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July 16, 2019

The Honorable Richard Neal
Chairman
Ways and Means Committee
U.S. House of Representatives
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Kevin Brady
Ranking Member
Ways and Means Committee
U.S. House of Representatives
1102 Longworth House Office Building
Washington, DC 20515

RE: Request for Congressional Oversight of Department of Health and Human Services' Routine Failure to Report Medical Malpractice Payments to the National Practitioner Data Bank

Dear Chairman Neal and Ranking Member Brady:

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, respectfully requests that your committee conduct urgently needed oversight hearings regarding the Department of Health and Human Services' (HHS's) decades-long failure to report all malpractice payments made on behalf of its own health care practitioners to the National Practitioner Data Bank (NPDB).

Our review of the records regarding HHS's reporting to the NPDB of medical malpractice payments made under the Federal Tort Claims Act revealed that, as of December 31, 2016, the HHS had failed to submit to the NPDB 2,113 reports of medical malpractice payments made on behalf of HHS health care practitioners (mainly physicians[1]) from 1994 to 2016, in violation of both the 1986 Health Care Quality Improvement Act (HCQIA), which established the NPDB, and a 1990 HHS policy directive from the HHS Assistant Secretary for Health that was reaffirmed in 2014 by a decision memorandum signed by the HHS Secretary. As a result, nearly two-thirds (63%) of the 3,352 malpractice payment reports that should have been submitted by the HHS to the NPDB from 1994 to 2016 were not submitted.

Moreover, despite a 2005 Office of Inspector General report criticizing the HHS's failure to report medical malpractice payments, HHS agencies have continued to defy the HCQIA requirements and the clear HHS policy directives by withholding reports of most medical malpractice payments made on behalf of HHS health care practitioners from the NPDB.

These reporting failures by the HHS, the government agency charged with operating the NPDB, are deeply troubling. We therefore are requesting congressional oversight and action to remedy this serious HHS noncompliance with the obligation to report medical malpractice payments to the NPDB.

Background

The NPDB is a cumulative repository, going back to September 1, 1990, of all reports containing information on medical malpractice payments; state licensing board disciplinary actions; and other adverse actions, such as hospital credentialing actions, related to U.S. health care practitioners. The

[1] Health care practitioners encompass physicians, nurses, dentists, pharmacists, mental health practitioners, and others. According to the NPDB Data Analysis Tool, 78% of medical malpractice payments from 1990 through 2018 involved physicians. See https://www.npdb.hrsa.gov/analysistool/. Accessed July 2, 2019.

NPDB was established under the HCQIA to prevent health care practitioners from moving from state to state or from hospital to hospital without existing disclosure or ability to discover previous damaging performance.[2] The NPDB information linked to named health care practitioners is only accessible to hospitals, other health care entities, and state licensure boards to facilitate their background checks and ongoing credentialing and, if needed, disciplinary actions.

The critical importance of such background checks has been documented by the NPDB, which found that from fiscal year (FY) 2008 through FY 2011, use of such NPDB reports resulted in between approximately 51,000 and 57,000 licensing or credentialing decisions annually by licensing boards and hospitals that limited practitioners' ability to practice.[3]

To maximize the usefulness of these essential background checks, the NPDB must include all reportable malpractice payments made on behalf of, and adverse actions taken against, all health care practitioners.

HHS Implementation of Requirements for Reporting HHS Malpractice Payments

The HCQIA requires that whenever a private insurer or self-insured health care entity makes a payment in settlement (or partial settlement) of, or in satisfaction of a judgment in, a medical malpractice action or claim, the insurer or health care entity must submit to the NPDB a report of the medical malpractice payment that includes the name of any physician or licensed health care practitioner for whose benefit the medical malpractice payment was made.[4] Under the HCQIA, federal health care services agencies, such as the National Institutes of Health (NIH), Indian Health Service (IHS), and Health Resources and Services Administration (HRSA), are required to report to the NPDB malpractice payments made on behalf of the agencies' health care practitioners. (We acknowledge that the HHS has asserted that the HCQIA does not impose any reporting requirements on the HHS.[5]) Importantly, the HCQIA requirements for reporting malpractice payments apply regardless of any determination as to whether the standard of care was met.

Consistent with the HCQIA requirements for reporting medical malpractice payments, on October 15, 1990 — less than two months after the NPDB started operating — the HHS Assistant Secretary for Health issued a policy directive to Public Health Service agency heads stipulating that payments for all settled or adjudicated HHS medical malpractice cases must be reported to the NPDB along with the names of the HHS health care practitioners who provided the treatment giving rise to the claim.[6] This policy directive applies to all cases regardless of whether the standard of care has been determined to have been met. The only exception is for those cases in which the adverse patient outcome that resulted in the medical malpractice payment was due solely to a system breakdown (for example, a medical equipment failure), rather than the fault of any health care practitioner.

Since 2004, once a medical malpractice claim has been paid pursuant to a settlement or court judgment, the HHS Office of General Counsel sends the case to the HHS Medical Claims Review Panel (MCRP).[7] The MCRP is a peer review group that includes medical staff from the NIH, IHS, HRSA, and other HHS agencies. The MCRP, which was established around 1994, is responsible for (1) making a determination

[2] https://www.npdb.hrsa.gov/topNavigation/aboutUs.jsp. Accessed July 2, 2019.
[3] https://www.hrsa.gov/sites/default/files/about/budget/performancereport2013.pdf. Accessed July 2, 2019.
[4] 42 U.S.C § 11131.
[5] https://www.citizen.org/wp-content/uploads/2223a.pdf. Accessed July 2, 2019.
[6] Described in the October 11, 2005, HHS Inspector General report on HHS Agencies' Compliance With the National Practitioner Data Bank Malpractice Reporting Policy. https://oig.hhs.gov/oei/reports/oei-12-04-00310.pdf. Accessed July 2, 2019.
[7] *Ibid.* According to the OIG, prior to 2004, almost all claims were reviewed by the MCRP prior to settlement or litigation.

as to whether the adverse patient outcome that resulted in the medical malpractice payment was due solely to a system breakdown; (2) identifying by name the HHS health care practitioners who provided the treatment giving rise to the claim; and (3) if the adverse patient outcome that resulted in the medical malpractice payment was not found to be due solely to a system breakdown, determining whether the standard of care was met by each named HHS health care practitioner who provided the treatment giving rise to the claim.[8] The 1990 HHS policy directive mandates that all such named practitioners be reported to the NPDB regardless of whether the MCRP determines that the standard of care was met.

A decision memorandum signed by then-HHS Secretary Kathleen Sebelius on May 22, 2014, noted that "[c]urrent 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** [emphasis added].[9] The memorandum reaffirmed the 1990 HHS policy directive requiring reporting.

Data on the HHS's Failure to Report Medical Malpractice Payments to the NPDB, 1994 to 2016

Based on documents obtained by Public Citizen from the HHS under the Freedom of Information Act, we assessed the extent of the HHS's failure to submit medical malpractice payment reports to the NPDB for the following HHS agencies that employ, or are otherwise responsible for malpractice coverage of, health care practitioners: the NIH, IHS, and HRSA.[10] We found the following:

- From 1994 to 2016, 2,698 medical malpractice payments were made by these three HHS agencies. For those payments that did not solely involve a system breakdown, the MCRP made 3,352 standard-of-care determinations regarding individual HHS licensed health care practitioners who provided the treatment giving rise to these claims, which should have resulted in 3,352 separate medical malpractice payment reports being submitted to the NPDB under the HCQIA and the 1990 HHS policy directive.

- As of December 31, 2016, of the 3,352 MCRP determinations regarding individual HHS licensed health care practitioners that should have resulted in medical malpractice payment reports being submitted to the NPDB, the majority — 2,113 (63%) — did not have a report submitted to the NPDB; only 1,239 (37%) had a report submitted. It is our understanding that the situation has not materially changed since 2016.

- The MCRP found that the standard of care had been met for 1,769 (53%) of the determinations regarding individual HHS licensed health care practitioners that should have resulted in medical malpractice payment reports being submitted to the NPDB and that the standard of care had *not* been met for 1,583 (47%) of these determinations.

- Of the 1,583 MCRP determinations regarding individual HHS licensed health care practitioners that the standard of care had *not* been met, at least 344 (22%) did not have a medical malpractice payment report submitted to the NPDB.[11]

[8] From approximately 1990 to 1993, NIH, IHS, and HRSA made these determinations for their own health care practitioners.
[9] https://www.citizen.org/wp-content/uploads/2223a.pdf. Accessed July 2, 2019.
[10] The HHS pays for HHS-funded community health center physicians who are not HHS employees. However, these physicians are still subject to the same HHS NPDB medical malpractice reporting policy as other HHS physicians.
[11] Since the MCRP had determined that the standard of care had *not* been met for 1,583 of the determinations regarding individual HHS licensed health care practitioners and the total number of all malpractice payment reports submitted to the NPDB was just 1,239, at least 344 (1,583-1,239) of the MCRP determinations for which the standard of care was determined *not* to have been met had not been reported to the NPDB.

