value (millions of 2020\$)	Discount rate (percent)	Time horizon	Annualized, millions of 2020\$ per year
\$60.2 to \$177.2	7	2021–2030	\$8.6 to \$25.2.
\$67.7 to \$199.3	3	2021–2030	\$7.9 to \$23.4.

7. Sensitivity Analysis

One commenter noted that conducting a retrospective analysis can be as time-consuming and expensive as a prospective regulatory analysis, suggesting the Department’s estimates of the time and expense of Reviews may be understated. The Department believes that on average Reviews of rulemakings implemented after the RFA are likely to be less time consuming than those implemented before. Moreover, 250 to 500 hours is the amount of time estimated to produce a full initial RFA analysis, which requires more time than a section 610 review, even one where no RFA analysis was conducted when the rulemaking was promulgated. Nevertheless, for the sake of testing the sensitivity of the cost estimates for Reviews, the Department calculates the costs of Reviews assuming all Reviews take 250 to 500 hours, rather than the assumption of 40 to 100 hours for post-RFA regulations made above. In this case, the present value of the total cost of Reviews (A, B and D in table 4) would rise to \$26.5 to \$53.0 million from \$6.1 to \$14.1 million (at a seven percent discount rate), and would rise to \$29.7 to \$59.4 million from \$6.8 to \$15.8 million (at a three percent discount rate).

However, there are also reasons to believe the costs estimated in table 4 are overestimated. First, this final rule permits the Secretary to extend by up to one year the expiration date for

particular regulations. Having this option might have the effect of pushing back the time horizon for certain Reviews and Assessments by one year. This would suggest the costs presented in table 4 above are overestimated to the extent that the present value of these costs will fall as some costs are pushed into the future. Assuming all costs are pushed back by one year, discounting the total costs by one additional year at a seven percent discount rate yields a present value of total costs in the range of \$56.3 million to \$165.6 million, and at a three percent rate yields a present value of total costs in the range of \$65.7 to \$193.5 million. These potential reduced costs are one reason the Department has decided to modify the final rule from its proposed form.

Similarly, the costs of monitoring might be pushed into the future if the Secretary exercises his or her right to extend the completion date by one year at a time, up to three times, with respect to amendment or rescission of regulations after Review. Assuming amended or rescinded regulations are pushed back three years in the future, the present value of monitoring costs would fall to \$42.6 to \$127.9 million at a seven percent discount rate and to \$53.8 to \$161.3 million at a three percent discount rate. If, as some commenters stated, this final rule resulted in the Department issuing fewer new notices of proposed rulemaking, the reduction in commenting costs from the reduction in

new notices of proposed rulemaking would cause the monitoring costs from this final rule to drop.

8. Other Possible Costs

Some commenters noted that there might be other sources of cost associated with this rulemaking other than those cited in the regulatory impact analysis accompanying the proposed rule. Some of these costs have been accounted for above, such as the cost of monitoring or the potential for Reviews to take longer than estimated in the proposed rule. Other commenters cited increased uncertainty to businesses and members of the regulated community as a possible cost due to the increased chance that rules may expire in the future. The Department does not believe uncertainty among the regulated community will add significantly to the costs of this rulemaking for the following reasons. The Department’s sporadic use of periodic retrospective review—notwithstanding the RFA and Executive Orders—itself leads to “uncertainty” about how robustly the Department implements directives that make for good policy.²⁶⁵ To the extent that the Department can maintain compliance with its obligations, this should build trust in the Department

²⁶⁵ To the extent this uncertainty has been lessened because the public has seen how the Department has implemented these directives over the course of many years, the same can be said for this final rule once it has been implemented for several years.

and reduce uncertainty (offsetting some or all of the uncertainty discussed by the commenters, if such uncertainty exists). Further, as noted above, the Department plans to release information about the 18,000 regulations under its authority and when they were adopted, such that any uncertainty surrounding the expiration dates of the Department's various rulemakings will be reduced substantially, if not entirely. Additional measures to mitigate private costs are discussed in the "Operationalization of This Final Rule" section of this final rule.

Second, the Department notes that many states have sunset provisions that are a routine part of their regulatory processes. New Jersey, Indiana, and North Carolina have sunset provisions for their regulations. Missouri has a sunset provision for regulations, which is tied to a periodic review requirement.²⁶⁶ Colorado, California, and Texas have sunset review processes for entire boards, commissions, and agencies. Some states have an annual sunset review process for their entire administrative code.²⁶⁷ Although the sunset clause is rarely exercised, there nevertheless is always the possibility the entire regulatory code will expire in these states in any particular year. In fact, two states (Idaho and Rhode Island) replaced their regulatory codes in recent years as part of sunset processes, and these experiences seemed to work relatively seamlessly.²⁶⁸

Similarly, many major federal laws have sunset clauses attached to them. Notable among these are the Patriot Act, enacted in the aftermath of the 9/11 terrorist attack, and tax laws passed as part of the budget reconciliation process under the Byrd Rule in the U.S. Senate. Federal agencies like the Food and Drug Administration within the Department periodically go through a reauthorization process, not unlike a sunset review.²⁶⁹ Sunset provisions are also routinely used in other countries, notably in Australia, Canada and the United Kingdom. A recent OECD report noted that just under half of OECD member countries have some form of sunset arrangements in place.²⁷⁰ In Australia, since the passage of the

Legislation Act of 2003,²⁷¹ all regulations (known as legislative instruments), with some exceptions, automatically expire 10 years after enactment unless parliament acts to extend the period or a replacement instrument is adopted.²⁷² The Australian Federal Register of Legislation (the equivalent of the **Federal Register** in the United States) maintains the sunset dates for qualifying legislation and provides notice about legislative instruments set to expire soon.²⁷³ The Department also plans to provide advance notice of expiration dates, and will provide updates on its progress conducting its regulatory reviews.

