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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

#### 42 CFR Part 3

RIN 0991-AB53

#### Patient Safety and Quality Improvement: Civil Money Penalty Inflation Adjustment

**AGENCY:** Office for Civil Rights, Office of the Secretary, HHS.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Health and Human Services is publishing this companion proposed rule to the direct final rule, published elsewhere in this issue of the **Federal Register**, which amends the Patient Safety and Quality Improvement Rule by adjusting for inflation the maximum civil money penalty amount for violations of the confidentiality provisions of the Rule. We are proposing to amend the penalty amount to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990.

**DATES:** Submit written or electronic comments on this proposed rule by September 24, 2009. If significant adverse comment is received on this proposed rule or the direct final rule (discussed in the **SUPPLEMENTARY INFORMATION** section), OCR will publish a timely withdrawal of the direct final rule in the **Federal Register**.

**ADDRESSES:** Send comments to one of the following addresses. Please do not submit duplicate comments. We will treat a comment directed to either the direct final rule or proposed rule as being directed towards both, therefore there is no need to submit comments on both documents.

- *Federal eRulemaking Portal:* You may submit electronic comments at <http://www.regulations.gov>. Follow the instructions for submitting electronic comments. Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.

- *Regular, Express, or Overnight Mail:* You may mail written comments (one original and two copies) to the following address only: U.S. Department of Health and Human Services, Office for Civil Rights, *Attention:* PSQIA CMP Adjustment (RIN 0991-AB53), Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, SW., Washington, DC 20201. Mailed

comments may be subject to delivery delays due to security procedures. Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

- *Hand Delivery or Courier:* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) to the following address only: Office for Civil Rights, *Attention:* PSQIA CMP Adjustment (RIN 0991-AB53), Hubert H. Humphrey Building, Room 509F, 200 Independence Avenue, SW., Washington, DC 20201. (Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

*Inspection of Public Comments:* All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. We will post all comments received before the close of the comment period at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:**

Andra Wicks, 202-205-2292.

**SUPPLEMENTARY INFORMATION:**

#### I. Use of a Direct Final Rule

The Department has chosen to concurrently issue this proposed rule as a direct final rule because we do not expect to receive any significant adverse comment on the rule. A direct final rule is a rule that provides an opportunity for comment and then automatically becomes effective on a later date if no significant adverse comments are received. We do not anticipate significant adverse comments because this rule's amendment is required by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note, as amended by the Debt Collection Improvement Act of 1996 (31 U.S.C. 3701)) (Inflation Adjustment Act), and the Department has no discretion in how it calculates the adjustment.

We are providing a 30-day comment period for both this proposed rule and the direct final rule. If no significant adverse comments are received, we will take no further action on this proposed rule and the direct final rule will become effective 60 days later. If we do not receive any significant adverse comments in response to the direct final rule or this proposed rule, the direct final rule will become effective on the date set forth in the **DATES** section of that

rule. If we receive significant adverse comments on this proposed rule or the direct final rule, we will publish a document withdrawing the direct final rule in the **Federal Register** prior to that date.

If we withdraw the direct final rule based on the receipt of any significant adverse comments, we will publish a final rule based on this proposed rule and any comments to the proposed or direct final rule.

The Department will not provide additional opportunity for comment.

#### II. Background

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), 42 U.S.C. 299b-21 to 299b-26, amended Title IX of the Public Health Service Act, 42 U.S.C. 299 *et seq.*, the authorizing statute for the Agency for Healthcare Research and Quality. The Patient Safety Act creates a voluntary program through which health care providers can share information related to patient safety events and concerns (known as patient safety work product (PSWP)) with patient safety organizations (PSOs) for the purpose of improving patient safety and the quality of care nationwide. The Patient Safety Act requires the Department of Health and Human Services ("HHS" or "the Department") to maintain a listing of PSOs. The Patient Safety Act provides that PSWP is both privileged and confidential. While participation in the patient safety program is voluntary, a violation of the Patient Safety Act's confidentiality requirements is subject to a civil money penalty (CMP) of up to \$10,000. 42 U.S.C. 299b-22(f).

On November 21, 2008, the Department promulgated regulations to implement the Patient Safety Act. 73 FR 70732, Nov. 21, 2008, adding 42 CFR part 3. The regulations provide for the listing and delisting of PSOs, the confidentiality and privilege protections of PSWP, and procedures for enforcement against violations of the regulations' confidentiality requirements. In particular, under § 3.404, a person who discloses identifiable PSWP in knowing or reckless violation of the Patient Safety Act and 42 CFR part 3 shall be subject to a CMP of not more than \$10,000 for each act constituting a violation.

The Agency for Healthcare Research and Quality administers the provisions of the regulations relating to PSOs. The Office for Civil Rights investigates and enforces compliance with the confidentiality provisions and, if warranted, may assess CMPs for knowing or reckless violations of confidentiality.

