DISCLAIMER
Regulatory Compliance Overview I provides a generic overview of regulatory compliance. This seminar does not alter or determine compliance responsibilities. Because interpretations and enforcement policy may change over time, we encourage you to routinely check all relevant regulatory agencies directly for the latest updates for clinical and/or organizational guidelines. If you have concerns about any aspect of the safety or quality of patient care in your organization, be aware that you may report these concerns directly to the appropriate Regulatory Agency.

DEFINITIONS
- Antibody ~ protein produced by immune cells to fight infection
- Breach ~ failure to do something that was promised
- CDC ~ Centers for Disease Control and Prevention
- CMS ~ Centers for Medicare and Medicaid Services
- Cohort ~ to group together patients with the same active infection, but no other infection
- Electrically Conductive Loop ~ complete circuit through which electricity is able to flow
- Ferromagnetic ~ able to be attracted by a magnet
- HBV ~ Hepatitis B Virus
- HCV ~ Hepatitis C Virus
- HIV ~ Human Immunodeficiency Virus; the cause of AIDS
- JCAHO ~ Joint Commission on the Accreditation of Healthcare Organizations
- LIP ~ Licensed Independent Practitioner; most often a physician, but also sometimes a nurse practitioner or other healthcare professional
- MRI ~ Magnetic Resonance Imaging
- MRSA ~ Methicillin-Resistant Staphylococcus Aureus
- NIOSH ~ National Institute of Occupational Safety and Health
- OIG ~ Office of the Inspector General of the Department of Health and Human Services (DHHS)
- OSHA ~ Occupational Safety and Health Administration
- PRN ~ as needed
- Projectile ~ an object as a weapon that is thrown, sent, or cast forward
- Pulsed Radiofrequency Fields ~ electromagnetic fields used during MRI to cause tissues of the body to give off magnetic resonance signals
- Restraint ~ any physical or chemical method for restricting a patient's movement, activity, or normal access to his or her own body
- Seclusion ~ involuntary confinement of a patient in a room alone
- TB ~ Tuberculosis
- Type I Latex Allergy ~ a relatively severe form of latex allergy
- Type IV Latex Allergy ~ a relatively minor form of latex allergy
- UTI ~ Urinary Tract Infection
- VRE ~ Vancomycin-Resistant Enterococci

LESSON 1 ~ INTRODUCTION
LEARNING OBJECTIVES
This course provides essential information for veteran clinical healthcare staff. If you are new to any of the topics presented here, consider taking the full-length course on that topic. This lesson will review and update knowledge of:
- Compliance and Ethics
- Patient Rights
- Patient Care and Protection
LESSON 2 ~ COMPLIANCE AND ETHICS

LEARNING OBJECTIVES
This lesson covers:
- Corporate Compliance
- Medical Ethics
- Sexual Harassment

CORPORATE COMPLIANCE
- **Applicable Laws and Regulations** ~ Corporate compliance means following business laws and regulations. Laws and regulations for healthcare are:
  - **Medicare Regulations**: Any facility that participates in Medicare must follow Medicare regulations. For example, facilities must:
    - Meet standards for quality of care
    - Not bill Medicare for unnecessary items or services
    - Not bill Medicare for costs or charges that are significantly higher than the usual cost or charge
    - Follow other rules for claims and billing
  - **False Claims Act**: The False Claims Act makes it illegal to submit a falsified bill to a government agency. This applies to healthcare because Medicare is a government agency.
  - **Stark Act**: The Ethics in Patient Referrals Act (EPRA) is commonly known as the Stark Act. This Act makes it illegal for physicians to refer patients to facilities or providers:
    - If the physician has a financial relationship with the facility or provider
    - If the physician's immediate family has a financial relationship with the facility or provider
    - Note: This law does not apply in certain cases.
  - **Anti-Kickback Statute**: The Medicare and Medicaid Patient Protection Act of 1987 is commonly referred to as the Anti-Kickback Statute (AKBS). This act makes it illegal to give or take kickbacks, bribes, or rebates for items or services that will be paid for by a government healthcare program.
  - **Sections of the Social Security Act**: The Social Security Act makes it illegal for hospitals to:
    - Knowingly pay physicians to encourage them to limit services to Medicare or Medicaid patients.
    - Offer gifts to Medicare or Medicaid patients to get their business.
  - **Mail and Wire Fraud Statutes**: Mail and wire fraud statutes make it illegal to use the U.S. Mail or electronic communication as part of a fraud.
  - **EMTALA**: The Emergency Medical Treatment and Active Labor Act (EMTALA) is commonly known as the Patient Anti-Dumping Statute. This statute requires Medicare hospitals to provide emergency services to all patients, whether or not the patient can pay.
  - **HIPAA**: HIPAA is the Health Insurance Portability and Accountability Act. This act requires healthcare businesses to follow standards for:
    - How to perform electronic transactions
    - Security of health information
    - Privacy of health information
    - Identifiers for employers
Potential Consequences of Non-compliance

