

Component V: Education

## Module B: Staff Development

## Topic 5: Regulatory

**I. Statement of Purpose**

To provide the learner with an understanding of the multiple regulatory requirements that impact care in the ambulatory setting.

**II. Terminology**

1. HIPAA – Health Insurance Portability and Accountability Act
2. Title X- the only federal grant program involved with providing care for family planning and reproductive health to low income clients
3. VAERS- Vaccine Adverse Event Reporting System
4. National Child Vaccine Injury Act- implemented to ensure adequate supply of vaccines, stabilize costs, and provide a forum for individuals injured by vaccines
5. CLIA- Clinical Laboratory Improvement Amendments
6. CMS – Centers for Medicare and Medicaid Services
7. ADA- Americans with Disabilities Act
8. LEP – Limited English Proficient

**III. Performance Standards:**

1. Discuss applicable regulatory guidelines appropriate to the practice setting and patient population as it relates to medical decision-making, health information privacy and protection of children
2. Describe how the patient's rights in the care setting are incorporated into daily practice
3. Identify what other protections are afforded to individuals who present for care

**IV. References**

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2. Chunta, K.S., and Katrancha, E.D. (2010) Using Problem-Based Learning in Staff Development: Strategies for Teaching Registered Nurses and New Graduate Nurses, *The Journal of Continuing Education in Nursing*, 41(12), 557-564
3. Ervin, N.E. et al, (2006) Environments of Care: A Curriculum Model for Preparing a New Generation of Nurses, *Journal of Nursing Education*, 45(2), 75-80
4. Farrell, G.A., Salmon, P. (2010) Challenging behavior: An action plan for education and training, *Contemporary Nurse*, 34(1), 110-118
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6. Kelly-Thomas, K. J. (1998) Clinical and Nursing Staff Development: Current Competence, Future Focus, (2<sup>nd</sup> Ed), Philadelphia, PA: Lippincott.
7. Laughlin, C.B., (2006) Core Curriculum for Ambulatory Care Nursing, (2<sup>nd</sup> Ed.) Pitman, NJ: AACN.
8. Loughmiller, D. and Godwin, D. (2010) Weaving a web of excellence through staff development and training, *Medical Laboratory Observer*, April, 10-16.

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10. Swan, B.A. (2007) Transitioning from Acute Care To Ambulatory Care, *Nursing Economics*, 25(2), 130-134

### Website

[http://www.medscape.com/viewarticle/547417\\_2](http://www.medscape.com/viewarticle/547417_2): Adult Learning Principles

<http://www.ci.newark.nj.us/userimages/downloads/Pat%20Bill%20of%20Rights.pdf>

Content Outline Theory Objectives	Suggested Learning Activities/Evaluation
<p><b>Objective 1</b>  <b>Discuss applicable regulatory guidelines appropriate to the practice setting and patient population as it relates to medical decision-making, health information privacy and protection of children</b></p> <p>A. Regulatory Requirements</p> <ol style="list-style-type: none"> <li>1. Regulations that Protect Patient Privacy               <ol style="list-style-type: none"> <li>a. HIPAA: The Health Insurance Portability and Accountability Act of 1996 provides protection for individuals whose private health information is held by covered entities.</li> <li>b. Outlines the safeguards that must be in place to protect this information from inappropriate disclosure.</li> </ol> </li> <li>2. Regulations that Impact Medical Decision-Making               <ol style="list-style-type: none"> <li>a. Two documents allow an individual to put in writing their desire for medical care                   <ol style="list-style-type: none"> <li>1) Medical Durable Power of Attorney: Identifies the individual that you are allowing to make health care decisions for you if you are incapacitated and cannot make them for yourself</li> <li>2) Living Will: Allows you to indicate the type of medical care you do or don't want if you become incapacitated and cannot speak for yourself</li> </ol> </li> </ol> </li> <li>3. Regulations Specific to Children/Emancipated Minors               <ol style="list-style-type: none"> <li>a. Title X and other regulatory statutes that provide guidance for providing care to minors who are presenting for care for pregnancy, sexually transmitted illness, HIV, drug or alcohol abuse, care for a crime-related injury or mental illness without involving their parents in care decisions.</li> <li>b. Supported by the American Academy of Pediatrics. It is important to clearly identify how</li> </ol> </li> </ol>	<p>Discuss appropriate strategies to protect privacy in the ambulatory care setting in providing care to a minor for a sexually transmitted disease. What barriers might exist that could result in a HIPAA violation? What could the consequences of a HIPAA violation in this situation be?</p> <p>Discuss how patient rights for disabled or non-English speaking patients are protected in your organization. What additional strategies could be implemented for these individuals to improve the care provided to them?</p> <p>Read the section on Regulatory Compliance and Patient Safety in the Core Curriculum for Ambulatory Care Nursing</p> <p>Discuss appropriate strategies to protect the privacy of a minor receiving care for a sexually transmitted disease. What barriers might exist that could result in a HIPAA violation? What could be the consequences of a HIPAA violation in this situation?</p>

