



NATIONAL ASSOCIATION OF  

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Community Health Centers

### **Important Content Note:**

This technical assistance resource was developed prior to the August 2017 release of the Health Center Compliance Manual by the Health Resources and Services Administration's (HRSA) Bureau of Primary Health Care (BPHC). The BPHC Compliance Manual, issued August 2017, indicates where PINS, PALs and other program guidance are now superseded or subsumed by the BPHC Compliance Manual.

See: <https://bphc.hrsa.gov/programrequirements/pdf/healthcentercompliancemanual.pdf>

## HR

## Information Bulletin #9

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**Note that in all Information Bulletins:**

The term “health center” refers to public or private nonprofit entities that: (1) receive grants under Section 330 of the Public Health Service Act (Section 330), including Sections 330(e), 330(f), 330(g) and 330(h) (collectively “Health Center Program Grants”); and (2) entities that have been determined by the Department of Health and Human Services (DHHS) to meet the Section 330-Related Requirements to receive funding without actually receiving a grant (“health center look-alikes”).

The term “Section 330-Related Requirements” refers to requirements set forth in:

- Health Center Program Statute: [Section 330 of the Public Health Service Act \(42 U.S.C. §254b\)](#),
- Program Regulations: [42 CFR Part 51c](#) and [42 CFR Parts 56.201-56.604](#)
- Health Center Program Requirements: <http://www.bphc.hrsa.gov/programrequirements/index.html>

The term “Grant Requirements” refers to Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards: 2 CFR Part 200, as adopted by DHHS at 45 CFR Part 75.

This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is published with the understanding that the publisher is not engaged in rendering legal, financial or other professional service. If legal advice or other expert assistance is required, the services of a competent professional should be sought.

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# The Duty to Disclose Adverse Information about Health Center Practitioners

As part of the credentialing process, health centers are accustomed to querying the National Practitioner Data Bank (“NPDB”) for information about a practitioner’s licensure, professional society membership, medical malpractice payment history, and record of clinical privileges.<sup>1</sup> This information allows health centers to assess the qualifications of applicants for clinical staff positions, as well as to fulfill deeming requirements for coverage under the Federal Tort Claims Act (“FTCA”).<sup>2</sup>

Thereafter, if serious issues about the qualifications or impairment of existing practitioners arise, health centers may be required to report information back to the NPDB. For example, health centers must notify the NPDB when they restrict or withdraw a physician’s privileges as part of a formal peer review process. Health centers must report clinical privileging actions taken against physicians and dentists, and medical malpractice payments made on behalf of all practitioners. Once an action is reported, it becomes available to licensing boards, hospitals and other eligible entities engaged in employment, affiliation and licensure decision when they query the NPDB on that same practitioner.

Indeed, when a health center has determined that a physician’s continued practice of medicine might endanger patients who are not patients of the health center, it may seek to notify the peer review committees of

1 See Policy Information Notice (PIN) 2001-16: Credentialing and Privileging of Health Center Practitioners and PIN 2002-22: Clarification of Bureau of Primary Health Care Credentialing and Privileging Policy Outlined in Policy Information Notice 2001-16.

2 42 U.S.C. § 233(h)(2).

local hospitals in which the physician has privileges, or to disclose information to other health centers or potential employers who make credentialing inquiries. By reporting to the NPDB, that information becomes automatically accessible to eligible entities making those hiring and credentialing decisions.

To assist health centers with understanding their reporting obligations when they take adverse actions against health care practitioners as well as the pertinent legal considerations in making voluntary disclosures of such information, this Information Bulletin:

- ◆ Describes reporting duties to the National Practitioner Data Bank;
- ◆ Discusses legal considerations for making voluntary disclosures; and
- ◆ Describes reporting duties under the Patient Safety and Quality Improvement Act of 2005.

It should be noted that this Bulletin focuses on federal requirements. State law may impose more stringent requirements on health centers for reporting adverse privileging or medical events. Health centers are advised to contact local counsel in regard to state reporting requirements.