When a provider is convicted of breaking any of the laws described on the previous screens, penalties can include:
- Criminal fines
- Civil damages
- Jail time
- Exclusion from Medicare or other government programs.

In addition, a conviction can lead to serious public relations harm.

Compliance Program

To help prevent misconduct, healthcare facilities have corporate compliance programs. A good compliance program reduces the risk of error or fraud. It does so by giving guidelines for how to do your job in an ethical and legal way. A copy of your facility's compliance program should be readily available to you. Ask your supervisor for more information.

Medical Ethics

Four Guiding Principles

The four basic concepts of medical ethics are:
- **Beneficence**: Beneficence means that healthcare providers have a duty to:
  - Promote good.
  - Act in the best interests of their patients.
  - Act in the best interest of society as a whole.
- **Non-maleficence**: Non-maleficence means that healthcare providers have a duty to:
  - Do no harm to their patients.
  - Do no harm to society.
- **Respect for Patient Autonomy**: This principle means that healthcare providers have a duty to protect the patient’s ability to make informed decisions about his or her own medical care.
- **Justice**: Justice means that healthcare providers have a duty to be fair to the community as a whole. In particular, providers have a duty to protect and promote the fair distribution of healthcare resources.

Ethical Dilemmas

Unfortunately, the four guiding principles sometimes conflict. To address ethical conflicts, you must be able to take into account:
- The guiding principles of medical ethics
- The particular circumstances of each situation.

Current Issues

Some of the important issues in medical ethics today relate to:
- **Patient-Provider Relationship**: Ethics in the patient-provider relationship relate to:
  - Nature of the Relationship
    - Be professional and responsible in the care of patients.
    - Treat patients with compassion and respect.
    - Maintain appropriate boundaries with patients.
  - Finances and Payment
    - Expect to be paid fairly for your services.
    - But remember that your duty to patients comes before money. Providers have an ethical duty to care for patients, whether or not they can pay.
  - Patient Confidentiality ~ Protect the confidentiality of your patients.
  - Disclosure and Informed Consent
    - Fully disclose patient health status and treatment options.
    - This makes it possible for patients to exercise the right to give informed consent or refusal for treatment.
  - Medical Risk
    - Expect your workplace to limit your risk of infection through an infection-control program.
    - It is unethical to refuse to treat a patient because of his or her infectious state.
End-of-Life Care: Ethics in the care of patients near the end of life relate to:

- Palliative Care
  - The goal of palliative care is not to cure the patient. The goal is to provide comfort.
  - Understand the importance of addressing all of the patient's comfort needs near the end of life. This includes psychosocial, spiritual, and physical needs.
  - Stay up-to-date on the legality and ethics of using high-dose opiates for physical pain.
- End-of-Life Decisions
  - Patients have the right to refuse life-sustaining treatment.
  - Respect this right and this decision.
- Withdrawing Life-Sustaining Treatment
  - Withdrawing and withholding life-sustaining treatment are ethically and legally equivalent. Both are ethical and legal when the patient has given informed consent.
  - Be sure to check your facility's policies on withholding and withdrawing life-sustaining treatment.
- Physician-Assisted Suicide and Euthanasia
  - The ethics of assisted suicide and euthanasia are controversial. Both practices are illegal in most states.
  - Do not confuse these practices with 1) a patient's informed decision to refuse life-sustaining treatment, or 2) unintentional shortening of life, as a result of treating pain with high-dose opiates.

