library reference anticipates seeking to enter all or part of the material contained therein into the evidentiary record, the notice also shall identify portions expected to be entered and the expected sponsor(s).

(iii) *Labels and descriptions.* Material filed as a library reference shall be labeled in a manner consistent with standard Commission notation and any other conditions the presiding officer or Commission establishes. In addition, material designated as a library reference shall include a preface or summary addressing the following matters:

(A) The proceeding and document or issue to which the material relates;

(B) The identity of the participant designating the library reference;

(C) The identity of the witness or witnesses who will be sponsoring the material or the reason why a sponsoring witness or witnesses cannot be identified; and, to the extent feasible,

(D) Other library references or testimony that utilize information or conclusions developed therein. In addition, the preface or summary shall explicitly indicate whether the library reference is an update or revision to a library reference filed in another Commission proceeding, and provide adequate identification of the predecessor material.

(iv) *Electronic version.* Material filed as a library reference shall also be made available in an electronic version, absent a showing of why an electronic version cannot be supplied or should not be required to be supplied. The electronic version shall include the same, or similar, information required to be included in the preface or summary.

(v) *Status of library references.* Designation of material as a library reference and acceptance in the Commission's docket section does not confer evidentiary status. The evidentiary status of the material is governed by this section.

* * * * *

Dated: December 17, 1998.

Margaret P. Crenshaw,

Secretary.

[FR Doc. 98–33909 Filed 12–23–98; 8:45 am]

BILLING CODE 7710–FW–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

45 CFR Part 60

RIN 0906–AA41

National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: This Notice of Proposed Rulemaking (NPRM) proposes amendments to the existing regulations implementing the Health Care Quality Improvement Act of l986, establishing the National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners (the Data Bank). The proposed regulations would amend the existing reporting requirements regarding payments on medical malpractice claims or actions in order to include reports on payments made on behalf of those practitioners who provided the medical care that is the subject of the claim or action, whether or not they were named as defendants in the claim or action. These amendments are designed to prevent the evasion of Data Bank medical malpractice payments reporting requirements.

DATES: Comments on this proposed rule are invited. To be considered, comments must be received by February 22, 1999.

ADDRESSES: Written comments should be addressed to Neil Sampson, Acting Associate Administrator, Bureau of Health Professions (BHPr), Health Resources and Services Administration, Room 8–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. All comments received will be available for public inspection and copying at the Office of Research and Planning, BHPr, Room 8–67, Parklawn Building, at the above address, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas C. Croft, Director, Division of Quality Assurance, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8A–55, 5600 Fishers Lane, Rockville, Maryland 20857; telephone: (301) 443–2300.

SUPPLEMENTARY INFORMATION: The Assistant Secretary for Health, Department of Health and Human Services, with the approval of the Secretary, published in the **Federal Register** on October 17, 1989 (54 FR 42722), regulations implementing the Health Care Quality Improvement Act of 1986 (the Act), title IV of Public Law 99–660 (42 U.S.C. 11101 *et seq.*), through the establishment of the National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners (the Data Bank). Those regulations are codified at 45 CFR part 60.

Among other items of information that must be reported to the Data Bank, section 421 of the Act requires that each entity that makes a payment in settlement or satisfaction of a ''medical malpractice action or claim'' must report certain information ''respecting the payment and circumstances thereof'' (section 421(a)). The information to be so reported includes ''the name of any physician or licensed health care practitioner for whose benefit the payment is made'' (section 421(b)(1)). The term ''medical malpractice action or claim'' is defined for purposes of the Act in section 431(7), to mean—

* * * a written claim or demand for payment based on a health care provider's furnishing (or failure to furnish) health care services, and includes the filing of a cause of action, based on the law of tort, brought in any court of any State of the United States seeking monetary damages.

Thus, the Act provides for the reporting, by the payer, of any payment made for the benefit of a health care practitioner resulting from any ''written claim or demand for payment'' based on ''furnishing (or failure to furnish) health care services.''

In implementing this requirement in the regulations published on October 17, 1989, the Secretary included in § 60.7(a), entitled ''*Who must report,*'' language stating that the provision applies to a payer who makes a payment ''for the benefit of'' a health care practitioner

* * * in settlement of or in satisfaction in whole or in part of *a claim or a judgment against such* * * * *health care practitioner* for medical malpractice. [Emphasis added.]

It has come to the Department's attention that there have been instances in which a plaintiff in a malpractice action has agreed to dismiss a defendant health care practitioner from a proceeding, leaving or substituting a hospital or other corporate entity as defendant, at least in part for the purpose of allowing the practitioner to avoid having a report on a malpractice payment made on his or her behalf submitted to the Data Bank. The

Department recognizes that this has occurred especially in cases when the counsel of a self-insured hospital or other self-insured corporate entity (which employs the defendant health care practitioner) has actively pursued having the defendant health care practitioner's name dropped from a proceeding, leaving or substituting the hospital or other corporate entity as the defendant, to avoid having to report the practitioner.

