



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
99 Chauncy Street, 11th Floor, Boston, MA 02111
617-753-8000

DEVAL L. PATRICK
GOVERNOR

TIMOTHY P. MURRAY
LIEUTENANT GOVERNOR

JUDYANN BIGBY, MD
SECRETARY

JOHN AUERBACH
COMMISSIONER

CIRCULAR LETTER: DHCQ 10-01-527

TO: Chief Executive Officer
Ambulatory Surgical Centers

FROM: Alice Bonner, PhD, RN
Director, Bureau of Healthcare Safety and Quality

DATE: January 25, 2010

RE: Ambulatory Surgical Centers Reporting Requirements
1. Healthcare Associated Infections Reporting Requirements
2. Personnel Immunizations

1. Healthcare Associated Infections

The purpose of this letter is to inform freestanding ambulatory surgical centers (ASCs) of the requirements for the collection and reporting of selected healthcare associated infection (HAI) data pursuant to Clinic Licensure regulations at 105 CMR 140.309. The relevant part of the regulation states that:

(B) HAI Reporting by Ambulatory Surgery Centers

(1) No later than June 1, 2010 each ASC shall:

(a) register with the National Healthcare Safety Net (NHSN); and

(b) grant access to the Department and the Betsy Lehman Center (BLC), in accordance with guidelines of the Department, to:

1. healthcare-associated infection data elements reportable to the NHSN; and

2. clinic-specific reports generated by the NHSN.

(2) Each ASC shall collect and submit to the National Healthcare Safety Net (NHSN) and then grant access as provided under 105 CMR 140.309 (B) to the Department and the Betsy Lehman Center to healthcare associated infection data elements.

(3) Each ASC shall collect and submit to the Department and the Betsy Lehman Center other data related to infection control, including process measures, in accordance with guidelines of the Department.

See full text in Attachment 1.

As noted above, the regulation requires that ASCs enroll in NHSN as the platform for data submission and reporting. However, NHSN does not currently have a module dedicated to ASCs. Until such time as one is developed, ASCs will use the module developed for hospitals to collect surgical site infection (SSI) data. Because the procedures listed in this module are primarily for hospital in-patient surgeries, the Department has identified one reportable HAI which is applicable to ASCs.

As of June 1, 2010, only ASCs that perform herniorrhaphies* will be required to enroll in NHSN and report herniorrhaphy-related SSIs to the Department. See Attachment 3 for the ICD-9 codes. All other ASCs are exempt from the June, 2010 reporting requirement for the time being. Exempt ASCs will be required to enroll and report when NHSN offers a specific ASC module or expands their current list of procedures and/or the Department issues further guidelines.

The Department will distribute detailed instructions on the procedures to the person designated as responsible for infection prevention and control for NHSN enrollment including documentation of data definitions, reporting process, granting access to the Department and entering Massachusetts race and ethnicity codes. The instructions will provide an explanation of the NHSN training requirements for those administering and using the system. The Department and the Betsy Lehman Center for Patient Safety and Medical Error Reduction will be offering training to assist with implementation. Dates and details will be announced. The Centers for Disease Control is available for consultation during and after enrollment. Additional information on NHSN can be found on their home page at www.cdc.gov/dhqp/nhsn/html.

As ASCs begin to prepare for implementation of the regulation, they should consider how to best identify cases of SSIs. Since most patients schedule their follow-up visits with a surgeon's private office, ASCs face challenges in tracking SSIs. The Department recommends that ASCs consider reviewing their existing surveillance systems to assess its effectiveness in capturing herniorrhaphy-related SSIs.

In order to have more information on ASCs, the Department requests that all ASCs provide the following:

1. Name of facility
2. Address
3. Name of person responsible for infection prevention and control
4. Email for that person
5. Phone number for that person
6. Whether or not your facility performs herniorrhaphies
7. If your facility performs herniorrhaphies, please provide the total number performed in 2009 using the ICD-9 codes referenced in Attachment 3.

Please send this information to Roberta Bernstein at roberta.bernstein@state.ma.us or fax 617-753-8125 by February 8, 2010. If you would prefer, you can use the form in Attachment 4.

2. Personnel Immunizations

In addition to 105 CMR 140.309, all ASCs shall collect and report influenza immunizations of personnel pursuant to 105 CMR 140.150. The regulation requires that clinics "ensure that all personnel are vaccinated with seasonal influenza vaccine . . . and vaccinated against pandemic or novel influenza virus(es) . . ." For 2009-2010, clinics are not required to report data to the Department. ASCs will be required to submit the numbers of personnel vaccinated for the 2010-2011 season. Further instructions will be issued prior to the 2010-2011 season. See Appendix 2 for the full text of the regulation.

If you have any questions, please contact Roberta Bernstein at roberta.bernstein@state.ma.us, or Eileen McHale at eileen.mchale@state.ma.us, 617-753-7324.

Thank you for your cooperation.

*The definition of a herniorrhaphy used by NHSN is: repair of inguinal, femoral, umbilical or anterior abdominal wall hernia; does not include repair of diaphragmatic or hiatal hernias or hernias at other body sites.

Attachment 1
Ambulatory Surgical Center HAI Regulation

140.309: Ambulatory Surgery Center Healthcare-associated Infection Data Collection, Submission and Reporting

(A) Definitions.

Betsy Lehman Center means the Betsy Lehman Center for Patient Safety and Medical Error Reduction established pursuant to M.G.L. c. 6A, § 16E.

Healthcare-associated Infection (HAI), means a localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that:

- (1) occurs in a patient in an ambulatory surgery center (ASC); and
- (2) was not present or incubating at the time of the admission during which the reaction occurs; and
- (3) meets the criteria for a specific infection site as defined by the federal Centers for Disease Control and Prevention and its National Healthcare Safety Network.