Peer Relationships: Ethics around peer relationships include:

- Protect patients from incompetent providers.
- Help colleagues who lack competency or need consultation.
- Request consultation, as needed.
- Work with other providers to optimize patient care.
- Be respectful of one another.
- Discipline colleagues who have engaged in fraud or other misconduct.

Ethics of Practice and Responsibilities to Society: Ethics around responsibilities to society include:

- Advocate for the health and wellbeing of the public.
- Report communicable diseases as required by law.
- Provide the general public with accurate information about healthcare and preventive medicine.
- Work to ensure that all members of the community have access to healthcare.
- Serve as an expert witness when needed, in civil and criminal legal proceedings.

SEXUAL HARASSMENT
Title VII of the Civil Rights Act of 1964 defines sexual harassment. To work toward eliminating sexual harassment in your facility:

- Be aware of the definition of sexual harassment.
- If you are a victim, confront the harasser directly, if you feel able to do so.
- Follow your facility's policies and procedures for reporting harassment.

Summary of Title VII definition of Sexual Harassment:

- Sexual harassment involves sexual advances, requests for sexual favors or other sexual conduct.
- When these actions are unwelcome and affect job status, interfere with work performance or create a hostile work environment.
LESSON 3 ~ PATIENT RIGHTS

LEARNING OBJECTIVES
This lesson addresses:
- Confidentiality
- Patient Participation in Treatment Decisions
- Disclosure and Informed Consent
- Advance Directives
- Access to Emergency Service
- Respect, Safety, and Nondiscrimination
- Grievances

CONFIDENTIALITY
Patients have the right to privacy and confidentiality. Always use a private place for:
- Case discussion and consultation
- Patient examination and treatment

A patient's medical records may be shared with:
- Clinicians directly involved in the patient's case
- Regulatory agencies looking into a facility's quality of care
- Other people with a legal or regulatory right to see the records.

Protected healthcare information should not be shared with ANYONE else. Only authorized employees should have access to areas where medical records are stored.

♦ HIPAA: The HIPPA Privacy Rule is part of HIPAA.
- The Privacy Rule:
  - Sets standards for allowed disclosures of patient information
  - Sets standards for protecting the privacy of patient information
  - Sets severe civil and criminal penalties for people who violate a patient's privacy
- To maintain compliance with HIPAA:
  - Share patient health information only with people who need to know.
  - When there is a need to know, share the minimum amount of information to meet this need.

♦ Necessary Breaches: Patient confidentiality is not absolute.
- A provider may have a duty to breach confidentiality when there is a conflict between:
  - Patient autonomy the right of the patient to control his or her own health information, and
  - Non-malfeasance protecting the patient or others from harm.
- Examples are:
  - A patient threatens serious self-harm or harm to someone else.
  - The patient is a suspected victim of child abuse or neglect.
  - The information relates to a crime.
  - The patient is a healthcare provider, and has a condition that makes him or her a danger to patients.
  - The patient is not fit to drive.
- Before revealing patient information, be sure to check state and local law. Review HIPAA guidelines for allowed disclosures of protected health information. If you decide to go forward with a disclosure:
  - Talk to the patient first. Ask for the patient's consent. Ideally, the patient will consent to the disclosure. If not, it is still okay to reveal the information, if you have determined that it is legal and ethical to do so.
  - Disclose the information in a way that minimizes any harm to the patient.
  - Follow state and federal guidelines for disclosing the information.
PARTICIPATION IN TREATMENT DECISIONS

♦ Disclosure: Patients have the right to:
  ▪ Participate in decisions about their care
  ▪ Set the course of their treatment
  ▪ Refuse treatment

To make informed decisions about treatment, patients must be given full and accurate information.

♦ Informed Consent: Healthcare professionals must discuss all treatment options with their patients. This includes the option of no treatment. For each treatment option, the patient needs to know:
  ▪ Risks
  ▪ Benefits
  ▪ Potential medical consequences

The patient can then give informed consent or refusal for treatment. Note: Minors do not have the right to consent for treatment. Parents must accept or refuse treatment for their minor children.