The Australian government also notes that sunset provisions are a useful way to spur periodic review of regulations, stating in a report that "Sunsetting provides an opportunity for agencies to review and streamline legislative instruments. It is an important mechanism for reducing red tape, delivering clearer laws and aligning existing legislation with current government policy."²⁷⁴

The Republic of Korea (ROK) enacted regulatory sunset legislation in the late 1990s and formed a Regulatory Reform Committee (RRC) to review newly-introduced regulations and to improve the quality of existing regulations.²⁷⁵ According to a report from the OECD, "The overall aim of the sunset clause is to periodically review regulations in order to determine whether it will be retained or abolished."²⁷⁶ In 2009, ROK broadened the scope of its regulatory sunset process by tying in requirements for retrospective analysis.²⁷⁷ About 20 percent of existing regulations are reviewed every three to five years and rescinded if found to "not serve the originally intended purpose."²⁷⁸ Moreover, according to the OECD, "[i]n 2014, the RRC set goals to reduce the economic regulations by 10% . . . As a result, 995 out of 9,876 economic

regulations were improved, which amounts to 10.1% of the total."²⁷⁹

These jurisdictions' sunset provisions do not all work identically to this final rule. However, in some ways this final rule is more lax than these other jurisdictions' sunset provisions, because the requirements to extend expiration dates are more modest compared to some other jurisdictions. For example, conducting an Assessment, and when necessary, a Review, is a relatively easy way to extend an expiration date compared to having to initiate an entirely new rulemaking. If the sunset reviews in these other jurisdictions do not create tremendous uncertainty, it stands to reason that neither will this final rule.

Some commenters expressed concern that regulations might accidentally expire due to the Department not timely conducting an Assessment or Review. The Department intends to review all regulations subject to this final rule, and that any regulations that are eliminated will be formally rescinded following the Review process. This is consistent with the experiences of other jurisdictions with sunset provisions, where rules (or boards or commissions) are first subjected to a review process before they are reauthorized or rescinded. As an example, Idaho recently conducted a sunset review of its entire regulatory code. While a significant number of rule chapters were eliminated as part of that effort, those chapters were rescinded as part of a deliberate review process.

New Jersey is a state that attaches a 7-year sunset provision to regulations. According to the Office of Administrative Law in the state, it is a relatively rare phenomenon that rules expire due to administrative error.²⁸⁰ Similarly, accidental expiration of rules appears to be uncommon in Missouri, a state that connects a sunset provision to a periodic review requirement, much like this final rule.²⁸¹

Data from North Carolina's sunset review process can be informative about the extent to which rules are likely to be rescinded, modified, or kept without change as part of a sunset review. A North Carolina public policy organization found that 19,361 rules were reviewed as part of that state's sunset review process in recent years.²⁸²

²⁶⁶ Missouri Revised Statutes, Title XXXVI § 536.175.5.

²⁶⁷ Utah Code Ann. § 63G-3-502(2) (2020); Idaho Code Ann. § 67-5292 (2020).

²⁶⁸ James Broughel, *The Mighty Waves of Regulatory Reform: Regulatory Budgets and the Future of Cost-Benefit Analysis*, 3 Bus. Entrepreneurship & Tax L. Rev. 206, at 216 (2019).

²⁶⁹ See FDA Reauthorization Act of 2017, Public Law 115-52 (Aug. 18, 2017).

²⁷⁰ OECD, *Reviewing the Stock of Regulation*, at 25 (2020).

²⁷¹ *Legislation Act 2003* (Cth) (Austl.).

²⁷² Australian Gov't Att'y Gen.'s Dep't, Guide to Managing the Sunsetting of Legislative Instruments, at 6 (July 2020), <https://www.ag.gov.au/sites/default/files/2020-07/Guide%20to%20Managing%20Sunsetting%20of%20Legislative%20Instruments.pdf>.

²⁷³ "Federal Register of Legislation," Australian Government, accessed November 30, 2020, <https://www.legislation.gov.au/Browse/Results/BySunsetDate/LegislativeInstruments/SunsettingSoon/2022/0/0/>.

²⁷⁴ *Id.* at 3.

²⁷⁵ OECD, *Regulatory Policy in Korea: Towards Better Regulation* (2017).

²⁷⁶ *Id.* at 20.

²⁷⁷ *Id.* at 71.

²⁷⁸ *Id.* at 41.

²⁷⁹ *Id.* at 84.

²⁸⁰ Personal communication with an official from the New Jersey Office of Administrative Law (Dec. 9, 2020).

²⁸¹ Personal communication with an official from the Missouri Office of the Attorney General (Dec. 31, 2020).

²⁸² Jon Sanders, *Rule removal under periodic review has slowed down, but a new law tightens the*
Continued

Of these, 5,542 were sent back through the rule adoption process (28.6%), presumably to be updated, and 11,811 rules were automatically re-upped with no change (61.0%). About 10 percent of regulations reviewed under the recent sunset review process were rescinded,²⁸³ and this occurred under the supervision of the state Rules Review Commission that was overseeing the process.

These numbers reinforce that there is little empirical basis to support fears that thousands of regulations might accidentally expire as a result of the Department's final regulation. The experiences in Idaho, New Jersey, Missouri and North Carolina demonstrate that sunset reviews tend to be orderly processes. Even in states like Idaho and Rhode Island, where significant portions of their regulatory codes were eliminated in recent years, these processes took place in an orderly fashion under the supervision of the state budget offices in those states.

Moreover, the Department has built in safeguards to prevent inadvertent expiration of regulations, such as seeking comment on the proposed rule regarding regulations that are important to Assess and Review, and enabling the public to submit comments requesting that the Department commence an Assessment or Review. Most importantly, the Department plans to release a list of when all of the regulations under its authority were created and last modified. This can be used to easily determine the expiration date of all regulations under its authority, which will significantly lower the chance any regulation might expire accidentally. The fact that a schedule of the Department's rules, along with their corresponding creation and modification dates, will be made public by the Department means the public will also be aware of which rules are scheduled to expire and when, thereby providing an additional safeguard against accidental expirations. Additionally, the timeline for initial reviews of older regulations has also been extended to five years in this final rule, with the option of a one-year extension, which should give the Department ample time to conduct

Assessments and Reviews and should result in few, if any, accidental expirations.

One might worry that periodic reviews may distract from other potentially beneficial rulemakings, which could impose a cost that the Department has not fully considered in the proposed rule. However, there is some indication that when regulators are undergoing retrospective review efforts, if a rulemaking is an urgent priority to them, they often find ways to justify it as part of their reviews, even if the rulemaking would have occurred absent the review.²⁸⁴ In other words, regulators maintain some flexibility to enact necessary new regulations by folding them into retrospective reviews, including the amendment and rescission process, alleviating some of the concern raised by the commenters. To the extent that any new rulemaking is displaced as a result of reviews required by the current regulation, it is likely to be the case that relatively lower priority rulemakings are displaced first (as presumably the Department will first implement high priority regulations before moving on to lower priority regulations).