This practice makes it possible for practitioners whose negligent or substandard care has resulted in compensable injury to patients to evade having that fact appear in the Data Bank, since the payment is arguably not in satisfaction of a claim or judgment against the practitioner. Such a result is clearly inconsistent with the Congressional purpose, explicit in the Act, of

> restrict[ing] the ability of incompetent [practitioners] to move from State to State without disclosure or discovery of the [practitioner's] previous damaging or incompetent performance.

See section 401(2) of the Act. Since the regulation quoted above, literally read, does permit a result so at odds with the purposes of the statute, the Secretary proposes to revise it. The Department does recognize that there are legitimate situations when it is impossible to identify a practitioner(s) for whose benefit the payment was made. For example, a situation could occur wherein a power failure causes a heart monitor to cease functioning leading to an injury or death, which ultimately leads to a malpractice payment. In these very limited circumstances, the Secretary proposes to require that the reporter state the sequence of events that led to the payment, why the practitioner could not be identified, and the amount of the payment. The Department will use this information to identify medical malpractice reporters that appear to make a practice of not identifying specific practitioners.

The Department proposes to amend paragraphs (a) and (b) of § 60.7 as follows:

1. Paragraph (a) would be revised by removing the reference to a claim or judgment ''against such physician, dentist, or other health care practitioner'' and adding language from section 421(a) of the Act; and

2. Paragraph (b)(1) would be revised to state explicitly that the reference in that provision to the practitioner ''for whose benefit the payment is made'' includes ''each practitioner whose acts or omissions were the basis of the action or claim.''

A new paragraph (b)(2) would require that in situations where it is impossible to identify the practitioner for whose benefit the payment was made, the payor must report a statement of the facts and why the practitioner could not be identified and the amount of the payment. Due to the fact that the hospital is no longer the primary place of practice for many practitioners, new paragraph (b)(2) would further require the payer to include not only the name of each hospital with which the practitioner is affiliated, but also the name of each health care entity with which the practitioner is affiliated. Former paragraphs (b)(2) and (b)(3) are being redesignated as paragraphs (b)(3) and (b)(4) respectively.

These changes are intended to make clear that the reach of the term ''practitioner for whose benefit the payment is made'' as it is used in the Act and the regulations extends to any practitioner whose acts or omissions were the basis for the action or claim, regardless of whether that practitioner is a named defendant in a malpractice action. It thus becomes the responsibility of the payer, during the course of its review of the merits of the claim, to identify any practitioner whose professional conduct was at issue in any malpractice action or claim that has resulted in a payment, and to report that practitioner to the Data Bank.

The Secretary notes that, consistent with Congressional purpose explicit in the Act, § 60.7(d), entitled ''*Interpretation of Information*'' states:

> A payment in settlement of a medical malpractice action or claim shall not be construed as creating a presumption that medical malpractice has occurred.

This provision remains in the rule and is one of the basic tenets of the Data Bank.

Economic Impact

Executive Order 12866 requires that all regulations reflect consideration of alternatives, of costs, of benefits, of incentives, of equity, and of available information. Regulations must meet certain standards, such as avoiding unnecessary burden. Regulations which are ''significant'' because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues, require special analysis.

The Department believes that the resources required to implement the requirement in these regulations are minimal. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA), and the Small Business Regulatory Enforcement Act of 1996, which amended the RFA, the Secretary certifies that these regulations will not have a significant impact on a substantial number of small entities. For the same reasons, the Secretary has also determined that this does not meet the criteria for a major rule as defined under Executive Order 12866. The NPRM would amend the existing reporting requirements regarding payments on medical malpractice claims or actions in order to include reports on payments made on behalf of those practitioners who provided care that is the subject of the claims, whether or not they were named as defendants in the medical malpractice claim or action. As such, the proposed rule would have no major effect on the economy or on Federal expenditures.

Paperwork Reduction Act of 1995

The National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners regulations contain information collections which have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 and assigned control number 0915–0126. One of the approved reporting requirements will be affected by the proposed amendments. As required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3507(d)), the Department has submitted a copy of this proposal rule to the Office of Management and Budget for its review of this information collection requirement.

Collection of Information: National Practitioner Data Bank For Adverse Information on Physicians and Other Health Care Practitioners.

Description: The NPRM would amend the existing reporting requirements regarding payments on medical malpractice claims or actions in order to include reports on payments made for the benefit of those practitioners whose acts or omissions were the basis of the action or claim, whether or not they were named as defendants in the medical malpractice claim or action.

