DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Rockville, Maryland 20857

TO: The Secretary
Through: DS_____
COS_____
ES_____

FROM: Administrator

DATE: May 20, 2014

SUBJECT: A Review of the Department of Health and Human Services' Reporting Policy of Health Care Practitioners to the National Practitioner Data Bank – **DECISION**

ISSUE

In 1986, Congress enacted the Health Care Quality Improvement Act (HCQIA) which created the National Practitioner Data Bank (NPDB) to serve as a repository of adverse action reports against practitioners. The HCQIA requires that payments made by an insurance company, hospital, or other third party, on behalf of a health care practitioner in settlement of a claim or judgment made against that health care practitioner, be reported to the NPDB

Although the law does not impose any reporting requirements on the Department of Health and Human Services (HHS), in 1990, the Secretary established a policy for reporting to the NPDB. This policy states that all malpractice payments made as a result of a claim or suit filed against the U.S. Government will be reported to the NPDB. The practitioner primarily responsible for providing the care will be named in the report, regardless of whether the standard of care was met. The only exception is for those cases in which the adverse event was caused by a system failure.

Current HHS reporting practices are inconsistent with the written policy in that only those malpractice payments where the practitioner failed to meet the standard of care are reported. The Medical Claims Review Panel (MCRP), chartered by the Secretary, provides peer review of paid claims in order to decide which individuals need to be named to the NPDB.

During a January 2012 meeting of HHS agency heads, it was recommended that HHS amend its policy, in order to be consistent with current practice. The revised HHS policy would state that practitioners will only be reported to the NPDB when the MCRP has identified the practitioner(s) primarily responsible for providing the care and determined that the standard of care was not met by those practitioners. The Health Resources and Services Administration (HRSA), as the staff lead for supporting the MCRP, seeks your decision on whether to change the 1990 policy.

BACKGROUND

The HCQIA was enacted because the U.S. Congress found that the increasing occurrence of medical malpractice litigation and the need to improve the quality of medical care warranted

greater efforts than those that could be undertaken by any individual state. There was also a national need to restrict the ability of incompetent physicians from moving state-to-state without disclosure or discovery of the physician's previous damaging or incompetent performance. Therefore, Congress sought to collect information, including medical malpractice payments adverse licensure actions, and Medicare and Medicaid exclusions via the NPDB.

When Congress created the NPDB, it recognized that medical malpractice settlements are sometimes made for reasons other than professional competence, and specifically provided in the law that a report of a medical malpractice payment shall not be construed as creating a presumption that medical malpractice occurred. Health care entities (e.g., hospitals, HMOs), with a formal peer review process in place, query the NPDB for information. The NPDB serves as a flagging system designed to stimulate a comprehensive review of health care practitioners' professional credentials.

The HCQIA requires that payments made by an insurance company, hospital, or other third party, on behalf of a health care practitioner in settlement of a claim or judgment made against that health care practitioner, be reported to the NPDB. However, the statute does not explicitly require HHS or other federal departments to report medical malpractice settlements or court judgments to the NPDB. Instead, the law requires that HHS enter into Memoranda of Agreement with the Department of Defense (DOD) and the Department of Veterans Affairs (VA) regarding their reporting policies. These agreements, dated November 1990 and September 1997, respectively, outline DOD and VA reporting practices. Initially, DOD's policy was to report all medical malpractice payments to the NPDB. In May 2004, DOD modified its reporting procedures. The current policies of both DOD and VA require the submission of a medical malpractice payment report to the NPDB only when it is determined that a practitioner failed to meet the standard of care. Each Department has created peer review committees to determine whether the standard of care was met in individual cases and to identify the practitioner(s) whose medical care gave rise to the claim. Reportedly, the rationale for DOD and VA's current policies is to protect their practitioners who met the standard of care from being named in a report to the NPDB as a result of lawsuits being settled at the discretion of the government.

Under the HCQIA, HHS was not required to report Public Health Service (PHS) providers to the NPDB. However, in 1990, the Assistant Secretary for Health (ASH) issued a policy stating that health care practitioners who are employees of the PHS, or considered employees under the Federal Tort Claims Act (FTCA), would be reported to the NPDB in cases where they are named and a payment is made in a medical malpractice claim, except where the damages were caused by system failure, e.g., the deviation from the applicable standard of care is beyond the control of the practitioner. In those cases where the standard of care is met, the HHS policy calls for this fact to be noted in the report to the NPDB. Although the policy requires all malpractice reports to be submitted (similar to the private sector), the HHS practice since 1990 has been to only report those malpractice payment cases where the practitioner failed to meet the standard of care. HHS agencies that either employ or support practitioners that were affected by this decision are HRSA, the Indian Health Service (IHS), and the National Institutes of Health (NIH).

The HHS OIG has noted the inconsistency between the HHS policy and its practice in a 2005 report and annually in its Compendium of Unimplemented Recommendations. In addition, the

nonprofit consumer advocacy group, Public Citizen, regularly inquires about HHS' efforts to come into compliance with its own policy.