Unfortunately, it is unknown with certainty whether Department rules impose benefits in excess of costs on average. The vast majority of Department rules do not have cost-benefit reports associated with them. Even for those that do, there are large uncertainties, and the literature suggests that many regulations are having estimated impacts that, over time, differ from what was estimated at the time the regulations were promulgated.²⁸⁵ This suggests that if a regulation did expire accidentally, this could be a cost or a benefit of this final rule, depending on the circumstances, since it is unknown whether the net benefits of the preponderance of Department rules are positive or negative. Regulations that are rescinded through sunset procedures are

sometimes obviously problematic, such that their removal is uncontroversial. And if a regulation accidentally expired, it could very well be because neither the Department nor interested members of the public saw a discernible benefit from the regulation. Regulations with discernible benefits are unlikely to go under the radar.

A related concern in comments is that Assessments and Reviews will take Department time and resources away from responding to the COVID-19 pandemic. Under this final rule, no Assessments or Reviews need to be completed until the end of 2026, well after the COVID-19 pandemic is likely to have subsided. Hence it is unlikely that this final rule will hamper the response to the pandemic.

The Department recognizes that this final rule requires the Department to undertake certain tasks. But given the importance of retrospective review, the Department believes that review should be a priority and it is willing to commit the necessary resources towards performing Assessments and Reviews.²⁸⁶

The expertise of Department analysts may also be best leveraged through Assessments and Reviews that could facilitate the Department's response to future pandemics or emergencies. As noted earlier, the Department waived or exercised enforcement discretion with respect to many regulations as part of its response to the pandemic. A review of those regulations is entirely appropriate to determine whether those regulations are undermining Department goals. Additionally, the COVID-19 pandemic has raised serious questions about whether certain Department regulations are protecting public health or otherwise achieving their objectives. In fact, it is possible that in the coming years even absent this final rule the Department would find it necessary to conduct in-depth reviews of Department regulations given the need to suspend, waive, or exercise enforcement discretion with respect to certain regulations during the COVID-19 pandemic. If such reviews would have taken place even absent this final rule, the cost of this final rule could be significantly lower than estimated (since those costs would be built into the baseline scenario).

Some commenters cited a report that stated "sunset requirements produce perfunctory reviews and waste

process, The John Locke Found.: The Locker Room (July 22, 2019), <https://lockerroom.johnlocke.org/2019/07/22/rule-removal-under-periodic-review-has-slowed-down-but-a-new-law-tightens-the-process/>.

²⁸³ Jon Sanders, *Rule removal under periodic review has slowed down, but a new law tightens the process*, The John Locke Found.: The Locker Room (July 22, 2019), <https://lockerroom.johnlocke.org/2019/07/22/rule-removal-under-periodic-review-has-slowed-down-but-a-new-law-tightens-the-process/>.

²⁸⁴ Randall Lutter, *Regulatory Policy: What Role for Retrospective Analysis and Review?*, 4 J. Benefit-Cost Analysis 17 (2013).

²⁸⁵ 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); Winston Harrington, *Grading Estimates of the Benefits and Costs of Federal Regulation*, at 33 (Resources for the Future, Discussion Paper No. 06–39, 2006), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=937357; Richard Morgenstern, *Retrospective Analysis of U.S. Federal Environmental Regulation*, 9 J. Benefit-Cost Analysis 285, at 294 (2018).

²⁸⁶ See also *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) (courts "have no basis for reordering agency priorities. The agency is in a unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way.").

resources.”²⁸⁷ Indeed, the same report was cited in the preamble of the proposed version of this rule. However, as noted in the proposed rule’s preamble, this statement from the report does not appear to be supported by the evidence. For example, the report noted that some states have repealed their sunset provisions, highlighting that “North Carolina was first to repeal its sunset law, and many other states quickly followed suit,” and concluded that “sunset provisions quickly proved to be an expensive, cumbersome, and disappointing method for enhancing legislative control.”²⁸⁸ However, North Carolina reenacted a sunset process for regulations in 2013²⁸⁹ (after the report in question was published). Moreover, not every jurisdiction uses sunset provisions as a mechanism for enhancing legislative control. As already noted, the purpose of sunset provisions is often to spur retrospective review and analysis of regulation or legislation, not necessarily to empower the legislative branch of government. Nor is it the Department’s intention with this final rule to enhance legislative control, but instead to encourage more retrospective review and improve outcomes resulting from the Department’s regulations.

Sunset provisions are set up in institutionally diverse ways across diverse jurisdictions. Different jurisdictions set different expiration time horizons on rules and grant authority to different governing bodies to decide whether regulations should be extended or not. New Jersey and Indiana grant the authority to renew regulations to the regulating agency, not the legislature (similar to this final rule). Meanwhile, Idaho and Tennessee task the legislature with renewing regulations.

While legal scholars have sometimes argued that sunset provisions have a useful role to play in strengthening legislative control,²⁹⁰ sunset provisions’ benefits in terms of improving the impacts of regulations are equally if not more important than these legislative oversight or separation of powers issues. It may be the case that sometimes legislators do not want or do not have time to devote to in-depth reviews of large numbers of regulations, which is

perhaps why sunset reviews that engage the legislature have sometimes turned into pro forma exercises.²⁹¹ In other words, it seems likely that the criticisms of sunset provisions that have appeared sporadically in the academic literature may relate to whether sunsets spur legislative engagement in rulemaking, rather than whether they are useful in terms of spurring retrospective review (where there seems to be less controversy).

To conclude, the Department acknowledges that some categories of costs have not been quantified here. While other categories of costs do exist than those calculated in table 4, they may be subject to greater uncertainty, be more challenging to estimate, or be relatively minor such that their estimation would not substantially alter the conclusions of this cost analysis.

As is common practice, this regulatory impact analysis has not sought to quantify the benefits of this final rule, but the Department believes they will be substantial.

E. Summary of Regulatory Impact Analysis

A forcing mechanism will help ensure robust compliance with the Department’s statutory obligations, which will strengthen the rule of law in the United States. Given how much of federal spending is driven by Department spending, regulatory reviews may also constitute a way to cut the federal budget deficit. If the Department is not able to review its own regulations in a timely manner, it is not clear how any member of the public can be expected to comply with all of the regulations the Department has written for them (plus all of the regulations issued by other federal, state, and local agencies). Fortunately, the Department intends to timely Assess and (where needed) Review those regulations not exempt from this final rule. Even if for some reason the Department cannot, it has provided itself an opportunity to delay the expiration date where the public interest requires so doing.

Regulatory Flexibility Act

The Department has examined the economic implications of this final 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.

The Regulatory Impact Analysis in the prior section also satisfies the Department’s obligation to conduct a regulatory flexibility analysis under section 604. For the reasons described in this final rule, this final rule will benefit small entities.

