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NPDB: The Guidebook Changes and How They May Affect You

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NPDB Background

- In 1987, Congress authorized federal government to collect sanctions information taken by state licensing authorities against health care practitioners and health care entities.
- Patrick v. Burget (1988)
 - U.S. Supreme Court reversed a Circuit Court of Appeals decision which had found that the state action doctrine exempted peer review conduct from antitrust liability.
 - The effect of the decision was to reinstate a civil judgment against physicians on a on a medical staff for their "bad faith" peer review.
 - In response to concerns that physicians would not participate in peer review activities and that incompetent physicians were moving from state to state to avoid detection in 1990, the law was amended to add any negative findings by peer review or accreditation entities.

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NPDB Background cont'd

- In 1999, final regulations passed leading to the formation of the health care Integrity and Protection Data Bank ("HIPDB") which received and disclosed certain final adverse actions, such as licensure, certification, criminal and civil convictions and exclusions from state and federal health care programs based on health care fraud and abuse violations.
- In 2013, NPDB and HIPDB operations were consolidated.



Eligible Entities that Report to and Query the NPDB

Table B-1 Eligible Entities that Report to and Query the NPDB, Part 1

Each of the three major statutes governing NPDB operations has its own set of eligible entities with specific reporting and querying requirements. Eligible entities are responsible for complying with all reporting and/or querying requirements that apply; some entities may qualify as more than one type of eligible entity.

Title IV Requirements

<u>Entity</u>	<u>Report</u>	<u>Query</u>
Medical malpractice payers	Required	Prohibited
Hospitals	Required	Required
Health care entities that provide health care services and follow a formal peer review process for the purpose of furthering quality health care	Required	Optional
Professional societies that follow a formal peer review process for the purpose of furthering quality health care	Required	Optional
Boards of medical examiners	Required	Optional
Other State licensing boards	No Requirement	Optional
DEA	Required	Prohibited
OIG	Required	Prohibited

Refer to Table B-1, Part 2, for additional information on reporting and querying requirement.



Eligible Entities that Report to and Query the NPDB cont'd

Table B-2 Eligible Entities that Report to and Query the NPDB, Part 2

Each of the three major statutes governing NPDB operations has its own set of eligible entities with specific reporting and querying requirements. Eligible entities are responsible for complying with all reporting and/or querying requirements that apply; some entities may qualify as more than one type of eligible entity.

Section 1921 and Section 1128E Requirements			
<u>Entity</u>	Report	Query	
Hospitals*	Required	Prohibited	
Health care entities that provide health care services and follow a formal peer review process for the purpose of furthering quality health care	Required	Required	
Professional societies that follow a formal peer review process for the purpose of furthering quality health care	Required	Optional	
Health plans	Required	Optional	
Quality improvement organizations	No Requirement	Optional**	
State licensing and certification authorities	Required (§ 1921)	Optional	
Peer review organizations	Required (§ 1921)	Optional**	
Private accreditation organizations	Required (§ 1921)	Optional	
State law enforcement agencies, including State prosecutors***	Required (§ 1921)	Prohibited	
State Medicaid fraud control units***	Required (§ 1921)	Prohibited	
State agencies administering or supervising the administration of State health care programs***	Required (§ 1921)	Optional	
Agencies administering Federal health care programs, including private entities administering such programs under contract	Required (§ 1128E)	Optional	
Federal licensing and certification agencies	Required (§ 1128E)	Optional	
Federal law enforcement officials and agencies, including Federal prosecutors	Required (§ 1128E)	Optional	
*Under Title IV/ Hereitel are required to account AIRDD	·		

^{*}Under Title IV, Hospital are required to query to NPDB.

Refer to Table B-1, Part 1, for additional information on reporting and querying requirements.



^{**} As described in Chapter D: Queries, with a few limited exceptions, these entities have access to all of the information reported under Section 1921 and Section 1128F.

^{***}NPD regulations defined "state law or fraud enforcement agency" as including but not limited to these entities.

