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CLINTON MEMORIAL HOSPITAL

New Provider Orientation

Dear Staff Member:

Greetings and welcome to Clinton Memorial Hospital Regional Health System! On behalf of our hospital and team, I extend a heartfelt welcome to you as a valuable addition to our esteemed group of healthcare professionals.

At CMH, we recognize that healthcare is a collaborative effort, and the dedication of our team plays a pivotal role in positively impacting the lives of both our patients and the Southwest Ohio community. Our overarching vision is to be the healthcare destination of choice in the region, and achieving this goal relies on the recruitment and retention of exemplary healthcare providers such as yourself.

Leading our medical staff is Dr. Rajiv Patel, our Chief of Staff, who guides us in our commitment to delivering high-quality care to every patient, each and every day. Your active involvement in our medical staff will undoubtedly contribute to our collective ability to provide exceptional care to the diverse patient population at CMH.

We are privileged to have a dedicated group of healthcare providers who consistently prioritize the needs of our patients. Your expertise and commitment align seamlessly with our mission, and we are confident that your contributions will further enhance the quality of care we provide.

Please feel free to reach out to me at any time with your ideas, questions, or concerns. I am eager to collaborate with you as we collectively strive to improve the health and well-being of the wonderful people residing in Southwest Ohio.

Once again, welcome aboard! We are excited to have you as a valued member of our healthcare family.

Best regards,

Clinton Memorial Hospital Chief Executive Officer

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Dear Staff Member:

Additional Informative Information:

You can find the Medical Staff Rules and Regulations and the Medical Staff By-Laws and the complete Physician Orientation on the www.cmhregional.com website and click on "About Us" and then click on Provider Resources.

We hope that you find your membership to the medical staff at Clinton Memorial Hospital to be beneficial and welcoming.

If you have questions, please feel free to contact our Medical Staff office at (937) 382-9314

Sincerely,

Medical Staff Services
610 W. Main St.
Wilmington, OH 45177
(937) 382-6633 FAX

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Expectations of Healthcare Providers Granted Privileges at Clinton Memorial Hospital

This document describes the expectations that physicians have of each other as members of our medical staff. The expectations described below reflect current medical staff bylaws, policies and procedures and organizational policies. This document is designed to bring together the most important issues found in those documents and key concepts reflecting our medical staff's culture and vision. While these expectations will provide a guide for the medical staff in selecting measures of physician competency, not every expectation will be directly measured.

Medical staff leaders will work to improve individual and aggregate medical staff performance through non-punitive approaches and providing appropriate positive and constructive feedback that allows each physician the opportunity to grow and develop in his or her capabilities to provide outstanding patient care and valuable contributions to our hospital.

Professionalism: Practitioners are expected to demonstrate behaviors that reflect a commitment to continuous professional development, ethical practice, an understanding and sensitivity to diversity, and a responsible attitude toward their patients, their profession, and society as evidenced by the following:

1. Act in a professional, respectful manner at all times to enhance a spirit of cooperation and mutual respect and trust among members of the patient care team.
2. Address disagreements in a constructive, respectful manner away from patients or other non-involved caregivers.
3. Respond to requests for inpatient consultations in a timely manner by performing the consult or otherwise notifying the referring physician by the procedure indicated in the medical staff rules and regulations.
4. Respond promptly to nursing requests for patient care needs.
5. Participate in emergency room call coverage as determined by the Medical Staff policy.
6. Respond in the spirit of continuous improvement when contacted regarding concerns about patient care.
7. In the spirit of early assistance, help to identify issues affecting the physical and mental health of fellow medical staff members and cooperate with programs designed to provide assistance.
8. Make positive contributions to the medical staff by participating actively in medical staff functions, serving when requested and by responding in a timely manner when input is requested.

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Interpersonal and Communication Skills: Practitioners are expected to demonstrate interpersonal and communication skills that enable them to establish and maintain professional relationships with patients, families, and other members of health care teams as evidenced by the following:

1. Refrain from inappropriate behavior including but not limited to impulsive, disruptive, sexually harassing or disrespectful behavior or documentation in the medical record that does not directly relate to the patient clinical status or plan of care and is derogatory or inflammatory.
2. Communicate effectively with physicians, other caregivers, patients and families to ensure accurate transfer of information through appropriate oral and written methods according to hospital policies.
3. Support the medical staff's efforts to maintain patient satisfaction rates for physicians.
4. Maintain medical records consistent with the medical staff bylaws, rules, regulations and policies including but not limited to chart entry legibility and timely completion of History and Physical examination reports, Operative Reports, procedure notes, appropriate abbreviations and discharge summaries.
5. Request inpatient consultations by providing adequate communication with the consultant including a clear reason for consultation and, for urgent or emergent requests, make direct physician-to-physician contact.