Congressional Review Act

The Congressional Review Act (CRA) defines a “major rule” as “any rule that the Administrator of the Office of Information and Regulatory Affairs

²⁸⁷ Jason A. Schwartz, 52 *Experiments with Regulatory Review*, Inst. for Pol’y Integrity, at 24 (Nov. 2010), https://policyintegrity.org/files/publications/52_Experiments_with_Regulatory_Review.pdf.

²⁸⁸ *Id.* at 33.

²⁸⁹ Regulatory Reform Act of 2013, H.B. 74, 2013 Gen. Assemb., 2013 Sess. (N.C. 2013).

²⁹⁰ Jonathan H. Adler & Christopher Walker, *Delegation and Time*, 105 Iowa L. Rev. 1931 (2020).

²⁹¹ Robert W. Hahn, *State and Federal Regulatory Reform: A Comparative Analysis*, 29 The J. Legal Stud. 873 (2000).

(OIRA) of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of \$100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.” 5 U.S.C. 804(2). Based on the analysis of this final rule under Executive Order 12866, this rule is expected to be a major rule for purposes of the CRA. The Department will comply with the CRA’s requirements to inform Congress.

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 \$156 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.

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 final 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 final rule does not impose substantial direct costs on State and local governments or have federalism implications as defined in Executive

Order 13132. The final 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 final rule—either the findings of a Review determining a regulation should be amended, or a failure to perform an Assessment or Review. Thus, this final rule would impose no substantial direct costs on State and local governments.

The Department notes, though, that this final rule might indirectly have beneficial federalism implications. Among other things, the Reviews called for by this final rule require the Department to determine if certain Department 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 final 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.

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 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 final rule would apply to and amend certain 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 an Assessment or Review, this final 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, for the reasons described in this final rule’s Regulatory Impact Analysis, the Department concludes that the benefits to the public, including families, that flow from periodic Assessments and 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 Assess or 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. If, pursuant to this final rule, the Department amends or rescinds a regulation, it would conduct any required assessment of the policy on families at the time of such rulemaking.

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 final 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.

42 CFR Part 1000

Administrative practice and procedure.

45 CFR Part 8

Administrative practice and procedure.

45 CFR Part 200

Administrative practice and procedure.

45 CFR Part 300

Administrative practice and procedure.

45 CFR Part 403

Administrative practice and procedure.

45 CFR Part 1010

Administrative practice and procedure.

45 CFR Part 1390

Administrative practice and procedure.

For the reasons set forth in the preamble, the Department amends 21 CFR, chapter I, 42 CFR chapters I, IV, and V; 45 CFR subtitle A; and 45 CFR subtitle B, chapters II, III, IV, X, and XIII, as follows:

Title 21—Food and Drugs**CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES****■ 1. Add 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; 5 U.S.C. 610; 15 U.S.C. 402; 15 U.S.C. 409; 15 U.S.C. 1261–1276; 15 U.S.C. 1333; 15 U.S.C. 1451–1461; 15 U.S.C. 4402; 18 U.S.C. 1905; 19 U.S.C. 1490–1491; 19 U.S.C. 2531–2582; 21 U.S.C. 41–50; 21 U.S.C. 141–149; 21 U.S.C. 301 *et seq.*; 21 U.S.C. 355 note; 21 U.S.C. 301–397; 21 U.S.C. 467f; 21 U.S.C. 679; 21 U.S.C. 821; 21 U.S.C. 1034; 21 U.S.C. 1401–1403; 28 U.S.C. 2112; 35 U.S.C. 156; 42 U.S.C. 201–262; 42 U.S.C. 263a; 42 U.S.C. 263b–263n; 42 U.S.C. 264; 42 U.S.C. 265; 42 U.S.C. 271; 42 U.S.C. 300aa–28; 42 U.S.C. 300u–300u–5; 42 U.S.C. 4321; 42 U.S.C. 4332; 42 U.S.C. 7671 *et seq.*; Sec. 121, Pub. L. 105–115, 111 Stat. 2296; Pub. L. 107–109; Pub. L. 107–188, 116 Stat. 594, 668–69; Pub. L. 108–155; Secs. 201 and 202, Pub. L. 111–31, 123 Stat. 1776; Secs. 901(b) and 906(d), Pub. L. 111–31; Pub. L. 111–353, 124 Stat. 3885, 3889; Pub. L. 113–54.

§ 6.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued

by the Secretary or his delegates or sub-delegates in this chapter.

(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 Sections 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 Sections 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 Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section 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 of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

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

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

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

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

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest

requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact 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 rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

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

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking 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 rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section 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) of this section to amend or rescind the Section. 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, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(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 Section shall be completed.

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

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections 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) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

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

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

(6) Sections related solely to Federal Government procurement.

(7) Sections 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) 21 CFR parts 131, 133, 135–137, 139, 145, 146, 150, 152, 155, 156, 158, 160, 161, 163–166, 168, and 169.

(9) 21 CFR parts 331–333, 335–336, 338, 340–341, 343–344, 346–350, 352, 355, 357, and 358.

(10) 21 CFR parts 862, 864, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, 892, 895, and 898.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose

assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(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

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 2. Add 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; 5 U.S.C. 610, 8 U.S.C. 1182, 8 U.S.C. 1222, 29 U.S.C. 670(a), 30 U.S.C. 957, 31 U.S.C. 9701, 42 U.S.C. 216, 42 U.S.C. 241, 42 U.S.C. 300a-4, 42 U.S.C. 10801, 42 U.S.C. 1302, 42 U.S.C. 1395hh, 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. 243, 42 U.S.C. 247b, 247c, 42 U.S.C. 247d-6e, 31 U.S.C. 1243 note, 42 U.S.C. 252, 42 U.S.C. 254c, 42 U.S.C. 262a, 42 U.S.C. 256b, 42 U.S.C. 263, 42 U.S.C. 263a, 42 U.S.C. 264-271, 42 U.S.C. 273-274d; 42 U.S.C. 274e; 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. 289a, 42 U.S.C. 289b, 42 U.S.C. 290aa, *et seq.*, 42 U.S.C. 290aa(d), 42 U.S.C. 290aa(m), 42 U.S.C. 290cc-21, *et seq.*, 42 U.S.C. 290dd-2, 42 U.S.C. 290kk, *et seq.*, 42 U.S.C. 300 through 300a-6, 42 U.S.C. 300cc-16, 42 U.S.C. 300mm-300mm-61, 42

U.S.C. 300x-21, *et seq.*, 42 U.S.C. 7384n, 42 U.S.C. 7384q, 42 U.S.C. 6939a.