<p>care is delivered to minors so that patient privacy is maintained.</p> <p>B. Regulations in Mandated Reporting</p> <ol style="list-style-type: none"> <li>1. Abuse situations <ol style="list-style-type: none"> <li>a. The California Child Abuse Reporting Law is found in Penal Code Sections 11165 – 11174.3.</li> <li>b. Outlines those individuals who are required to report a situation</li> <li>c. The definition for abuse.</li> </ol> </li> <li>2. Disease Reporting <ol style="list-style-type: none"> <li>a. Diseases considered to be of great public concern are mandated to be reported</li> <li>b. To the US Centers for Disease Control and Prevention</li> <li>c. Requirement of all medical providers</li> <li>d. The state has a list of diseases to be reported</li> <li>e. Also needs to be reported to the Centers for Disease Control and Prevention</li> </ol> </li> <li>3. Vaccine Injury <ol style="list-style-type: none"> <li>a. The National Childhood Vaccine Injury Act was enacted in 1986 to stabilize vaccine costs, provide for vaccine accessibility and compensate individuals who are injured by vaccines</li> <li>b. US Department of Health and Human Services, the Department of Justice and US Court of Federal Claims</li> <li>c. Claims for compensation are not litigated in civil court but are heard by US Federal Claims Court <ol style="list-style-type: none"> <li>1) Decides who will be compensated</li> <li>2) Monies are paid through the Vaccine Compensation Trust Fund</li> </ol> </li> <li>d. Vaccine Adverse Event Reporting System (VAERS)</li> <li>e. Vaccine Injury Compensation Program (VICP)</li> </ol> </li> </ol> <p>C. Regulations involving Laboratory/Point of Care Testing</p> <ol style="list-style-type: none"> <li>1. CMS regulates all laboratory testing performed on humans, excluding research <ol style="list-style-type: none"> <li>a. Goal is to ensure excellent laboratory testing</li> <li>b. CLIA (Clinical Laboratory Improvement Amendments) regulates all laboratory testing as well as any waive testing done in the ambulatory care setting</li> </ol> </li> </ol> <p>D. Legal Issues for Ambulatory Care Nursing</p> <ol style="list-style-type: none"> <li>1. Similar to acute care setting with the exception of telehealth</li> <li>2. Documentation is necessary to outline the</li> </ol>	
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<p>communication between the patient and the healthcare provider whether that communication occurred in the clinical setting or over the telephone</p> <ol style="list-style-type: none"> <li>a. Telehealth nursing: Telehealth nursing allows access to care at distance but requires the same level of documentation as care provided in the clinical setting.</li> </ol> <p>E. Error Reporting</p> <ol style="list-style-type: none"> <li>1. Report errors in care and adverse patient outcomes, (unrelated to those events related to vaccines which are reported through another mechanism)</li> <li>2. Through the appropriate route and to the correct regulatory agency</li> <li>3. Includes reporting an unsafe process or situation before it causes patient harm             <ol style="list-style-type: none"> <li>a. Incident Reports</li> <li>b. Near Miss Error Reporting (see website in references for citation)</li> </ol> </li> </ol>	
<p><b>Objective 2</b>  <b>Describe how the patient's rights in the care setting are incorporated into daily practice</b></p> <p>A. Patient Rights</p> <ol style="list-style-type: none"> <li>1. Patient Bill of Rights: Patients who receive care in the ambulatory care setting have the following rights:             <ol style="list-style-type: none"> <li>a. The right to know of the Patient Rights document</li> <li>b. The right to know the type of care provided and the name of the individuals providing that care, including the cost of the care</li> <li>c. The right to know if anyone from an educational institution is providing care to them as well as the right to refuse their participation</li> <li>d. The right to have their medical condition explained to them in an understandable way</li> <li>e. The right to participate in their plan of care, including refusal of treatment</li> <li>f. The right to participate in research or refuse to participate</li> <li>g. The right to voice grievances and make recommendations for improvement</li> <li>h. The right to be free of physical or mental abuse or coercion</li> <li>i. The right to have their private health information protected to the extent identified by the individual unless required by law</li> <li>j. To be treated with courtesy</li> <li>k. To not be required to work at the ambulatory care</li> </ol> </li> </ol>	<p>Discuss how the patient rights for disabled or non-English speaking patients are protected in your organization. What additional strategies could be implemented for these individuals to improve the care provided to them?</p> <p>Read the section on Regulatory Compliance and Patient Safety in the Core Curriculum for Ambulatory Care Nursing</p>

