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Draft Hospital Licensure Requirements Mandate Reporting of 24 Serious Events

Since late 2008, the Virginia Department of Health, Office of Licensure and Certification (“OLC”) has been working with an advisory group of healthcare industry stakeholders to review and revise the licensure regulations for inpatient hospitals in Virginia. This is the first time the licensure requirements have undergone a comprehensive revision since they were first promulgated. Therefore, the new regulations will have a significant impact on Virginia hospitals.

An initial “exposure draft” of the new licensure regulations was released at the beginning of this month by the OLC for review and comment by Virginia’s hospitals and health systems.¹ Hospitals and health systems are encouraged to review the draft regulations. While the draft licensure requirements are more up-to-date and consistent with today’s industry standards than the licensure requirements currently in effect, the draft regulations pose several concerns for hospitals.

I. Serious Reportable Events

The proposed licensure regulation that generates the greatest concern among hospitals requires hospitals to

make written reports to the OLC of the following list of “serious reportable events”:

1. Unanticipated deaths or premature loss of a major function, not related to the natural course of a patient’s illness or underlying condition, including but not limited to:
 - a. Brain injury;
 - b. Any permanent paralysis;
 - c. Loss of limb or organ;
 - d. Birth injury;
 - e. Impairment of sight or hearing;
2. A patient death or serious disability or injury associated with:
 - a. The use of contaminated drugs, devices or biologics;
 - b. The use or function of a device in patient care in which the device is used or functions other than as expected;
 - c. Intravascular air embolism;
 - d. A fall;
 - e. An electric shock; or
 - f. The use of restraints or bedrails
3. Surgery performed on the wrong patient or wrong body part or the wrong surgical procedure performed;
4. Unintended retention of a foreign

¹ The exposure draft may be accessed online at www.vdh.virginia.gov/OLC/regulatoryproject.htm (Click on “Exposure Draft of the Regulations for the Licensure of Hospitals in Virginia”).



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object in a patient after surgery or other procedure;

5. Subjecting a patient to a procedure or treatment not ordered or intended by the patient's physician, excluding procedures not requiring a physician's order and collection of specimens for laboratory study obtained by non-invasive means or routine phlebotomy;

6. Medication errors that result in injury, disability or death;

7. A patient suicide while admitted to the hospital;

8. An abduction of a patient of any age;

9. A maternal death or serious disability associated with labor or delivery in a low-risk pregnancy;

10. A death or serious disability associated with failure to identify and treat hyperbilirubinemia in neonates;

11. An infant discharged to the wrong family;

12. Artificial insemination with the wrong donor sperm or donor egg;

13. A stage 3 or 4 pressure ulcer acquired after admission to the hospital;

14. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;

15. Poisoning involving patients;

16. Sexual assault or rape of a patient or staff member while in the hospital;

17. A death or significant injury of a patient or staff member resulting

from a physical assault that occurs within or on the hospital grounds;

18. A hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities;

19. Elopements from inpatient psychiatric units or elopements by minors who are inpatients; elopements of psychiatric patients from outpatient or emergency departments thought to be a danger to themselves or others;

20. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist or other licensed healthcare practitioner;

21. A major malfunction of a facility system such as heating, ventilation, electrical, electronic information management, or a water supply that affects patient care or services within the hospital, including any unanticipated interruption in power to a facility, as well as any event that triggers the use of the back-up generator for more than 6 hours;

22. A fire or internal disaster that disrupts patient care services or causes harm to patients and staff;

23. Personnel actions that disrupts normal patient care and services; and

24. Any other incident reported to the malpractice insurance carrier or self-insurance program or in compliance with the federal Safe Medical Devices Act of 1990.

Although hospitals are currently required to disclose certain incidents to other state and federal regulatory agencies, hospitals are not required to report the above listed incidents to the OLC under the current licensure requirements. Many of the above



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listed reportable incidents are overly broad. Not only will compliance with the new requirement result in increased costs and administrative burdens, it will also subject hospitals to heightened public scrutiny and increased liability exposure. Although the draft regulations expressly state that “records that are confidential under federal or state law shall be maintained as confidential by the OLC and shall not be further disclosed except as permitted by law,” this statement provides little protection to the hospitals. Many of the items listed above are not required to be maintained as confidential under state or federal law.

II. New Licensure Requirements for Freestanding Patient Care Services, Critical Access Hospitals and Long Term Acute Care Hospitals

Other draft licensure regulations may generate additional concern among hospitals, particularly those imposing new licensure requirements for off-campus hospital departments (referred to as “freestanding patient care services”), Critical Access Hospitals and Long Term Acute Care Hospitals. Such provisions appear to summarize the OLC’s previously unwritten policies and other existing regulations (e.g., Medicare requirements) governing these types of facilities. But the draft regulations require additional clarification at this time.

III. Opportunities for Comment

The OLC has requested written comments on the exposure draft by 5:00 p.m. on August 24, 2009. The OLC will consider comments received on the exposure draft as it develops proposed regulations for presentation to the Board of Health for approval in October 2009. Once the Board approves the regulations, the regulations will be subject to the

formal regulatory process, which includes a 60-day comment period on the proposed regulations.

Although there will be another opportunity to comment on the proposed licensure requirements during the formal regulatory process, HDJN encourages its clients to participate in the informal commenting process now. Active participation in the regulatory process at this early stage will enhance hospitals’ ability to influence the development of these important licensure regulations.

For more information about the OLC’s new licensure requirements for inpatient hospitals, please contact Emily Towey at 804-967-9604, or by e-mail at etowey@hdjn.com. Additional information about Hancock, Daniel, Johnson & Nagle, PC is available on the firm’s website at www.hdjn.com



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