after the date of publication for the earliest issue in the group.

(a) The * * * scope of a group registration. * * *
   When the Office issues a group registration under paragraph (e) of this section, the registration covers each issue in the group and each issue is registered as a separate collective work. When the Office issues a group registration under paragraph (g), (h), (i), or (k) of this section, the registration covers each work in the group and each work is registered as a separate work. For purposes of registration, the group as a whole is not considered a compilation, a collective work, or a derivative work under section 101, 103(b), or 504(c)(1) of title 17 of the United States Code.

7. Add §202.18 to read as follows:

§202.18 Access to electronic works.

(a) Access to electronic works received under §202.4(e) will be available only to authorized users at Library of Congress premises in accordance with the policies listed below. Library staff may access such content off-site as part of their assigned duties via a secure connection.

(b) Access to each individual electronic work received under §202.4(e) will be limited, at any one time, to two Library of Congress authorized users via a secure server over a secure network that serves Library of Congress premises.

(c) The Library of Congress will not make electronic works received under §202.4(e) available to the public over the internet without rightsholders’ permissions.

(d) “Authorized user” means Library of Congress staff, contractors, and registered researchers, and Members, staff and officers of the U.S. House of Representatives and the U.S. Senate for the purposes of this section.


8. In §202.19, revise paragraph (d)(2)(ix) to read as follows:

§202.19 Deposit of published copies or phonorecords for the Library of Congress.

(a) The * * * scope of a group registration. * * *
   (d) * * *

   (2) * * *

   (ix) In the case of published newspapers, a deposit submitted pursuant to and in compliance with the group registration option under §202.4(e) shall be deemed to satisfy the mandatory deposit obligation under this section.

   Dated: January 10, 2018.

Karyn Temple Claggett,
Acting Register of Copyrights and Director of the U.S. Copyright Office.

Approved by:
Carla D. Hayden,
Librarian of Congress.

[FR Doc. 2018-01838 Filed 1–29–18; 8:45 am]

BILLING CODE 1410–30–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 424

[CMS–6059–N8]

Medicare, Medicaid, and Children’s Health Insurance Programs: Announcement of the Extension of Temporary Moratoria on Enrollment of Part B Non-Emergency Ground Ambulance Suppliers and Home Health Agencies in Designated Geographic Locations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Extension of temporary moratoria.

SUMMARY: This document announces the extension of statewide temporary moratoria on the enrollment of new Medicare Part B non-emergency ground ambulance suppliers and providers and Medicare home health agencies, subunits, and branch locations in Florida, Illinois, Michigan, Texas, Pennsylvania, and New Jersey, as applicable, to prevent and combat fraud, waste, and abuse. This extension also applies to the enrollment of new non-emergency ground ambulance suppliers and home health agencies, subunits, and branch locations in Medicaid and the Children’s Health Insurance Program in those states. For purposes of these moratoria, providers that were participating as network providers in one or more Medicaid managed care organizations prior to January 1, 2018 will not be considered “newly enrolling” when they are required to enroll with the State Medicaid agency pursuant to a new statutory requirement, and thus will not be subject to the moratoria.


FOR FURTHER INFORMATION CONTACT: Jung Kim, (410) 786–9370.

News media representatives must contact CMS’ Public Affairs Office at (202) 690–6145 or email them at press@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. CMS’ Implementation of Temporary Enrollment Moratoria

The Social Security Act (the Act) provides the Secretary with tools and resources to combat fraud, waste, and abuse in Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP). In particular, section 1866(j)(7) of the Act provides the Secretary with authority to impose a temporary moratorium on the enrollment of new Medicare, Medicaid, or CHIP providers and suppliers, including categories of providers and suppliers, if the Secretary determines that a moratorium is necessary to prevent or combat fraud, waste, or abuse under these programs. Regarding Medicaid, section 1902(k)(4) of the Act requires States to comply with any moratorium imposed by the Secretary unless the State determines that the imposition of such moratorium would adversely impact Medicaid beneficiaries’ access to care. In addition, section 2107(e)(1)(F) of the Act provides that the Medicaid provision in section 1902(k) of the Act is also applicable to CHIP.

In the February 2, 2011 Federal Register (76 FR 5862), CMS published a final rule with comment period titled, “Medicare, Medicaid, and Children’s Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers,” which implemented section 1866(j)(7) of the Act by establishing new regulations at 42 CFR 424.570. Under §424.570(a)(2)(i) and (iv), CMS, or CMS in consultation with the Department of Health and Human Services’ Office of Inspector General (HHS OIG) or the Department of Justice (DOJ), or both, may impose a temporary moratorium on newly enrolling Medicare providers and suppliers if CMS determines that there is a significant potential for fraud, waste, or abuse with respect to a particular provider or supplier type, or particular geographic locations, or both. At §424.570(a)(1)(iii), CMS stated that it would announce any temporary moratorium in a Federal Register document that includes the rationale for the imposition of such moratorium. This document fulfills that requirement.

