

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

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PUBLIC CITIZEN, INC.,)	
1600 20th Street NW)	
Washington, DC 20009,)	
)	
Plaintiff,)	
)	
v.)	
)	
DEPARTMENT OF HEALTH AND)	Civil Action No. 16-1520
HUMAN SERVICES,)	
200 Independence Avenue SW)	
Washington, DC 20201,)	
)	
SYLVIA MATHEWS BURWELL,)	
in her official capacity as Secretary of)	
Health and Human Services)	
200 Independence Avenue SW)	
Washington, DC 20201, and)	
)	
HEALTH RESOURCES AND)	
SERVICES ADMINISTRATION,)	
5600 Fishers Lane)	
Rockville, MD 20857,)	
)	
Defendants.)	
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COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. Plaintiff Public Citizen, Inc., brings this action pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 702 and 706, to compel agency action unreasonably delayed. Specifically, Public Citizen seeks to compel defendants Department of Health and Human Services (HHS), Secretary of Health and Human Services Sylvia Mathews Burwell, and the Health Resources and Services Administration (HRSA) to act on Public Citizen’s May 2014 citizen petition requesting prompt issuance of a notice of proposed rulemaking (NPRM) to close the so-called “corporate shield loophole” contained in 45 C.F.R. § 60.7, which undermines the

effective collection of data on medical malpractice claims and actions by the National Practitioner Data Bank (NPDB).

2. In the more than two years since receiving Public Citizen's citizen petition, defendants have neither granted nor denied the requested action. To protect patients from preventable injury and substandard medical care, Public Citizen seeks a declaration that defendants have acted unlawfully by withholding action on the citizen petition and an order requiring defendants to act.

PARTIES

3. Plaintiff Public Citizen is a national non-profit, public-interest organization located in Washington, DC, with hundreds of thousands of members and supporters nationwide. Since its founding in 1971, Public Citizen has worked before Congress, regulatory agencies, and the courts to advance the interests of its members on a wide range of consumer-protection issues, including health issues. Public Citizen submitted the citizen petition at issue in this case.

4. Defendant HHS is an agency of the federal government, and defendant HRSA is a component agency within HHS. Defendant Sylvia Mathews Burwell is the Secretary of HHS. She is being sued in her official capacity. Secretary Burwell is charged with administering or delegating administration of the NPDB. 42 U.S.C. § 11134(b). HRSA administers the NPDB.

JURISDICTION

5. This Court has jurisdiction pursuant to 28 U.S.C. § 1331.

FACTS

6. Between 44,000 and 98,000 Americans die in hospitals each year due to preventable medical errors. Inst. of Med., *To Err is Human* 1 (1999), <http://bit.ly/1MaO9L5>. The annual cost to society for medical errors in hospitals has been estimated to be between \$17

billion and \$29 billion. *Id.* According to a study of medical malpractice payments made from 2005 to 2014, 1 percent of doctors were responsible for 32 percent of paid claims, while 94 percent of doctors were not responsible for any payments. David M. Studdert et al., *Prevalence and Characteristics of Physicians Prone to Malpractice Claims*, 374 N. Engl. J. Med. 354, 356 (2016). This study found that the risk of a doctor making a future payment increased with the number of previous paid claims. *Id.* at 357.

7. The NPDB “is an electronic information repository . . . contain[ing] information on medical malpractice payments and certain adverse actions related to health care practitioners, entities, providers, and suppliers.” *About Us*, NPDB, HHS, www.npdb.hrsa.gov/topNavigation/aboutUs.jsp (last visited July 25, 2016).

8. The Health Care Quality Improvement Act of 1986 (HCQIA) created the NPDB in response to “a national need to restrict the ability of incompetent physicians to move from State to State without disclosure or discovery of the physician’s previous damaging or incompetent performance.” 42 U.S.C. § 11101(2).

9. The HCQIA requires that “[e]ach entity . . . 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 . . . information respecting the payment and circumstances thereof,” including, among other things, “the name of any physician or licensed health care practitioner for whose benefit the payment is made.” 42 U.S.C. § 11131.

10. HRSA maintains the information reported pursuant to § 11131 in the NPDB and makes that information available to hospitals, licensure boards, and managed care organizations to facilitate background checks and credentialing. *See id.* § 11134-11137. Hospitals are required

to query the NPDB in certain circumstances, such as when a physician applies for clinical privileges at the hospital and every two years thereafter. *Id.* § 11135. Medical licensing boards and other health care organizations, such as HMOs, may also query under certain circumstances. *Id.* § 11137.

11. The NPDB is the only relatively comprehensive national source for malpractice and medical disciplinary information, and thus hospitals and other health care entities depend on it to ascertain whether physicians, dentists, and other health care practitioners have a history of malpractice.

12. Public Citizen estimated, using HRSA data, that 48,075 licensure, credentialing, or membership decisions were affected in 2007 by new information provided in response to NPDB queries. Public Citizen, *Hospitals Drop the Ball on Physician Oversight* 6 & n.7 (2009), <http://www.citizen.org/documents/18731.pdf>.

13. In 1989, HHS issued a regulation, codified at 45 C.F.R. § 60.7, governing reporting of medical malpractice payments to the NPDB. Under the regulation, a reporting entity must report information about a health care practitioner for whose benefit a payment is made only if the payment was made “in settlement of or in satisfaction in whole or in part of a claim or a judgment against such health care practitioner for medical malpractice.” 45 C.F.R. § 60.7(a).

14. The regulation is understood, including by HRSA, not to require reporting to the NPDB of information about a health care practitioner whose acts or omissions were the basis of a malpractice claim or action if the plaintiff dismisses the practitioner as a defendant from the proceeding prior to a settlement or judgment, leaving or substituting a hospital or other corporate entity as the defendant, and if the practitioner is not identified in the settlement or judgment. The aspect of the regulation that does not require the name of a practitioner whose acts or omissions

were the basis of the claim or action to be reported in circumstances in which the practitioner is dismissed prior to a settlement or judgment is commonly referred to as the “corporate shield loophole.”

15. In 1998, HRSA issued an NPRM proposing to amend 45 C.F.R. § 60.7 to close the corporate shield loophole. The NPRM explained that the 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 Data Bank.” HRSA, National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Medical Malpractice Payments Reporting Requirements, 63 Fed. Reg. 71255 (Dec. 24, 1998). In response to comments on that NPRM, HRSA stated in April 2000 that its goal was to publish a new NPRM by the end of 2000 and that it expected to finalize regulations for implementation in 2001. However, the agency never issued a new proposal and never finalized the 1998 proposal. The rulemaking remained on the HHS Unified Agenda for several years and was withdrawn by HRSA in April 2009 without explanation.

16. On May 29, 2014, Public Citizen sent a citizen petition to HHS and HRSA urging the issuance of a proposed rule to close the corporate shield loophole. The petition discussed the language of the statute and regulation, the urgency of closing the loophole for public health and effective medical malpractice payment reporting, and counterarguments presented in opposition to HRSA’s 1998 proposal. It also suggested specific language for an amended regulation.

17. To date, defendants have not issued a decision on the citizen petition.

18. Evidence suggests that the problem created by the corporate shield loophole has worsened since HRSA proposed revising its regulation. As the citizen petition described, physicians have become increasingly more likely to be employees of hospitals and other health

care corporate entities: the total number of independent practitioners declined from 57 percent physicians in 2000 to 39 percent in 2012. *See also* Accenture, *The (Independent) Doctor Will NOT See You Now* 1 (2015), <http://bit.ly/1WETQ7I> (projecting decline to 33 percent in 2016). Physicians who are employed by hospitals or other corporate entities are more likely to be shielded from malpractice payment reporting through the corporate shield loophole.

19. As the citizen petition also described, the number of medical malpractice payments reported to the NPDB decreased for a decade through 2013. That pattern continued in 2014, the last year for which HRSA released statistics, when the number of payments reported to the NPDB decreased by more than 4 percent from 2013. *See NPDB Research Statistics*, NPDB, HHS, <http://1.usa.gov/1TYI3k0>. All in all, about two-thirds as many total medical malpractice payments were reported to the NPDB in 2014 as in 2004. *Id.*

20. The considerable danger to public health caused by the availability of the corporate shield loophole warrants expeditious action on Public Citizen's citizen petition, particularly given the substantial amount of time—over seventeen years—that has passed since HRSA first proposed amending its regulation in response to concerns about the loophole. The pace of defendants' decisional process has lagged unreasonably in light of the nature and extent of the public health interests at stake.

CLAIMS FOR RELIEF

21. Defendants' failure to act on Public Citizen's citizen petition constitutes agency action unlawfully withheld or unreasonably delayed, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(1).

22. Defendants' failure to act on Public Citizen's citizen petition is not in accordance with law and violates the Administrative Procedure Act, 5 U.S.C. § 706(2)(A).

WHEREFORE, plaintiff requests that this Court

- A. Declare unlawful defendants' failure to act on Public Citizen's citizen petition;
- B. Order defendants to issue a decision on Public Citizen's citizen petition within 30 days of the Court's order;
- C. Award Public Citizen its reasonable costs and attorney's fees under 28 U.S.C. § 2412; and
- D. Grant all other appropriate relief.

Respectfully submitted,

/s/ Adina H. Rosenbaum
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Dated: July 26, 2016