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August 12, 2014

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Dear Secretary Burwell:

Public Citizen, a consumer advocacy group with more than 300,000 members and supporters nationwide, is writing to applaud the recent determination by the Department of Health and Human Services (HHS) regarding reporting of medical malpractice payments to the National Practitioner Data Bank (NPDB). In particular, HHS determined that a notice of an adverse event under Oregon's 2013 Resolution of Adverse Health Care Incidents law and a pre-litigation notice under Massachusetts' 2012 Disclosure, Apology, and Offer (DA&O) law both qualify as a "written claim or demand for payment" under the Health Care Quality Improvement Act of 1986 (HCQIA). As a result, payments resulting from such notices must be reported to the NPDB as medical malpractice payments, assuming all other conditions for defining a reportable medical malpractice payment are met.

The HHS determination, documented in the enclosed decision memorandum, is exactly the action we sought in our September 10, 2013, letter to then-Secretary Kathleen Sebelius.¹ In that letter, we expressed serious concern that the Oregon law threatened the viability of the NPDB as a comprehensive and reliable source of data regarding malpractice payouts, particularly if other states were to follow Oregon's lead. The Oregon law, among other things, sought to create a loophole that would allow malpractice insurance companies and other entities to avoid reporting to the NPDB any malpractice payments made on behalf of physicians and other health care practitioners that were negotiated through a mediation process specified under the new law. We argued that such state-level efforts to facilitate malpractice settlements by increasing secrecy and preventing reporting to the NPDB of medical malpractice payments made on behalf of practitioners must not be permitted. We strongly urged HHS to take prompt action clarifying that all such payments must be reported to the NPDB, as required under federal law.

In making its well-reasoned and favorable determination, HHS noted the following points in support of its decision:

¹ Carome M, Wolfe S. Letter to Secretary of Health and Human Services Kathleen Sebelius regarding Oregon's 2013 Resolution of Adverse Health Care Incidents law and medical malpractice payment reporting to the National Practitioner Data Bank. September 10, 2013. <http://www.citizen.org/hrg2155>. Accessed July 30, 2014.

- This approach is most consistent with the NPDB's current policies and practices, especially when considering the similarities between pre-litigation settlement proceedings and the Massachusetts and Oregon models.
- Since there is no statutory authority that allows for determinations of reportability to be based on whether an individual practitioner met the standard of care, this is the only option where payments made on behalf of negligent practitioners would be reported.
- This option ensures that reporting requirements are the same across the country regardless of differing state laws on medical malpractice reform.

We agree with the HHS assessment.

We recognize that a single malpractice payment is not necessarily a good indicator of the quality of care provided by a physician or other practitioner. Yet research has shown that a pattern of malpractice payments is an excellent indicator of whether a physician has quality-of-care problems and may need retraining, proctoring, or other serious action to ensure the safety of their future patients. If state efforts succeed in creating a legal basis to avoid reporting malpractice payments to the NPDB, it would become more difficult, if not impossible, for NPDB users, such as hospitals and medical boards, to identify such patterns of malpractice by a practitioner when they conduct background checks through the NPDB.

The determination made by HHS in the enclosed decision memorandum is an important first step toward preserving the integrity and viability of the NPDB as a comprehensive, reliable source of data regarding malpractice payouts. More importantly, the department's action will help to ensure patient safety throughout the country.

As a second step, in order to implement this important decision, HHS needs to notify appropriate government officials within Oregon and Massachusetts — as well as within any other states contemplating enactment of similar malpractice reform laws — about the decision and ensure that policies in those states are changed to conform with this important clarification of the law regarding reporting of medical malpractice payments to the NPDB. If this has already occurred, please send us the confirming documents. If this has not occurred, we urge you to do so immediately.

Sincerely,



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

Public Citizen

August 12, 2014, Letter to Secretary Burwell Regarding State
Medical Malpractice Reform Laws and Reporting to the NPBD

A handwritten signature in black ink, appearing to read "Sidney Wolfe" with a stylized flourish at the end.

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

cc: Mary K. Wakefield, Ph.D., R.N., Administrator, Health Resources and Services
Administration, HHS
Governor John Kitzhaber, State of Oregon
Governor Deval Patrick, Commonwealth of Massachusetts

Enclosure



TO: The Secretary
Through: DS _____
COS _____
ES _____

FROM: Administrator

DATE: May 20, 2014

SUBJECT: Appropriate Medical Malpractice Payment Reporting to the National Practitioner Data Bank (NPDB) in Light of Recent Medical Malpractice Reforms in Massachusetts and Oregon – **DECISION**

ISSUE

The purpose of this memo is to ask you for a decision regarding whether payments made under Massachusetts's and Oregon's state medical liability laws are required to be reported to the NPDB as medical malpractice payments. HRSA supports the objectives of these reform models, but recognizes that there are potential implications for medical malpractice reporting to the NPDB. This memo also seeks a decision regarding one of these requests regarding whether payments from verbal demands for restitution must be reported to the NPDB.