In accordance with section 1866(j)(7)(B) of the Act, there is no judicial review under sections 1869 and
2013 (78 FR 46339). We exercised this authority (February 2, 2011, 76 FR 5870), home health agency subunits and branch locations (hereafter referred to as HHAs) in Miami-Dade County, Florida and Cook County, Illinois, as well as surrounding counties, and Medicare Part B ground ambulance suppliers in Harris County, Texas and surrounding counties, in a notice issued on July 31, 2013 (78 FR 46339). We exercised this authority again in a notice published on February 4, 2014 (79 FR 6475) when we extended the existing moratoria for an additional 6 months and expanded them to include enrollment of HHAs in Broward County, Florida; Dallas County, Texas; Harris County, Texas; and Wayne County, Michigan and surrounding counties, and enrollment of ground ambulance suppliers in Philadelphia, Pennsylvania and surrounding counties. Then, we further extended these moratoria in documents issued on August 1, 2014 (79 FR 44702), February 2, 2015 (80 FR 5551), July 28, 2015 (80 FR 44967), and February 2, 2016 (81 FR 5444). On August 3, 2016 (81 FR 51120), we extended the current moratoria for an additional 6 months and expanded them to statewide for the enrollment of new HHAs in Florida, Illinois, Michigan, and Texas, and Part B non-emergency ambulance suppliers in New Jersey, Pennsylvania, and Texas. Our August 3, 2016 publication also announced the lifting of temporary moratoria for all Part B emergency ambulance suppliers. On January 9, 2017 (82 FR 2363) and July 28, 2017 (82 FR 35122), CMS again issued a document to extend the temporary moratoria for a period of 6 months. On September 1, 2017, CMS lifted the statewide temporary moratorium on the enrollment of new Medicare Part B non-emergency ground ambulance suppliers in Texas under the authority of §424.570(d). This lifting of the moratorium also applied to Medicaid and CHIP in Texas. This decision was a result of the Presidential Disaster Declaration signed on August 25, 2017 for several counties in the State of Texas due to Hurricane Harvey. Upon declaration of the disaster, CMS carefully reviewed the potential impact of continued moratoria in Texas, and decided to lift the temporary enrollment moratorium on non-emergency ground ambulance suppliers in Texas in order to aid in the disaster response. CMS published a formal announcement of this decision on November 3, 2017 (82 FR 51274).

B. Determination of the Need for Moratoria

In imposing these enrollment moratoria, CMS considered both qualitative and quantitative factors suggesting a high risk of fraud, waste, or abuse. CMS relied on law enforcement’s longstanding experience with ongoing and emerging fraud trends and activities through civil, criminal, and administrative investigations and prosecutions. CMS’ determination of a high risk of fraud, waste, or abuse in these provider and supplier types within these geographic locations was then confirmed through data analysis, which relied on factors the agency identified as strong indicators of risk. (For a more detailed explanation of this determination process and of these authorities, see the July 31, 2013 notice (78 FR 46339) or February 4, 2014 moratoria document (79 FR 6475)).

Because fraud schemes are highly migratory and transitory in nature, many of CMS’ program integrity authorities and anti-fraud activities are designed to allow the agency to adapt to emerging fraud in different locations. The laws and regulations governing CMS’ moratoria authority give us flexibility to use any and all relevant criteria for future moratoria, and CMS may rely on additional or different criteria as the basis for future moratoria.

1. Application to Medicaid and the Children’s Health Insurance Program (CHIP)

The February 2, 2011, final rule also implemented section 1902(kk)(4) of the Act, establishing new Medicaid regulations at § 455.470. Under § 455.470(a)(1) through (5), the Secretary may impose a temporary moratorium, in accordance with § 424.570, on the enrollment of new providers or provider types after consulting with any affected State Medicaid agencies. The State Medicaid agency must impose a temporary moratorium on the enrollment of new providers or provider types identified by the Secretary as posing an increased risk to the Medicaid program unless the State determines that the imposition of such moratorium would adversely affect Medicaid beneficiaries’ access to medical assistance and so notifies the Secretary. The final rule also implemented section 2107(e)(1)(D) of the Act by providing, at § 457.990 of the regulations, that all of the provisions that apply to Medicaid under sections 1902(a)(77) and 1902(kk) of the Act, as well as the implementing regulations, also apply to CHIP.