ADVANCE DIRECTIVES

♦ Patients have the right to make decisions about their care. This is true even when they are no longer able to communicate those decisions. An Advance Directive is a legal document that helps protect this right. There are two types of advance directives:
  ▪ Living will: A living will is a legal document that records which types of medical care a patient does or does not want at the end of life.
  ▪ Durable Power of Attorney for Healthcare: This also may be called a Medical Power of Attorney. It is a legal document that gives a representative the power to make healthcare decisions for the patient.

♦ To help support the patient's right to make healthcare choices:
  ▪ Encourage all patients over the age of 18 to complete one or both types of Advance Directive.
  ▪ Honor the choices expressed in an Advance Directive.

♦ JCAHO requires that accredited hospital must:
  ▪ Have and use consistent policies for advance directives.
  ▪ Give all adults written information about their right to accept or refuse treatment.
  ▪ Provide equal access to care for all patients, whether or not they have an advance directive.
  ▪ Document whether or not each patient has an advance directive.
  ▪ Allow patients to review and revise their advance directives.
  ▪ Make sure that appropriate staff members know about each patient's advance directive.
  ▪ Help patients write advance directives, or refer patients to sources of help, if requested.
  ▪ Allow healthcare professionals to honor advance directives within the limits of the law and the capacities of the hospital.
  ▪ Document and honor patient wishes for organ donation, within the limits of the law and the capacities of the hospital.

ACCESS TO EMERGENCY SERVICES

♦ Prudent Layperson: Patients have the right to emergency medical treatment. However, patients and insurance companies can disagree about the need for emergency care. To solve this problem, insurance companies must use a standard definition for the need for ER services. This definition uses the idea of a “prudent layperson.” Under this definition, a person has need for ER services if he or she has signs or symptoms that a reasonable non-medical person would consider an emergency.

Example: A person has severe chest pains. He thinks he is having a heart attack. He goes to the emergency room. Tests show that the problem is heartburn. The patient's insurance company must reimburse for the emergency services even though the symptoms did not turn
out to be a medical emergency. Why? Because services were provided based on symptoms
that would cause a reasonable person to fear an emergency.

♦ **EMTALA**: Under EMTALA, all hospitals that participate in Medicare must provide emergency
services to all patients, whether or not they can pay. For a hospital to comply with EMTALA:
  ▪ When a patient comes to the emergency department, the hospital must screen for a medical
    emergency.
  ▪ If an emergency medical condition is found, the hospital must provide stabilizing treatment.
  ▪ Patients with emergency medical conditions may not be transferred out of the hospital for
economic reasons.

**RESPECT, SAFETY AND NONDISCRIMINATION**
♦ **Respect**: Patients have the right to respectful care. Respect means valuing the patient's needs,
desires, feelings and ideas. Treat patients with common courtesy. For example:
  ▪ Knock and wait before entering a patient’s room.
  ▪ Respond politely to patients.
  ▪ Listen to patients.
  ▪ Remain compassionate.

♦ **Safety**: Patients have the right to safety and security. Do your part to ensure a safe environment
of care for your patients. Know your facility's policies for environmental safety, infection control
and security.

♦ **Nondiscrimination**: All patients have the right to fair and equal delivery of healthcare services.
This is true regardless of race, ethnicity, national origin, religion, political affiliation, level of
education, place of residence or business, age, gender, marital status, personal appearance,
mental or physical disability, sexual orientation, genetic information, or source of payment.

**GRIEVANCES**
♦ Patients have the right to complain about the quality of their healthcare. Many patient complaints
can be addressed quickly. When complaints cannot be resolved quickly and easily, patients have
the right to file a grievance. A grievance is a formal complaint.

♦ If a patient wants to file a grievance:
  ▪ Explain the grievance process at your facility. This includes the name of the staff person the
    patient should contact.
  ▪ Explain that grievances may be filed with state agencies. This is true whether or not the patient
    has already used the facility's internal grievance process.
  ▪ Give the patient the phone number and address for filing a grievance with the state.