Eligible Entities that Report to and Query the NPDB cont'd

- Hospitals required to report and query.
- Other health care entities optional.
 - Must provide health care services.
 - Must follow a formal peer review process to further quality health care.
 - Is broad in scope and <u>can</u> apply to HMOs, PPOs, group practices, nursing facilities, patient centered medical homes and ACOs.
 - If it provides health care services and performs peer reviews for the purpose of furthering health care, it must report and may query at any time.

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Eligible Entities that Report to and Query the NPDB cont'd

- Question: A hospital merged with another hospital. Should they continue to query separately using two different DBIDs?
 - If a physician becomes a member of both medical staffs when applying/reapplying to one or the other, then only one query required.



Subject of Reports

Table C-1: Examples of Health Care Practitioners, Part 1

The following lists of health care practitioners are provided solely for illustration. Since licensure and certification requirements vary from State to State, there may be additional categories of health care practitioners not reflected on the following lists, and there may be categories listed below that do not satisfy the definition of health care practitioner for particular States. Each entity that reports to or queries the NPDB is responsible for determining which categories of health care practitioners are licensed or otherwise authorized by their State to provide health care services.

Chiropractor

Counselor

Counselor, Mental Health

Professional Counselor

Professional Counselor, Alcohol

Professional Counselor, Family/Marriage

Professional Counselor, Substance Abuse

Marriage and Family Therapist

Dental Service Provider

Dentist

Dental Resident

Dental Assistant

Dental Therapist/Dental Health Aide

Dental Hygienist

Denturist

Dietitian/Nutritionist

Dietitian

Nutritionist

Emergency Medical Technician (EMT)

EMT. Basic

EMT, Cardiac/Critical Care

EMT, Intermediate

EMT, Paramedic

Eye and Vision Service Provider

Ocularist

Optician

Optometrist

Nurse - Advanced, Registered, Vocational

Registered (Professional) Nurse

Nurse Anesthetist

Nurse Midwife

Nurse Practitioner

Doctor of Nursing Practice

Clinical Nurse Specialist

Licensed Practical or Vocational Nurse

Nurses Aide, Home Health Aide, Other Aide

Certified Nurse Aide/Certified Nurse

Assistant

Nurses Aide

Home Health Aide (Homemaker)

Health Care Aide/Direct Care Worker

Certified or Qualified Medication Aide

Pharmacy Service Provider

Pharmacist

Pharmacist Intern

Pharmacist. Nuclear

Pharmacy Assistant

Pharmacy Technician

Physicians

Physician (MD)

Physician Intern/Resident (MD)

Osteopathic Physician (DO)

Osteopathic Physician Intern/Resident (DO)



Subject of Reports cont'd

Table C-1: Examples of Health Care Practitioners, Part 2

Physician Assistant

Physician Assistant, Allopathic Physician Assistant, Osteopathic

Podiatric Service Provider

Podiatrist

Podiatric Assistant

Psychologist, Psychological Assistant

Psychologist

School Psychologist

Psychological Assistant, Associate,

Examiner

Rehabilitative, Respiratory, and Restorative Service Practitioner

Art/Recreation Therapist

Massage Therapist

Occupational Therapist

Occupational Therapy Assistant

Physical Therapist

Physical Therapy Assistant

Rehabilitation Therapist

Respiratory Therapist

Respiratory Therapy Technician

Social Worker

Speech, Language, and Hearing Service Provider

Audiologist

Speech/Language Pathologist

Bearing Aid (or Instrument) Specialist,

Dealer, Dispenser, or Fitter

Technologist/Technician

Medical or Clinical Laboratory

Technologist

Medical or Clinical Laboratory Technician

Surgical Technologist

Surgical Assistant

Cytotechnologist

Nuclear Medicine Technologist

Radiation Therapy Technologist

Radiologic Technologist

X-Ray Technician or Operator

Limited X-Ray Machine Operator (LXMO)

Other Health Care Practitioner

Acupuncturist

Athletic Trainer

Homeopath

Medical Assistant

Midwife, Lay (non-nurse)