A decision on whether payments made under these alternative models are reportable to the NPDB as medical malpractice payment reports could influence other states as they develop similar models. A decision to require broad reporting could be viewed as inconsistent with the Administration's efforts to encourage states to reform their malpractice laws and improve patient safety by fostering disclosure of errors. In contrast, a decision to limit reporting might be viewed as being in conflict with the NPDB's statutory intent of full reporting of actions and consistent reporting across states.

BACKGROUND

Medical Malpractice Reforms and Departmental Initiatives. Although the Massachusetts and Oregon medical malpractice reform models are the only two existing models of their type, based in legislation, other states (including Florida and Georgia) are examining similar models for future implementation.

Within the Department, the Agency for Healthcare Research and Quality (AHRQ) has played a central role in encouraging medical liability reform. Specifically, in September 2009, President Obama directed the establishment of an initiative that would help states and health care systems test models that meet the following goals:

- Put patient safety first and work to reduce preventable injuries.
- Foster better communication between practitioners and their patients.
- Ensure that patients are compensated in a fair and timely manner for medical injuries, while also reducing the incidence of frivolous lawsuits.
- Reduce liability premiums.¹

In response to this directive, in June 2010, AHRQ announced \$23.2 million for seven 3-year demonstration grants, thirteen 1-year planning grants, and a contract to evaluate the initiative and its projects as part of a Medical Liability Reform and Patient Safety Initiative. Planning grants are complete, and the demonstration grants will be finished in 2014. Massachusetts received one of these planning grants and used the funds to support efforts to lay the ground work for its current medical malpractice reform law, known as the Massachusetts Disclosure, Apology, and Offer (DA&O) law. A \$2 million, multi-year evaluation of the initiative is underway, with one published progress report thus far. AHRQ expects a report on the planning grants by mid-2014, and a report on the demonstration projects is currently under review.

Dr. Richard Kronick, AHRQ's Director, has noted that, while AHRQ-funded research has not specifically addressed the NPDB, some of these research projects have highlighted that NPDB reporting is a barrier to practitioner participation in, and adoption of, communication and resolution programs.

Many states already have apology and disclosure laws, which offer legal protection for practitioners who disclose or express remorse when something unplanned happens during treatment. These evidentiary laws protect health care practitioners' statements of disclosure and sympathy from being used as evidence of liability. The Massachusetts and Oregon models contain elements of disclosure and open discussion between practitioners and patients when adverse events result from medical treatment. However, both models go beyond these basic elements and incorporate the potential for financial restitution outside of the court system.

NPDB's Medical Malpractice Reporting Requirements. A payment 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, is reportable to the NPDB. The key elements for determining if a medical malpractice payment is reportable are:

- 1) Payment made;
- 2) By a third party;
- 3) For the benefit of a health care practitioner; and
- 4) Against whom a medical malpractice claim or judgment was made.

Federal law requires that all payments made on behalf of a practitioner be reported, regardless of the standard of care or whether the practitioner is found to be responsible for the injury or whether a systems error caused the injury. The NPDB statute and regulations make no mention

¹ Medical Liability Reform and Patient Safety Initiative Progress Report. AHRQ. Retrieved Jan. 13, 2014, from <http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/liability/medliabrep.html>.

of determining NPDB reportability based on whether the standard of care was met. The legislative history makes clear that Congress intended that all medical malpractice payment and settlements should be reported regardless of standard of care determinations.

The NPDB statute defines a medical malpractice claim as “a written claim or demand for payment based on a health care provider’s furnishing (or failure to furnish) health care services, and includes the filing of a cause of action, based on the law of tort, brought in any court of any State or the United States seeking monetary damages.” Claims include, but are not limited to, any cause of action brought in any state or federal court or other adjudicative body that includes a demand for payment. The Department has consistently interpreted the phrase “written claim or demand for payment” as requiring a *written* claim or *written* demand for payment and excludes verbal demands for the purposes of defining a claim. Should a patient only verbally demand compensation from a provider, any resulting payment would not be reportable. A change in this policy would require rulemaking.

Under our current policies, there are circumstances in which no reporting is required. For example, if a provider or health care entity initiates the settlement and no written claim or demand for payment is made, then no report is required.² While it appears that under both the Massachusetts and Oregon models, a provider-initiated settlement may not include a written claim as defined by NPDB statute, there may be situations where a patient makes a written claim or demand for payment after the provider initiates disclosure proceedings, requiring reporting of any resulting payment. Therefore, this exemption would apply only to provider-initiated claims that do not include a patient-initiated written claim or demand for payment.

Massachusetts State Law. The Massachusetts DA&O law, effective November 5, 2012, incorporates mandatory pre-litigation conversations and financial compensation in certain cases. Although Massachusetts is the first state of which we are aware to enact this type of medical malpractice legislation, some hospitals and health care systems in the U.S. have implemented similar models.

An AHRQ planning grant helped lead to this. The law requires that a patient must file a notice with the health care provider and engage in discussions with the health care provider prior to initiating a medical malpractice action. This includes a 6-month resolution period to allow the patient, practitioner, and insurer to settle the patient’s claims prior to starting litigation. An action under the DA&O model may be initiated by a patient or a hospital with a DA&O resolution process in place.

As a pilot program, six hospitals have operationalized the DA&O law as a process called CARE (Communication, Apology, and Resolution). As of February 2014, 270 cases have gone through

² In the six hospitals in Massachusetts implementing a communication, apology, and resolution program under this law, only eight percent (26 cases out of 270 as of February 2014) were initiated by patients through the formal, court-based notice of intent to litigate.

the CARE model; 28 resulting in a referral to hospital insurers for potential offers of compensation.³ No payments have been made under this model as of February 2014.

Three of the four elements needed to determine whether a medical malpractice payment is reportable to the NPDB are clearly satisfied in the Massachusetts DA&O model. However, some interpretation is required to determine whether the last element, the making of a medical malpractice claim, is present. The Department has historically defined claims broadly, to include payments resulting from informal written demands for payment and those resulting from pre-litigation settlements. While a written demand for payment by a claimant is at the core of a malpractice claim, a notice filed under the Massachusetts DA&O process may or may not include a written demand for payment. Considering a notice filed under the Massachusetts DA&O process that includes a written demand for payment as a "claim" as defined in the NPDB statute is a straightforward reading of the NPDB law and is consistent with previous departmental practice.

Massachusetts proposed that only DA&O payments made when an individual practitioner has failed to meet the standard of care (in contrast to when the system is responsible) would be reported. Because there is no legal support for interpreting the NPDB statute in the manner requested, it is not presented as an option. The Department could consider whether to pursue an A-19 to request that the statute be changed to allow for medical malpractice reporting based on standard of care determinations. However, such a course of action would likely take a significant amount of time and the results would be uncertain.

The Department could choose to interpret the definition of "claim" to exclude all Massachusetts DA&O settlements. As Massachusetts has made it impossible for patients to pursue a medical malpractice action until the waiting period is over, the Department could interpret an initial notice filed in the DA&O process as outside the NPDB definition of "claim." The clear disadvantage of this option is that all DA&O settlements would then be excluded from reporting, including those instances in which a provider was found to have violated the standard of care. Because this interpretation could be viewed as inconsistent with previous practice, the Office of the General Counsel has recommended that if such an interpretation is adopted, it be done so through rulemaking.

Supporters of the DA&O model responsible for implementing the pilot programs propose the standard of care distinction be applied due to concerns that reporting providers who have met the standard of care can unduly harm these providers' reputations. The NPDB could partially mitigate concerns by explaining reporting features that allow reporters to identify whether the standard of care has been met. The NPDB report form could be changed to reflect whether a provider has met the standard of care or not. This could be done through the addition of checkboxes on the NPDB reporting form on which the reporting entity may indicate whether the standard of care was met.

³ The majority of cases (242 or 90 percent), did not meet the criteria for compensation, meaning that either the standard of care was met, or the patient was not significantly harmed. In all cases referred to the hospitals' insurers, the standard of care was not met.

Oregon State Law. Oregon signed into law on March 18, 2013, a bill that represents a new approach to medical liability reform. The bill creates a process known as “Early Discussion and Resolution” which refers to a confidential, voluntary, and structured way for health care facilities or providers and patients to notify, discuss, and (if necessary) mediate serious adverse events as a litigation alternative. This new process will not be in place until July 2014.

Under the new system, health care facilities or providers and patients engage in voluntary confidential pre-litigation conversations. Early Discussion and Resolution consists of four components: notice of adverse event; discussion; mediation; and litigation. When a serious adverse event occurs, health care organizations, providers, or patients may file a notice of adverse event with the Oregon Patient Safety Commission (Commission). After this notice is filed, the parties engage in discussions and possibly mediation, through which an offer of compensation may be made. Because Early Discussion and Resolution will not be implemented until July 2014, the Commission is engaged in activities to fully define the process and has yet to determine certain elements such as how payments are made.⁴ Participation in Oregon’s pre-suit mediation process is voluntary, and it is not yet known how often this process will be used by patients in place of filing suit in court.

The Oregon law was explicitly designed to avoid medical malpractice reporting to the NPDB for any claims that are part of the new process that do not proceed to litigation. The Oregon law states that a notice of adverse event filed pursuant to the Oregon process is not “a written claim or demand for payment.” This language is the same language used in the NPDB statute to define reportable payments.

The NPDB has no history of allowing states to define requirements for reporting. A notice of adverse event that includes a written claim for payment can be interpreted as a claim under NPDB regulations when applying the same broad definition as applied to pre-litigation settlements. A finding that a notice of adverse event that includes a written demand for payment is a claim is consistent with current NPDB policy and would be consistent with a finding that the notice under Massachusetts’ law is a claim.

Alternatively, the Department could define the term “written claim or demand” as not including actions arising through the Oregon model and other comparable systems. A decision to exclude such actions from the reporting requirements may encourage other states to implement similar models. The clear disadvantage of this option is that all settlements would be excluded from reporting, including those instances in which a provider violated the standard of care. Given that this interpretation is not as straightforward and could be viewed as inconsistent with previous practice, the Office of the General Counsel has recommended that if such an interpretation is adopted, it be done so through rulemaking.

⁴ Outstanding questions about how payments are made and whether a practitioner is identified on a settlement could affect a future reportability decision. We are asking for a decision on reportability based on the current facts around the definition of a claim, with an understanding that future developments in the process may affect a future decision. It is important to issue a decision now as to whether a claim exists and payments are required to be reported, because other states may follow Oregon’s lead in developing laws with similar language if we are silent on this issue.

Stakeholder Requests. HRSA recently received several requests to review current NPDB medical malpractice payment reporting policies. Public Citizen asked that the Department: 1) change current policy to require that payments resulting from *all* demands for payment, whether written or verbal, be reportable; and 2) clarify that payments made under Oregon's new law are reportable to the NPDB. Governor John Kitzhaber wrote to you urging that payments under Oregon's new law be deemed non-reportable. In addition, a Massachusetts stakeholder group contacted the Department to determine whether settlements under the Massachusetts DA&O law are reportable to the NPDB. This group has advocated that only settlements where a provider has been found to violate the standard of care under the Massachusetts DA&O process should be reportable to the NPDB, and proposes not reporting settlements under the DA&O process where the standard of care is found to have been met.

ISSUES AND OPTIONS

ISSUE 1: Whether payments made under Massachusetts' DA&O model and Oregon's early discussion and resolution law are reportable to the NPDB.

Option 1: Assuming all other reporting requirements are met, interpret the NPDB statute as requiring that all payments that include a written claim or demand for payment made under Massachusetts' DA&O model and Oregon's early discussion and resolution model are reportable. (HRSA recommends this option.)

DISCUSSION: This option includes a determination that patient-initiated claims that include a written demand for payment under these models are legally defined by the NPDB statute as "written claims," regardless of state attempts to define them otherwise. Only payments that result from a "written claim or demand for payment" are reportable to the NPDB. The Department determines what qualifies as a "written claim or demand for payment" and, under this option, would find that Massachusetts' pre-litigation notice and Oregon's notice of an adverse event qualify as "written claims" pursuant to federal law, when they include a written demand for payment.

If this option is adopted, HRSA will take steps to signal support of the goals of these programs. For example, HRSA will issue guidance explaining when reporting is not required (e.g., when the provider initiates the settlement and no written demand for payment is made). HRSA also will consider revising the report form to include a check-box where reporters can indicate whether the standard of care was met.

Pros:

- This approach is the most consistent with the NPDB's current policies and practices, especially when considering the similarities between pre-litigation settlement proceedings and the Massachusetts and Oregon models.
- Since there is no statutory authority that allows for determinations of reportability to be based on whether an individual practitioner met the standard of care, this is the only option where payments made on behalf of negligent practitioners would be reported.

- This option ensures that reporting requirements are the same across the country regardless of differing state laws on medical malpractice reform.

Cons:

- HRSA's decision could be seen as a barrier to the goals of improving patient safety and quality of care. A pro-reporting stance could be viewed as inconsistent with other Department initiatives.
- Stakeholders in various states may feel that the universal application of the NPDB statute is unfair given the efforts of some states to reform medical malpractice liability. This will be viewed as unwillingness by the Department to support their initiatives.