Section 1866(j)(7) of the Act authorizes imposition of a temporary enrollment moratorium for Medicare, Medicaid, and/or CHIP, “if the Secretary determines that such moratorium is necessary to prevent or combat fraud, waste, or abuse under either such program.” While there may be exceptions, CMS believes that generally, a category of providers or suppliers that poses a risk to the Medicare program also poses a similar risk to Medicaid and CHIP. Many of the anti-fraud provisions in the Act reflect this concept of “reciprocal risk” in which a provider that poses a risk to one program poses a risk to the other programs. For example, section 1902(a)(39) of the Act requires State Medicaid agencies to terminate the participation of an individual or entity if such individual or entity is

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1 As noted in the preamble to the final rule with comment period implementing the moratorium authority (February 2, 2011, 76 FR 5870), home health agency subunits and branch locations are subject to the moratorium to the same extent as any other newly enrolling home health agency.

2 CMS has identified an error in the provider and beneficiary saturation data described in our July 31, 2013 Federal Register notice (78 FR 46339). We have subsequently revised the methodology by which we determine provider and beneficiary saturation. Following these revisions to the methodology, we strengthened application of our current 2016 methodology to the 2013 data, and determined that the 2013 decision to impose the moratorium would not have been impacted had the revised methodology been applied. Provider saturation remains one of the criteria used to determine whether to implement a moratorium. CMS has made market saturation data publicly available at https://data.cms.gov/market-saturation.

3 CMS also concurrently announced a demonstration under the authority provided in section 402(a)(11) of the Social Security Amendments of 1967 (U.S.C. 1395f-1395b) that allows for access to care-based exceptions to the moratoria in certain limited circumstances after a heightened review of that provider has been conducted. This exception process also applies to Medicaid and CHIP providers in each state. This announcement may be found in the Federal Register document issued on August 3, 2016 (81 FR 51116).
Medicaid Agencies and with the appropriate State partners, and CMS carefully evaluated access for the target moratorium locations with every imposition and extension of the moratoria. Prior to imposing and extending these moratoria, CMS reviewed Medicare data for these areas and found no concerns with beneficiary access to HHAs or ground ambulance suppliers. CMS also consulted with the appropriate State Medicaid Agencies and with the appropriate State Departments of Emergency Medical Services to determine if the moratoria would create access to care concerns for Medicaid and CHIP beneficiaries. All of CMS’ State partners were supportive of CMS’ analysis and proposals, and together with CMS, determined that continuation of these moratoria would not create access to care issues for Medicaid or CHIP beneficiaries.

5. When a Temporary Moratorium Does Not Apply

Under § 424.570(a)(1)(iii), a temporary moratorium does not apply to any of the following: (1) Changes in practice location (2) Changes in provider or supplier information, such as phone number or address; or (3) Changes in ownership (except changes in ownership of HHAs that require initial enrollment under § 424.550). Also, in accordance with § 424.570(a)(1)(iv), a temporary moratorium does not apply to any enrollment application that a Medicare contractor has already approved, but has not yet entered into the Provider Enrollment, Chain, and Ownership System (PECOS) at the time the moratorium is imposed.

6. Lifting a Temporary Moratorium

In accordance with § 424.570(b), a temporary enrollment moratorium imposed by CMS will remain in effect for 6 months. If CMS deems it necessary, the moratorium may be extended in 6-month increments. CMS will evaluate whether to extend or lift the moratorium before the end of the initial 6-month period and, if applicable, any subsequent moratorium periods. If one or more of the moratoria announced in this document are extended, CMS will publish a document regarding such extensions in the Federal Register.

As provided in § 424.570(d), CMS may lift a moratorium at any time if the President declares an area a disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, if circumstances warranting the imposition of a moratorium have abated, if the Secretary has declared a public health emergency, or if, in the judgment of the Secretary, the moratorium is no longer needed.

Once a moratorium is lifted, the provider or supplier types that were unable to enroll because of the moratorium will be designated to the “high” screening level in accordance with §§ 424.518(c)(3)(iii) and 455.450(e)(2) if such provider or supplier applies at any time within 6 months from the date the moratorium was lifted.