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## THE NATIONAL PRACTITIONER DATA BANK: AN OVERVIEW

Established by the Health Care Quality Improvement Act of 1986,<sup>3</sup> the NPDB is intended to be a means of increasing the quality of care by restricting the ability of incompetent physicians and other practitioners to move from state to state without disclosure or discovery of previous medical malpractice payments, adverse actions involving licensure, clinical privileges, professional society memberships, health-related civil and criminal convictions, and exclusions from Medicare and Medicaid.

The Health Resources and Services Administration (“HRSA”), within the U.S. Department of Health and Human Services (“HHS”) is the government agency responsible for the administration of the NPDB. The NPDB collects information on medical malpractice payments resulting from settlements and final judgments, as well as adverse licensure, clinical privileging, and professional society membership actions. The NPDB also contains information regarding practitioners who have been declared ineligible to participate in Medicare, Medicaid, and other health care programs. State licensing boards, hospitals, defined health care entities, professional societies, and certain federal and state agencies are some of the eligible entities with reporting responsibilities and access to information in the NPDB, though the extent of each entity’s participation varies.

The federal requirements for disclosure and reporting information to the NPDB are set forth in Part 60 of Title 45 of the Code of Federal Regulations.<sup>4</sup> These regulations permit a health center to query the NPDB when entering an employment or affiliation

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3 Pub. L. No. 99-660, Title IV § 402, 42 U.S.C. §§ 11101-11152.

4 45 C.F.R. Part 60.

relationship with physicians and mid-level providers (including physician assistants and nurse practitioners), as well as social workers, clinical psychologists, and a host of other types of practitioners who may comprise the health center's clinical staff, provided that the health center has a formal peer review process.<sup>5</sup> Given that checking adverse licensure action history is a key element of the credentialing and privileging process, accessing practitioner information in the NPDB is an excellent resource for eligible health centers.

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## REPORTING DUTIES TO THE NATIONAL PRACTITIONER DATA BANK

Eligible health centers are required to report certain information about their practitioners to the NPDB in two circumstances: (1) the making of medical malpractice payments; and (2) the taking of adverse privilege actions. These reports help to ensure the information available in the NPDB for other potential health care employers is complete. The report must contain a narrative description of the reasons for the adverse privilege action. The narrative description

should clearly describe the reportable action, use sufficient detail, and include a summary of the relevant findings and the basis for the reportable action. HRSA has published general guidance to assist providers with satisfying this requirement.<sup>6</sup>

It is important to recognize that an eligible health center that fails to make a required report to the NPDB can lose the significant protection that normally immunizes peer review activity from liability under state lawsuits.<sup>7</sup> This protection applies to liability under any federal or state law (e.g. antitrust or defamation actions) except for liability under state and federal civil rights laws. If HRSA determines that an eligible health center has substantially failed to report information to NPDB, then the health center will lose all of its liability protections for a period of three years from that date forward.<sup>8</sup>

## Medical Malpractice Payments

An eligible health center must file a report with the NPDB when the health center (as opposed to insurance company or the federal government on behalf of a health center)<sup>9</sup> makes a medical malpractice payment (either a lump sum or the first of multiple payments