### III. The Inflation Adjustment Act

Congress enacted the Inflation Adjustment Act based on its findings that the impact of CMPs had been reduced by inflation and that reducing the impact of CMPs had weakened their deterrent effect. Inflation Adjustment Act § 2, 28 U.S.C. 2461 note. In general, the Inflation Adjustment Act requires Federal agencies to issue regulations to adjust for inflation each CMP provided by law within their jurisdiction. The Inflation Adjustment Act applies to civil penalties found within the Public Health Service Act, such as the Patient Safety Act's CMP provision.<sup>1</sup>

The Inflation Adjustment Act directs agencies to issue regulations to adjust CMPs under their authority by October 23, 1996, and to make additional adjustments at least once every four years thereafter. Because the Patient Safety Act was enacted after October 23, 1996, we interpret the Inflation Adjustment Act as requiring the Department to issue a regulation to adjust for inflation the Patient Safety Act's CMP amount at least once every four years, beginning from the Patient Safety Act's date of enactment, which was July 29, 2005. Thus, we are proposing this rule four years from the Patient Safety Act's enactment.

### IV. Description of Amendment

The Inflation Adjustment Act provides for the adjustment of a penalty amount through a three-step process. First, we calculate an increase in the penalty amount by a "cost-of-living adjustment." Inflation Adjustment Act § 5(a), 28 U.S.C. 2461 note. The Inflation Adjustment Act defines the cost-of-living adjustment as "the percentage (if any) for each civil monetary penalty by which—(1) The Consumer Price Index for the month of June of the calendar year preceding the adjustment, exceeds (2) the Consumer Price Index for the month of June of the calendar year in which the amount of such civil monetary penalty was last set or adjusted pursuant to law." Inflation Adjustment Act § 5(b), 28 U.S.C. 2461 note. Second, we round the adjustment amount pursuant to the methodology set forth in section 5(a) of the Inflation Adjustment Act, which rounds the

increase based on the size of the underlying penalty, as follows:

- Any increase determined under this subsection shall be rounded to the nearest—
- (1) Multiple of \$10 in the case of penalties less than or equal to \$100;
  - (2) Multiple of \$100 in the case of penalties greater than \$100 but less than or equal to \$1,000;
  - (3) Multiple of \$1,000 in the case of penalties greater than \$1,000 but less than or equal to \$10,000;
  - (4) Multiple of \$5,000 in the case of penalties greater than \$10,000 but less than or equal to \$100,000;
  - (5) Multiple of \$10,000 in the case of penalties greater than \$100,000 but less than or equal to \$200,000; and
  - (6) Multiple of \$25,000 in the case of penalties greater than \$200,000.

Third, pursuant to the Debt Collection Improvement Act of 1996 § 31001(s)(2)'s amendment to the Inflation Adjustment Act, we must limit the first adjustment of a CMP to ten percent of the penalty amount.

With respect to step 1 of the adjustment, the Consumer Price Index (CPI) for June of 2008 (the calendar year preceding this adjustment) was 218.815.<sup>2</sup> The CPI for June of 2005 (the calendar year in which the Patient Safety Act CMP was last set) was 194.5. The percent change in these CPIs is an increase of 12.5 percent. This leads to an unrounded increase in the Patient Safety Act's CMP of \$1,250.

Under step 2, we round the amount of the increase (\$1,250) based on the size of the penalty (\$10,000). Because the penalty of \$10,000 is "greater than \$1,000 but less than or equal to \$10,000," we round the increase to the nearest multiple of \$1,000. This leads to a rounded increase of \$1,000, for an increased penalty of \$11,000.

Step 3 requires that the first adjustment to a civil penalty be limited to 10 percent of the penalty amount. This is the first adjustment to the Patient Safety Act's CMP. Therefore, this 10 percent cap is applicable. Pursuant to this cap, the adjusted penalty cannot exceed \$11,000. Because the adjusted penalty is \$11,000, it does not exceed the cap. Accordingly, the Patient Safety Act's revised maximum CMP amount, after adjusting for inflation pursuant to the Inflation Adjustment Act, is \$11,000.

Based on the above, we are proposing to amend 42 CFR 3.404(b) to provide

that the Secretary may impose a CMP of not more than \$11,000, rather than the current limit of \$10,000, for a violation of the Patient Safety Act's confidentiality requirements.

### V. Environmental Impact

We have determined under 21 CFR 25.30(a) and (h) that the proposed action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### VI. Paperwork Reduction Act 1995

We have concluded that the CMP adjustment in this proposed rule is not subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) because it does not constitute a "collection of information." That is, the adjustment does not require disclosure of any information to the Department, third parties, or the public.

### VII. Federalism

The Department has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects 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. Accordingly, we have concluded that the rule does not contain policies that have Federalism implications as defined in the Executive Order and, consequently, a Federalism summary impact statement is not required.

### VIII. Analysis of Impacts

The Department has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Department believes that this proposed rule is not a significant regulatory action under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any

<sup>1</sup> We note that § 4 of the Inflation Adjustment Act, found at 28 U.S.C. 2461 note, excludes a small number of statutes, such as the Social Security Act, from the requirement for agencies to adjust their CMPs for inflation. Because the CMPs for title II, subtitle F (Administrative Simplification) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are found at section 1176 of the Social Security Act, the Department has not made similar inflation adjustments to the HIPAA administrative simplification CMPs at 45 CFR 160.404.