II. Extension of Home Health and Ambulance Moratoria—Geographic Locations

CMS currently has in place statewide moratoria on newly enrolling HHAs in Florida, Illinois, Michigan, and Texas and Part B non-emergency ambulance suppliers in New Jersey and Pennsylvania. Under section 1932(d)(6)(A) of the Act, network providers in a Medicaid managed care organization are required to enroll with the State Medicaid agency no later than January 1, 2018. For purposes of these moratoria, providers that were participating as network providers in one or more managed care organizations before January 1, 2018 will not be considered “newly enrolling” when they are required to enroll with the State under this statutory requirement; and thus will not be subject to the moratoria.

As provided in § 424.570(b), CMS may deem it necessary to extend previously-imposed moratoria in 6-month increments. Under this authority, CMS is extending the temporary moratoria on the Medicare enrollment of HHAs and Part B non-emergency ground ambulance providers and suppliers in the geographic locations discussed herein. Under the regulations at § 455.470 and § 457.990, these moratoria also apply to the enrollment of HHAs and non-emergency ground ambulance providers and suppliers in Medicaid and CHIP in those locations. Under § 424.570(b), CMS is required to publish a document in the Federal Register announcing any extension of a moratorium, and this extension of moratoria document fulfills that requirement.
these moratoria will not create an access to care issue for Medicaid or CHIP beneficiaries in the affected states at this time. CMS also reviewed Medicare data for these states and found there are no current problems with access to HHAs or ground ambulance providers or suppliers. Nevertheless, the agency will continue to monitor these locations to make sure that no access to care issues arise in the future.

Based upon our consultation with law enforcement and consideration of the factors and activities described previously, CMS has determined that the current temporary enrollment moratorium should be extended for an additional 6 months.

III. Summary of the Moratoria Locations

CMS is executing its authority under sections 1866(j)(7), 1902(kk)(4), and 2107(e)(1)(D) of the Act to extend and implement temporary enrollment moratoria on HHAs for all counties in Florida, Illinois, Michigan, and Texas, as well as Part B non-emergency ground ambulance providers and suppliers for all counties in New Jersey and Pennsylvania.

IV. Clarification of Right to Judicial Review

Section 1866(j)(7)(B) of the Act states that there shall be no judicial review under section 1869, section 1878, or otherwise, of a temporary moratorium imposed on the enrollment of new providers of services and suppliers if the Secretary determines that the moratorium is necessary to prevent or combat fraud, waste, or abuse. Accordingly, our regulations at 42 CFR 498.5(l)(4) state that for appeals of denials based on a temporary moratorium, the scope of review will be limited to whether the temporary moratorium applies to the provider or supplier appealing the denial. The agency’s basis for imposing a temporary moratorium is not subject to review. Our regulations do not limit the right to seek judicial review of a final agency decision that the temporary moratorium applies to a particular provider or supplier. In the preamble to the February 2, 2011 (76 FR 5918) final rule with comment period establishing this regulation, we explained that “a provider or supplier may administratively appeal an adverse determination based on the imposition of a temporary moratorium up to and including the Department Appeal Board (DAB) level of review.”

We are clarifying that providers and suppliers that have received unfavorable decisions in accordance with the limited scope of review described in §498.5(l)(4) may seek judicial review of those decisions after they exhaust their administrative appeals. However, we reiterate that section 1866(j)(7)(B) of the Act precludes judicial review of the agency’s basis for imposing a temporary moratorium.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

VI. Regulatory Impact Statement

CMS has examined the impact of this document as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major regulatory actions with economically significant effects ($100 million or more in any 1 year). This document will prevent the enrollment of new home health providers and Part B non-emergency ground ambulance suppliers in Medicare, Medicaid, and CHIP in certain states. Though savings may accrue by denying enrollments, the monetary amount cannot be quantified. Since the imposition of the initial moratoria on July 31, 2013, more than 1187 HHAs and 24 ambulance companies in all geographic areas affected by the moratoria had their applications denied. We have found the number of applications that are denied after 60 days declines dramatically, as most providers and suppliers will not submit applications during the moratoria period. Therefore, this document does not reach the economic threshold, and thus is not considered a major action.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any one year. Individuals and states are not included in the definition of a small entity. CMS is not preparing an analysis for the RFA because it has determined, and the Secretary certifies, that this document will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if an action may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, CMS defines a small rural hospital as a hospital that is located outside of a metropolitan statistical area (MSA) for Medicare payment purposes and has fewer than 100 beds. CMS is not preparing an analysis for section 1102(b) of the Act because it has determined, and the Secretary certifies, that this document will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any regulatory action whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately $148 million. This document will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13771, titled “Reducing Regulation and Controlling Regulatory Costs,” was issued on January 30, 2017 (82 FR 9339, February 3, 2017). It has been determined that this notice is a transfer notice that does not impose more than de minimis costs and thus is not a regulatory action for the purposes of E.O. 13771.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed regulatory action (and subsequent final action) that imposes substantial direct requirement costs on state and local governments, preempts
state law, or otherwise has Federalism implications. Because this document does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this document was reviewed by the Office of Management and Budget.