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- 5 A formal peer review process means the conduct of professional review activities (such as privileging) through formally adopted written procedures that provide a practitioner with adequate notice and an opportunity for hearings. The authors are aware of reviewers requesting to see written peer review policies from health centers during FTCA site visits. All health centers are expected to have formal privileging processes that meet the standards of national accrediting agencies such as the Joint Commission on Accreditation of Health Care Organizations (JCAHO) and the Accreditation Association for Ambulatory Health Care, Inc. (AAAH). The health center should have an appeal process for licensed independent practitioners (physicians, dentists, nurse practitioners, and nurse midwives) if a decision is made to discontinue or deny clinical privileges. An appeal process is optional for other licensed or certified health care practitioners. For more information on credentialing and privileging, see PIN 2002-22.
- 6 NPDB, "Submitting a Factually-Sufficient Narrative", available at <http://www.npdb.hrsa.gov/hcorg/submittingAFactuallySufficientNarrative.jsp>, accessed Dec. 17, 2014.
- 7 42 U.S.C. § 11111(a)(D), (b).
- 8 Insofar as a loss of immunization does not result in the health center's loss of deeming under FTCA, the loss of liability protections for peer review actions does not affect a health center's FTCA coverage of medical malpractice.
- 9 An insurance company directly files a report to the NPDB even if the health center pays a deductible towards the medical malpractice payment. Note, however, if a payment is made on an FTCA claim, then the claim is then reviewed by the Medical Claims Review Panel (MCRP) to determine whether the practitioner met the standard of care for purposes of reporting to the NPDB. See "Federal Tort Claims Act Health Center Policy Manual," July 21, 2014, available at <http://www.bphc.hrsa.gov/policiesregulations/policies/ftcahcpcpolicymanualpdf.pdf>. If the MCRP determines that the malpractice was a result of a "systems failure," as opposed to an individual practitioner's error(s), the MCRP will not report the payment to the NPDB.

but not a deductible) for the benefit of a physician, dentist, or other licensed or authorized health care practitioner in settlement of, or in satisfaction in whole or in part of, a written claim or a judgment against the individual practitioner.<sup>10</sup> For the purposes of determining whether a payment is reportable, it must be made on behalf of a practitioner who is both named in the complaint and the final judgment or settlement. However, an eligible health center does not need to report a medical malpractice payment if the payment results from a suit or claim made solely against the health center that does not identify an individual practitioner, or as a result of something other than a written complaint or claim demanding monetary payment for damages.

The health center must file a report to the NPDB within 30 days of the date a payment is made and, simultaneously send a copy of the report to the appropriate licensing board.<sup>11</sup> Use of the NPDB's report-forwarding feature can automate this requirement, sending the report directly to the appropriate state licensing board as chosen by the reporting health center. These reports must contain certain information about the health care practitioner for whom payment was made, as well as information about the health center. The NPDB website ([www.npdb-hipdb.hrsa.gov](http://www.npdb-hipdb.hrsa.gov)) provides a form for reporting medical malpractice payments, which health centers can use to gather the required information.

A health center that fails to make a required report on a medical malpractice payment is subject to the imposition of civil money penalties by the Office of Inspector General ("OIG") of up to \$10,000 for each payment involved.

## Adverse Privilege Actions

An eligible health center must report to the NPDB when one of its physician's or dentist's privileges are reduced, restricted, suspended, revoked or denied for a period of more than 30 days, as well as when it accepts a physician's or dentist's surrender or restriction of clinical privileges either:

1. While under investigation for possible professional incompetence or improper professional conduct; or
2. In return for not conducting an investigation or professional review action.

Health centers may voluntarily report adverse actions that adversely affect the privileges of licensed health care practitioners other than physicians and dentists, such as mid-level providers, social workers, clinical psychologists, etc.

When required to report actions involving physicians or dentists to the NPDB, health centers must file the report within 30 days from the date the adverse action was taken or privileges were voluntarily surrendered. Each report submitted to the NPDB must be printed and mailed to the appropriate state licensing board for its use, along with the "Report Verification Document" the health center receives back from the NPDB documenting successful processing of the report. As with medical malpractice payments, the NPDB system is set up to electronically submit the report to licensing boards indicated by the reporting entity at the time the report is filed.

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10 A written complaint or claim can include, but is not limited to, the filing of a cause of action based on state tort law in any state or court or other adjudicative body, such as a claims arbitration board.

11 Health centers should also check state law to determine whether they must report directly to the state medical licensing board (e.g., independent of the copy of the NPDB report) since the state may require different information to be reported.

## SUMMARY OF REPORTING DUTIES

National Practitioner Data Bank	Mandatory Reporting to the NPDB	Voluntary Reporting to the NPDB	Date Reportable	Reporting to State Licensing Boards
Medical Malpractice Payments (lump sum or the first of multiple payments)	Payments for the benefit of physicians, dentists, or other licensed or authorized practitioners	No	Within 30 days from date payment is made	Yes
Adverse Privilege Actions (reductions, restrictions, suspensions, revocations or denials)	Actions affecting physicians or dentists	Actions affecting other licensed or authorized health care practitioners	Within 30 days from date of adverse action	If reporting to NPDB is mandatory, then required within 30 days from date of adverse action.

## LEGAL CONSIDERATIONS FOR MAKING VOLUNTARY DISCLOSURES

Traditionally, most employers have been counseled not to disclose unfavorable information about former employees due to potential risks of defamation actions or other types of liability. While this fear is understandable, several legal considerations should guide health centers to reconsider that policy, at least in regard to health practitioners, as a means of preventing unqualified or impaired practitioners from being re-employed by other health centers or providers.

### Defamation Lawsuits

Although defending any defamation lawsuit will be time-consuming and expensive, health centers should recognize that the truth is always an absolute defense. This means that a disclosure (so long as it is truthful) is not illegal, even if it reflects unfavorably on the former employee (e.g., “Dr. Jones repeatedly missed work and

failed to call in to alert his superior of her absence.”). Accordingly, health centers should limit disclosures about former employees to factual statements to help minimize the risk of defamation liability.

### Health Care Quality Improvement Act of 1986

The Health Care Quality Improvement Act of 1986 (the same legislation which established the NPDB) provides broad immunity from state and federal liability to any person who provides information to a professional review body (such as a hospital’s peer review committee) regarding the competence or professional conduct of a physician, unless the information is false, and the person providing such information knew it was false.<sup>12</sup> Additionally, many state peer review laws provide similar immunity to providers who share information with other entities in the credentialing process.

12 Pub. L. No. 99-660, Title IV, § 402, 42 U.S.C. § 11111. The Act also provides liability protections to health care entities that file reports with the NPDB and State licensing boards. 42 U.S.C. § 11137(c).

## Negligent Misrepresentation

A health center may face liability based on theories of intentional and negligent misrepresentation if it makes affirmative misrepresentations when providing a reference for an employee to another potential employer. In a 2008 case, the U.S. Court of Appeals for the 5<sup>th</sup> Circuit found that a physician's former partners were liable for writing misleading referral letters that described the physician, who, due to his negligence and addiction to narcotics, left a patient undergoing a routine tubal ligation in a permanent vegetative state, as "excellent". The Court reasoned that a party does not have an affirmative duty to disclose negative information; however, a party does have a duty to not make affirmative misrepresentations and may be held liable for doing so.<sup>13</sup> Interestingly, the 5<sup>th</sup> Circuit disagreed with the lower court's holding that the physician's place of employment had an affirmative duty to disclose the physician's negligence and drug-addiction.<sup>14</sup> Although this case is not binding on other courts, it may reflect how other courts would approach the issue.

## Recommendations

In sum, a health center and its practitioners should carefully consider how they disclose adverse information about a practitioner in response to requests from hospital and health center credentialing committees, or in other circumstances when a practitioner's continued practice of medicine might endanger patients who are not patients of the health center.

Prior to making voluntary disclosures of adverse information, health centers should:

- ◆ Require practitioners, when seeking a reference for employment for another health care provider, to sign a release from any liability for providing true information about the practitioner's employment;

- ◆ Ensure that any disclosures are truthful and do not include statements of opinion, suspicion, conjecture, or outright misrepresentation; and
- ◆ Confirm that the requesting party is a professional review body making the request in connection with professional review activities.

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## REPORTING DUTIES UNDER PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005

Enacted on July 29, 2005, the Patient Safety and Quality Improvement Act of 2005<sup>15</sup> ("Patient Safety Act") encourages health care providers to voluntarily report patient safety information, medical errors, and "near misses" to certified Patient Safety Organizations ("PSOs").<sup>16</sup> In order to facilitate such disclosure, the Patient Safety Act establishes certain legal privilege and confidentiality protections for any data developed by PSOs or prepared by health care providers and delivered to PSOs.