Naturopath

Orlhotics/Prosthetics Fitter

Perfusionist

Psychiatric Technician



Reporting Requirements and Query Access

	Table C-3 Su	mmary of Reporting Requirement	s and Query Acces	s, Part 1
Law	Who Reports?	What is Reported	Who is Reported?	Who May Query/Request Information?
Title IV	Medical malpractice payers	Medical malpractice payments resulting from a written claim or judgment	Practitioners	Hospitals (required by law) Other health care entities with formal peer review Professional societies with formal peer review State medical and dental boards and other State licensing boards
	State medical and dental boards	Certain adverse licensure actions related to professional competence or conduct	Physicians and dentists	
	Hospitals other health care entities with formal peer review	Certain adverse clinical privileges actions related to professional competence or conduct	Physicians and dentists Other practitioners (optional)	
	Professional societies with formal peer review	Certain adverse professional society membership actions related to professional competence or conduct	Physicians and dentists Other practitioners (optional	Plaintiff's attorney/pro se plaintiff (limited circumstances) Health care practitioners (selfquery) Researchers (de-identified
	DEA	DEA controlled-substance registration actions*		
	OIG	Exclusions from participation in Medicare, Medicaid, and other Federal health care programs*	Practitioners	

^{*}This information is reported to the NPDB under Title IV based on a memorandum of understanding.



Reporting Requirements and Query Access cont'd

	Table C	-3 Summary of Reporting F	Requirements and Query	Access, Part 2
Law	Who Reports?	What is Reported	Who is Reported?	Who May Query/Request Information?
	Peer review organizations	Negative actions or findings by peer review organizations	Practitioners	
	Private accreditation organizations	Negative actions or findings by private accreditation organizations	Entities, providers, and suppliers	Lloopitale and other health care entities *
	State licensing and certification authorities	State licensing and certification actions	Practitioners, entities, providers, and suppliers	Hospitals and other health care entities * Professional societies with formal peer review * Quality improvement organizations * State licensing and certification authorities Agencies administering Federal health care programs, including private entities administering such programs under contract Federal licensing and certification agencies Health plans State law enforcement agencies *** State Medicaid fraud control units *** State agencies administering or supervising the
Section 1921	State law enforcement agencies*** State Medicaid fraud control units*** State agencies administering or supervising the administration of state health care programs*** Federal and State prosecutors	Exclusions from a State health care program Health care-related civil judgments in State court Health care-related State criminal convictions Other adjudicated actions or decisions	Practitioners, providers, and suppliers	
Section 1128E	Federal agencies Health plans	Federal licensing and certification actions ** Exclusions from a Federal health care program ** Health care-related Federal or State criminal convictions ** Health care-related civil judgments in Federal or State court Other adjudicated actions or decisions		administration of State health care programs *** Federal law enforcement officials and agencies Practitioners, entities, providers, and suppliers (self-query) Researchers (de-identified, statistical data, only)

^{*}As more fully explained in Chapter D: Queries, with a few limited exceptions, these entities have access to all of the information reported under Section 1921 and Section 1128F

NPDB regulations define "state law or fraud enforcement agency" as including but not limited to these entities.

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^{**} Reported by Federal agencies only.

Reporting Requirements and Query Access cont'd

- Question: Can eligible entities report on health care practitioners who are not physicians or dentists?
 - Yes



	Table D-1 Information Available to Queries as Authorized by Law, Part 1		
Law	Authorized Queries	Available Information	Subjects of Reports
		Medical malpractice payments	Practitioners
	Hospitals (required by law) Other health care entities with formal peer review	Certain adverse licensure actions taken by State medical and dental boards	Physicians and dentists
	Professional societies with formal peer review	Certain adverse clinical privileges actions	Primarily Physicians and dentists
Title IV	State medical and dental boards and other State licensing boards	Certain adverse professional society membership actions	Primarily Physicians and dentists
circumstances)	·	DEA controlled-substance registration actions	Practitioners
	ealth care practitioners (self-query)	Exclusions from Medicare, Medicaid, and other Federal health care programs	Practitioners