2005 Office of Inspector General Report of Investigation of HHS Noncompliance with Medical Malpractice Reporting; Recommendations Still Not Implemented More Than 13 Years Later

The HHS failure to report to the NPDB all malpractice payments made on behalf of HHS health care practitioners, as required by the HCQIA and the 1990 HHS policy directive, has been a long-standing problem. More than fifteen years ago, in 2003, concerns about HHS failure to report medical malpractice payments to the NPDB prompted an investigation by the HHS Office of Inspector General (OIG). In its October 2005 report of that investigation, the OIG found that, as of October 2004, 474 HHS medical malpractice payments from the period June 1997 through September 2004 should have been reported to the NPDB but had not been.[12] Importantly, of the 474 medical malpractice payments that had not been reported to the NPDB as of late 2004, the MCRP had determined that the standard of care had not been meet for 327 (69%).

According to the OIG report, this department-wide underreporting was caused by several factors, including (1) lost medical malpractice files, (2) incomplete information in medical malpractice files, (3) a 1998 decision by the MCRP to not identify to the NPDB those health care practitioners who met the standard of care (a decision that was and still is inconsistent with the HCQIA and long-standing HHS policy), and (4) the failure to replace a key Program Support Center claims official or to reassign his NPDB reporting duties.

In a September 14, 2004, email, the Federation of State Medical Boards advised the HHS OIG that compliance with reporting requirements "…is essential in assuring that state medical boards receive sufficient information to evaluate the performance of licensees in fulfilling their responsibilities of public protection."[13]

The New York Times, in an October 19, 2005, article[14] about the OIG report, observed, "Federal health agencies routinely flout a requirement to report any cases in which they pay medical malpractice claims against the government, federal investigators said… Such reports are meant to protect the public against incompetent doctors. Hospitals and health plans check such information before hiring doctors or granting them privileges."

Senator Ron Wyden, co-author of the legislation that created the NPDB, noted to *The New York Times* that "It is imperative that the federal government fully comply with the reporting requirements. The National Practitioner Data Bank is only as good as the information it contains."

Daniel Levinson, the HHS Inspector General, told *The New York Times* that the HHS failure to report "deprives state licensing boards of information they need when they decide to grant, restrict or revoke doctor's licenses." Moreover, he said, "underreporting of the department's own medical malpractice cases lessens the usefulness of the National Practitioner Data Bank and undermines departmental efforts to regulate private and public sector compliance" with the reporting requirements.

The 2005 OIG report recommended that HHS agencies implement a corrective action process that would address unreported medical malpractice payments, improve internal controls involving case file management, and assign staff to assume responsibility for addressing practitioner questions and complaints and data entry of reports to the NPDB.[15] Disturbingly, our analysis of HHS records related to

[12] https://oig.hhs.gov/oei/reports/oei-12-04-00310.pdf. Accessed July 2, 2019.
[13] *Ibid*.
[14] https://www.nytimes.com/2005/10/19/politics/study-finds-failure-to-file-malpractice-data.html. Accessed July 2, 2019.
[15] https://oig.hhs.gov/oei/reports/oei-12-04-00310.pdf. Accessed July 2, 2019.

the reporting of HHS medical malpractice payments to the NPDB indicates that HHS agencies have failed to implement the OIG's 2005 recommendations.

According to a senior HHS official, as of December 31, 2018, HHS agencies were still failing to comply with the requirements regarding the reporting of medical malpractice payments.

Conclusions and Requested Congressional Action

The HHS's ongoing failure to report to the NPDB all medical malpractice payments made on behalf of HHS health care practitioners, in accordance with the requirements of the HCQIA and the department's own written policy directive, has compromised patient safety and the integrity of the NPDB. In addition, the HHS can hardly expect other entities to comply with NPDB reporting requirements for medical malpractice payments when the department itself fails to comply with these reporting requirements for such payments made on behalf of HHS health care practitioners.

It is particularly egregious that although HHS leadership — consistent with the requirements of the HCQIA — twice (in 1990 and 2014) set forth an explicit policy directive requiring the reporting to the NPDB of all medical malpractice payments made on behalf on any HHS health care practitioners regardless of whether the standard of care was met, the department has itself routinely failed to meet these requirements, resulting in a failure to submit to the NPDB at least 2,113 malpractice payment reports for payments made between 1994 and 2016. HHS's reporting failures have continued even after the OIG issued its 2005 report highlighting noncompliance and made recommendations to correct it.

We acknowledge that the MCRP plays a legitimate role in the HHS's NPDB reporting process because individual practitioners are not named as defendants in claims and settlements or judgments made under the Federal Tort Claims Act. However, for the purposes of submitting medical malpractice payment reports to the NPDB, the only relevant MCRP determinations are whether the adverse patient outcome that resulted in a medical malpractice payment was solely due to a system breakdown, and if not, which practitioners provided the treatment giving rise to the claim. As specified in the original 1990 HHS policy directive and in its reaffirmation by the HHS Secretary in 2014, the MCRP's determination of whether the standard of care was met is irrelevant to the requirements for reporting to the NPDB.