A PSO is a private entity certified by the HHS' Agency for Healthcare Research and Quality as having met certain criteria, allowing providers to participate in patient safety activities and share sensitive information relating to patient safety events without fear of legal

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13 See generally *Kadlec Med. Ctr. v. Lakeview Anesthesia Assocs.*, No. Civ.A 04-0997, 2005 WL 1309153 (E.D. La. May 19, 2005), *aff'd in part, rev'd in part, remanded*, 527 F.3d 412 (5th Cir. 2008), *cert. denied*, 129 S. Ct. 631 (Dec. 1, 2008).

14 In the event that an employer discloses information that creates a "misapprehension" about qualifications, or if the disclosures *are* misleading, the 5<sup>th</sup> Circuit held that the employer has a duty to clarify the information provided.

15 Pub. L. No. 109-41, § 2(a)(5), 42 U.S.C. §§ 299b-21 to -26.

16 The implementing regulations may be found at 42 C.F.R. Part 3; see also 73 Fed. Reg. 70732 (Nov. 21, 2008).

discovery. PSOs are charged with analyzing patient safety data collected from providers, including health centers, and developing and disseminating recommendations, protocols, and best practices to providers on how to improve patient safety.

PSOs are intended to encourage a culture of safety among providers and provide feedback and assistance to effectively minimize patient risk. As such, while conducting its activities, PSOs must maintain procedures to preserve confidentiality with respect to patient safety data.

A PSO must disclose any potential conflict of interest, including any legal, financial, or contractual relationship it has with a provider. Because PSOs must have contracts with providers to receive and review patient safety data, health centers should ensure such contracts have been executed prior to reporting any data to them.

## Key Terms under the Patient Safety Act

### Patient Safety Work Product (“PSWP”)

PSWP is defined as any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements (or copies of any of this material) that:

- (1) Could improve patient safety, health care quality, or health care outcomes; and
  - a. are assembled or developed by a provider *for reporting to a PSO and are reported to a PSO*, which includes information that is documented as *within a patient safety evaluation system for reporting to a PSO*, and such documentation includes the *date the information entered the patient safety evaluation system*; or

- b. are developed by a PSO for the *conduct of patient safety activities*; or

- (2) identify or constitute the deliberations or *analysis* of, or identify the fact of reporting pursuant to, a patient safety evaluation system.<sup>17</sup>

However, PSWP does not include a patient’s medical record, billing, and discharge information, or any other original patient or provider information. Importantly, the definition of PSWP explicitly excludes information that is collected, maintained, or developed separately from a patient safety evaluation system, even if it is reported to a PSO.

### Patient Safety Evaluation Systems (“PSES”)

A provider’s PSES is the system by which an organization collects, manages, or analyzes information for reporting to a PSO. It is unique and specific to a provider. HHS does not require that organizations document their PSES, but notes that doing so would clearly establish when information would be considered PSWP. HHS “encourage[s]” providers to document their PSES as best practice.<sup>18</sup>

All activities engaged in by a PSO related to operating, and providing feedback to participants in, a PSES constitute protected patient safety activities under the Patient Safety Act, including information about events, errors, near-misses, quality improvement data, and other patient safety data. Providers may voluntarily remove, and document the removal of, information from their PSES that has not yet been reported to a PSO, but by doing so, the information is no longer PSWP.

<sup>17</sup> 42 C.F.R. §3.20, emphasis added.

<sup>18</sup> 70738 Fed. Reg. 70738.

## Privilege and Confidentiality Protections

PSWP created by PSOs or shared with PSOs by providers is subject to confidentiality and privilege protections. A person who knowingly or recklessly discloses identifiable PSWP in violation of the Patient Safety Act is subject to civil monetary penalties of up to \$10,000 for each act constituting a violation.

### Legal Privilege

Typically, PSWP is privileged and may not be:

- (1) Subject to a federal, state, local, or tribal civil, criminal, or administrative subpoena or order, including in a federal, state, local, or tribal civil or administrative disciplinary proceeding against a provider;
- (2) Subject to discovery in connection with a federal, state, local, or tribal civil, criminal, or administrative proceeding, including in a federal, state, local, or tribal civil or administrative disciplinary proceeding against a provider;
- (3) Subject to disclosure pursuant to Freedom of Information Act (FOIA) or any other similar federal, state, local, or tribal law;
- (4) Admitted as evidence in any federal, state, local, or tribal governmental civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudicatory proceeding, including any such proceeding against a provider; or
- (5) Admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under state law;

### Confidentiality

All PSWP is deemed confidential and may not be disclosed except as permitted below:

- ◆ Disclosure to carry out patient safety activities;
- ◆ Disclosure to conduct research, evaluations, or demonstration projects authorized by HHS (to the extent allowed by HIPAA);
- ◆ Disclosure by a provider to the FDA for an FDA-regulated product or activity;
- ◆ Disclosure by a provider to an accrediting body that accredits that the provider;
- ◆ Disclosure for business operations deemed necessary by HHS and which are consistent with the law;
- ◆ Disclosure to a law enforcement authority relating the commission of a crime (to the extent necessary);
- ◆ Disclosure to persons other than PSOs and the PSWP does not include materials that assess the quality of care of an identifiable provider or describe or pertain to one or more actions or failures to act by an identifiable provider.

## Exceptions

The legal privilege and confidentiality protections do not apply to disclosure of relevant PSWP for in the following situations:

- ◆ Disclosure in criminal proceedings once a court has made a determination that the PSWP contains evidence of a criminal act, the PSWP is material to the proceeding, and the PSWP is not reasonably available from any other source;
- ◆ Disclosure to permit equitable relief for an individual to seek redress from retaliatory action taken against him or her for reporting information to a PSO;
- ◆ Disclosure authorized by each provider identified in the PSWP; and
- ◆ Disclosure of non-identifiable PSWP.

Non-identifiable PSWP is work product that:

- ◆ Does not identify any provider that is a subject of the work product or providers that participate in activities that are a subject of the work product;
- ◆ Would not constitute individually identifiable health information (as defined by the Health Insurance Portability and Accountability Act [HIPAA] privacy standards); and
- ◆ Would not allow identification of an individual who reported information to a provider or PSO.

## Non-Retaliation

As referenced above, health centers are prohibited from taking action against employees who report in good faith relevant patient safety information to PSOs or to a provider with the intent of having that information reported to a PSO. Under the Patient Safety Act, reporters are protected from:

- ◆ Adverse employment actions, including an individual's loss of employment, denial of promotion, or denial of any employment benefit for which the individual would otherwise be eligible.
- ◆ Adverse evaluations or decisions made in relation to accreditation, certification, credentialing, or licensing of the individual.

Employees may seek equitable relief (e.g., reinstatement, back pay, and restoration of benefits) against employers that retaliate against them for reporting patient-safety information.

## State Laws

Some states have mandatory reporting laws that may require a health center to report medical errors or patient safety information. Because reporting under the Patient Safety Act is voluntary, and not mandatory, the Act does not preempt or alter existing state reporting requirements. Consequently, a health center will continue to be subject to state reporting laws even if it chooses to voluntarily report data to a PSO.

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## CONCLUSION

Because state and reporting requirements regarding adverse actions are extremely varied, health centers should develop policies and procedures to establish a reporting system to ensure that mandated reports are timely made to the NPDB and state licensing boards. Ideally, the reporting system would identify:

- ◆ Which health care practitioners and events are subject to reporting;
- ◆ What events must be reported;
- ◆ What level of detail to report;

- ◆ What staff position is responsible for filing the report;
- ◆ To whom the report must be filed; and
- ◆ In what format the filing should be done.

To help avoid serious risks to patient safety, health centers should also consider making voluntary disclosures to professional review bodies about health care practitioners and adverse medical events. Prior to doing so, a health center should establish policies that govern what information will be disclosed, to whom it will be disclosed, and how it will be disclosed.

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