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TO: All Licensed Healthcare Facilities

FROM: Michael J. Kennedy, Esquire *MJK*
Acting Assistant Commissioner
Division of Certificate of Need and Licensing

DATE: March 19, 2026

RE: Requirement to Produce All Requested Documentation

This guidance memorandum is to inform licensed healthcare facilities of the requirement to produce documentation requested by Department staff and to clarify information that is protected from disclosure.

Pursuant to the Health Care Facilities Planning Act (N.J.S.A. 26:2H-1, *et seq.*) (the Act), the Commissioner of the Department of Health, including the Commissioner's, designees, is authorized to inspect all health care facilities and to enforce licensing rules.

The Act, provides "[at] the request of the [C]ommissioner, health care facilities shall furnish to the Department such reports and information as it may require to effectuate the provisions and purposes of this act, excluding confidential communications from patients." N.J.S.A. 26:2H-5(e).

The Patient Safety and Quality Improvement Act of 2005 (42 U.S.C. §§ 299b-21 to 299b-26) establishes privilege and confidentiality protections for patient safety work product (PSWP). PSWP is limited to data, reports, records, analyses, or statements developed by a provider for reporting to a Patient Safety Organization (PSO), or developed by a PSO, for the purpose of improving patient safety and health care quality.

PSQIA does not preempt state or federal reporting obligations. Facilities remain responsible for submitting to the Department all information required by law or regulation, including, but not limited to, adverse event reports, infection control reports, licensure and certification documentation, patient care records, and other materials necessary for regulatory oversight. Such information is expressly excluded from the definition of PSWP under 42 C.F.R. § 3.20 and must be disclosed to the Department upon request.

Only documents and analyses created exclusively for reporting to a PSO, and not otherwise collected or maintained to satisfy state or federal requirements, qualify as PSWP and are not subject to mandatory disclosure.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), specifically the Privacy Rule at 45 C.F.R. § 164.512, permits the disclosure of protected health information (PHI) to state agencies without patient authorization when such disclosure is necessary for the agencies to carry out their health, safety, or licensing authority.

Pursuant to 45 C.F.R. § 164.512(d), covered entities may disclose PHI to a health oversight agency for activities authorized by law, including audits; investigations; inspections; licensure; and disciplinary actions necessary for oversight of the health care system, government benefit programs, and regulatory compliance. Similarly, 45 C.F.R. § 164.512(b) authorizes disclosure of PHI to public health authorities that are legally authorized to collect or receive such information for purposes of preventing or controlling disease, injury, or disability, and for conducting public health surveillance, investigations, and interventions.

Accordingly, disclosures of PHI to the Department, when the Department is acting within its statutory authority to protect public health and safety and to oversee the licensure and regulation of health care facilities, are consistent with HIPAA and do not require individual patient authorization.

It is essential that Department staff be provided access to all requested de-identified information and documentation required to effectuate the Department's regulatory authority. Further, in the case of records kept electronically, producing documentation includes providing direct access to electronic records to surveyors, and also providing a printed copy if requested by Department staff.

The Department may take enforcement action against facilities that fail to comply with this requirement, including issuing a civil monetary penalty, pursuant to N.J.A.C. 8:43E-3.4.

Any questions regarding this memo may be directed to Nicole Pine at Nicole.Pine@doh.nj.gov.