**LESSON 4 ~ PATIENT CARE AND PROTECTION**

**LEARNING OBJECTIVES**
This lesson covers:
  ▪ Developmentally Appropriate Care
  ▪ Cultural Competence
  ▪ Restraint and Seclusion
  ▪ Patient Assault and Abuse in the healthcare setting
  ▪ Victims of Abuse and Neglect

**DEVELOPMENTALLY APPROPRIATE CARE**
  At each stage of life, human beings tend to:
  ▪ Face specific challenges.
  ▪ Reach specific milestones.
Understanding these challenges and milestones helps you provide developmentally appropriate care. Under JCAHO standards, a provider is competent in providing developmentally appropriate care if he or she can:
- Determine a patient's status, taking into account the patient's chronological age.
- Identify a patient's needs, taking into account the patient's chronological and developmental age.
- Provide care appropriate to a patient's age and developmental needs.

**CULTURAL COMPETENCE**

Cultural competence means providing medical care in a way that takes into account each patient's values, beliefs, and practices. Culturally competent care promotes health and healing. Examples of culturally competent care include:
- If a patient values spirituality, find a way to integrate spiritual and medical practices for healing.
- If a family elder must participate in all medical decisions in a patient's culture, be certain to involve the elder in the care of that patient.

**RESTRAINT AND SECLUSION**

♦ **Medical and Surgical**
- Restraint used for medical or surgical reasons must:
  - Help with medical healing, or
  - Help treat medical symptoms.
- Per JCAHO, medical / surgical restraint may be used only:
  - In response to dangerous behavior on the part of the patient, or
  - As a component of planned care or an approved protocol.
- Use of restraint has risks. Therefore, all healthcare facilities should work toward reducing or eliminating use of restraint. Facilities should:
  - Intervene early to avoid later need for restraint.
  - Find alternatives to restraints.
- If medical or surgical restraint must be used, it should be used only with clinical justification. Restraint should NEVER be used for:
  - Disciplinary reasons
  - Convenience
- Restraint may be initiated only upon the order of an LIP. At regular intervals, qualified staff must assess the restrained patient:
  - To evaluate the continued need for restraint
  - To ensure overall physical and mental wellbeing of the patient
- As long as restraint is clinically justified; the LIP must examine the patient at least once a day. The LIP then must renew the original order for restraint or write a new one. Use of restraint must be documented in the medical record.

♦ **Behavioral Healthcare**
- Behavioral healthcare restraint or seclusion is for patients with behavioral or emotional problems. It is used to stop dangerous patient behavior in a crisis situation.
- Behavioral healthcare restraint and seclusion have physical and psychological risks. Therefore, all facilities should work toward preventing, reducing, or eliminating the use of behavioral healthcare restraint and seclusion. For example:
  - Use restraint / seclusion only in crisis situations.
  - Intervene early to prevent the development of a crisis situation.
  - Whenever possible, use non-physical methods to deal with behavioral problems.
  - Release patients from restraint / seclusion as soon as they meet established behavioral criteria.
All staff members involved in the use of behavioral restraint and seclusion must be trained and competent. Training should include techniques for imposing restraint and seclusion in a way that ensures patient safety and dignity. Restraint or seclusion must be ordered by an LIP:
- Orders must be issued on a case-by-case basis.
- Orders must be time-limited.
- PRN orders are NOT acceptable.

After a patient is placed in restraint or seclusion, the patient must be monitored for health and safety continuously. At least every 15 minutes, the patient must be assessed for and assisted with physical / psychological status and needs, as appropriate for the type of restraint / seclusion used.

JCAHO requires that patients restrained or secluded for behavioral healthcare reasons must be reevaluated:
- Every four hours for patients if 18 years of age or older.
- Every two hours for patients ages 9 to 17.
- Every hour for patients under 9 years of age.
  **Note:** your state or your facility may require more frequent evaluations.

The LIP must perform at least every other evaluation. Other qualified staff may perform the non-LIP evaluations. At each evaluation, the LIP or healthcare staff must:
- Help the patient regain control.
- Reevaluate the need for restraint / seclusion.
- Issue a new order for restraint / seclusion (LIP), or consult with the LIP to request a new order (healthcare staff), as needed.

Restraint / seclusion must be documented in the medical record.

**PATIENT ASSAULT AND ABUSE**

♦ Patient abuse by a healthcare provider is a breach of medical ethics. Assault and abuse are also crimes. These crimes are punishable by imprisonment and fines. In some cases, the criminal penalties for assault and battery are especially severe when the victim is a patient.