Dated: January 12, 2018.
Seema Verma,
Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2018–01783 Filed 1–29–18; 8:45 am]
BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR
Office of the Secretary of the Interior

43 CFR Part 10
[NPS–WASO–NAGPRA–24780;
PPWQPADU0/PPMPRLE1Y.Y00000]
RIN 1024–AE40

Civil Penalties Inflation Adjustments

AGENCY: Office of the Secretary, Interior.

ACTION: Final rule.

SUMMARY: This rule revises U.S. Department of the Interior regulations implementing the Native American Graves Protection and Repatriation Act to provide for annual adjustments of civil penalties to account for inflation under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget guidance. The purpose of these adjustments is to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statutes.

DATES: This rule is effective on January 30, 2018.

FOR FURTHER INFORMATION CONTACT: Melanie O’Brien, Manager, National NAGPRA Program, National Park Service, 1849 C Street NW, Washington, DC 20240.

SUPPLEMENTARY INFORMATION:

I. Background

On November 2, 2015, the President signed into law the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) ("the Act"). The Act requires Federal agencies to adjust the level of civil monetary penalties with an initial “catch-up” adjustment through rulemaking and then make subsequent annual adjustments for inflation no later than January 15 of each year.

II. Calculation of Annual Adjustments

The Office of Management and Budget (OMB) recently issued guidance to assist Federal agencies in implementing the annual adjustments required by the Act which agencies must complete by January 15, 2018. See December 15, 2017, Memorandum for the Heads of Executive Departments and Agencies, from Mick Mulvaney, Director, Office of Management and Budget, re: Implementation of Penalty Inflation Adjustments for 2018, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (M–18–03). The guidance states that the cost-of-living adjustment multiplier for 2018, based on the Consumer Price Index (CPI–U) for the month of October 2017, not seasonally adjusted, is 1.02041. (The annual inflation adjustments are based on the percent change between the October CPI–U preceding the date of the adjustment, and the prior year’s October CPI–U.) The guidance instructs agencies to complete the 2018 annual adjustment by multiplying each applicable penalty by the multiplier, 1.02041, and rounding to the nearest dollar. Further, the guidance instructs agencies to apply the multiplier to the most recent penalty amount that includes the catch-up adjustment required by the Act.

The annual adjustment applies to all civil monetary penalties with a dollar amount that are subject to the Act. A civil monetary penalty is any assessment with a dollar amount that is levied for a violation of a Federal civil statute or regulation, and is assessed or enforceable through a civil action in Federal court or an administrative proceeding. A civil monetary penalty does not include a penalty levied for violation of a criminal statute, or fees for services, licenses, permits, or other regulatory review. This final rule adjusts the following civil monetary penalties contained in the Department regulations implementing the Native American Graves Protection and Repatriation Act (NAGPRA) for 2018 by multiplying 1.02041 by each penalty amount as updated by the catch-up adjustment made in 2017:

<table>
<thead>
<tr>
<th>CFR citation</th>
<th>Description of the penalty</th>
<th>Current penalty including catch-up adjustment</th>
<th>Annual adjustment (multiplier)</th>
<th>Adjusted penalty</th>
</tr>
</thead>
<tbody>
<tr>
<td>43 CFR 10.12(g)(2)</td>
<td>Failure of Museum to Comply</td>
<td>$6,533</td>
<td>1.02041</td>
<td>$6,666</td>
</tr>
<tr>
<td>43 CFR 10.12(g)(3)</td>
<td>Continued Failure to Comply Per Day</td>
<td>$1,307</td>
<td>1.02041</td>
<td>$1,334</td>
</tr>
</tbody>
</table>

Consistent with the Act, the adjusted penalty levels for 2018 will take effect immediately upon the effective date of the adjustment. The adjusted penalty levels for 2018 will apply to penalties assessed after that date including, if consistent with agency policy, assessments associated with violations that occurred on or after November 2, 2015. The Act does not, however, change previously assessed penalties that the Department is collecting or has collected. Nor does the Act change an agency’s existing statutory authorities to adjust penalties.

III. Procedural Requirements

A. Regulatory Planning and Review (E.O. 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs in the Office of Management and Budget will review all significant rules. The Office of Information and Regulatory Affairs has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation’s regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed