PUBLICCITIZEN

1600 20th Street, NW • Washington, D.C. 20009 • 202/588-1000 • www.citizen.org

January 31, 2014

Ernia Hughes
Acting Director of the Division of Practitioner Data Banks
Bureau of Health Professions
Health Resources and Services Administration
Department of Health & Human Services
5600 Fishers Lane, Room 8-103
Rockville, Maryland 20857

Submitted electronically to: NPDBPolicy@hrsa.gov

RE: Comments on the November 2013 Draft Revision of the National Practitioner Data Bank Guidebook

Dear Ms. Hughes:

Public Citizen, a consumer advocacy organization with more than 300,000 members and supporters nationwide, provides the following comments regarding the proposed draft revision of the National Practitioner Data Bank (NPDB) Guidebook. Below, we provide specific citations or excerpts from the draft Guidebook in italics, followed by our comments.

PAGE E-12:

> ***Submitting a Copy of the Report to the Appropriate State Licensing Board or State Licensing or Certification Authority***
>
> *Eligible entities that report certain actions to the NPDB also are required to provide a copy of the NPDB Report Verification Document for an Initial Report, Correction Report, Revision-To-Action Report, or Void Report to the appropriate State licensing board or State licensing or certification authority. These actions include:…*
>
> - *Clinical privileges actions – reporters must submit a copy to the appropriate State licensing board.*

PAGE E-34:

> ***Submitting a Copy of the Report to a State Licensing Board***
>
> *A copy of the Report Verification Document that health care entities receive after a clinical privileges action report is processed successfully by the NPDB must be provided*

to the appropriate State licensing board. Alternatively, NPDB reporters may elect to send an electronic version of the report to the appropriate State licensing board through the Data Bank's Electronic Report Forwarding service, provided the State board has agreed to accept electronic notices of an action.

Public Citizen's comments:

In conducting our recent work on hospital reporting to the NPDB, we learned that some state medical boards do not always receive copies of clinical privileges action reports. This appears to be the case when a physician is licensed in more than one state and only one of the state medical boards, usually the state in which the sanction takes place, is provided a copy of the hospital's clinical privileges action report.

Specific language to address this problem should be inserted into the guidebook. This could be accomplished by stating in the above cited paragraphs that "the appropriate State licensing board" means any state licensing board from which the practitioner holds a license known to the reporter. The Health Resources and Services Administration (HRSA) also should consider seeking authority to impose penalties for entities that fail to notify all appropriate state licensing boards.

PAGE E-16:

Identifying Practitioners

In order for a particular health care practitioner to be named in an MMPR submitted to the NPDB, the practitioner must be named in both the written complaint or claim demanding monetary payment for damages and the settlement release or final adjudication, if any.… A practitioner named in the written complaint or claim who is subsequently dismissed from the lawsuit and not named in the settlement release should not be reported to the NPDB.

PAGE E-17:

Dismissal of a Defendant from a Lawsuit

If a defendant health care practitioner is dismissed from a lawsuit prior to settlement or judgment, a payment made to settle a medical malpractice claim or action should not be reported to the NPDB for that defendant health care practitioner. However, if the dismissal results from a condition in the settlement or release, the payment must be reported to the Data Bank. In the first instance, there is no payment for the benefit of the health care practitioner because the individual has been dismissed from the action independently of the settlement or release. In the latter instance, if the practitioner is dismissed from the lawsuit in consideration of the payment being made in settlement of the lawsuit, the payment can only be construed as a payment for the benefit of the health care practitioner and must be reported.

Public Citizen's comments:

> The statement in the excerpt above from page E-16 that "[a] practitioner named in the written complaint or claim who is subsequently dismissed from the lawsuit and not named in the settlement release should not be reported to the NPDB" is misleading. It fails to account for the significant exception described in the excerpt above from page E-17. This problem could be addressed by revising the sentence to read as follows (proposed changes in bold and underlined):
>
> > A practitioner named in the written complaint or claim who is subsequently dismissed from the lawsuit and not named in the settlement release should not be reported to the NPDB**, unless the dismissal results from a condition in the settlement or release.**
>
> In addition, the first sentence of the above excerpt from page E-17 is misleading and should be clarified with sufficient detail that the reader does not have to dig deeper into the paragraph to realize that there is a significant exception to the general policy statement. Because of the wording of the first sentence, the whole paragraph is confusing as written. Confusion could be avoided by revising the first sentence to read as follows (proposed changes in bold and underlined):
>
> > If a defendant health care practitioner is dismissed from a lawsuit prior to settlement or judgment **independent of the settlement or release**, a payment made to settle a medical malpractice claim or action should not be reported to the NPDB for that defendant health care practitioner.

PAGE E-16:

> ***Identifying Practitioners***
>
> *In order for a particular health care practitioner to be named in an MMPR submitted to the NPDB, the practitioner must be named in both the written complaint or claim demanding monetary payment for damages and the settlement release or final adjudication, if any. Practitioners named in the release but not in the written demand or as defendants in the lawsuit should not be reported to the NPDB.*

PAGE E-23:

> ***Table E-4: Determining if Medical Malpractice Payments Must be Reported***
>
> *…A practitioner's fee refunded by an entity (including a solo incorporated practitioner) as the result of a written demand. Reportable? Yes*

PAGE E-25

7. If a patient makes an oral demand for payment for damages, should the resulting payment be reported to the NPDB?

No. Only payments resulting from written demands must be reported to the NPDB. Even if the practitioner transmits the demand in writing to the medical malpractice payer, the payment should not be reported if the patient's only demand was oral. However, if a subsequent written claim or demand is received from the patient and then a payment is made by an entity (including a solo incorporated practitioner), that payment must be reported….

8. A patient made a written demand for a refund for services and, in response, the practitioner made the payment out of her personal funds. Should the payment be reported to the NPDB?

No. A refund made by an individual out of personal funds should not be reported to the NPDB. However, if the practitioner's malpractice insurer reimburses the practitioner for her out-of-pocket expenses, the insurer must report the payment.

Public Citizen's comments:

The discussion of "written demands" with respect to the reporting of medical malpractice payments to the NPDB fails to address the recently enacted Oregon law (77th Oregon Legislative Assembly — 2013 Regular Session, SB 483: "Resolution of Adverse Health Care Incidents.") This law seeks to facilitate malpractice settlements by allowing physicians to initiate a mediation process if they believe they have committed malpractice.

The Oregon law creates a loophole that will hinder the ability of hospitals, state medical boards, health maintenance organizations, and similar entities to detect doctors with a history of medical malpractice payments, thereby potentially allowing unsafe doctors to continue practicing without responsible oversight or retraining.

Under the Oregon law, if the injured patient (or his or her survivors) agrees to a mediated payment, it is deemed as not having been made in response to a written demand for payment. This is where the loophole lies. As reflected in the above excerpts, the NPDB Guidebook provides that only payments made in response to a written demand are reportable, so these malpractice payments would not be reportable to the NPDB.

Public Citizen urges HHS to explicitly state that "for federal reporting purposes, any agreement to proceed with malpractice mediation constitutes a written demand for payment by the claimant, regardless of any contrary wording in state law." We believe that the intent of the Federal Health Care Quality Improvement Act must prevail over this loophole, which has already been used by at least one state to avoid the reporting of mediated medical malpractice payouts.

PAGE E-23:

Table E-4: Determining if Medical Malpractice Payments Must be Reported, First Action

A malpractice settlement or court judgment that includes a stipulation that the terms are kept confidential. Reportable? Yes

Public Citizen's comments:

The table notes the confidential medical malpractice settlements or judgments (i.e., settlements subject to "gag orders") must be reported.

The Guidebook should explain how HRSA monitors this requirement and should describe the enforcement mechanisms used by the agency to ensure compliance. Noting such mechanisms in the Guidebook likely would enhance compliance.

PAGE E-23:

Table E-4: Determining if Medical Malpractice Payments Must be Reported, Eleventh Action

A practitioner defendant released from a medical malpractice lawsuit as a condition of settlement. Reportable? Yes

Public Citizen's comments:

The Guidebook should explain how HRSA monitors this requirement and should describe the enforcement mechanisms used by the agency to ensure compliance. Noting such mechanisms in the Guidebook likely would enhance compliance.

PAGE E-26:

Examples 14

14. A defendant health care practitioner agreed to settle a medical malpractice claim in exchange for being dismissed from a lawsuit. All parties involved in the lawsuit agreed to the condition. Should the resulting payment be reported to the NPDB?

Yes. Because the payment is the result of the condition that the defendant health care practitioner be dismissed from the lawsuit, the payment can only be construed as a payment for the benefit of the health care practitioner and must be reported to the Data Bank.

Public Citizen's comments:

> According to the Guidebook, if a defendant was dismissed from the lawsuit prior to settlement and the dismissal results solely from a condition in the settlement or release, the payment is reportable. Because this example gets to the heart of the corporate shield issue, HRSA should clarify whether the answer to question 14 above applies whether the referenced health care provider is a private-practice, fee-for-service physician or a hospital employee. The Guidebook also should clearly spell out how it will monitor to ensure that nothing improper took place (e.g., the practitioner, in order to avoid being reported to the NPDB, only agreed to the payment as long as he or she was dismissed from the lawsuit, and as a result, no report was submitted to the NPDB).

