

**ACTION:** Direct final rule; confirmation of effective date.

**SUMMARY:** In accordance with a determination by the Director of the Office of Management and Budget (OMB) that the direct final rule (“Use of Ozone Depleting Substances”) published on October 26, 2016, is excluded from the memorandum of January 20, 2017, from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” this action confirms the effective date of February 23, 2017, for the direct final rule.

**DATES:** The effective date of the direct final rule that published on October 26, 2016, at 81 FR 74298, is confirmed to be February 23, 2017.

**FOR FURTHER INFORMATION CONTACT:** Daniel Orr, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6246, Silver Spring, MD 20993, 240-402-0979, [daniel.orr@fda.hhs.gov](mailto:daniel.orr@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** On October 26, 2016, the Food and Drug Administration (FDA or Agency) issued a direct final rule amending the regulation on uses of ozone-depleting substances (ODSs), including chlorofluorocarbons, to remove the designations for sterile aerosol talc administered intrapleurally by thoracoscopy for human use and metered-dose atropine sulfate aerosol human drugs administered by oral inhalation as “essential uses” under the Clean Air Act. FDA took this action because alternative products that do not use ODSs are now available, and because these products are no longer being marketed in versions that contain ODSs. FDA did not receive any significant adverse comments regarding the direct final rule, which was published with an effective date of February 23, 2017.

A memorandum of January 20, 2017 (82 FR 8346), from the Assistant to the President and Chief of Staff, entitled “Regulatory Freeze Pending Review,” directed the heads of Executive Departments and Agencies to temporarily postpone for 60 days from the date of the memorandum the effective dates of all regulations that had been published in the **Federal Register** but had not yet taken effect, for the purpose of “reviewing questions of fact, law, and policy they raise.” The memorandum also stated that the Director of OMB may exclude certain regulations if they “affect critical health, safety, financial, or national security matters, or for some other reason.”

Pursuant to the memorandum, the Director of OMB has excluded the direct final rule that published on October 26, 2016, at 81 FR 74298, from the directive to delay the effective date of certain regulations. The Department, therefore, confirms that the effective date of the direct final rule is February 23, 2017.

Dated: February 22, 2017.

**Thomas E. Price,**  
Secretary.

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## DEPARTMENT OF THE INTERIOR

### National Indian Gaming Commission

#### 25 CFR Part 575

#### Annual Adjustment of Civil Monetary Penalty To Reflect Inflation

**AGENCY:** National Indian Gaming Commission, Department of the Interior.

**ACTION:** Final rule.

**SUMMARY:** In compliance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the Act) and Office of Management and Budget (OMB) guidance, the National Indian Gaming Commission (NIGC or Commission) is amending its civil monetary penalty rule to reflect an annual adjustment for inflation in order to improve the penalty’s effectiveness and maintain its deterrent effect. The Act provides that the new penalty level must apply to penalties assessed after the effective date of the increase, including when the penalties whose associated violation predate the increase.

**DATES:** This final rule is effective February 28, 2017.

**FOR FURTHER INFORMATION CONTACT:** Contact Armando J. Acosta, Senior Attorney, Office of General Counsel, National Indian Gaming Commission, at (202) 632-7003; fax (202) 632-7066 (not toll-free numbers).

#### 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). Beginning in 2017, the Act requires agencies to make annual inflationary adjustments to their civil monetary penalties by January 15th of each year, in accordance with yearly OMB guidance.

##### II. Calculation of Annual Adjustment

On December 16, 2016, OMB issued guidance to agencies to calculate the annual adjustment. See Memorandum for the Heads of Executive Departments and Agencies, from Shaun Donovan, Director, Office of Management and Budget, Subject: *Implementation of the 2017 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015*. According to OMB, the cost-of-living adjustment multiplier for 2017, based on the Consumer Price Index (CPI-U) for the month of October 2016, not seasonally adjusted, is 1.01636.

Pursuant to this guidance, the Commission has calculated the annual adjustment level of the civil monetary penalty contained in 25 CFR 575.4 (“The Chairman may assess a civil fine, not to exceed \$49,467 per violation, against a tribe, management contractor, or individual operating Indian gaming for each notice of violation . . .”). The 2017 adjusted level of the civil monetary penalty is \$50,276 (\$49,467 × 1.01636).

