violations of law that are not strictly within its statutory or other authority or may compile information in the course of an investigation which may not be relevant to a specific prosecution. It is impossible to determine in advance what information collected during an investigation will be important or crucial to the apprehension of fugitives. In the interests of effective law enforcement, it is necessary to retain such information in this system of records because it can aid in establishing patterns of criminal activity and can provide valuable leads for federal and other law enforcement agencies. This consideration applies equally to information acquired from, or collated or analyzed for, both law enforcement agencies and agencies of the U.S. foreign intelligence community and military community.

(7) From subsection (e)(2) because in a criminal, civil, or regulatory investigation, prosecution, or proceeding, the requirement that information be collected to the greatest extent practicable from the subject individual would present a serious impediment to law enforcement because the subject of the investigation, prosecution, or proceeding would be placed on notice as to the existence and nature of the investigation, prosecution, and proceeding and would therefore be able to avoid detection or apprehension, to influence witnesses improperly, to destroy evidence, or to fabricate testimony. Moreover, thorough and effective investigation and prosecution may require seeking information from a number of different sources.

(8) From subsection (e)(3) (to the extent applicable) because the requirement that individuals supplying information be provided a form stating the requirements of subsection (e)(3) would constitute a serious impediment to law enforcement in that it could compromise the existence of a confidential investigation or reveal the identity of witnesses or confidential informants and endanger their lives, health, and physical safety. The individual could seriously interfere with undercover investigative techniques and could take appropriate steps to evade the investigation or flee a specific area.

(9) From subsections (e)(4)(G), (H) and (I) because this system is exempt from the access provisions of subsection (d) pursuant to subsections (j) and (k) of the Privacy Act.

(10) From subsection (e)(5) because the acquisition, collation, and analysis of information for law enforcement purposes from various agencies does not permit a determination in advance or a prediction of what information will be matched with other information and thus whether it is accurate, relevant, timely and complete. With the passage of time, seemingly irrelevant or untimely information may acquire new significance as further investigation brings new details to light and the accuracy of such information can often only be determined in a court of law. The restrictions imposed by subsection (e)(5) would restrict the ability of trained investigators, intelligence analysts, and government attorneys to exercise their judgment in collating and analyzing information and would impede the development of criminal or other intelligence necessary for effective law enforcement.

(11) From subsection (e)(8) because the individual notice requirements of subsection (e)(8) could present a serious impediment to law enforcement by revealing investigative techniques, procedures, evidence, or interest and interfering with the ability to issue warrants or subpoenas, and could give persons sufficient warning to evade investigative efforts.

(12) From subsections (f) and (g) because these subsections are inapplicable to the extent that the system is exempt from other specific subsections of the Privacy Act.

Dated: August 18, 2009.

Nancy C. Libin,

Chief Privacy and Civil Liberties Officer.

[FR Doc. E9–20364 Filed 8–24–09; 8:45 am]

BILLING CODE 4410–14–P

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: Direct final rule.

SUMMARY: The Department of Health and Human Services 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 amending the penalty amount to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990. We are using direct final rulemaking for this action because we expect that there will be no significant adverse comment on the rule.

DATES: This rule is effective November 23, 2009 without further action, unless significant adverse comment is received by September 24, 2009. If significant adverse comment is received, OCR will publish a timely withdrawal of the document 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 (discussed in the **SUPPLEMENTARY INFORMATION** section) 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 issue this 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.

As reflected in the **DATES** section above, for this direct final rule we are providing a 30-day comment period, and the rule will then become effective 60 days later if no significant adverse comments are received. If we do not receive any significant adverse comments in response to the direct final rule or the proposed rule discussed below, this rule will become effective on the date set forth in the **DATES** section. If we receive significant adverse comments to this direct final rule or the proposed rule, we will publish a document withdrawing this final rule in the **Federal Register** prior to that date.

In the proposed rule section of this issue of the **Federal Register**, we are concurrently proposing and soliciting comments on this rule. If we withdraw this direct final rule based on the receipt of any significant adverse comments, we will publish a final rule based on the 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 and 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.[1]

[1] 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.

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 issuing 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.[2] 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 amending 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 this 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 direct final 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.

[2] 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/cpiai.txt.*

VII. Federalism

The Department has analyzed this direct final 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 direct final 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 direct final 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 significant impact of a rule on small entities. Because this direct final 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.[3] The Department does not expect this direct final rule to result in any 1-year expenditure that would meet or exceed this amount.

[3] 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).

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, amend part 3 of title 42 of the Code of Federal Regulations 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. E9–20419 Filed 8–24–09; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 202, 209, 214, 227, 237, and 252

Defense Federal Acquisition Regulation Supplement; Technical Amendments

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD is making technical amendments to the Defense Federal