Patient Care: Practitioners are expected to provide patient care that is compassionate, appropriate, and effective for the promotion of health, prevention of illness, treatment of disease and at the end of life as evidenced by the following:

1. Provide for patient comfort, including prompt and effective management of acute and chronic pain according to accepted standards in the medical literature.
2. Discuss end-of-life issues when appropriate to a patient's condition, including advance directives and patient and family support, and honor patient desires.
3. Provide effective patient care that consistently meets or exceeds medical staff or appropriate external standards of care as defined by comparative outcome data, medical literature and results of peer review activities.
4. Assure that each patient is evaluated by a physician as defined in the bylaws, rules and regulations and document findings in the medical record at that time.
5. Cooperate with hospital efforts to implement methods to systematically enhance disease prevention.
6. If applicable, supervise residents, students and allied health professionals to assure patients receive the highest quality of care.

Practice Based Learning and Improvement: Practitioners are expected to be able to use scientific evidence and methods to investigate, evaluate, and improve patient care as evidenced by the following:

1. Review your individual and specialty data for all dimensions of performance and utilize this data to for self improvement to continuously improve patient care.

2. Respond in a constructive manner when contacted regarding concerns about patient care.

3. Use hospital information technology to manage information and access on-line medical information.

4. Facilitate the learning of students, trainees and other health care professionals

5/2010 References

ACGME Board February 13, 2007
CMH Medical Staff Rules and Regulations 3/2006
CMH Medical Staff Bylaws 11/2004
CMH Policies and Procedures and Organizational Policies
The Greeley Company 2010

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EMTALA

The Emergency Medical Treatment and Labor Act (EMTALA) is a federal statute that addresses how hospitals deliver emergency medical services to the public. Known as the "anti-dumping" law, it prohibits a hospital emergency department (ED) from delaying care, refusing treatment, or transferring a patient to another hospital based on the patient's ability to pay for services.

A significant portion of our patients enter the hospital through the emergency department. Anyone with an emergency medical condition is provided a medical screening examination and necessary stabilization. In an emergency situation or if the patient is in active labor, we will not delay the medical screening and necessary stabilizing treatment in order to seek financial and demographic information. We do not admit, discharge or transfer patients with emergency medical conditions simply based on their ability or inability to pay.

Patients with emergency medical conditions will only be transferred to another hospital at the patient's request or if the patient's medical needs cannot be met at the RCCH hospital (*e.g.*, we do not have the capacity or capability) and appropriate care is knowingly available at another hospital. Patients will only be transferred after they have been stabilized within the capabilities and capacity of the transferring hospital, and are formally accepted for treatment at the receiving hospital. Patients are only transferred in strict compliance with state and Federal EMTALA regulatory and statutory requirements.

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- **Cancer Committee** meets the 1st Thursday of each quarter at 1200 in the Cancer Center Community Room
- K. Agarwal, MD- Diagnostic Radiologist
- W. Timperman, MD- Pathologist- Alternate- B. Nestok, MD
- R. Lovano, MD- Surgeon- Alternate- N. Roberts, MD
- J. Hatton, MD- Medical Oncologist
- **R. McClure, MD (Chair)**- Radiation Oncologist
- R. Lovano, MD- Cancer Liaison
- K. Andrews, RN- Cancer Program Administrator
- K. Andrews, RN- Oncology Nurse- Alternate- B. Griffith, RN
- M. Roth, LSW- Social Worker- Alternate- C. Morgan, LSW
- D. Fawley, CTR- Certified Tumor Registar
- J. Schumacher, RN- Quality Representative- Alternate- M. Powell, RN
- A. Pierce, RN- Palliative Care
- L. Zufall, LD- Dietitian
- M. Roth, LSW- Psychiatric/ Mental Health
- D. Fawley, CTR- Cancer Conference Coordinator
- J. Schumacher, RN- Quality Improvement Coordinator
- D. Fawley, CTR- Cancer Registry Quality Coordinator
- J. Reese, CNP- Community Outreach Coordinator
- K. Andrews, RN- Clinical Research Coordinator
- M. Roth, LSW- Psychosocial Services Coordinator

Credentials Committee meets the 4th Friday monthly at 730 a.m. in the board room

- Chairman- Mary Lou Inwood, MD
- Kenneth Vawter, MD
- Michael Clark, MD
- Tom Daskalakis, CEO
- Jamie Hunter, Director of Quality

General Medical Staff Meeting (combined with DOM & DOS meetings) business meeting the 2nd Tuesday of even months at 1800 in CMH conference rooms. All members of the medical staff and Advanced Practice Providers are invited to attend General Medical Staff Meetings.

Medical Staff Quality Improvement Committee meets 4th Wednesday bi-monthly in the board room

- Chairman- Walter Timperman, MD
- Mary Lou Inwood, MD
- Brian Weaver, MD
- David Cohen, MD
- Surmeet Bedi, MD
- Michael Clark, MD

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Performance Improvement

- We participate in and require documentation on the following core measures:
  - Emergency Department
  - Outpatient ED, Stroke, AMI, Chest Pain
  - OP Web Measures- Colons
  - Immunization
  - Stroke
  - Sepsis
  - Venous Thromboembolism
  - Perinatal Care Mom
  - Perinatal Care Baby

- Our goal is to be in the top 10% with all our core measure sets.