Table D-1 Information Available to Queries as Authorized by Law, Part 2			
Law	Authorized Queries	Available Information	Subjects of Reports
Other review Health Profes	The realth care entities with formal peer review* Health plans Professional societies with formal peer review* Quality improvement organizations* State licensing and certification authorities State law enforcement agencies** State Medicaid fraud control units** State agencies administering or supervising the administration of a State health care program** Agencies administering Federal health care programs, including private entities administering such programs under contract Federal licensing or certification agencies	Negative actions or findings by peer review organizations	Practitioners
		Negative actions or findings by private accreditation organizations	Entities, providers, and suppliers
		State licensure and certification actions	Practitioners, entities, providers, and suppliers
1921 and Section		Federal licensure and certification actions	
1128E		Exclusions from Federal or State health care programs*	
		Health care-related civil judgments in Federal or State court*	Health care practitioners, providers, and suppliers
		Health care-related criminal convictions in Federal or State court*	
	Practitioners, entities, providers, and suppliers requesting information concerning themselves (self-query)	Other adjudicated actions or decisions*	

^{*}Hospitals, other health care entities, professional societies, and quality improvement organizations are not authorized to receive certain adverse actions reported under Section 1921, including exclusions from State health care programs, health care-related criminal convictions and civil judgments in State court, and other adjudicated actions or decisions.

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^{**}NPDB regulations authorize State law or fraud enforcement agencies to query the NPDB. The regulations define a "state law or fraud enforcement agency" as including, but not limited to, these entities.

- Hospital obligation to query
 - When a physician, dentist or other health care practitioner applies for medical staff appointment <u>or</u> for clinical privileges at the hospital, including temporary privileges at <u>each</u> request.
 - Reappointment every two years.
 - When a practitioner seeks to add or expand existing clinical privileges.
- Residents and interns (house staff)
 - <u>No</u> if exercising privileges pursuant to a formal educational program.
 - <u>Yes</u> if exercising clinical privileges outside educational programs, i.e., moonlighting in ICU or ED.

- Emeritus, Honorary Members
 - Yes if on the Medical Staff even if not exercising clinical privileges.
- What if hospital fails to query?
 - Hospital will be presumed to be aware of NPDB information
 - A plaintiff's attorney or plaintiff representing him or herself will have access to information for use in litigation against the hospital. Needs to submit:
 - Letter requesting authorization to obtain information.
 - Supporting evidence that hospital did not make mandatory query regarding defendant physician/practitioner.
 - Identifying information about practitioner.
 - Allowed a one-time disclosure at the time hospital was required to query.

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- Question: Are hospitals required to document and maintain records of their requests for information?
 - <u>No</u> but serves as best evidence that a response was obtained. Response maintained for 45 days although NPDB maintains a query history of when queries were made but not the responses.



- Question: If a health care entity cannot find or did not receive a response to a query, may a copy be requested?
 - <u>No</u>. Must re-submit request. If query was paid for contact customer service. Do not submit a new query.



Centralized Credentialing

- If health care system has multiple qualifying health care entities at which a practitioner is allowed to exercise membership and/or clinical privileges only <u>one</u> query needs to be made if using a centralized peer review process and one decision making body.
- If each entity conducts its own credentialing and only grants membership/privilege at its site then query response cannot be shared and separate queries must be made.



Delegated Credentialing

- A health care entity that delegates its credentialing responsibilities to another entity is prohibited from receiving NPDB querying results.
- Different from use of an authorized agent who simply queries and receives information on behalf of the entity.
- Authorized agents cannot use a query response on behalf of more than one entity.
- If two separate entities choose the same authorized agent and are making a query on the same individual, agent must make two separate queries. Information cannot be shared — would violate confidentiality requirements.



Delegated Credentialing cont'd

- Question: Can NPDB report be shared including use in a hearing and appeal process?
 - Yes as long as the individuals are part of the credentialing/privileging/peer review/hearing process.



Delegated Credentialing cont'd

- Question: Can a hospital share an NPDB report with an unrelated health care entity if authorized to do so by the practitioner?
 - <u>No</u> if not a part of the hospital's investigation or peer review process.