PAGE E-32:

> ***Temporary Clinical Privileges***
>
> *For the purpose of reporting to the NPDB, no distinction is made between temporary clinical privileges (including but not limited to emergency and disaster clinical privileges) and clinical privileges. If, however, temporary privileges are awarded to a physician or dentist for a specific amount of time, with no opportunity for renewal, and the temporary privileges expire while the practitioner is under investigation, a report should not be submitted with the NPDB. In this scenario, there is no opportunity to renew the temporary clinical privileges, so the expiration of the temporary privileges while under investigation cannot be considered a nonrenewal or surrender of clinical privileges while under investigation.*

Public Citizen's comments:

> The Guidebook states that if a physician does not renew temporary privileges while under investigation, a report does not need to be submitted to the NPDB. We believe that public safety is compromised when a practitioner with time-limited temporary (i.e., non-renewable) privileges is under investigation and is not reported. If the investigation was related to performance or conduct issues and there is sufficient evidence for a potential report had the practitioner continued employment, this should be a reportable action.

PAGE E-35:

> ***Sanctions for Failing to Report to the NPDB***
>
> *A hospital or other health care entity that has substantially failed to submit adverse clinical privileges reports can lose, for 3 years, the immunity protections provided under Title IV for professional review actions it takes against physicians and dentists based on their professional competence and professional conduct.*

Public Citizen's comments:

> The Guidebook notes that a health care entity can lose its immunity protection if it fails to substantially comply with reporting requirements regarding adverse clinical privileges actions. However, it fails to mention the compliance mechanism that HRSA will use to monitor and enforce compliance. As noted previously, the Guidebook's describing such oversight activities, such as HRSA or Office of Inspector General (OIG) on-site reviews or Joint Commission oversight of reporting, could enhance compliance.

PAGE E-38:

> ***Q&A: Reporting Clinical Privileges Actions***
>
> ***4. A physician applying for renewal of his hospital clinical privileges falsified his application by omitting information about an ongoing licensure investigation. The hospital took a professional review action to deny his renewal application, which the medical executive committee considered to be related to the practitioner's professional conduct, even though there was no actual patient harm. Should this be reported to the NPDB?***
>
> *A clinical privileges action must be reported to the NPDB if it is the result of a professional review action that relates to professional competence or conduct that adversely affects, or could adversely affect, the health or welfare of a patient and lasts for a period longer than 30 days. Whether an action affects or could affect patient health or welfare is generally a determination that must be made by the entity taking the action. If, in the opinion of the medical executive committee, the practitioner's falsification of his application could adversely affect the health or welfare of a patient, and the action is the result of a professional review, the action must be reported to the NPDB.*

Public Citizen's comments:

> In this example, the Guidebook states that the hospital denied the renewal because it considered the falsification related to professional conduct. However, the Guidebook allows the hospital to determine whether the action should be reported.
>
> Since such falsifications routinely should be considered to involve "professional conduct" that "could adversely affect the health or welfare of a patient," such clinical privileges action should be reported to the NPDB and should not be left to the discretion of the hospital. The discussion of the example should be modified accordingly.

PAGE E-46:

> ***REPORTING ADVERSE PROFESSIONAL SOCIETY MEMBERSHIP ACTIONS***
>
> *Professional societies must report professional review actions based on reasons related to professional competence or professional conduct that adversely affect the membership*

of a physician or dentist. Professional societies may report such adverse membership actions when taken against health care practitioners other than physicians and dentists.

Public Citizen's comments:

In a September 27, 2012, letter to Secretary Sebelius about professional society reporting, Public Citizen stated the following (http://www.citizen.org/documents/2074.pdf):

> When HHS implemented the NPDB, it failed to require the reporting to the NPDB of physicians who voluntarily resign from membership in professional societies while under formal peer-review investigation by such societies for allegations of unethical conduct, even though section 423 of Title IV could have been reasonably interpreted as imposing such a requirement.

We also noted that in 1993 the American Psychiatric Association (APA) tried to submit to the NPDB reports of physicians who resigned from APA membership, usually for sexual misconduct. APA informed HHS that it submitted such reports in the belief that they may be helpful in protecting the public from unethical conduct by physicians. Yet HHS refused to accept the reports because the HHS General Counsel opined at the time that the NPDB legislation did not specifically authorize professional associations to report voluntary resignations from membership in such societies.