<p>setting unless it is part of the patient's treatment and is performed voluntarily</p> <ol style="list-style-type: none"> <li>l. To not be denied civil or religious liberties, including the right to independent personal decisions</li> <li>m. To not be discriminated against for race, religion, age, nationality or ability to pay</li> </ol>	
<p><b>Objective 3</b>  <b>Identify what other protections are afforded individuals who present for care</b></p> <p>A. Additional Patient Protections:</p> <ol style="list-style-type: none"> <li>1. Americans with Disabilities Act: prohibits discrimination of individuals with disabilities, and includes discrimination in employment, access to goods, facilities and public accommodation</li> <li>2. Physicians' offices are considered facilities of public accommodation</li> <li>3. Auxiliary aids must be provided</li> <li>4. Individuals with HIV are also regarded as disabled under the ADA legislation</li> </ol> <p>B. Translation Services</p> <ol style="list-style-type: none"> <li>1. 17% of individuals speak a language other than English at home. It is important that these LEP (limited English proficient) individuals are able to communicate with their healthcare providers</li> <li>2. Organizations which receive federal funds are required to assess the language needs of their clients and to provide appropriate access to such services as necessary to support communication between the client and their healthcare provider</li> <li>3. This protection of civil rights is supported by the Department of Justice and the Department of Health and Human Services</li> </ol> <p>C. Regulatory agencies oversee scope of practice and continuing competency</p> <ol style="list-style-type: none"> <li>1. Medical Assistants: Much of the care provided in the ambulatory care setting is accomplished by Medical Assistants. The scope of practice for these individuals is outlined by the State. Certification is available and requires continuing education for re-certification</li> <li>2. Physicians, Nurses and Midlevel Providers <ol style="list-style-type: none"> <li>a. Physicians in the ambulatory care environment oversee the practice of nurse practitioners and other mid-level providers, like physician assistants</li> <li>b. Individuals work under protocols for care that have been developed collaboratively</li> </ol> </li> </ol>	

<ul style="list-style-type: none"> <li>c. Regulations for licensure and scope of practice are not different in the ambulatory setting as it is in the acute care environment</li> <li>3. Registered Nurses and Licensed Practical Nurses: The Board of Registered Nursing oversees the practice and licensure of nurses in the ambulatory care setting. <ul style="list-style-type: none"> <li>a. Scope of practice remains the same as in the acute care environment, unless the nurse is working under a standardized protocol that has met the requirements of the State Board</li> </ul> </li> <li>D. Other Regulatory Agencies <ul style="list-style-type: none"> <li>1. NCQA: National Committee for Quality Assurance: not-for-profit independent organization that provides public reports on the quality of health plans, health care providers and individual physicians</li> <li>2. AAAHC: Accreditation Association for Ambulatory Health Care: private non-profit agency that offers voluntary, peer-based review of services in ambulatory care. Accreditation is available, however, the findings on a care setting are not provided to the public</li> <li>3. Joint Commission is an independent, not-for-profit organization that evaluates health care organizations in the US and offers accreditation for compliance to their standards. Standards that apply to ambulatory care include <ul style="list-style-type: none"> <li>a. Patient rights to be involved in the care decisions</li> <li>b. Rights to informed consent</li> <li>c. Respect for patient wishes in end of life decisions</li> <li>d. Rights to pain management</li> <li>e. Appropriate assessment prior to undergoing invasive procedures or moderate or deep sedation</li> <li>f. Policies for carrying out waived testing</li> <li>g. Infection control surveillance consistent with CDC guidelines</li> <li>h. Data collection for performance improvement</li> <li>i. Identification and management of sentinel events</li> <li>j. Appropriate storage of medications</li> <li>k. Appropriate oversight for patient safety utilizing clinical guidelines</li> <li>l. Organization providing safety in all areas of the patient setting</li> <li>m. Maintaining and protecting patient's private health information</li> <li>n. Program for orientation and ongoing competency of staff</li> </ul> </li> </ul> </li> </ul>	
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