§ 1.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(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 Sections 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 Sections 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 Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section 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 of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

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

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

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

(2) The last year in which the Department assessed and (if review of the Section is required) reviewed the Section shall be the year during which the findings of the assessment and (if

required) the review of a Section are published in the **Federal Register** pursuant to paragraph (f) of this section.

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact 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 rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

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

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking 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 rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section 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) of this section to amend or rescind the Section. 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, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(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 Section shall be completed.

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

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections 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) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

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

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

(6) Sections related solely to Federal Government procurement.

(7) Sections 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 100.3.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose

assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(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]

CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 3. Add part 404 to subchapter A 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; 5 U.S.C. 610; 31 U.S.C. 9701; 42 U.S.C. 263a; 42 U.S.C. 273; 42 U.S.C. 300e; 42 U.S.C. 300e–5; 42 U.S.C. 300e–9; 42 U.S.C. 405(a); 42 U.S.C. 1302; 42 U.S.C. 1306; 42 U.S.C. 1315a; 42 U.S.C. 1320a–7; 42 U.S.C. 1320a–7j; 42 U.S.C. 1320b–8; 42 U.S.C. 1320b–12; 42 U.S.C. 1395; 42 U.S.C. 1395aa(m); 42 U.S.C. 1395cc; 42 U.S.C. 1395d(d); 42 U.S.C. 1395ddd; 42 U.S.C. 1395eee(f); 42 U.S.C. 1395f(b); 42 U.S.C. 1395ff; 42 U.S.C. 1395g; 42 U.S.C. 1395hh; 42 U.S.C. 1395i; 42 U.S.C. 1395i–3; 42 U.S.C. 1395j(a), (i), (n), and (t); 42 U.S.C. 1395jj; 42 U.S.C. 1395kk; 42 U.S.C. 1395m; 42 U.S.C. 1395nn; 42 U.S.C. 1395rr; 42 U.S.C. 1395rr(b)(l); 42 U.S.C. 1395tt; 42 U.S.C. 1395w–5; 42 U.S.C. 1395w–101 through 1395w–152; 42 U.S.C. 1395ww; 42 U.S.C. 1395ww(k); 42 U.S.C. 1395x; 1395x(e), the sentence following 1395x(s)(11) through 1395x(s)(16); 42 U.S.C. 1395x(v); 42 U.S.C. 1395y(a); 42 U.S.C. 1396r; 42 U.S.C. 1396r–8; 42 U.S.C. 1396u–4(f); 44 U.S.C. Chapter 35; Section 1331 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–

148, 124 Stat. 119), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, 124 Stat. 1029); Pub. L. 112–202 amendments to 42 U.S.C. 263a; sec. 105, Pub. L. 114–10, 129 Stat. 87.

§ 404.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(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 Sections 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 Sections 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 Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section 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 of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

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

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

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

(2) The last year in which the Department assessed and (if review of

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

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact 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 rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

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

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking 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 rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section 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) of this section to amend or rescind the Section. 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, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(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 Section shall be completed.

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

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections 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) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

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

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

(6) Sections related solely to Federal Government procurement.

(7) Sections 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 payment update rules.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(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]

CHAPTER V—OFFICE OF INSPECTOR GENERAL—HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 4. Add subpart A to part 1000 to read as follows:

PART 1000—Introduction, General Definitions

Subpart A—Review of regulations

Sec.

1000.1 Retrospective Review of Existing Regulations

1000.2 through 1000.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 31 U.S.C. 6101 note; 42 U.S.C. 262a; 42 U.S.C. 405(a); 42 U.S.C. 405(b); 42 U.S.C. 405(d); 42 U.S.C. 405(e); 42 U.S.C. 1302; 42 U.S.C. 1320; 42 U.S.C. 1320a–7(d)(b); 1320b–10; 42 U.S.C. 1320c–5; 42 U.S.C. 1395cc(b)(2)(D), (E), and (F); 42 U.S.C. 1395cc(j); 42 U.S.C. 1395dd(d)(1); 42 U.S.C. 1395hh; 42 U.S.C. 1395mm; 42 U.S.C. 1395nn(g); 42 U.S.C. 1395ss(d); 42 U.S.C. 1395u(j); 42 U.S.C. 1395u(k); 42 U.S.C. 1395w–104(e)(6); 42 U.S.C. 1395w–141(i)(3); 42 U.S.C. 1395y(d); 42 U.S.C. 1395y(e); 42 U.S.C. 1396(a)(4)(A); 42 U.S.C. 1396a(p); 42 U.S.C. 1396a(a)(39); 42 U.S.C. 1396a(a)(41); 42 U.S.C. 1396a(a)(61); 42 U.S.C. 1396b(a)(6); 42 U.S.C. 1396b(b)(3); 42 U.S.C. 1396b(i)(2); 42 U.S.C. 1396b(m); 42 U.S.C. 1396b(q); 42 U.S.C. 1842(j)(1)(D)(iv);

42 U.S.C. 1842(k)(1); 42 U.S.C. 11131(c); 42 U.S.C. 11137(b)(2).

§ 1000.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(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 Sections 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 Sections 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 Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section 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 of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

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

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

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

(2) The last year in which the Department assessed and (if review of the Section is required) reviewed the Section shall be the year during which the findings of the assessment and (if

required) the review of a Section are published in the **Federal Register** pursuant to paragraph (f) of this section.

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact 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 rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

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

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking 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 rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section 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) of this section to amend or rescind the Section. 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, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(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 Section shall be completed.

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

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections 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) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

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

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

(6) Sections related solely to Federal Government procurement.

(7) Sections 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 1001.952.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose assessment or review it is commencing.

It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(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.

§§ 1000.2 through 1000.5 [Reserved]

Title 45—Public Welfare

Subtitle A—Department of Health and Human Services

■ 5. Add part 8 to read as follows:

PART 8—REVIEW OF REGULATIONS

Sec.