The merits of amending the current HHS policy have been debated within the Department for more than two decades. Specifically, some argue that the unique circumstances of providing care as a federal practitioner merit a different approach to NPDB reporting as allowed by the law. These arguments include:

- Through the MCRP, HHS has a process in place to assess malpractice cases and determine whether or not the standard of care was met and/or whether a system error occurred. This information is used to make improvements in care delivery. The process achieves the HCQIA goal of improving the quality of care without reporting practitioners who were found to have met the standard of care. Practitioners who do not meet the standard of care would continue to be reported. Thus, the other stated goal of HCQIA (tracking incompetent physician performance) would continue to be met.

- Federal practitioners generally serve a higher percentage of high risk patients, oftentimes in under-resourced circumstances, which can lead to a higher frequency of poor outcomes.

- Practitioners working on behalf of the federal programs are more likely to be sued given the size of the federal government and its tendency to settle cases.

- Private sector practitioners are more likely to know that a suit has been filed concerning their care because they must be named in the suit and they are ordered by the court to reply. In contrast, suits filed under the Federal Tort Claims Act (FTCA) can be initiated against the federal government with no requirement that the practitioner in question respond.

- Private sector practitioners can often select a medical malpractice insurer based on its settlement policies and some also have the option to obtain their own attorney to represent their interests. FTCA-covered practitioners cannot select their malpractice carrier and the attorneys defending the FTCA claim are concerned with the interests of the United States, not those of the practitioner.

- Some private sector practitioners are able to take advantage of a provision in the HCQIA which allows payments made for the benefit of a corporation such as a clinic, group practice, or hospital, not to be reported (i.e., corporate shield). This exception is not applicable to federal government practitioners.

- Certain private practitioners are able to exercise the option to settle claims independent of the malpractice insurer, guaranteeing that they would not be reported to the NPDB. This option is not available to federal practitioners.

State considerations/activity
As detailed in another decision memo for your review, Massachusetts and Oregon have both passed legislation establishing alternative models of disclosure and apology of medical malpractice Both states have written HHS requesting that their new medical malpractice systems be excepted from standard NPDB reporting; however, these new systems may conflict with the NPDB's legislation and efforts relating to disclosure and sharing of comparable information across states.

Below are the options for the HS NPDB reporting policy for your consideration.

OPTIONS AND DISCUSSION

These options below are a product of HRSA meetings with agency heads and PHS practitioners.

OPTION 1: Comply with the current written policy, which states that all payments relating to medical malpractice are to be reported to the NPDB and require Operating Divisions to note, in the narrative portion of such reports, whether the practitioner met the standard of care. To facilitate the collection and mining of this data under this option the NPDB report format would be revised to include a check-box for reporting entities to note if the standard of care was met or not met.

Pros:

- Consistent with private sector requirements where there is no exemption from reporting a payment when the practitioner meets the standard of care.
- Eliminates the potential for private sector criticism that HHS is creating a separate and more generous rule for its programs.
- Addresses the OIG recommendation for corrective action to assure full reporting consistent with the current written policy.

Cons:

- May adversely affect practitioner retention and recruitment to federally sponsored health care sites.
- Is inconsistent with the reporting practices and policies of other federal agencies, i.e., DoD and VA.

OPTION 2: Revise the current written policy to only report payments relating to medical malpractice to the NPDB when it is determined that the practitioner did not meet the standard of care.

Pros:

- The purpose of the statute is met without reporting practitioners that have met the standard of care.
- Consistent with DoD and VA's reporting policy; makes policy across the federal government consistent.
- Conforms to actual HHS practice that has been followed for the past 22 years.
- Addresses the OIG recommendation for corrective action to assure reporting of appropriate cases.

Cons:

- Inconsistent with private sector requirements.

- Increases exposure to criticism from the private sector and patient safety advocates, like Public Citizen, that HHS is creating separate and more generous rules for itself.

OPTION 3: Seek a legislative change to the HCQIA exempting the reporting of medical malpractice payments when the standard of care is met.

Pros:

- Would address concerns about the fairness of reporting all malpractice payments, even those where the practitioner met the standard of care.
- If done in conjunction with Option 2, could create the same rules for the private and governmental sectors.

Cons:

- A functional equivalent of the MCRP does not exist in the private sector. Thus it is unclear how the new standard could be implemented uniformly.
- Legislative change to the HCQIA would be difficult, lengthy, and unpredictable.
- Creating a functional MCRP equivalent in the private sector would mandate costly changes in the peer review process, as well as result in different practices by entities depending on their resource levels.

Mary Wakefield

Mary K. Wakefield, Ph.D., R.N.

DECISION

Option 1
Approved ✓ Disapproved _____ Need More Information _____

Option 2
Approved _____ Disapproved _____ Need More Information _____

Option 3
Approved _____ Disapproved _____ Need More Information _____

Kathleen Sebelius

May 22, 2014
Date

Kathleen Sebelius
Secretary

Attachments:
Tab A – Proposed Revisions to the HHS MCRP Charter

TAB A

DEPARTMENT OF HEALTH AND HUMAN SERVICES
MEDICAL CLAIMS REVIEW PANEL
CHARTER

A. PURPOSE

The Department of Health and Human Services (HHS) Medical Claims Review Panel (MCRP) shall assist HHS in meeting its responsibility to provide quality health care in its operated and funded facilities and by health care practitioners therein. The collective clinical knowledge and expertise of the membership shall be applied to the review of claims of medical negligence and substandard care, addressing issues such as standards of care and practitioner competence.