As we stated in our September 2012 letter, it is our position that section 423 of Title IV could be reasonably interpreted as imposing such a requirement. Furthermore, as our letter noted, "For the sake of patient safety, Public Citizen urges HHS to take the necessary action to either amend the HHS regulations at 42 C.F.R. part 60 or the department's policy interpretation of these regulations.…"

PAGE E-54:

Consent Agreements

Any State licensure or certification action that meets NPDB reporting requirements must be reported, regardless of whether the action was imposed through board order, consent agreement, or other method. It is the action itself, rather than the method by which the action was taken, that determines whether the action must be reported. For example, if a State licensing board issues a reprimand through a consent agreement, the reprimand is reportable.

Public Citizen's comments:

This section needs greater depth since most state medical boards use consent agreements extensively. As a January 26, 2012, Public Citizen e-mail to Cynthia Grubbs, the former NPDB Director, noted:

> Since a majority of medical board actions apparently involve consent orders, and you note that "the NPDB and HIPDB definitions do not explicitly mention Consent Orders or Letters of Concern," we believe that the issue of consent orders (and possibly Letters of Concern) should be reviewed by HRSA and/or the Office of Inspector General to determine what impact, if any, such orders are having on the integrity and usefulness of the NPDB. (The fact that some consent orders and letters of concern cases are reported to the Federation of State Medical Boards but not to the NPDB is another reason to be concerned).

With respect to the pervasiveness of consent orders, a landmark 1990 Office of Inspector General report on state medical boards (http://oig.hhs.gov/oei/reports/oei-01-89-00560.pdf) noted the following:

> The majority of disciplinary actions that State boards have been taking against physicians are based on consent agreements.
>
> The evidence on this point is compelling. In our survey encompassing disciplinary actions taken in 1988 in eight randomly selected States, 57 percent of the actions were based on consent (or as they are often called "stipulated") agreements. Similarly, in each of our four case study States, a clear majority of actions have been resolved in this manner in recent years.
>
> Trend data concerning this issue are not usually available in the States, but there are strong signs that the proportion of cases being resolved through consent agreements has been rising sharply. Whereas only 21 States had the authority to settle cases in this manner in 1986, 41 did by 1989. And board officials and reports suggest that the boards have been quite active in taking advantage of this authority. In Connecticut, for instance, the proportion of cases decided through consent agreements rose from 69 percent in 1986 to 72 percent in 1987 to 89 percent in 1988. In Texas, the rise during the same period was from 76 percent to 77 percent to 89 percent. in 1989., the increase continued, reaching 95 percent.
>
> Given the increasing numbers of referrals and complaints, the staff shortages, and the cumbersome review processes, it is understandable why boards find a consent agreement so attractive compared with the alternative of a full evidentiary hearing. As one board official noted, "It allows appropriate action to be taken without taking up a lot of board time." Yet, as the proportion of cases so settled exceeds 50 percent and, indeed, nears 100 percent in some places, one wonders if the "appropriate" board action is always being taken-if the pressure to settle might not be leading some boards in some cases to act more leniently than the violation would warrant.

> One also wonders about the extent to which such settlements, when they represent the initial disciplinary action against a physician, will impede or complicate actions against that same physician by other States in which he or she is licensed. Without a prior action involving a full evidentiary hearing, another jurisdiction may face the prospect of conducting additional investigative work of its own.

In addition, some of the consent orders that Public Citizen reviewed include a provision explicitly noting that the board agrees to not report the physician to the NPDB. From a compliance standpoint, this seems in violation of the NPDB statute. The Guidebook should be revised to address this issue.

PAGE E-73:

> ***REPORTING PRIVATE ACCREDITATION ORGANIZATION NEGATIVE ACTIONS OR FINDINGS***
>
> *Private accreditation organizations are required to report to the NPDB certain negative actions or findings against health care entities, providers, and suppliers. These negative actions or findings are defined in NPDB regulations as a final determination of denial or termination of an accreditation status that indicates a risk to the safety of a patient, or patients, or quality of health care services. The actions taken must be as a result of formal proceedings. The health care entity, provider, or supplier must be licensed or otherwise authorized by the State to provide health care services.*

Public Citizen's comments:

> The Guidebook appears to state that only final negative accreditation actions are reportable. However, the Joint Commission, the largest accreditation organization, issues a sanction entitled "preliminary denial of accreditation."
>
> It is our understanding that appeals could last months, putting patients at risk. Furthermore, the number of hospitals that have won appeals is so low that the Joint Commission has been unable to provide numbers. Therefore, Public Citizen recommends that any negative accreditation action, regardless of its provisional status, be reportable.

Thank you for the opportunity to provide comments on the draft revision of the NPDB Guidebook.

Sincerely,

Alan Levine
Researcher
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.
Founder and Senior Adviser
Public Citizen's Health Research Group

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group