8.1 Retrospective Review of Existing Regulations

8.2 through 8.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 504(c)(1); 5 U.S.C. 552; 5 U.S.C. 552a; 5 U.S.C. 553; 5 U.S.C. 5514; 5 U.S.C. 7301; 8 U.S.C. 1182(e); 8 U.S.C. 1182(j)(2)(A); 18 U.S.C. 207(j); 18 U.S.C. 1905; 20 U.S.C. 91; 20 U.S.C. 1405; 20 U.S.C. 1681 *et seq.*; 20 U.S.C. 1681 through 1688; 21 U.S.C. 1174; 22 U.S.C. 2151b(f) (*e.g.*, Pub. L. 116–6, Div. F, sec. 7018); 22 U.S.C. 2451 *et seq.*; 22 U.S.C. 7631(d); 22 U.S.C. 7631(f); 26 U.S.C. 36B; 26 U.S.C. 5000A(d)(2); 28 U.S.C. 2672; 29 U.S.C. 669(a)(5); 29 U.S.C. 794; 31 U.S.C. 1243 note; 31 U.S.C. 1352; 31 U.S.C. 3711(d); 31 U.S.C. 3720A; 31 U.S.C. 3720D; 31 U.S.C. 3721; 31 U.S.C. 3801–3812; 31 U.S.C. 6506; 31 U.S.C. 7501–7507; 31 U.S.C. 9701; 40 U.S.C. 121(c); 40 U.S.C. 318–318d; 40 U.S.C. 484; 40 U.S.C. 484(k); 40 U.S.C. 486; 42 U.S.C. 216; 42 U.S.C. 216(b); 42 U.S.C. 238n; 42 U.S.C. 263a(f)(1)(E); 42 U.S.C. 280g–1(d); 42 U.S.C. 289(a); 42 U.S.C. 289b–1; 42 U.S.C. 290bb–36(f); 42 U.S.C. 290dd–2; 42 U.S.C. 299c–4; 42 U.S.C. 300a–7; 42 U.S.C. 300aa–11; 42 U.S.C. 300gg through 300gg–63; 42 U.S.C. 300gg–1 through 300gg–5; 42 U.S.C. 300gg–11 through 300gg–23; 42 U.S.C. 300gg–18; 42 U.S.C. 300gg–91; 42 U.S.C. 300gg–92; 42 U.S.C. 300gg–94; 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 42 U.S.C. 300jj–52; 42 U.S.C. 300w *et seq.*; 42 U.S.C.

300x *et seq.*; 42 U.S.C. 300y *et seq.*; 42 U.S.C. 618; 42 U.S.C. 622(b); 42 U.S.C. 629b(a); 42 U.S.C. 652(a); 42 U.S.C. 652(d); 42 U.S.C. 654A; 42 U.S.C. 671(a); 42 U.S.C. 701 *et seq.*; 42 U.S.C. 1302; 42 U.S.C. 1302(a); 42 U.S.C. 1306(c); 42 U.S.C. 1310; 42 U.S.C. 1315; 42 U.S.C. 1315a; 42 U.S.C. 1320a–1; 42 U.S.C. 1320a–7e; 42 U.S.C. 1320c–11; 42 U.S.C. 1395cc(f); 42 U.S.C. 1320d–2 (note); 42 U.S.C. 1320d–1320d–9; 42 U.S.C. 1395i–3; 42 U.S.C. 1395i–5; 42 U.S.C. 1395w–22(j)(3)(B); 42 U.S.C. 1395w–26; 42 U.S.C. 1395w–27; 42 U.S.C. 1395x; 42 U.S.C. 1396a; 42 U.S.C. 1396a(a); 42 U.S.C. 1396a(w)(3); 42 U.S.C. 1396f; 42 U.S.C. 1396g; 42 U.S.C. 1396r–2; 42 U.S.C. 1396s(c)(2)(B)(ii); 42 U.S.C. 1396u–2(b)(3)(B); 42 U.S.C. 1397 *et seq.*; 42 U.S.C. 1397j–1(b); 42 U.S.C. 2000d *et seq.*; 42 U.S.C. 2000d–1; 42 U.S.C. 2942; 42 U.S.C. 3334; 42 U.S.C. 3505; 42 U.S.C. 3535(d); 42 U.S.C. 5106i(a); 42 U.S.C. 6101 *et seq.*; 42 U.S.C. 8621 *et seq.*; 42 U.S.C. 9858; 42 U.S.C. 9901 *et seq.*; 42 U.S.C. 11101–11152; 42 U.S.C. 11411; 42 U.S.C. 14406; 42 U.S.C. 18021–18024; 42 U.S.C. 18031–18033; 42 U.S.C. 18041(a); 42 U.S.C. 18041–18042; 42 U.S.C. 18044; 42 U.S.C. 18051; 42 U.S.C. 18054; 42 U.S.C. 18061 through 18063; 42 U.S.C. 18071; 42 U.S.C. 18081–18083; 42 U.S.C. 18113; 42 U.S.C. 18116; 48 U.S.C. 1469a; 50 U.S.C. App. 2061–2171; 27 Stat. 395; Sec. 1(a), 80 Stat. 306; secs. 1, 5, 6, and 7 of Reorganization Plan No. 1 of 1953, 18 FR 2053, 67 Stat. 631 and authorities cited in the Appendix; Sec. 203, 63 Stat. 385; Section 213, Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, Pub. L. 91–646, 84 Stat. 1894 (42 U.S.C. 4633) as amended by the Surface Transportation and Uniform Relocation Assistance Act of 1987, Title IV of Pub. L. 100–17, 101 Stat. 246–256 (42 U.S.C. 4601 note); Sec. 223, 58 Stat. 683, as amended by 81 Stat. 539; 42 U.S.C. 217b; Sec. 602, 78 Stat. 252; Sec. 501 of Pub. L. 100–77, 101 Stat. 509–10, 42 U.S.C. 11411; Pub. L. 100–259, 102 Stat. 28 (Mar. 22, 1988); 5 U.S.C. 301, Pub. L. 100–259, 102 Stat. 28 (Mar. 22, 1988); Public Law 101–410, Sec. 701 of Public Law 114–74, 31 U.S.C. 3801–3812; Section 5301 of Pub. L. 100–690, the Anti-Drug Abuse Act of 1988, 102 Stat. 4310, 21 U.S.C. 853a; secs. 13400–13424, Pub. L. 111–5, 123 Stat. 258–279; Sec. 1101 of the Patient Protection and Affordable Care Act (Pub. L. 111–148); Section 1103 of the Patient Protection and Affordable Care Act (Pub. L. 111–148); secs. 1104 and 10109 of Pub. L. 111–148, 124 Stat. 146–154 and 915–917; Title I of the Affordable Care Act, Sections 1311, 1312, 1411, 1412, Pub. L. 111–148, 124 Stat. 119; Medicare Advantage (*e.g.*, Pub. L. 115–245, Div. B, sec. 209); the Weldon Amendment (*e.g.*, Pub. L. 115–245, Div. B, sec. 507(d)); 5 U.S.C. 610.