Time Frame for Reporting

Table E-2: Time Frame for Reporting		
Types of Actions that Must Be Reported	When Information Must be Reported	
Medical malpractice payments		
Certain adverse licensure actions related to professional competence or conduct (reported under Title IV)		
Certain adverse professional society membership actions related to professional competence or conduct	Within 20 days of the date the action was taken or the payment was	
Certain adverse professional society membership actions related to professional competence or conduct	Within 30 days of the date the action was taken or the payment was issued, beginning with actions occurring on or after September 1, 1990	
DEA controlled-substance registration actions or practitioners (reported under Title IV)		
Exclusions from participation in Medicare, Medicaid, and other Federal health care programs (reported under Title IV)		
Negative actions or findings taken by peer review organizations Negative actions or findings taken by private accreditation organizations	Within 30 days of the date the action was taken, beginning with actions occurring on or after January 1, 1992	
State Licensure and certification actions		
Federal licensure and certification actions		
Health care-related criminal convictions in Federal or State Court	Within 30 days of the date the action was taken, beginning with actions	
Health care-related civil judgments in a Federal or State health care program	occurring on or after August 21, 1996	
Other adjudicated actions or decisions		



Types of Reports

- Initial Report
 - Affected practitioner receives a copy.
 - Report needs to be factually accurate.
- Correction Report
 - Submitted when error identified.
 - Replaces the original Initial Report.
 - Practitioner receives a copy and sends also to any person or entity who queried and received a copy of the erroneous report in the past three years.

Types of Reports cont'd

 Hospital also needs to send the corrected report to the appropriate state licensing board or certification authority.

Void Report

- A report submitted in error or if action was not reportable or action overturned on appeal.
- Notification sent to practitioner and any person or entity which received previous report during past three years.
- Void Report removed from record.



Types of Reports cont'd

- Revision-to-Action Report
 - Is a report which modifies but does not replace the Initial Report. Both become part of the discloseable record. Examples include:
 - Initial 90 day suspension reduced to 45 days.
 - State medical boards decision to reprimand physician changed to a probation when physician fails to complete required continuing education credits.



Narrative Descriptions

- "Must include sufficient detail to ensure future queriers have a clear understanding of what the subject of the report is alleged to have done and the nature of the event upon which the report is based."
- Should be limited to the official findings or facts of the case.
- Should consult with legal counsel before filing.



Narrative Descriptions cont'd

- Question: May a reporting organization provide a copy of the NPDB report to the practitioner?
 - Yes, but identifying information should be removed. NPDB automatically sends instructions on how to get an official copy.



Reporting Adverse Clinical Privileges Actions

- Decisions must be based on a physician's or dentists professional competence or conduct that adversely affects, or could adversely affect, the health or welfare of a patient.
- Decision is made by the reporting health care entity.
- Reporting non-physicians is optional.



- Professional review actions that adversely affect a physician's or dentist's clinical privileges for more than 30 days.
- Acceptance of surrender or restriction of clinical privileges while under investigation or in return for not conducting such an investigation or not taking a professional review action that otherwise would be required to be reported to the NPDB.
- Adverse actions include:
 - Reducing
 - Restricting
 - Suspending
 - Revoking
 - Non-renewal of membership/privileges based on professional competence or conduct.

- Question: What is 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?
 - No real clear definition. Appears that entity has some flexibility in deciding what does and what does not constitute a professional review action.



- Draft states that censures, admonishments and reprimands greater than 30 days are reportable.
 - WRONG Physician privileges are not adversely affected by these decisions. Same for monitoring, practicing and mandatory consultations.
- Decisions based on failure to pay dues, failure to maintain insurance, employment disputes or other business issues are <u>not</u> reportable.
- Revocations based on failure to become board certified or some other similar eligibility criteria are <u>not</u> reportable.
- If multiple adverse actions taken which are each otherwise reportable, only one report is required but should use narrative description to explain all actions taken.

- Question: If a physician's initial application or request for expanded privileges is denied, is this decision reportable?
 - Depends on whether the decision was the product of a professional review action based on clinical competency or simply that physician did not satisfy eligibility criteria.
 - Example: Physician did not have appropriate experience to obtain specialized surgical privileges beyond core privileges – not reportable.
 - Example: Did not have minimum number of privileges not reportable.



- Question: If a physician's privileges are automatically terminated because his license was revoked, is this decision reportable?
 - No because there was no professional review action



- Question: If an employed physician is terminated based on professional competency issues, is the termination reportable?
 - Yes if there was a professional review action, which rarely takes place. No if there was not.