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Reduce the Risk of Healthcare Associated Infections

- CDC hand hygiene guidelines are followed. Use soap and running water, rub hands vigorously for 15 seconds, rinse well and dry hands with a paper towel. If hands are not visibly soiled, an alcohol-based foam gel may be used.
- Deaths resulting from healthcare associated infection are treated as a sentinel event. A root cause analysis will be conducted to determine how and why the patient acquired the infection.

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Patient Rights

- Introduce yourself by name to the patient.
- Ask permission to allow students or other approved outsiders to be present while care is being given.
- Obtain informed consent. When a surgical and/or invasive procedure is to be performed, it is the responsibility of the physician performing the procedure to provide information about the procedure to the patient, answer any questions raised by the patient and obtain consent.
- **Physicians must wear a name badge without obstruction to photo, name and title.**

Protect Patient Confidential Information

Be mindful of your surroundings,
and remember that voices can be overheard
when having in-person conversations
AND when using cell phones.

Breaches in patient confidentiality can occur anywhere...

At the Hospital
- Hallways
- Cafeteria
- Elevators
- Nurses' stations
- Break rooms
- Parking lot

In the Community
- Neighborhood events
- Sports games
- Parties
- Stores
- Restaurants
- Church

Quality Mgmt\JCAHO\092016

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CASE MANAGEMENT

- Case Management reviews all patients in the hospital for medical necessity criteria and discharge planning needs.
- Case Managers are available to assist the Physician and staff to coordinate the care of the patient.
- Social workers assist with complex discharge issues and psychosocial needs of the patient and/or family.
- You may reach case management from 7 a.m. to 11 p.m. at extension 9318.

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Fire Safety

If you discover a fire (RACE):

- Remove persons in immediate danger.
- Alarm- pull the fire alarm and call the switchboard operator to give location of the fire.
- Contain the fire by closing doors and windows.
- Extinguish the fire if possible or evacuate.

To Use the fire extinguicher (PASS):

- Pull the pin in the handle.
- Aim the nozzle at the base of the fire.
- Squeeze the handles.
- Sweep back and forth at the base of the fire.

You must call the switchboard in conjunction with pulling the fire alarm and give the location of the fire.

CMH
REGIONAL HEALTH SYSTEM

Sepsis
Severe Sepsis and Septic Shock

Objectives:

- Understand the criteria for Sepsis, Severe Sepsis and Septic Shock
- Understand the treatment for Severe Sepsis by utilizing the CMH Severe Sepsis/Septic Shock Protocol (you may print the protocol for reference)

What is Sepsis?

- Sepsis is a life threatening condition that arises when the body's response to an infection injures its own tissues and organs.

- Sepsis leads to shock, multiple organ failure and death, especially if not recognized early and treated promptly.

How does Sepsis impact our patients?

- Sepsis kills more people each year than Breast Cancer, Colorectal Cancer, Pancreatic Cancer, and Prostate Cancer COMBINED!
- Sepsis has a high mortality in part because the early symptoms are not recognized.
- In 2014 Sepsis accounted for 48% of Acute Care Deaths.

Why has CMS made Severe Sepsis/Septic Shock a core measure?

- All of the measures outlined in our protocol were based on the Surviving Sepsis Campaign and align with measures from the Centers for Medicare and Medicaid Services. (CMS)

- Studies show using a sepsis protocol had decreased mortality.

Why does the Severe Sepsis/Septic Shock core measure matter to me?

- It’s the best care we can give to our patients.
- The results of our care is reported on the Hospital Compare website.
- Future payments from CMS will be based, in part, by our performance on this measure.

Sepsis Criteria:

- Known or Suspected Infection

  (Physician **or** RN documentation)

(Can be confirmed, suspected, or possible)

Examples of RN documentation: "In ED earlier, diagnosed with UTI." "Currently on oral antibiotics for pneumonia."

And

- 2 or more SIRS (Systemic Inflammatory Response Syndrome) criteria, which are:
  Temperature <96.8 **or** >100.9
  Heart Rate >90 bpm
  Respiratory Rate >20/min
  WBC count <4,000 or >12,000 **or** >10% Bands

Severe Sepsis = Sepsis + Acute Organ Dysfunction

- **Acute** Organ Dysfunction is defined by any **ONE** of the following:

Lactate >2mmol/L

INR >1.5 **or** aPTT >60 seconds

Platelet count <100,000

Bilirubin >2mg/dL

Creatinine >2, **or** urine output <0.5 mL/kg/hour for 2 hours

Systolic Blood Pressure (SBP) <90 mmHg, **or** mean arterial pressure < 65 mmHg, **or** decrease in SBP more than 40 mmHg from previously recorded SBP

- **Abnormal lab values from a chronic condition will not meet criteria.**

Septic Shock

- Septic shock = Severe Sepsis with hypotension unresponsive to fluid resuscitation (30ml/kg)

OR

- Lactate >4

Hypotension is defined as:

Systolic blood pressure <90 **or**

Mean Arterial pressure <65 **or**

Decrease of Systolic blood pressure >40 points

Points to Remember:

- This core measure is **all or nothing**, meaning we either provided the best possible care or we did not. No partial credit for doing some of the treatments outlined.