Option 2: Interpret the NPDB statute as providing that no payments made under the Massachusetts, Oregon, and similar laws are reportable, because there is no medical malpractice claim. This option would be implemented through the rulemaking process.

DISCUSSION: The argument in favor of not requiring Massachusetts or Oregon to report payments made under their models requires a narrow interpretation of NPDB's definition of a medical malpractice action or claim. In Massachusetts, the 6-month time period mandated in the DA&O statute distinguishes the DA&O process from other types of claims. In Oregon, the early discussion and resolution process creates a separate process from traditional medical malpractice claims. Because these processes occur outside of the traditional medical malpractice system, it could be argued that there is no medical malpractice claim for purposes of NPDB reporting.

This option would allow states some latitude to design medical malpractice reform systems that do not result in NPDB reports by excluding claims made under the Oregon model and other similar systems from the NPDB definition for "written claim or demand."

Pros:

- This option signals a stronger support of state medical malpractice liability reform models.

Cons:

- There will be no reports on payments made on behalf of some practitioners who were negligent or violated the standard of care, which runs counter to the NPDB mission of patient protection, and fails to deliver on the expectation that the NPDB is the comprehensive source for medical malpractice payment reporting.
- Permitting negligent practitioners to avoid being reported to the NPDB reduces the transparency that is associated with readily disclosing errors as a tactic to prompt corrective action and enhanced patient safety and could negatively impact patient safety.
- This approach will reduce the amount of information available through the NPDB and will place limitations on the type of information available to health care entities making privileging and other similar decisions.
- This interpretation is inconsistent with the Department's broad historical interpretation of the term "claim."

- This interpretation would make NPDB reporting of medical malpractice payments dependent upon state medical malpractice reforms and would create inconsistency across states, weakening the data set by introducing variation in what is reported from state to state.

ISSUE 2: Whether medical malpractice payments from all demands for payment, verbal or written, must be reported to the NPDB.

Option 1: Require medical malpractice payments resulting from all demands for payment, whether written or verbal, be reportable to the NPDB.

DISCUSSION: This option would require a regulatory change. Currently, only medical malpractice payments resulting from a written demand are required to be reported. If an individual makes a claim or demand for payment in only a non-written form (e.g., phone, interpersonal conversation), any payment made to settle this claim is not reportable to the NPDB.

Pros:

- This option increases the amount of medical malpractice information in the NPDB, which may be useful for health care entities making employment, licensing, and privileging decisions.

Cons:

- Given the difficulty of verifying verbal demands, payment information based only on verbal demands may be inconsistently reported to the NPDB, and, therefore, be of limited use to health care entities querying the NPDB.
- This option creates enforceability challenges for the Department and reporting entities because it will be difficult to verify the authenticity of verbal notifications and track non-written demands for payment.
- This interpretation is inconsistent with the manner in which NPDB reporting requirements have been interpreted since the inception of the program.
- This change in policy may be viewed as a barrier to structuring medical malpractice reform efforts by stakeholders and advocates with the goals of improving patient safety and quality of care.

Option 2: Keep current policy intact and require that only payments resulting from written demands for payment are reportable to the NPDB. (HRSA recommends this option.)

DISCUSSION: This option allows the Department to clarify that only medical malpractice payments resulting from a written demand are required to be reported. If an individual makes a claim or demand for payment only in a non-written form (e.g., phone, interpersonal conversation), any payment made to settle this claim is not reportable to the NPDB.

Pros:

- This option preserves the value of the information in the NPDB by keeping payments resulting from unverifiable verbal claims out of the NPDB.
- By requiring only payments made from written demands be reported, the NPDB maintains a more enforceable and verifiable requirement.
- This interpretation is consistent with the manner in which NPDB reporting requirements have been interpreted since the inception of the program.

Cons:

- Information that could be obtained concerning verbal demands for payment may be viewed as useful information for health care entities making employment, licensing, and privileging decisions.

Mary Wakefield

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

DECISION

ISSUE 1: Whether payments made under Massachusetts' DA&O model and Oregon's state law are reportable to the NPDB.

Option 1
Approved Disapproved _____ Need More Information _____

Option 2
Approved _____ Disapproved _____ Need More Information _____

ISSUE 2: Whether medical malpractice payments from all demands for payment, verbal or written, must be reported to the NPDB.

Option 1
Approved _____ Disapproved _____ Need More Information _____

Option 2
Approved Disapproved _____ Need More Information _____

Kathleen Sebelius
Kathleen Sebelius

05/22/14
Date