§ 8.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this subtitle.

(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 Sections 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 Sections 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 Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section 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 of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

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

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

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

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

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time

for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact 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 rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

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

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking 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 rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section 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) of this section to amend or rescind the Section. 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, no more than three times, for a total of

not more than five years (inclusive of the initial two-year period).

(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 Section shall be completed.

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

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections 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) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

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

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

(6) Sections related solely to Federal Government procurement.

(7) Sections 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 Notice of Benefit and Payment Parameters update rules.

(h) When the Department commences the process of performing an assessment or review, it shall state on a Department-managed website the Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by

which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(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.

§ 8.2 through 8.5 [Reserved]

Subtitle B—Regulations Relating to Public Welfare

CHAPTER II—OFFICE OF FAMILY ASSISTANCE (ASSISTANCE PROGRAMS), ADMINISTRATION FOR CHILDREN AND FAMILIES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 6. Add part 200 to read as follows:

PART 200—REVIEW OF REGULATIONS

Sec.

200.1 Retrospective Review of Existing Regulations

200.2 through 200.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 24 U.S.C. 321–329; 31 U.S.C. 7501 *et seq.*; 42 U.S.C. 301; 42 U.S.C. 303; 42 U.S.C. 601; 42 U.S.C. 601 note; 42 U.S.C. 602; 42 U.S.C. 602 (note); 42 U.S.C. 602(a)(44); 42 U.S.C. 603; 42 U.S.C. 603(a)(4); 42 U.S.C. 604; 42 U.S.C. 605; 42 U.S.C. 606; 42 U.S.C. 607; 42 U.S.C. 608; 42 U.S.C. 609; 42 U.S.C. 610; 42 U.S.C. 611; 42 U.S.C. 612; 42 U.S.C. 613; 42 U.S.C. 613(i); 42 U.S.C. 616; 42 U.S.C. 619; 42 U.S.C. 654; 42 U.S.C. 862a; 42 U.S.C. 1202; 42 U.S.C. 1203; 42 U.S.C. 1301; 42 U.S.C. 1302; 42 U.S.C. 1306(a); 42 U.S.C. 1308; 42 U.S.C. 1313; 42 U.S.C. 1316; 1320b–7; 42 U.S.C. 1973gg–5; 42 U.S.C. 1337; 42 U.S.C. 1352; 42 U.S.C. 1353; 42 U.S.C. 1382 (note); 42 U.S.C. 1383 (note); sections 1, 5, 6, and 7 of Reorganization Plan No. 1 of 1953, 67 Stat. 631; Secs. 1–11, 74 Stat. 308–310; Sec. 302, 75 Stat. 142, sec. 1102, 49 Stat. 647; sec. 6 of Pub. L. 94–114, 89 Stat. 579; Pub. L. No. 97–248, 96 Stat. 324, and Pub. L. No. 99–603, 100 Stat. 3359; sec. 4 of Pub. L. 97–458, 96 Stat. 2513; sec. 2 of Pub. L. 98–64, 97 Stat. 365; sec. 1883 of Pub. L. 99–514, 100 Stat. 2916; sec. 15 of Pub. L. 100–241, 101 Stat. 1812; sec. 105(f) of Pub. L. 100–383, 102 Stat. 908; sec. 206(d) of Pub. L. 100–383, 102 Stat. 914; sec. 105(i) of Pub. L. 100–707, 102 Stat. 4693; sec. 1(a) of Pub. L. 101–201, 103 Stat. 1795; sec. 10405 of Pub. L. 101–239, 103 Stat. 2489; sec. 501(c) of Pub. L. 101–392, 104 Stat. 831; sec. 6(h)(2) of Pub. L. 101–426, 104 Stat. 925; and sec. 471(a) of Pub. L. 102–325, 106

Stat. 606; Sec. 7102, Pub. L. 109–171, 120 Stat. 135; Public Law 111–5; Sec. 4004, Pub. L. 112–96, 126 Stat. 197; 49 Stat. 647.

§ 200.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(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 Sections 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 Sections 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 Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section 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 of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

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

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

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

(2) The last year in which the Department assessed and (if review of the Section is required) reviewed the Section shall be the year during which

the findings of the assessment and (if required) the review of a Section are published in the **Federal Register** pursuant to paragraph (f) of this section.

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact 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 rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

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

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking 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 rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section 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) of this section to amend or rescind the Section. 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, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(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 Section shall be completed.

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

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections 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) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

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

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

(6) Sections related solely to Federal Government procurement.

(7) Sections 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 Section(s) whose

assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(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.

§ 200.2 through 200.5 [Reserved]

CHAPTER III—OFFICE OF CHILD SUPPORT ENFORCEMENT (CHILD SUPPORT ENFORCEMENT PROGRAM), ADMINISTRATION FOR CHILDREN AND FAMILIES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 7. Add part 300 to read as follows:

PART 300—REVIEW OF REGULATIONS

Sec.

300.1 Retrospective Review of Existing Regulations

300.2 through 300.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 25 U.S.C. 1603(12); 25 U.S.C. 1621e; 42 U.S.C. 609(a)(8); 42 U.S.C. 651 through 658; 42 U.S.C. 652(a)(4) and (g); 42 U.S.C. 654(15)(A); 42 U.S.C. 655(f); 42 U.S.C. 658a; 42 U.S.C. 659a; 42 U.S.C. 660; 42 U.S.C. 663; 42 U.S.C. 664; 42 U.S.C. 666 through 669A; 42 U.S.C. 1301; 42 U.S.C. 1302; 42 U.S.C. 1396a(a)(25); 42 U.S.C. 1396b(d)(2); 42 U.S.C. 1396b(o); 42 U.S.C. 1396b(p); 42 U.S.C. 1396(k).

§ 300.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(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 Sections 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 Sections 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 Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section 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 of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

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

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

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

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

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination,

which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact 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 rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

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

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking 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 rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section 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) of this section to amend or rescind the Section. 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, no more than three times, for a total of

not more than five years (inclusive of the initial two-year period).

(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 Section shall be completed.

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

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections 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) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

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

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

(6) Sections related solely to Federal Government procurement.

(7) Sections 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 Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on

Regulations.gov where the public can submit comments requesting that the Department assess or review a Section.

(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.

§ 300.2 through 300.5 [Reserved]

CHAPTER IV—OFFICE OF REFUGEE RESETTLEMENT, ADMINISTRATION FOR CHILDREN AND FAMILIES DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 8. Add part 403 to read as follows:

PART 403—REVIEW OF REGULATIONS

Sec.