<sup>2</sup> The Inflation Adjustment Act defines "Consumer Price Index" as "the Consumer Price Index for all-urban consumers published by the Department of Labor." Historic data on the Consumer Price Index for all-urban consumers, including the data relied upon in this rulemaking, can be found at <ftp://ftp.bls.gov/pub/special.requests/cpi/cpiiai.txt>.

significant impact of a rule on small entities. Because this proposed rule simply adjusts the maximum amount of a CMP, and because the adjustment is required by the Inflation Adjustment Act, the Department certifies that the rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any 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 \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product.<sup>3</sup> The Department does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

#### List of Subjects in 42 CFR Part 3

Administrative practice and procedure, Civil money penalty, Confidentiality, Conflict of interests, Courts, Freedom of information, Health, Health care, Health facilities, Health insurance, Health professions, Health records, Hospitals, Investigations, Law enforcement, Medical research, Organization and functions, Patient, Patient safety, Privacy, Privilege, Public health, Reporting and recordkeeping requirements, Safety, State and local governments, Technical assistance.

For the reasons stated in the preamble, HHS proposes to amend part 3 of title 42 of the Code of Federal Register as follows:

#### PART 3—PATIENT SAFETY ORGANIZATIONS AND PATIENT SAFETY WORK PRODUCT

1. The authority citation for part 3 continues to read:

**Authority:** 42 U.S.C. 216, 299b–21 through 299b–26; 42 U.S.C. 299c–6.

2. Amend § 3.404 by revising paragraph (b) to read as follows:

#### § 3.404 Amount of a civil money penalty.

\* \* \* \* \*

(b) The Secretary may impose a civil money penalty in the amount of not more than \$11,000.

Dated: August 18, 2009.

**Kathleen Sebelius,**  
Secretary.

[FR Doc. E9–20418 Filed 8–24–09; 8:45 am]  
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## DEPARTMENT OF TRANSPORTATION

### Federal Motor Carrier Safety Administration

#### 49 CFR Part 385

[Docket No. FMCSA–2001–11061]

RIN 2126–AB17

#### New Entrant Safety Assurance Process: Implementation of Section 210(b) of the Motor Carrier Safety Improvement Act of 1999

**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.

**ACTION:** Advance notice of proposed rulemaking (ANPRM); request for comments.

**SUMMARY:** The Federal Motor Carrier Safety Administration (FMCSA) requests comment on the methods the Agency should consider implementing to provide further assurance that a new applicant carrier is knowledgeable about the applicable safety requirements before being granted New Entrant authority. We are considering whether to implement a proficiency examination as part of our revised New Entrant Safety Assurance Process and seek information concerning issues that should be considered in the development and use of such an examination. In addition, the Agency requests comments on other alternatives to a proficiency examination to complement the assurances already in place that new entrant carriers are knowledgeable about applicable safety requirements. This notice responds to issues raised by Advocates for Highway and Auto Safety (Advocates) regarding new entrant applicant knowledgeability. **DATES:** Send your comments on or before October 26, 2009.

**ADDRESSES:** You may submit comments identified by FDMS Docket ID Number FMCSA–2001–11061 by any of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments.
- **Mail:** Docket Management Facility: U.S. Department of Transportation, 1200

New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

- **Hand Delivery or Courier:** West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

- **Fax:** 202–493–2251.

**Instructions:** For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading under the **SUPPLEMENTARY INFORMATION** caption of this document. Note that all comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. Please see the Privacy Act heading below.

**Privacy Act:** Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477) or you may visit <http://DocketInfo.dot.gov>.

**Docket:** For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> or the street address listed above. Follow the online instructions for accessing the dockets.

**FOR FURTHER INFORMATION CONTACT:** Mr. Richard Johnson, New Entrant Program Specialist, (202) 366–0476, [richard.johnson@dot.gov](mailto:richard.johnson@dot.gov). Business hours are from 8 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

#### SUPPLEMENTARY INFORMATION:

##### Public Participation

The Federal eRulemaking Portal (<http://www.regulations.gov>) is available 24 hours each day, 365 days each year. You can get electronic submission and retrieval help and guidelines under the "How to Use This Site" menu option.

Comments received after the comment closing date will be included in the docket, and we will consider late comments to the extent practicable.

##### Legal Basis for the Rulemaking

Under 49 U.S.C. 31144, the Secretary of Transportation (Secretary) is required to determine whether a new motor vehicle owner or operator is fit to operate safely. Section 210(a) of the Motor Carrier Safety Improvement Act of 1999 [Pub. L. 106–159, 113 Stat. 1764, December 9, 1999] (MCSIA) added

<sup>3</sup> According to the U.S. Department of Commerce, Bureau of Economic Analysis, the implicit price deflator for gross domestic product was indexed at 92.106 in 1995 (the year of the Unfunded Mandates Reform Act) and 122.422 in 2008. See <http://www.bea.gov/national/nipaweb/> (Table 1.1.9).