Withdrawal of Applications

- Voluntary withdrawal of an initial application prior to a final professional review action generally not reportable.
- If application is withdrawn at time of reappointment while under investigation for incompetence or improper professional conduct or in return for not conducting an investigation or taking professional review action then withdrawal <u>is</u> reportable.
- Denial of application and application withdrawal reportable even if physician had no knowledge of the investigation.
 - Many commentators objected to this statement as being inherently unfair.
 - Data bank on record as stating that physician's misleading or false representations on an initial application is reportable if accurate information would have led to a denial.



Investigations

- This section of the Draft is the most controversial.
- Routine investigations are not reportable.
- Surrender or restriction of privileges while under investigation or to avoid an investigation is reportable.
- OPPEs not reportable because the standards apply for everyone.
- "If the formal peer review process is used when issues relating to competence or conduct are identified or when a need to monitor a physician's performance is triggered based on a single event or pattern of events ... this is considered an investigation for the purposes of reporting to the NPDB." (E31)

- Should have documented evidence of an investigation if reporting a surrender of privileges such as minutes, orders, notices.
- "An investigation is not limited to a health care entity's gathering of facts. An investigation begins as soon as the health care entity begins an inquiry and does not end until the health care entity's decision making authority takes a final action or formally closes an investigation."
- "For NPDB reporting purposes, the term 'investigation' is not controlled by how that term may be defined in a health care entity's bylaws or policies or procedures."
- "A routine or general review of cases is <u>not</u> an investigation."



- "A routine review of a particular practitioner is <u>not</u> an investigation."
- Question 16 at E-41: "After receiving multiple quality of care complaints about a physician, a hospital initiated an investigation (referral to as a Focused Professional Evaluation [FPPE]. During the investigation, the physician resigned her clinical privileges at the hospital. Since there was no professional review action taken, should a report be submitted to the NPDB?
 - "Yes. The investigation (the FPPE) was triggered by an event involving professional competence and centered on the physician's performance outside the scope of a routine review. Since the physician resigned her clinical privileges while under investigation, a report must be submitted to the NPDB."

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- The NPDB's position on what constitutes an investigation for reporting purposes, including the determination that an FPPE is an investigation, has been universally criticized by such organizations as The Joint Commission, NAMSS, AHA and the NPDB Guidebook, Work Group. Comments include the following:
 - The use of OPPEs and FPPEs was established to TJC to help serve as "part of a continuous process of evaluation to ensure a high quality and safe health care system."
 - Hospitals required to impose an FPPE on all new applications does not mean they are under an investigation.
 - Characterization of an FPPE as an investigation might lead a hospital and medical staff to avoid using FPPEs.

- Hospital and medical staff should be able to define what constitutes an investigation in their bylaws consistent with the statute and regulations.
- Peer review activities should not be characterized as investigation.
- Imposition of an FPPE does not typically trigger hearing rights and therefore a hospital would almost be required to provide a hearing if it wants to access the immunity protections under HCQIA.



- Investigations are more typically triggered when there is a formal request for corrective action by the MEC or hospital. The reviews and analyses which take place before this request including OPPE/FPPEs are viewed as normal, routine peer review activity.
- If imposition of a FPPE plan is not reportable neither should resignation before or after imposition of an FPPE plan – privileges are not limited.



Summary Suspensions

- Are reportable if in effect for more than 30 days even though there is no final decision.
- Should be limited to where action is needed to protect patients from "imminent danger".
- Determine if some lesser form of remedial action will suffice.
- Hearing panels oftentimes overturn summary suspensions.
- Consider requiring that at least two individuals, one clinician and one administrator, must concur before imposing

Summary Suspensions cont'd

- If suspension is reversed or modified then appropriate report needs to be submitted such as a Void Report or a Reversion-to-Action.
- Use if different terms, i.e., emergency, precautions immediate, makes no difference.



Proctoring/Monitoring/Mandatory Consultations

- Imposition of a monitoring/proctoring/mandatory consultation is <u>not</u> reportable because physician can still exercise clinical privileges.
- If a Department Chair or other individual must approve a procedure or has veto authority then action is reportable.



Sanctions for Failing to Report

- Can lose the HCQIA immunity protections for 3 years.
- Health care entity, if it is determined to have substantially failed in reporting an adverse decision, will be given an opportunity to either comply without a penalty or to request a hearing.



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