May 29, 2014

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Mary K. Wakefield, Ph.D., R.N.
Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Secretary Sebelius and Administrator Wakefield:

Public Citizen, a consumer advocacy organization with more than 300,000 members and supporters nationwide, hereby petitions the Department of Health and Human Services (HHS) to promptly issue a new notice of proposed rulemaking (NPRM) that would amend the existing requirements for reporting to the National Practitioner Data Bank (NPDB or Data Bank) payments on medical malpractice claims or actions. The amendments sought under this petition should clarify that, consistent with the federal statute establishing the NPDB, a report of medical malpractice payment must be submitted to the NPDB in the names of any practitioners on whose behalf the malpractice payment was made, whether or not they were named as defendants in the claim or action.

Such an NPRM was first issued by the Health Resources and Services Administration (HRSA) on December 24, 1998, but later withdrawn. The NPRM noted that such amendments would prevent evasion of NPDB medical practice payment reporting requirements by use of what is commonly referred to as the “corporate shield” loophole, which is permitted by the original, existing HHS regulations at 45 C.F.R.§ 60.7 finalized in 1989. The use of the corporate shield loophole involves a practice in which a plaintiff in a malpractice action agrees to dismiss a defendant health care practitioner from a proceeding, thereby leaving or substituting a hospital or other corporate entity as the defendant. This often occurs in response to a request from counsel of a self-insured hospital or other corporate entity that employs the defendant health care practitioner. The loophole is used, at least in part, for the purpose of allowing the practitioner to avoid having a report of a malpractice payment made on his or her behalf submitted to the NPDB. As HRSA itself noted in its NPRM, the corporate shield loophole “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 [NPDB]."

On April 17, 2000, in response to public comments raising concern about the impact of the 1998 NPRM as originally published, HRSA published a notice indicating that a new NPRM would be published for public comment, with a goal of publishing the revised proposed rule by the end of 2000. The agency further noted that new final regulations likely would be implemented in 2001. The rulemaking proposal remained on the HHS Unified Agenda for several years, but it was withdrawn abruptly by HRSA on April 21, 2009, without explanation.

Evidence suggests that the corporate shield loophole is used more frequently today than it was in 1998 when HRSA first sought to close the loophole. Since then, as discussed below in section E, the percentage of physicians who are employed by hospitals and other corporate entities (as opposed to those who are in private practice) has increased markedly. Therefore, the number of doctors who are potentially able to take advantage of the corporate shield loophole has similarly increased. Meanwhile, the number of malpractice payments made on behalf of physicians reported to the NPDB has steadily fallen for the past decade. We suspect that the use of the corporate shield loophole has contributed to this trend.

Use of the corporate shield loophole by hospitals and other corporate entities likely has progressively reduced the comprehensiveness of malpractice payment data reported to the NPDB.

We recognize that a single malpractice payment is not necessarily a good indicator of the quality of care provided by a physician, dentist, or other health care practitioner. Yet research has shown that a pattern of malpractice payments is an excellent indicator of which practitioners have quality-of-care problems and may need retraining, proctoring, or some other serious action to ensure the safety of their future patients. When malpractice payments are not reported to the NPDB or when reports are submitted but fail to identify all health care practitioners for whose benefit the payment was made, it becomes more difficult, if not impossible, for NPDB users to identify such patterns of malpractice by a practitioner.

It is imperative that HRSA promptly move forward with promulgating an appropriately worded revised rule that effectively closes the corporate shield loophole regarding the NPDB so that any health care practitioner for whose benefit a malpractice payment is made is reported to the NPDB, regardless of whether the practitioner is specifically named as a defendant in the claim or action.

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A. Overview of the NPDB

The NPDB was authorized by the Health Care Quality Improvement Act of 1986 (HCQIA) and began operation on September 1, 1990, after publication of implementing regulations and creation of the NPDB’s computer system.

The NPDB plays a central role in ensuring patient safety by providing the most comprehensive, reliable information concerning the malpractice payment and disciplinary history of physicians, dentists, and other health care practitioners to licensing boards, credentialing authorities, peer reviewers, and other users.