403.1 Retrospective Review of Existing Regulations

403.2 through 403.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 6 U.S.C. 279; 8 U.S.C. 1103(a)(3); 8 U.S.C. 1232; 8 U.S.C. 1255a note; 8 U.S.C. 1522 note; 8 U.S.C. 1522(a)(9); 42 U.S.C. 15607(d).

§ 403.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(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 Sections 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 Sections 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 Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section 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 of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

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

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

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

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

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant

economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact 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 rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

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

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking 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 rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section 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) of this section to amend or rescind the Section. 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, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(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 Section shall be completed.

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

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections 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) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

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

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

(6) Sections related solely to Federal Government procurement.

(7) Sections 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 Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received.

There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(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.

§ 403.2 through 403.5 [Reserved]

CHAPTER X—OFFICE OF COMMUNITY SERVICES, ADMINISTRATION FOR CHILDREN AND FAMILIES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 9. Add part 1010 to read as follows:

PART 1010—REVIEW OF REGULATIONS

Sec.

1010.1 Retrospective Review of Existing Regulations

1010.2 through 1010.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 42 U.S.C. 604 nt.; 42 U.S.C. 9901 *et seq.*; 42 U.S.C. 11302 (101 Stat. 485); 42 U.S.C. 11461–11464; 42 U.S.C. 11472 (101 Stat. 532–533).

§ 1010.1 Retrospective Review of Existing Regulations

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(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 Sections 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 Sections 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 Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section 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 of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by

the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

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

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

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

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

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact 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 rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

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

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking 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 rulemaking since the rulemaking was promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section 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) of this section to amend or rescind the Section. 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, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(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 Section shall be completed.

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

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections 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) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

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

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

(6) Sections related solely to Federal Government procurement.

(7) Sections 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 Section(s) whose assessment or review it is commencing. It shall also announce once a month in the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(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.

§ 1010.2 through 1010.5 [Reserved]

CHAPTER XIII—ADMINISTRATION FOR CHILDREN AND FAMILIES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ 10. Add subchapter A to read as follows:

SUBCHAPTER A—[include your preferred subchapter heading]

PART 1300—REVIEW OF REGULATIONS

Sec.

1300.1 Retrospective Review of Existing Regulations.

1300.2 through 1390.5 [Reserved]

Authority: 5 U.S.C. 301; 5 U.S.C. 610; 29 U.S.C. 709; 29 U.S.C. 3343; 42 U.S.C. 620 *et*

seq., 42 U.S.C. 670 *et seq.*; 42 U.S.C. 1302; 42 U.S.C. 1395b–4; 42 U.S.C. 2991, *et seq.*; 42 U.S.C. 3001 *et seq.*; Title III of the Older Americans Act; 42 U.S.C. 3001; Title VI, Part A of the Older Americans Act; 42 U.S.C. 3001; Title VI Part B of the Older Americans Act; 42 U.S.C. 3515e; 42 U.S.C. 5701; 42 U.S.C. 9801 *et seq.*; 42 U.S.C. 10401 *et seq.*; 42 U.S.C. 15001 *et seq.*

§ 1300.1 Retrospective Review of Existing Regulations.

(a) This section applies to and shall be deemed to amend all regulations issued by the Secretary or his delegates or sub-delegates in this chapter.

(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 Sections 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 Sections 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 Sections upon a substantial number of small entities.

(3) *Section* (when capitalized) shall mean a section of the Code of Federal Regulations. For example, 42 CFR 2.13 is a Section, and 42 CFR 2.14 is another Section (see 1 CFR 21.11).

(4) *Year of the Section's promulgation* shall mean the year the Section 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 of that term in section 610 of title 5 of the United States Code.

(c)(1) Unless a Section expires earlier or is rescinded, all Sections issued by the Secretary or his delegates or sub-delegates in this chapter shall expire at the end of:

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

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

(iii) Ten calendar years after the last year in which the Department assessed and (if review of the Section is required pursuant to paragraph (d) of this

section) reviewed the Section, whichever is latest.

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

(3)(i) If, prior to the expiration of a Section under paragraph (c)(1) of this section, the Secretary makes a written determination that the public interest requires continuation of the Section in force beyond the date on which the Section would otherwise expire under paragraph (c)(1), the Secretary may continue the Section in force one time for a period stated in the determination, which shall not exceed one calendar year.

(ii) The Department shall promptly publish in the **Federal Register** any written determination under paragraph (c)(3)(i) of this section.

(iii) The authority of the Secretary under paragraph (c)(3)(i) of this section is not delegable and may be exercised only by the Secretary or, when the office of the Secretary is vacant or the Secretary has become unable to perform the functions and duties of the office of the Secretary, by the individual acting as Secretary in accordance with the law.

(d) The Department is required to review those rulemakings (and any amendments or additions that may have been added thereafter) that the Department assesses have a significant economic impact upon a substantial number of small entities. In reviewing rulemakings to minimize any significant economic impact 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 rulemaking, consideration of which shall include but not be limited to the extent to which the rulemaking defines terms or sets standards used in or otherwise applicable to other Federal rules;

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

(3) The complexity of the rulemaking;

(4) The extent to which the rulemaking 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 rulemaking since the rulemaking was

promulgated or the last time the rulemaking was reviewed by the Department; and

(6) Whether the rulemaking complies with applicable law.

(e) If the review concludes the Section 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) of this section to amend or rescind the Section. 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, no more than three times, for a total of not more than five years (inclusive of the initial two-year period).

(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 Section shall be completed.

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

(1) Sections that are prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Section and as to what is prescribed by the Section. For Sections 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) Sections whose expiration pursuant to this section would violate any other Federal law.

(3) This section.

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

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

(6) Sections related solely to Federal Government procurement.

(7) Sections 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 Section(s) whose assessment or review it is commencing. It shall also announce once a month in

the **Federal Register** those new assessments or reviews that it has commenced in the last month. The Department will create a docket on *Regulations.gov* for each assessment or review that the Department is conducting. The public will be able to submit comments to the dockets of each rulemaking being assessed or reviewed. Each docket shall specify the date by which comments must be received. There shall also be a general docket on *Regulations.gov* where the public can submit comments requesting that the Department assess or review a Section.

(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.

§ 1300.2 through 1300.5 [Reserved]

Dated: January 8, 2021.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2021-00597 Filed 1-15-21; 8:45 am]

BILLING CODE 4150-26-P