Description of Respondents: Business or other for-profit, not-for-profit institutions.

Estimated Annual Reporting Burden: The section number and the estimated change in reporting burden are as follows:

§ 60.7

	*Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Currently approved burden	150	105.33	15,800	.75	11,850
Actual current volume	425	44.7	19,000	.75	14,250
Total burden after amendment	625	60.8	38,000	.75	28,500
Reporting due to this NPRM	300	63.33	19,000	.75	14,250

*The number of entities reporting payments was underestimated in the last clearance request. The estimate of 150 entities was based on the fact that fewer than 100 large insurers are responsible for 80–85 percent of the reports. A check of the Data Bank records for 1997 showed that many more entities than expected file one or two reports per year, and that a total of 425 entities filed reports in 1997. That number is expected to increase by about 50 percent (rounded to 625) with the change in the regulation. The total number of reports filed is expected to double from the 1997 level of 19,000 to 38,000 per year. The Department believes that the resources required to implement the requirement in these regulations are minimal.

There is no reliable way to forecast the increase in medical malpractice reports as a result of this regulation. However, in conversations with many individuals such as plaintiffs' and defendants' attorneys, representatives from self-insured health care entities, and malpractice insurers, the most common estimate is that the Data Bank currently receives reports on 50 percent of the medical malpractice payments being made. Most of the new reports will not be made by current reporters. Instead, there will be a sizeable increase in the number of new reporters (estimated at 200), with each new reporter filing only a small number of reports in a single year. The 63.33 reports per respondent represent an average over all types of respondents, from the large insurers who submit hundreds of reports per year to the small reporters (mainly self-insured hospitals and other self-insured corporate entities) that may submit one or two reports per year.

Request for Comment: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information shall have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Written comments and recommendations concerning the proposed information collection should be sent to: Wendy Taylor, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503. OMB is required to make a decision concerning the collection of information contained in these proposed regulations between 30 and 60 days after publication of this document in the **Federal Register**. This does not affect the deadline of the public to comment to the Department on the proposed regulations.

List of Subjects in 45 CFR Part 60

Claims, Fraud, Health, Health maintenance organizations (HMOs), Health professions, Hospitals, Insurance companies, Malpractice, Reporting and recordkeeping requirements.

Dated: October 3, 1997.

Claude E. Fox,

Acting Administrator, Health Resources and Services Administration.

Approved: August 24, 1998.

Donna E. Shalala,

Secretary.

Accordingly, 45 CFR part 60 is proposed to be amended as set forth below:

PART 60—NATIONAL PRACTITIONER DATA BANK FOR ADVERSE INFORMATION ON PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS

1. The authority citation for 45 CFR part 60 continues to read as follows:

Authority: Secs. 401–432 of the Health Care Quality Improvement Act of 1986, Pub. L. 99–660, 100 Stat. 3784–3794, as amended by sec. 402 of Pub. L. 100–177, 101 Stat. 1007–1008 (42 U.S.C. 11101–11152).

2. Section 60.7 is amended by revising paragraph (a); by revising the introductory texts to paragraphs (b) and (b)(1); by revising paragraph (b)(1)(ix); by redesignating paragraphs (b)(2) and (3) as paragraphs (b)(3) and (4) and by adding a new paragraph (b)(2). As so amended, § 60.7 reads in pertinent part as follows:

§ 60.7 Reporting medical malpractice payments.

(a) *Who must report.* Each entity, including an insurance company, which makes a payment under an insurance policy, self-insurance, or otherwise, for the benefit of a physician, dentist or other health care practitioner in settlement (or partial settlement) of, or in satisfaction of a judgment in, a medical malpractice action or claim shall report information respecting the payment and circumstances thereof, as set forth in paragraph (b) of this section, to the Data Bank and to the appropriate State licensing board(s) in the State in which the act or omission upon which the medical malpractice claim was based. For purposes of this section, the waiver of an outstanding debt is not construed as a ''payment'' and is not required to be reported.

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the following information:

(1) With respect to the physician, dentist, or other health care practitioner for whose benefit the payment is made, including each practitioner whose acts or omissions were the basis of the action or claim—

* * * * *

(ix) Name of each hospital and health care entity with which he or she is affiliated, if known;

(2) If the physician, dentist, or other health care practitioner could not be identified—

(i) A statement of such fact and an explanation of the inability to make the identification, and

(ii) The amount of the payment.

* * * * *

[FR Doc. 98–34066 Filed 12–23–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 16

[USCG–1998–4469]

RIN 2115–AF67

Management Information System (MIS) Requirements

AGENCY: Coast Guard, DOT.