During the nearly three decades since the NPDB was envisioned and eventually established, the health care environment has significantly changed, but the policies governing the NPDB have unfortunately not evolved to meet the challenges created by such changes. As a result, the NPDB’s viability as a reliable source of practitioner information is threatened. The NPDB is recognized as the gold standard for such information, providing important background checks on physicians and other health care providers to hospitals, medical boards, health maintenance organizations, and other authorized users. But it will no longer be regarded in this way in the future unless necessary regulatory changes are made to close the corporate shield loophole.

B. Statutory requirements for reporting medical malpractice payments

The NPDB was established by 42 U.S.C. § 11131, which specifies the following requirements for reporting medical malpractice payments to HHS:

(a) In general

Each entity (including an insurance company) which makes payment under a policy of insurance, self-insurance, or otherwise in settlement (or partial settlement) of, or in satisfaction of a judgment in, a medical malpractice action or claim shall report, in accordance with section 11134 of this title [Form of reporting], information respecting the payment and circumstances thereof.

(b) Information to be reported

The information to be reported under subsection (a) of this section includes—
(1) the name of any physician or licensed health care practitioner for whose benefit the payment is made,
(2) the amount of the payment,
(3) the name (if known) of any hospital with which the physician or practitioner is affiliated or associated,
(4) a description of the acts or omissions and injuries or illnesses upon which the action or claim was based, and
(5) such other information as the Secretary determines is required for appropriate interpretation of information reported under this section.
(c) Sanctions for failure to report

Any entity that fails to report information on a payment required to be reported under this section shall be subject to a civil money penalty of not more than $10,000 for each such payment involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1320a–7a of this title are imposed and collected under that section.

C. Current regulatory requirements for reporting medical malpractice payments: inconsistent with the statute

HHS published final regulations implementing 42 U.S.C. § 11131 on October 17, 1989, and the NPDB began operating in September 1990. The regulations, codified at 45 C.F.R. § 60.7, have not been amended since and include the following language pertinent here:

§ 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 of or in satisfaction in whole or in part of a claim or a judgment against such physician, dentist, or other health care practitioner for medical malpractice, must report information as set forth in paragraph (b) 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. …

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

(1) With respect to the physician, dentist or other health care practitioner for whose benefit the payment is made—
   (i) Name …
   (ix) Name of each hospital with which he or she is affiliated, if known;
(2) With respect to the reporting entity— …
   (iii) Relationship of the reporting entity of the physician, dentists, or other health care practitioner for whose benefit the payment is made;
(3) With respect to the judgment or settlement resulting in the payment— …
   (ii) Date or dates on which the act(s) or omission(s) which gave rise to the action or claim occurred…
   (vi) A description of the acts or omissions and injuries or illnesses upon which the action or claim was based...

The language of these 24-year-old regulations regarding the requirements for reporting malpractice payments unfortunately does not comport with the statute. Section 11131 requires that malpractice payments made “under a policy of insurance, self-insurance, or otherwise in settlement (or partial settlement) of, or in satisfaction of a judgment in, a medical malpractice action or claim” be reported and that such reports include “the name of any physician or licensed
health care practitioner for whose benefit the payment is made” and “a description of the acts or omissions … upon which the action or claim was based.” In contrast, under 45 C.F.R. 60.7(a), the only malpractice payments that must be reported are those specifically made “for the benefit of a physician, dentist or other health care practitioner in settlement of or in satisfaction in whole or in part of a claim or a judgment against such physician, dentist, or other health care practitioner” [emphasis added] for medical malpractice.” As a result, the regulation allows hospitals and other entities to avoid reporting certain malpractice payments made for the benefit of physicians or licensed health care practitioners that, under the statute, should be reported.

The difference between the statutory and regulatory language is subtle but significant. The statute requires reporting of all medical malpractice payments involving any physician or licensed health care practitioner for whose benefit the payment is made, regardless of the nature of the party (e.g., corporation or individual) named as the defendant in the claim and regardless of whether a claim or judgment was specifically against such physician or licensed health care practitioner. Under the statute, the name of the any practitioner for whose benefit a medical malpractice payment is made is one of several data elements that must be reported. However, the regulations require reporting of malpractice payments to the NPDB only if one or more physicians or other health care practitioners are named as defendants as part of the settlement of a claim or satisfaction of a judgment.

D. HRSA’s 1998 NPRM: the agency’s recognition that the regulations fail to comport with the statute

HHS has long recognized (a) the problem of underreporting of medical malpractice payments to the NDPB because of the corporate shield loophole and (b) the fact that this loophole is the direct result of language in the 1989 regulations that does not comport with the statutory language. HRSA took the necessary initial step to correct the regulations in 1998, when the agency published an NPRM that would have amended the regulations to align with the statutory language and close the unintended corporate shield loophole.4

In the preamble to that proposed rule, HRSA highlighted the discordance between the statutory requirement and the regulation. The agency further explained how the existing regulation undermined the intent of the statute that established the NPDB:5

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

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5 Ibid.
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 [to the NPDB].

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 restricting 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.

[Emphasis added]

To align the regulation with the statute and close the corporate shield loophole, HRSA proposed in its 1998 NPRM to amend 45 C.F.R. § 60.7 as follows (additions are marked in underline and deletions in strikeout in comparison to the current language).  

§ 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 in whole or in part of a claim or a judgment against such physician, dentist, or other health care practitioner for, 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:

6 Ibid.
(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.

The proposed revision to 45 C.F.R. §§ 60.7(a) and (b)(1) would have made the regulations consistent with 42 U.S.C. § 11131(a) and the intent of the HCQIA. In particular, the revision would have deleted the reference to a claim or judgment “against such physician, dentist, or other health care practitioner” — the language which created the corporate shield loophole — and substituted language taken directly from the statute. Similarly, 45 C.F.R. § 60.7(b)(1) would have been revised to state explicitly that the reference to the physician, dentist, or other health care practitioner for whose benefit the payment is made includes each practitioner whose acts or omissions were the basis for the malpractice action or claim. (The practitioners for whose benefit a malpractice payment is made in nearly all cases would have been involved in the acts or omissions upon which the action or claim was based, but the statutory language does not appear to mandate that this be the case for the reporting requirement to apply.)

These proposed amendments would have fully aligned the regulatory language with the statutory requirement that the name of each physician or licensed health care practitioner for whose benefit a medical practice payment was made, including those whose acts or omissions formed the basis for the action or claim, be reported to HHS — regardless of whether the physician or health care provider was named as a defendant in the final settlement or judgment.

In explaining the intent of these proposed amendments, HRSA stated the following:7

These changes are intended to make clear that the reach of the term “practitioner whose benefit the payment is made” as 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 the review of the merits of the claim, to identify any practitioner whose professional conduct was at issue in any malpractice action or claim that resulted in a payment, and to report that practitioner to the Data Bank.

7 Ibid.
The Secretary notes that, consistent with Congressional purpose explicit in the Act, Sec. 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.

The NPRM also proposed expanding the reporting requirement under 45 C.F.R. § 60.7(b)(1)(ix) to include the name of each health care entity with which a physician, dentist or other health care practitioner named in a malpractice payment report submitted to the NPDB is affiliated, if known. The current regulations limit this requirement to name of each hospital with which the practitioner is affiliated, if known.

Finally, the NPRM also proposed a new requirement (proposed 45 C.F.R. § 60.7(b)(2)) that medical malpractice payers, in situations in which it is impossible to identify the practitioner(s) for whose benefit the payment was made, report to the NPDB (a) a statement of such fact and an explanation of the inability to identify the practitioner; and (b) the amount of the payment.

Members of the public submitted 122 comments in response to HRSA’s 1998 NPRM. The commenters included 70 health-care-related organizations or their representatives and 52 health care practitioners.

Commenters opposing the proposed amendments offered the following comments:

- Hospitals and insurers either are unable to or should not have to decide which health care practitioners to report to the NPDB when a medical malpractice payment is made.

- The costs of researching and determining which practitioners should be reported are too burdensome.

- There is a lack of standards for determining who to report.

- Fewer malpractice lawsuits would be settled and more would be litigated in court.

None of these arguments opposing the amendments provided a sufficient basis for failing to revise the HHS regulations to make them consistent with the statute.

Notably, all 52 health care practitioners who commented were physicians from Michigan, and all submitted an identical or nearly identical two-paragraph letter opposing the NPRM. Their letters noted that “if a practitioner is dismissed from a lawsuit, they would still be reported to the Data Bank as having been named as a defendant. The change could damage the credibility of a physician who was wrongly named as a defendant in the first place.” Other commenters voiced similar concerns. Such comments, however, reflect a misunderstanding about the proposed amendments. In particular, the amendments would not have required that every practitioner named, but subsequently dismissed, as a defendant in a medical malpractice lawsuit that resulted in a malpractice payment be reported to the NPDB. Only those practitioners for whose benefit
the payment was made, including those whose acts or omissions were the basis of the action or claim, would be subject to the reporting requirement — consistent with the underlying statute.

On April 17, 2000, in response to the public comments, HRSA published a notice indicating that the agency intended to issue a second NPRM on NPDB medical malpractice payment reporting requirements for public comment.8 In that notice, the agency stated that “[g]iven the large number of thoughtful comments and the high level of concern that was voiced about the potential impact of the proposal as published [on December 24, 1998], HRSA believes it is imperative to gather additional data and conduct further analyses before proceeding.” The agency noted that its goal was to publish the revised proposed rule by the end of 2000 and that new final regulations likely would be implemented in 2001.

HRSA failed to meet these goals. It neither issued a new proposal nor finalized the 1998 proposal.

E. The importance of closing the corporate shield loophole

Trends in the employment of physicians in the years since the HHS regulations requiring reporting to the NPDB became effective have created circumstances that increase the likelihood that hospitals and other corporate entities will take advantage of the corporate shield loophole. When the regulations were promulgated in 1989, most physicians were self-employed in private practice and thus were named routinely in malpractice claims. In the case of malpractice claims paid against the U.S. government, the government reported payments to the NPDB and named practitioners when applicable.

Today, physicians are much more likely to be employees of hospitals and other health care corporate entities, making it more likely that they will be shielded from malpractice payment reporting through the corporate shield loophole. Researchers with Accenture analyzed data from the American Medical Association and the Medical Group Management Association-American College of Medical Practice Executives to determine trends in physician independence and practice ownership.9 Physicians were defined as independent if they owned at least part of a practice. The researchers found that in 2000, only 57 percent of physicians were in independent practice. By 2005, this percentage had dropped to 49 percent and by 2012 to 39 percent. The Accenture researchers projected that in 2013 only 36 percent of physicians would be in independent practice.10

In its National Practitioner Data Bank 2003 Annual Report,11 HRSA identified the corporate shield loophole as one ongoing factor affecting the adequacy of malpractice payment reporting to the NPDB. While noting that the corporate shield “may mask the extent of substandard care and

10 Ibid.
diminish NPDB’s usefulness as a flagging system,” the agency acknowledged that the extent to which the corporate shield was being used “cannot be measured with available data.” More recently in 2012, Cindy Grubbs, the then-Director of the NPDB, stated that agency officials had “no way of knowing how often” the corporate shield is used.12

Plaintiffs’ lawyers reported in 1999 that as a condition of settlement, doctors often insist on being dismissed as defendants in lawsuits in an effort to avoid being reported to the NPDB.13 Hospitals often accede to such requests in an effort to minimize unwanted publicity that may result from a claim going to trial and to maintain the “allegiance and loyalty and dedication of their [medical] staff.” One plaintiffs’ attorney in Washington, DC, who specialized in medical malpractice, stated that use of the corporate shield loophole is a “common subterfuge.”14

Several examples of the use of the corporate shield loophole have been reported by the media, including the following:

(1) A 33-year-old woman entered a Chicago hospital in the late 1990s vomiting and complaining of the worst headache of her life. She was diagnosed with a neck sprain and sent home. Ten days later, she suffered a massive stroke, leaving her paraplegic with half of her brain removed. The patient’s father sued the hospital and the doctor who treated her. After nearly three years of litigation, and just before the case went to a jury, the plaintiff agreed to dismiss the doctor as a defendant in the suit. The hospital, which employed the doctor, settled for $17.5 million. But this settlement apparently was never reported to the NPDB.15

(2) A 62-year old man was admitted to a Pittsburgh-area hospital in 2009 with a treatable condition involving bleeding on the brain. The patient subsequently died, and the patient’s family filed a malpractice suit against the hospital and four doctors, who were accused of making a series of critical errors leading to the man’s death. The case was settled in 2012 for $1.4 million after the hospital made, and the family did not oppose, a request to remove all four doctors as defendants in the case. Because of the corporate shield loophole, the malpractice payment on behalf of the four doctors apparently was not reported to the NPDB.16

NPDB statistics indicate that over the past 10 years there has been a 40 percent drop in the number of malpractice payments reported to the NPDB.17 While laws limiting patients’ ability to pursue damages in court for alleged medical malpractice (often referred to broadly as “tort reform”) are likely the primary reason for this trend, increasing use of the corporate shield is

14 Ibid.
17 Email communication to Public Citizen from HRSA.
another plausible contributing factor, although the extent of its use has not been quantified. In 2012, Brian Atchinson, president and Chief Executive Officer of the Physician Insurers Association of America reportedly said that underreporting of medical practice payments to the NPDB due to use of the corporate shield is increasing as more physicians become hospital employees.18

Whenever the corporate shield is used to avoid reporting a physician on whose behalf a malpractice payment has been made, the failure to report violates the requirements of 42 U.S.C. § 11131. Such failures pose a risk to the health and well-being of patients because they allow, in some cases, incompetent practitioners to move from one state or hospital to another state or hospital without disclosure or discovery of their previous damaging or incompetent performance through the NPDB.

The practical ramifications for the NPDB of not revising 45 C.F.R. § 60.7 to fully comport with 42 U.S.C. § 11131 may be substantial. Although the NPDB was once considered a nearly comprehensive listing of doctors and other health care providers on whose behalf malpractice payments had been made, there is no doubt that, because of the corporate shield loophole, some malpractice payments made for the benefit of physicians, dentists, and other health care practitioners are now shielded from reporting because they were made in the name of a hospital or other corporate entity. As a result, it impossible to know whether data on malpractice payments for a particular practitioner are complete. In addition, the resulting incompleteness of the data makes the NPDB’s information less reliable and useful for licensing boards, credentialing authorities, and other users.

F. Detailed description of requested actions

For the reasons summarized above, Public Citizen petitions HHS to promptly issue a new NPRM that would amend the existing requirements for reporting to the NPDB payments on medical malpractice claims or actions. The amendments should clarify that, consistent with the federal statute establishing the NPDB, reports of medical malpractice payments submitted to the NPDB must name all practitioners for whose benefit the malpractice payment was made, whether or not they were specifically named as defendants in the claim or action. Such action is necessary to ensure patient safety and to protect the integrity and usefulness of the NPDB.

Specifically, we suggest the following revisions to 45 C.F.R. § 60.7 (additions underlined and deletions in strikeout):

§ 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 in whole or in part of a claim or a judgment against such physician,
dentist, or other health care practitioner for in a medical malpractice, must 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— …

G. Conclusion

The NPDB provides health care entities, state medical boards and other users with an important tool in their efforts to ensure patient safety. To the extent that NPDB medical malpractice data is compromised by the corporate shield loophole, hospitals and other health care organizations that rely on the NPDB to protect patient safety are deprived of potentially life-saving information. We urge HHS to promptly revise 45 C.F.R. § 60.7 and close the corporate shield loophole.

Sincerely,

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