Presentation Time:

- Presentation time is the time the last criteria was met for severe sepsis **or** physician documentation of severe sepsis.
- This will start the clock for our interventions!

Presentation Time Example #1:

- All of the criteria for severe sepsis must be met within 6 hours of each other.

0800 Lactate = 2.3 (organ dysfunction)
So we look back at the previous 6 hours.
0630 vitals Resp rate 24 and HR 120 (2 SIRS criteria)
0700 physician documentation of "possible UTI" (infection criteria)

- All 3 criteria were met within 6 hours of each other ✓ Severe Sepsis Present ✓
- Since the lactate reported time at 0800 was the last of the three criteria, Severe Sepsis Presentation time = 0800

Presentation Time Example #2:

1200 WBC = 14,500 resulted (1 SIRS criteria)

Review the period 6 hours prior (0600-1200) for the other criteria

0900 physician documentation of pneumonia (infection criteria)

No sign of organ dysfunction in 0600-1200 time frame

Review period 6 hours after earliest criteria met at 0800 (0800-1400)

1300 the patient's BP is 88/50 (organ dysfunction)

- All 3 criteria were met within 6 hours of each other ✓ Severe Sepsis present ✓
- Since the time of the hypotension at 1330 was the last of the 3 criteria, the Presentation Time=1300

CMH Severe Sepsis / Septic Shock Protocol

Two Clocks

Severe Sepsis: 3 hour and 6 hour Counters

Septic Shock: 3 hour and 6 hour Counters

CMH Severe Sepsis / Septic Shock Protocol

Severe Sepsis 3 hour Counter:

To be completed within 3 hours of time of presentation:

1. Measure lactate level
2. Draw Blood cultures (before antibiotic administration)
3. Administer Broad Spectrum Antibiotics
4. Administer NS or Lactated Ringers 30ml/kg for hypotension **or** lactate >4mmol/L

CMH Severe Sepsis / Septic Shock Protocol

Severe Sepsis 6 hour Counter:

To be completed within 6 hours of time of presentation:

1. Repeat Lactate level (if initial lactate was >2)

CMH Severe Sepsis / Septic Shock Protocol

Septic Shock 3 hour Counter:

To be completed within 3 hours of time of presentation:

1. Measure lactate level
2. Draw Blood cultures (before antibiotic administration)
3. Administer Broad Spectrum Antibiotics
4. Administer NS or Lactated Ringers 30/ml/kg for hypotension **or** lactate >4mmol/L

CMH Severe Sepsis / Septic Shock Protocol

Septic Shock 6 hour Counter:

To be completed within 6 hours of time of presentation:

1. Repeat Lactate level (if initial lactate was >2)
2. If hypotension persists after fluid resuscitation begin vasopressors (see protocol)

Hypotension is defined as:

Systolic blood pressure <90 **or**

Mean Arterial pressure <65 **or**

Decrease of Systolic blood pressure >40 points

Documentation

- Document the Start time **and** End time of any boluses given.
- The physician order for any IV fluid bolus should include: Type of fluid, total volume to infuse and timeframe for infusion. Physicians will be given this education.

Cheat Sheet

Severe Sepsis	Septic Shock
Within 3 hours of presentation	
Measure Lactate Blood culture before antibiotics Antibiotics given	Measure Lactate Blood culture before antibiotics Antibiotics given Fluid Resuscitation 30ml/kg crystalloid *NS or LR*
Within 6 hours of presentation	
If initial Lactate elevated: **Repeat Lactate**	If hypotension persists after fluid: *SBP <90, MAP <65, ↓ SBP >40 points* **Vasopressors - *See list*** AND Repeat volume status and tissue perfusion assessment using either ***MD/PA/NP focused exam including*** : • **Vital Signs - *need all T, P, R, BP documentation includes values*** • **Cardiopulmonary Exam – *need reference to both heart and lungs*** • **Cap Refill evaluation** • **Peripheral pulse evaluation *include location*** • **Skin exam - *reference to color*** OR ***Any 2 of the following*** : • **CVP Measurement** • **Central Venous Oxygen measurement *SvO2 or ScvO2 - must be obtained via central venous catheter*** • **Bedside Cardiovascular Ultrasound** • **Passive Leg Raise or Fluid Challenge *PLR done by MD/PA/NP***

This is a lot of information, so your PI team is here to help!
PI will be conducting daily review of all our inpatients looking for Sepsis/Severe Sepsis and Septic shock.

We will be giving out pocket cards that will contain criteria and treatments for Severe Sepsis/Septic Shock.

We are all in this together!!!

