State of New Jersey
DEPARTMENT OF HEALTH
PO BOX 360
TRENTON, N.J. 08625-0360
www.nj.gov/health

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

KAITLAN BASTON, MD, MSc, DFASAM
Acting Commissioner

To: Licensed Health Care Facility CEO
Patient Safety Reporting System Liaisons

From: Mehnaz Mustafa
Executive Director, Health Care Quality Informatics

Subject: Inter Facility Disclosure of Health Information to Meet the Patient Safety Act Reporting Requirements

Date: November 27, 2023

In 2006, The New Jersey Department of Health (Department) adopted procedures and regulations at N.J.A.C. 8:43E-10 implementing the Patient Safety Act, N.J.S.A. 26:2H-12.23 through 12.25. These rules were enacted to increase the safety of patients and residents in New Jersey (NJ) health care facilities by reducing the frequency and severity of preventable adverse events (N.J.A.C. 8:43E-10.1(a)1.); and to assure the Department receives timely notification of various events in health care facilities that may significantly affect their ability to continue to deliver health care services and/or may pose a danger to the life or safety of patients or residents, employees, medical staff or the public (N.J.A.C. 8:43E-10.1(a)2.).

The Department has identified a significant number of adverse event reports for which there is insufficient information to determine if the event meets the statutory definition of a serious preventable adverse event (SPAE) for which a root cause analysis (RCA) is required. Many of these events occurred at one facility and the patient was either transferred or subsequently goes to another facility for follow up care, and the facility at which the event occurred is unable to obtain information about the adverse outcome for the patient from the facility providing follow-up care.

This prevents the facility where the event occurred from knowing the complete information about the adverse outcome for the patient, preventing the Department from requiring an RCA be completed and limiting any self-analysis for quality improvement by that facility where the event occurred. This undermines the goal of the Patient Safety Act.

If a patient is either transferred, or subsequently presents to a different facility for care following an event, additional information from that facility providing follow-up care may be required to determine the reportable status of the event.

In these situations, the facility at which the event occurred may reach out to the facility that provided follow-up treatment to obtain the required information. The Department is hereby indicating that this information may be provided to the initial reporting facility based on the following:

1) N.J.A.C. 8:43E-10.6(a), (b) and (e) require timely reporting of serious preventable adverse events (SPAEs) where it is reasonable to assume the event is related to the course of care at the facility. In addition, facilities are required to report SPAEs that occur at other licensed health care facilities to the Department.

2) The rules at N.J.A.C. 8:43E-10.6(c)2 indicate that the report of the event submitted to the Department shall include the full impact of the event on the patient or resident. The rules at N.J.A.C. 8:43E-10.6(l)1 indicate that the root cause analysis (RCA) of the event must include the adverse outcome for the patient or resident.

3) The rules at N.J.A.C. 8:43E-10.9 outline the confidentiality protections afforded by the Patient Safety reporting process.

4) The Centers for Disease Control (https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a1.htm) and the United States Department of Health and Human Services provide guidance (45 CFR 164.500 et seq.) permitting the sharing of protected health information (PHI) for the purpose of "Health care operations" that include, "Conducting quality assessment and improvement activities."

"General Provisions at 45 CFR 164.506. A covered entity may, without the individual's authorization:

- A covered entity may disclose protected health information to another covered entity for certain health care operation activities of the entity that receives the information if:
    - Each entity either has or had a relationship with the individual who is the subject of the information, and the protected health information pertains to the relationship; and
    - The disclosure is for a quality-related health care operations activity (i.e., the activities listed in paragraphs (1) and (2) of the definition of "health care operations" at 45 CFR 164.501) or for the purpose of health care fraud and abuse detection or compliance."

The NJ Department of Health supports the confidential disclosure of health information to the facility which has or had a relationship with the individual who is the subject of the information, and the protected health information pertains to that relationship, and the disclosure is for a quality-related health care operations activity (such as an adverse event report or root cause analysis).

The Department believes such sharing of confidential information upholds the goals of the Patient Safety Act and regulations. Thank you for your anticipated cooperation and commitment to Patient Safety.

If you have further questions, please contact the New Jersey Patient Safety Reporting System (PSRS) at 609-633-7759.

c. Jianping Huang, Director, Health Care Quality Assessment

Michael Kennedy, Executive Director, Certificate of Need and Health Facilities Licensing