National Healthcare Safety Network (NHSN) means the data collection network operated by the federal Centers for Disease Control and Prevention.

(B) HAI Reporting by Ambulatory Surgery Centers.

(1) No later than June 1, 2010 each ASC shall:

- (a) register with the NHSN; and
- (b) grant access to the Department and the Betsy Lehman Center, in accordance with guidelines of the Department, to:
 1. healthcare-associated infection data elements reportable to the NHSN; and
 2. clinic-specific reports generated by the NHSN.

(2) Each ASC shall collect and submit to the NHSN, and then grant access as provided under 105 CMR 140.309(B) to the Department and the Betsy Lehman Center to healthcare-associated infection data elements.

(3) Each ASC shall collect and submit to the Department and the Betsy Lehman Center other data related to infection control, including process measures, in accordance with guidelines of the Department.

Attachment 2
Ambulatory Surgical Center Influenza Vaccination Requirement

140.150: Requirement That Personnel Be Vaccinated Against Influenza Virus

(A) Definitions

(1) For purposes of 105 CMR 140.150, "personnel" means an individual or individuals employed by or affiliated with the clinic, whether directly, by contract with another entity, or as an independent contractor, paid or unpaid, including but not limited to employees, members of the clinical staff, contract employees or staff, students, and volunteers who either work at or come to the licensed clinic site, whether or not such individual(s) provides direct patient care.

(2) For purposes of 105 CMR 140.150, the requirement for "influenza vaccine" or "vaccination" means immunization by either influenza vaccine, inactivated or live; attenuated influenza vaccine including seasonal influenza vaccine pursuant to 105 CMR 140.150(B); and/or other influenza vaccine pursuant to 105 CMR 140.150(C).

(B) Each clinic shall ensure that all personnel are vaccinated with seasonal influenza vaccine unless an individual declines vaccination in accordance with 105 CMR 140.150(F). When feasible, and consistent with any guidelines of the Commissioner of Public Health or his/her designee, each clinic shall ensure that all personnel are vaccinated with seasonal influenza vaccine no later than December 15, 2009 and annually thereafter.

(C) Each clinic also shall ensure that all personnel are vaccinated against other pandemic or novel influenza virus(es) as specified in guidelines of the Commissioner or his/her designee, unless an individual declines vaccination in accordance with 105 CMR 140.150(F). Such guidelines may specify:

- (1) the categories of personnel that shall be vaccinated and the order of priority of vaccination of personnel, with priority for personnel with responsibility for direct patient care;
- (2) the influenza vaccine(s) to be administered;
- (3) the dates by which personnel must be vaccinated; and
- (4) any required reporting and data collection relating to the personnel vaccination requirement of 105 CMR 140.150(C).

(D) Each clinic shall provide all personnel with information about the risks and benefits of influenza vaccine.

(E) Each clinic shall notify all personnel of the influenza vaccination requirements of 105 CMR 140.150 and shall, at no cost to any personnel, provide or arrange for vaccination of all employees who cannot provide proof of current immunization against influenza, as required pursuant to 105 CMR 140.150(B) and (C), unless an individual declines vaccination in accordance with 105 CMR 140.150(F).

(F) Exceptions.

- (1) A clinic shall not require an individual to receive an influenza vaccine pursuant to 105 CMR 140.150(B) or (C) if:
 - (a) the vaccine is medically contraindicated, which means that administration of influenza vaccine to that individual would likely be detrimental to the individual's health;
 - (b) vaccination is against the individual's religious beliefs; or
 - (c) the individual declines the vaccine.

(2) An individual who declines vaccination for any reason shall sign a statement declining vaccination and certifying that he or she received information about the risks and benefits of influenza vaccine.

(G) Unavailability of Vaccine. A clinic shall not be required to provide or arrange for influenza vaccination during such times that the vaccine is unavailable for purchase, shipment, or administration by a third party, or when complying with an order of the Commissioner which restricts the use of the vaccine. A clinic shall obtain and administer influenza vaccine in accordance with 105 CMR 140.150 as soon as vaccine becomes available.

(H) Documentation.

(1) A clinic shall require and maintain for each individual proof of current vaccination against influenza virus pursuant to 105 CMR 140.150(B) and (C) or the individual's declination statement pursuant to 105 CMR 140.150(F).

(2) Each clinic shall maintain a central system to track the vaccination status of all personnel.

(3) If a clinic is unable to provide or arrange for influenza vaccination for any individual, it shall document the reasons such vaccination could not be provided or arranged for.

(I) Reporting and Data Collection.

Each clinic shall report information to the Department documenting the clinic's compliance with the personnel vaccination requirements of 105 CMR 140.150, in accordance with reporting and data collection guidelines of the Commissioner or his/her designee.

Attachment 3
List of Herniorrhaphy ICD-9-CM Codes*

NHSN Code	Operative Procedure	Description	ICD-9-CM Codes
HER	Herniorrhaphy	Repair of inguinal, femoral, umbilical, or anterior abdominal wall hernia; does not include repair of diaphragmatic or hiatal hernia or hernias at other body sites.	17.11-17.13, 17.21-17.24, 53.0053.05, 53.10-53.17, 53.21, 53.29, 53.31, 53.39, 53.41-54.43, 53.49, 53.51, 53.59, 53.61

Attachment 4
Contact Information – All ASCs

1. Name of facility

2. Address

2. Name of person responsible for infection prevention and control

3. Email for that person

4. Phone number for that person

5. Perform herniorrhaphies

Yes No

7. If you yes, the total number of herniorrhaphies performed in 2009 using the ICD-9 codes referenced in Attachment 3.

Please return to Roberta Bernstein at roberta.bernstein@state.ma.us or fax 617-753-8125.