A Roadmap for New Physicians

Avoiding Medicare and Medicaid Fraud and Abuse

U.S. Department of Health & Human Services
Office of Inspector General

Table of Contents

Introduction

Most physicians strive to work ethically, render high-quality medical care to their patients, and submit proper claims for payment. Society places enormous trust in physicians, and rightly so. Trust is at the core of the physician-patient relationship. When our health is at its most vulnerable, we rely on physicians to use their expert medical training to put us on the road to a healthy recovery.

The Federal Government also places enormous trust in physicians. Medicare, Medicaid, and other Federal health care programs rely on physicians' medical judgment to treat beneficiaries with appropriate services. When reimbursing physicians and hospitals for services provided to program beneficiaries, the Federal Government relies on physicians to submit accurate and truthful claims information.

The presence of some dishonest health care providers who exploit the health care system for illegal personal gain has created the need for laws that combat fraud and abuse and ensure appropriate quality medical care. This brochure assists physicians in understanding how to comply with these Federal laws by identifying "red flags" that could lead to potential liability in law enforcement and administrative actions. The information is organized around three types of relationships that physicians frequently encounter in their careers:

I. Relationships with payers,

II. Relationships with fellow physicians and other providers, and

III. Relationships with vendors.

The key issues addressed in this brochure are relevant to all physicians, regardless of specialty or practice setting.

Fraud and Abuse Laws

The five most important Federal fraud and abuse laws that apply to physicians are the False Claims Act (FCA), the Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark law), the Exclusion Authorities, and the Civil Monetary Penalties Law (CMPL). Government agencies, including the Department of Justice, the Department of Health & Human Services Office of Inspector General (OIG), and the Centers for Medicare & Medicaid Services (CMS), are charged with enforcing these laws. As you begin your career, it is crucial to understand these laws not only because following them is the right thing to do, but also because violating them could result in criminal penalties, civil fines, exclusion from the Federal health care programs, or loss of your medical license from your State medical board.

False Claims Act [31 U.S.C. §§ 3729–3733]

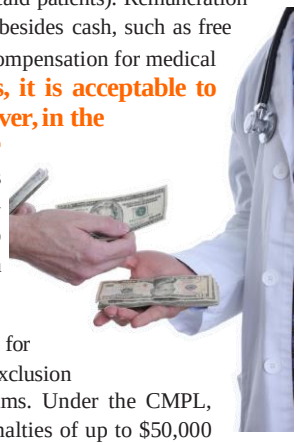
The civil FCA protects the Government from being overcharged or sold shoddy goods or services. **It is illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent.** Filing false claims may result in fines of up to three times the programs' loss plus $11,000 per claim filed. Under the civil FCA, each instance of an item or a service billed to Medicare or Medicaid counts as a claim, so fines can add up quickly. The fact that a claim results from a kickback or is made in violation of the Stark law also may render it false or fraudulent, creating liability under the civil FCA as well as the AKS or Stark law.

Under the civil FCA, no specific intent to defraud is required. The civil FCA defines "knowing" to include not only actual knowledge but also instances in which the person acted in deliberate ignorance or reckless disregard of the truth or falsity of the information. Further, the civil FCA contains a whistleblower provision that allows a private individual to file a lawsuit on behalf of the United States and entitles that whistleblower to a percentage of any recoveries. Whistleblowers could be current or ex-business partners, hospital or office staff, patients, or competitors.

There also is a criminal FCA (18 U.S.C. § 287). Criminal penalties for submitting false claims include imprisonment and criminal fines. Physicians have gone to prison for submitting false health care claims. OIG also may impose administrative civil monetary penalties for false or fraudulent claims, as discussed below.

Anti-Kickback Statute [42 U.S.C. § 1320a-7b(b)]

The AKS is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs (*e.g.*, drugs, supplies, or health care services for Medicare or Medicaid patients). Remuneration includes anything of value and can take many forms besides cash, such as free rent, expensive hotel stays and meals, and excessive compensation for medical directorships or consultancies. **In some industries, it is acceptable to reward those who refer business to you. However, in the Federal health care programs, paying for referrals is a crime.** The statute covers the payers of kickbacks—those who offer or pay remuneration—as well as the recipients of kickbacks—those who solicit or receive remuneration. Each party's intent is a key element of their liability under the AKS.



Criminal penalties and administrative sanctions for violating the AKS include fines, jail terms, and exclusion from participation in the Federal health care programs. Under the CMPL, physicians who pay or accept kickbacks also face penalties of up to $50,000 per kickback plus three times the amount of the remuneration.

Safe harbors protect certain payment and business practices that could otherwise implicate the AKS from criminal and civil prosecution. To be protected by a safe harbor, an arrangement must fit squarely in the safe harbor and satisfy all of its requirements. Some safe harbors address personal services and rental agreements, investments in ambulatory surgical centers, and payments to *bona fide* employees.

For additional information on safe harbors, see "OIG's Safe Harbor Regulations" available at http://oig.hhs.gov/fraud/safeharborregulations.asp.

As a physician, you are an attractive target for kickback schemes because you can be a source of referrals for fellow physicians or other health care providers and suppliers. You decide what drugs your patients use, which specialists they see, and what health care services and supplies they receive.