For 28 years, the HHS has violated the requirements of the HCQIA and its own reporting policy by not submitting most required medical malpractice payment reports to the NPDB for which the MCRP determined that the standard of care had been met and even for many payments for which a determination was made that the standard of care was *not* met. After 28 years, further delay in complying with these reporting requirements is unacceptable.

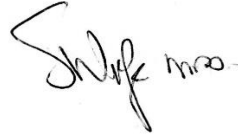
For the reasons set forth above, we ask the appropriate congressional committees to conduct oversight hearings regarding this noncompliance and take legislative action as needed to ensure that the HHS reports to the NPDB all medical malpractice payments made on behalf of HHS health care practitioners. Without these steps, the NPDB cannot achieve its full potential as an essential background check for all doctors. Legislation should include a provision mandating retroactive reporting, if the necessary records exist, of all medical malpractice payments made on behalf of HHS health care practitioners that have not yet been reported by the HHS to the NPDB since the NPDB opened.

In addition, we recommend that hearings be held to address other problems that undermine the NPDB. These problems are identified in the attached appendix.

Thank you for your attention to this important health care issue. We would be happy to meet with you or your staff to discuss our concerns and answer any questions.

Sincerely,

Al Levine
Volunteer
Public Citizen's Health Research Group



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Appendix – Additional NPDB Issues Needing Congressional Attention

1. Department of Veterans Affairs (VA) and Department of Defense (DOD): Analogous Noncompliance with Reporting Medical Malpractice Payments to the NPDB

The current policies of both the VA and DOD require the reporting of medical malpractice payments to the NPDB only when it is determined that a practitioner failed to meet the standard of care.

The VA, in response to a Public Citizen Freedom of Information Act request, reported that for the period fiscal years 1998 to 2013, 3,083 medical malpractice payments were not reported to the NPDB because the VA determined that the standard of care had been met in these cases. The VA also reported that 1,751 medical malpractice payments had been reported to the NPDB during this period. Thus, like HHS, the VA also did not report nearly two-thirds (64%) of its malpractice payments to the NPDB.

A 1998 evaluation of DOD medical malpractice payment reporting by the DOD Office of Inspector General determined that of the 124 medical malpractice payments reviewed, 70% had not been reported to the NPDB.[16] Furthermore, those payments that had been reported were not submitted in a timely manner. Commenting on these findings, the DOD OIG noted the following:

> [W]hen the NPDB was queried, healthcare entities did not have all relevant information available for making credentialing and privileging decisions…
>
> We believe that the congressional requirement for a memorandum of understanding between [HHS] and DoD to implement the section of the law addressing NPDB reporting demonstrates that Congress intended for DoD to report all malpractice payments.

2. Free NPDB Querying for State Medical Boards

The NPDB was created to reduce the likelihood that doctors disciplined by state medical boards or hospitals might continue to injure patients by relocating to another state or hospital where their reputations and track records were unknown. Because an NPDB query costs $2.00, most medical boards do not routinely query the NPDB. According to a recent *USA Today/Milwaukee Journal Sentinel* investigation in 2017, 30 of the nation's state medical boards checked the NPDB fewer than 100 times in 2017.[17] Furthermore, the report noted that more than 500 physicians who had had problems in one jurisdiction were allowed to practice in another.

According to Dr. Robert Oshel, the former head of research for the NPDB and a cosigner of this letter, based on his 15 years of experience with the NPDB, implementation of free queries for licensing boards would be among the most significant improvements that could be made to the NPDB since electronic reporting and querying replaced the initial mailing process.

Implementation of free querying could best be achieved through state medical board enrollment in continuous querying, a process in which a board would supply the NPDB with a list of all its licensees

[16] https://media.defense.gov/1998/Jun/26/2001713782/-1/-1/1/98-168.pdf, Accessed July 2, 2019.
[17] https://www.jsonline.com/story/news/investigations/2018/03/07/theres-tool-help-states-find-problem-doctors-why-do-so-few-use/400723002/. Accessed July 2, 2019.

and regularly update this list. The NPDB would then automatically inform the board immediately of any new reports involving its licensees.

3. Corporate Shield Loophole

The corporate shield involves a practice in which a plaintiff in a medical 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, to allow the practitioner to avoid having a report of a malpractice payment made on his or her behalf submitted to the NPDB. Use of the corporate shield has become a substantial problem in recent years as hospitals have acquired physician practices at a rapid rate and currently employ more than half of all active physicians. Increasing use of the corporate shield to evade reporting of practitioners on whose behalf malpractice payments have been made has reduced the comprehensiveness of malpractice payment data reported to the NPDB.

We believe the corporate shield loophole was created and enabled by the HHS's promulgation of regulations governing reporting medical malpractice payments to the NPDB that do not comport with the HCQIA. 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 HHS 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.