##### III. Regulatory Matters

###### *Regulatory Planning and Review*

This final rule is not a significant rule under Executive Order 12866.

(1) This rule will not have an effect of \$100 million or more on the economy or will not adversely affect, in a material way, the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities.

(2) This rule will not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) This rule does not involve entitlements, grants, user fees, or loan programs or the rights or obligations of recipients.

(4) This regulatory change does not raise novel legal or policy issues.

###### *Regulatory Flexibility Act*

The Commission certifies that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because the rule makes annual adjustments for inflation.

###### *Small Business Regulatory Enforcement Fairness Act*

This final rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. It will not result in the expenditure by state, local, or tribal governments, in the aggregate, or by the

private sector of \$100 million or more in any one year. The rule will not result in a major increase in costs or prices for consumers, individual industries, federal, state, or local government agencies, or geographic regions. Nor will this rule have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of the U.S.-based enterprises to compete with foreign-based enterprises.

#### *Unfunded Mandates Reform Act*

This final rule does not impose an unfunded mandate of more than \$100 million per year on state, local, or tribal governments or the private sector. The rule also does not have a significant or unique effect on state, local, or tribal governments or the private sector. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

#### *Takings*

Under the criteria in Executive Order 12630, this final rule does not affect individual property rights protected by the Fifth Amendment nor does it involve a compensable “taking.” Thus, a takings implication assessment is not required.

#### *Federalism*

Under the criteria in Executive Order 13132, this final rule has no substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

#### *Civil Justice Reform*

This final rule complies with the requirements of Executive Order 12988. Specifically, this rule has been reviewed to eliminate errors and ambiguity and

written to minimize litigation. It is written in clear language and contains clear legal standards.

#### *Consultation With Indian Tribes*

In accordance with the President’s memorandum of April 29, 1994, *Government-to-Government Relations with Native American Tribal Governments*, Executive Order 13175 (59 FR 22951, November 6, 2000), the Commission has determined that consultations with Indian gaming tribes is not practicable, as Congress has mandated that annual civil penalty adjustments in the Act be implemented no later than January 15th of each year.

#### *Paperwork Reduction Act*

This final rule does not affect any information collections under the Paperwork Reduction Act.

#### *National Environmental Policy Act*

This final rule does not constitute a major federal action significantly affecting the quality of the human environment.

#### *Information Quality Act*

In developing this final rule, the Commission did not conduct or use a study, experiment, or survey requiring peer review under the Information Quality Act (Pub. L. 106–554).

#### *Effects on the Energy Supply*

This final rule is not a significant energy action under the definition in Executive Order 13211. A Statement of Energy Effects is not required.

#### *Clarity of This Regulation*

The Commission is required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule that the Commission publishes must:

- (a) Be logically organized;

- (b) use the active voice to address readers directly;

- (c) use clear language rather than jargon;

- (d) be divided into short sections and sentences; and

- (e) use lists and tables wherever possible.

#### *Required Determinations Under the Administrative Procedure Act*

In accordance with the Act, agencies are to annually adjust civil monetary penalties without providing an opportunity for notice and comment, and without a delay in its effective date. Therefore, the Commission is not required to complete a notice and comment process prior to promulgation.

#### **List of Subjects in 25 CFR Part 575**

Administrative practice and procedure, Gaming, Indian lands, Penalties.

For the reasons set forth in the preamble, the Commission amends 25 CFR part 575 as follows:

#### **PART 575—CIVIL FINES**

- 1. The authority citation for part 575 continues to read as follows:

**Authority:** 25 U.S.C. 2705(a), 2706, 2713, 2715; and Sec. 701, Pub. L. 114–74, 129 Stat. 599.

#### **§ 575.4 [Amended]**

- 2. Amend the introductory text of § 575.4 by removing “\$49,467” and adding in its place “\$50,276”.

Dated: February 22, 2017.

**Jonodev O. Chaudhuri,**  
*Chairman.*

**Kathryn Isom-Clause,**  
*Vice Chairwoman.*

**E. Sequoyah Simermeyer,**  
*Associate Commissioner.*

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