Many people and companies want your patients' business and would pay you to send that business their way. Just as it is illegal for you to take money from providers and suppliers in return for the referral of your Medicare and Medicaid patients, it is illegal for you to pay others to refer their Medicare and Medicaid patients to you.

Kickbacks in health care can lead to:

- Overutilization
- Increased program costs
- Corruption of medical decisionmaking
- Patient steering
- Unfair competition

The kickback prohibition applies to all sources of referrals, even patients. For example, where the Medicare and Medicaid programs require patients to pay copays for services, you are generally required to collect that money from your patients. Routinely waiving these copays could implicate the AKS and you may not advertise that you will forgive copayments. However, you are free to waive a copayment if you make an individual determination that the patient cannot afford to pay or if your reasonable collection efforts fail. **It is also legal to provide free or discounted services to uninsured people.**

Besides the AKS, the beneficiary inducement statute (42 U.S.C. § 1320a-7a(a)(5)) also imposes civil monetary penalties on physicians who offer remuneration to Medicare and Medicaid beneficiaries to influence them to use their services.

The Government does not need to prove patient harm or financial loss to the programs to show that a physician violated the AKS. A physician can be guilty of violating the AKS even if the physician actually rendered the service and the service was medically necessary. **Taking money or gifts from a drug or device company or a durable medical equipment (DME) supplier is not justified by the argument that you would have prescribed that drug or ordered that wheelchair even without a kickback.**

Physician Self-Referral Law [42 U.S.C. § 1395nn]

The Physician Self-Referral Law, commonly referred to as the Stark law, prohibits physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements. For example, if you invest in an imaging center, the Stark law requires the resulting financial relationship to fit within an exception or you may not refer patients to the facility and the entity may not bill for the referred imaging services.

"Designated health services" are:

- clinical laboratory services;
- physical therapy, occupational therapy, and outpatient speech-language pathology services;
- radiology and certain other imaging services;
- radiation therapy services and supplies;
- DME and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.

The Stark law is a strict liability statute, which means proof of specific intent to violate the law is not required. The Stark law prohibits the submission, or causing the submission, of claims in violation of the law's restrictions on referrals. Penalties for physicians who violate the Stark law include fines as well as exclusion from participation in the Federal health care programs.

For more information, see CMS's Stark law Web site available at http://www.cms.gov/physicianselfreferral/.

Exclusion Statute [42 U.S.C. § 1320a-7]

OIG is legally required to exclude from participation in all Federal health care programs individuals and entities convicted of the following types of criminal offenses: (1) Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare or Medicaid; (2) patient abuse or neglect; (3) felony convictions for other health-care-related fraud, theft, or other financial misconduct; and (4) felony convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances. OIG has discretion to exclude individuals and entities on several other grounds, including misdemeanor convictions related to health care fraud other than Medicare or Medicaid fraud or misdemeanor convictions in connection with the unlawful manufacture, distribution, prescription, or dispensing of controlled substances; suspension, revocation, or surrender of a license to provide health care for reasons bearing on professional competence, professional performance, or financial integrity; provision of unnecessary or substandard services; submission of false or fraudulent claims to a Federal health care program; engaging in unlawful kickback arrangements; and defaulting on health education loan or scholarship obligations.

If you are excluded by OIG from participation in the Federal health care programs, then Medicare, Medicaid, and other Federal health care programs, such as TRICARE and the Veterans Health Administration, will not pay for items or services that you furnish, order, or prescribe. **Excluded physicians may not bill directly for treating Medicare and Medicaid patients, nor may their services be billed indirectly through an employer or a group practice.** In addition, if you furnish services to a patient on a private-pay basis, no order or prescription that you give to that patient will be reimbursable by any Federal health care program.

For more information, see OIG's Special Advisory Bulletin entitled "The Effect of Exclusion From Participation in Federal Health Care Programs" available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm.

You are responsible for ensuring that you do not employ or contract with excluded individuals or entities, whether in a physician practice, a clinic, or in any capacity or setting in which Federal health care programs may reimburse for the items or services furnished by those employees or contractors. This responsibility requires screening all current and prospective employees and contractors against OIG's List of Excluded Individuals and Entities. This online database can be accessed from OIG's Exclusion Web site. If you employ or contract with an excluded individual or entity and Federal health care program payment is made for items or services that person or entity furnishes, whether directly or indirectly, you may be subject to a civil monetary penalty and/or an obligation to repay any amounts attributable to the services of the excluded individual or entity.


For more information, see OIG's exclusion Web site available at http://oig.hhs.gov/fraud/exclusions.asp.