♦ To help protect your patients from assault:
  - Be aware of the warning signs of abuse.
  - Report suspected abuse immediately.
  - Manage your own stress appropriately.
  - Encourage your facility to include a criminal background check as part of its hiring process.
  - Take note of visitors on your unit.

**VICTIMS OF ABUSE AND NEGLECT**

♦ Patients also may be abused outside the healthcare setting. As a healthcare provider, you are in a unique position to identify victims of abuse.

♦ With regard to victims of abuse and neglect, JCAHO requires that accredited facilities:
  - **Educate:** Facilities must educate staff on the dynamics and signs and symptoms of abuse and neglect.
  - **Identify:** Facilities must establish criteria for identifying victims of assault, abuse, and neglect. These criteria should be used to identify victims at any time during their care.
  - **Assess:** Facilities must assess identified victims of abuse, or refer victims to outside agencies for assessment. If the facility performs abuse assessments, the assessment must preserve or document evidence of abuse, for potential legal proceedings.
  - **Refer:** Facilities must maintain a current list of relevant local agencies and resources, to facilitate referrals for victims.
  - **Report:** Facilities must report abuse and neglect according to state and local law.
<table>
<thead>
<tr>
<th><strong>DOMESTIC VIOLENCE</strong></th>
<th><strong>ELDER ABUSE &amp; NEGLECT</strong></th>
<th><strong>CHILD ABUSE &amp; NEGLECT</strong></th>
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<tr>
<td><strong>Educate</strong> yourself about the dynamics of abuse.</td>
<td>• The victim is an adult or adolescent. In the majority of cases, the victim is a woman.</td>
<td>• Child abuse may be physical, emotional or sexual.</td>
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<td>• The abuser is a person who is, was or wishes to be in an intimate relationship with the victim. In most cases, the abuser is a man.</td>
<td>• Child neglect occurs when a child’s basic needs are not met.</td>
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<td>• The abuse may be physical, sexual and/or psychological. The goal of the abuse is to control the victim.</td>
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<td><strong>Identify</strong> victims of abuse.</td>
<td>• Elders may be abused, neglected or exploited. This mistreatment may be physical, sexual, psychological or financial.</td>
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<td>• The perpetrator may be a family member or other caregiver.</td>
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<td><strong>Assess</strong> victims of abuse or refer for appropriate assessment.</td>
<td>• Children most often do not disclose abuse or neglect.</td>
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<td>• As part of a routine health history, ask adolescent and adult patients direct questions about domestic violence.</td>
<td>• Therefore, know and screen for the signs and symptoms of abuse.</td>
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<td></td>
<td>• Some victims may not disclose abuse. Therefore, know and screen for the signs and symptoms of abuse.</td>
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<td>• To assess a victim of elder abuse or neglect, evaluate the patient’s:</td>
<td>• Evidence of elder abuse should be documented as described for domestic violence.</td>
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<td>* access to healthcare</td>
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<td>* cognitive status</td>
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<td>* overall health and functional status</td>
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<td>* social and financial resources</td>
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<td>• Collect, store and transfer forensic evidence according to state and local evidence protocols.</td>
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<td>When child abuse is suspected:</td>
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<td>* perform a thorough pediatric health assessment</td>
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<td>* interview the parents, caretakers and the child, if possible. Interviews should be separate.</td>
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<td>* collect evidence as described for domestic violence</td>
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</tbody>
</table>
| **Refer** victims of abuse. | • For a list of agencies and resources on elder abuse and neglect see:  
* ElderAbuse.pdf | • For a list of agencies and resources on child abuse and neglect see:  
* ChildAbuse.pdf  
* ChildSexAbuse.pdf |

| **Report** abuse. | • Most states require healthcare providers to report certain cases of domestic violence.  
• Learn the reporting requirements in your state.  
| • Many states require healthcare providers to report known or suspected elder abuse and neglect.  
• Learn the reporting requirements in your state.  
| • All states require healthcare providers to report suspected child abuse and neglect.  
• Learn the laws in your state.  
• Be certain that you understand:  
* what you are required to report  
* how to report  
* protection for mandatory reporters  
* potential penalties for failure to report |