B. FUNCTION

The MCRP shall:

1. Review and evaluate the medical analyses performed by HHS employed practitioners and/or contract practitioners on all paid claims resulting from settlements or judgments for damage, injury, or death filed under the Federal Tort Claims Act (FTCA) against an HHS facility or health care practitioner covered under the FTCA.
2. Identify the practitioner(s) who provided the treatment giving rise to the claim and determine whether the standard of care was met.
3. Provide professional recommendations on opportunities to improve health care quality, to reduce or alleviate risk, and to improve patient safety within the context of cases reviewed.

C. REPORTS

The MCRP shall transmit a summary of each case reviewed to the relevant operating division (OPDIV). This summary shall include the name(s) of the practitioner(s) who provided the treatment giving rise to the claim for purposes of reporting medical malpractice payments pursuant to Department policy, state, and/or federal laws. Each OPDIV shall be responsible for reporting its medical malpractice payments to the National Practitioner Data Bank and to the appropriate state licensing board. No practitioner of record shall be reported, if the MCRP determines that the:

1. Health care provided did not deviate from the standard of care; or
2. Adverse event was solely the result of systems failure.

The Chairperson shall submit an annual report to the Secretary and each Agency Head represented on the MCRP regarding the issues brought before it, as well as decisions and any recommendations it makes.

D. RECONSIDERATIONS

A reconsideration of MCRP findings is a limited review that is designed to correct an error in the identification of the practitioner and/or the determination of the MCRP of the provision of substandard care. Each OPDIV shall develop its own procedures for the reconsideration process, within the boundaries of a reconsideration framework established by the MCRP. The decision on the reconsideration is final.

E. STRUCTURE

1. Organizational Locus
   The MCRP shall be functionally located within the Office of the Secretary.

2. Membership
   All members shall be licensed health care practitioners with appropriate clinical experience. The minimum number of members appointed by each Agency Head shall be as follows:
   a. Two physicians, one dentist, and one nurse from both the Health Resources and Services Administration (HRSA) and the Indian Health Service (IHS) (four from each Agency);
   b. two physicians from the National Institutes of Health (NIH);
   c. one physician each from the Substance Abuse and Mental Health Services Administration (SAMHSA); the Agency for Healthcare Research and Quality (AHRQ); the Food and Drug Administration (FDA); the Centers for Disease Control and Prevention (CDC); and the Centers for Medicare and Medicaid Services (CMS); and
   d. all representatives shall be selected by their respective Agency Head.

   In addition, each Agency Head shall designate one additional physician, and in the case of HRSA and IHS one additional nurse, as alternates.

   The Chairperson may increase membership in consideration of the MCRP's workload or other needs. This increase shall be accomplished through a request to Agency Heads to select and designate additional physician(s), dentist(s), nurse(s) or other health care professionals as needed to serve as MCRP members.

3. Chairperson and Vice-Chairperson
   The Chairperson shall be a licensed physician employed within the Office of the Assistant Secretary for Health (OASH) or an HHS OPDIV other than HRSA, IHS, or NIH. The Vice-Chairperson shall be a licensed health care practitioner employed by an HHS OPDIV. Both shall have the appropriate clinical experience and background. They shall be appointed by the Assistant Secretary for Health (ASH) from nominees recommended by Agency Heads, and shall report to the ASH.

4. Terms of Service
   Chairperson and Vice-Chairperson: The Chairperson and Vice-Chairperson shall each serve for a period of 2 years, with staggered terms to ensure continuity. Their terms of service may be extended for additional terms at the discretion of the ASH.

   All other members shall serve for a period of 3 years, which can be extended or terminated at the Agency Head's discretion. The length of term for each Agency representative shall be staggered to ensure continuity and ongoing experience within each

Agency. Termination or extension of a term of service shall be at the Agency Head's discretion.

5. Liability Protection
The participation of MCRP members as designated by their Agency Heads (or designee) is an assigned duty within the scope of their official federal employment and is therefore covered by the FTCA and other applicable law.

6. Support Services
Support services shall be provided by HRSA.

Support services include facilitation of meeting logistics, interaction with members, maintenance of MCRP case documents and policies and procedures, drafting of correspondence, annual reports, and other work required to support the MCRP.

7. Meetings
The MCRP shall meet monthly or as scheduled by the Chairperson. Members shall receive advance notice of all meetings.

8. Privacy and Confidentiality
The MCRP shall comply with all applicable Privacy Act and Confidentiality statutes and regulations.

F. DURATION
The MCRP shall function until terminated by the Secretary.

_____
Kathleen Sebelius
Secretary

_____
Date