Civil Monetary Penalties Law [42 U.S.C. § 1320a-7a]

OIG may seek civil monetary penalties and sometimes exclusion for a wide variety of conduct and is authorized to seek different amounts of penalties and assessments based on the type of violation at issue. Penalties range from $10,000 to $50,000 per violation. Some examples of CMPL violations include:

- presenting a claim that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- presenting a claim that the person knows or should know is for an item or service for which payment may not be made;
- violating the AKS;
- violating Medicare assignment provisions;
- violating the Medicare physician agreement;
- providing false or misleading information expected to influence a decision to discharge;
- failing to provide an adequate medical screening examination for patients who present to a hospital emergency department with an emergency medical condition or in labor; and
- making false statements or misrepresentations on applications or contracts to participate in the Federal health care programs.

I. Physician Relationships With Payers

During residency, you probably are not focused on who pays for your patients' care. Once you start practicing, it is important to understand who the payers are. The U.S. health care system relies heavily on third-party payers, and, therefore, your patients often are not the ones who pay most of their medical bills. Third-party payers include commercial insurers and the Federal and State governments. **When the Federal Government covers items or services rendered to Medicare and Medicaid beneficiaries, the Federal fraud and abuse laws apply.** Many States also have adopted similar laws that apply to your provision of care under State-financed programs and to private-pay patients. Consequently, you should recognize that the issues discussed here may apply to your care of all insured patients.

Accurate Coding and Billing

Payers trust you, as a physician, to provide necessary, cost-effective, and quality care. You exert significant influence over what services your patients receive, you control the documentation describing what services they actually received, and your documentation serves as the basis for bills sent to insurers for services you provided. The Government's payment of claims is generally based solely on your representations in the claims documents.

Because the Government invests so much trust in physicians on the front end, Congress provided powerful criminal, civil, and administrative enforcement tools for instances when unscrupulous providers abuse that trust. The Government has broad capabilities to audit claims and investigate providers when it has a reason to suspect fraud. Suspicion of fraud and abuse may be raised by irregular billing patterns or reports from others, including your staff, competitors, and patients.

When you submit a claim for services performed for a Medicare or Medicaid beneficiary, you are filing a bill with the Federal Government and certifying that you have earned the payment requested and complied with the billing requirements. If you knew or should have known that the submitted claim was false, then the attempt to collect unearned money constitutes a violation. A common type of false claim is "upcoding," which refers to using billing codes that reflect a more severe illness than actually existed or a more expensive treatment than was provided. Additional examples of improper claims include:

- billing for services that you did not actually render;
- billing for services that were not medically necessary;
- billing for services that were performed by an improperly supervised or unqualified employee;
- billing for services that were performed by an employee who has been excluded from participation in the Federal health care programs;
- billing for services of such low quality that they are virtually worthless; and
- billing separately for services already included in a global fee, like billing for an evaluation and management service the day after surgery.

CAUTION CAUTION CAUTION CAUTION CAUTION CAUTION CAUTION

Upcoding

Medicare pays for many physician services using Evaluation and Management (commonly referred to as "E&M") codes. New patient visits generally require more time than follow-up visits for established patients, and therefore E&M codes for new patients command higher reimbursement rates than E&M codes for established patients. An example of upcoding is an instance when you provide a follow-up office visit or follow-up inpatient consultation but bill using a higher level E&M code as if you had provided a comprehensive new patient office visit or an initial inpatient consultation.

Another example of upcoding related to E&M codes is misuse of Modifier 25. Modifier 25 allows additional payment for a separate E&M service rendered on the same day as a procedure. Upcoding occurs if a provider uses Modifier 25 to claim payment for an E&M service when the patient care rendered was not significant, was not separately identifiable, and was not above and beyond the care usually associated with the procedure.

CAUTION CAUTION CAUTION CAUTION CAUTION CAUTION CAUTION

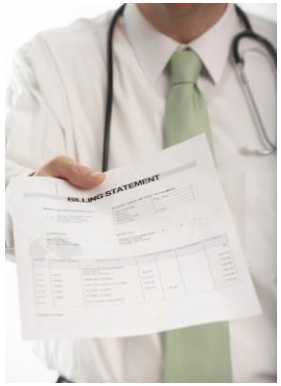
Case Examples of Fraudulent Billing

•A psychiatrist was fined $400,000 and permanently excluded from participating in the Federal health care programs for misrepresenting that he provided therapy sessions requiring 30 or 60 minutes of face-to-face time with the patient, when he had provided only medication checks for 15 minutes or less. The psychiatrist also misrepresented that he provided therapy sessions when in fact a non-licensed individual conducted the sessions.

•A dermatologist was sentenced to 2 years of probation and 6 months of home confinement and ordered to pay $2.9 million after he pled guilty to one count of obstruction of a criminal health care fraud investigation. The dermatologist admitted to falsifying lab tests and backdating letters to referring physicians to substantiate false diagnoses to make the documentation appear that his patients had Medicare- covered conditions when they did not.

•A cardiologist paid the Government $435,000 and entered into a 5-year Integrity Agreement with OIG to settle allegations that he knowingly submitted claims for consultation services that were not supported by patient medical records and did not meet the criteria for a consultation. The physician also allegedly knowingly submitted false claims for E&M services when he had already received payment for such services in connection with previous claims for nuclear stress testing.

• An endocrinologist billed routine blood draws as critical care blood draws. He paid $447,000 to settle allegations of upcoding and other billing violations.



Physician Documentation

Physicians should maintain accurate and complete medical records and documentation of the services they provide. Physicians also should ensure that the claims they submit for payment are supported by the documentation. The Medicare and Medicaid programs may review beneficiaries' medical records. **Good documentation practice helps ensure that your patients receive appropriate care from you and other providers who may rely on your records for patients' past medical histories.** It also helps you address challenges raised against the integrity of your bills. You may have heard the saying regarding malpractice litigation: "If you didn't document it, it's the same as if you didn't do it." The same can be said for Medicare and Medicaid billing.

For more information on physician documentation, see CMS's Documentation Guidelines for Evaluation and Management Services available at http://www.cms.gov/MLNEdWebGuide/25_EMDOC.asp.

Enrolling as a Medicare and Medicaid Provider With CMS

CMS is the Federal agency that administers the Medicare program and monitors the Medicaid programs run by each State. To obtain reimbursement from the Government for services provided to Federal health care program beneficiaries, you must:

1. **Obtain a National Provider Identifier (NPI).** An NPI is a unique health identifier for health care providers. You may apply for your NPI at https://nppes.cms.hhs.gov/NPPES/Welcome.do.
2. **Complete the appropriate Medicare Enrollment Application.** During the enrollment process, CMS collects information to ensure that you are qualified and eligible to enroll in the Medicare Program. Information about Medicare provider enrollment is available at http://www.cms.gov/MedicareProviderSupEnroll/.
3. **Complete your State-specific Medicaid Enrollment Application.** Information about Medicaid provider enrollment is available from your State Medicaid agency.

Once you become a Medicare and/or Medicaid provider, you are responsible for ensuring that claims submitted under your number are true and correct.

For tips you can share with your patients on how they can protect themselves from medical identity theft, see OIG's brochure entitled "Tips to Avoid Medical ID Theft" available at http://oig.hhs.gov/fraud/IDTheft/OIG_Medical_Identity_Theft_Brochure.pdf.

Prescription Authority

The Drug Enforcement Administration (DEA) is a Department of Justice agency responsible for enforcing the Controlled Substances Act. When you prepare to enter practice, you probably will apply for a DEA number that authorizes you to write prescriptions for controlled substances. You also will apply for your State medical license and any additional credentials your State requires for you to write prescriptions. You must ensure that you write prescriptions only for lawful purposes.

Case Examples of Misuse of Physician Provider and Prescription Numbers

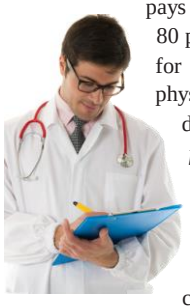
•A physician was ordered to pay $50,000 in restitution to the Government for falsely indicating on his provider number application that he was running his own practice when, in fact, a neurophysiologist was operating the practice and paying the physician a salary for the use of his number.

•An osteopathic physician was sentenced to 10 years in prison and ordered to pay $7.9 million in restitution after she accepted cash payments for signing preprinted prescriptions and Certificates of Medical Necessity for motorized wheelchairs for beneficiaries she never examined. More than 60 DME companies received Medicare and Medicaid payments based on her fraudulent prescriptions.

•An internal medicine physician pled guilty to Medicare fraud and to conspiring to dispense oxycodone, morphine, hydrocodone, and alprazolam. The physician allowed unauthorized and non-medical employees at his pain center to prescribe drugs using his pre-signed blank prescription forms. Prescriptions were issued in his name without adequate physical exams, proper diagnoses, or consideration of alternative treatment options. He paid $317,000 in restitution to the Government.

Assignment Issues in Medicare Reimbursement

Most physicians bill Medicare as participating providers, which is referred to as "accepting assignment." Each year, Medicare promulgates a fee schedule setting the reimbursement for each physician service. Once beneficiaries satisfy their annual deductible, Medicare pays 80 percent of the fee schedule amount and the beneficiary pays 20 percent. Participating providers receive the Medicare program's 80 percent directly from the Medicare program and bill the beneficiary for the remaining 20 percent. Accepting assignment means that the physician accepts the Medicare payment plus any copayment or deductible Medicare requires the patient to pay *as the full payment for the physician's services and that the physician will not seek any extra payment* (beyond the copayment or deductible) from the patient. Medicare participating physicians may not bill Medicare patients extra for services that are already covered by Medicare. Doing so is a violation of a physician's assignment agreement and can lead to penalties.



The second, less common, way to obtain Medicare reimbursement is to bill as a non-participating provider. Non-participating providers do not receive direct payment from the Medicare program. Rather, they bill their patients and the patients seek reimbursement from Medicare. Although non-participating providers are not subject to the assignment rules, they still must limit the dollar amount of their charges to Medicare patients. Generally, non-participating providers may not charge Medicare beneficiaries more than 15 percent in excess of the Medicare fee schedule amount. It is illegal to charge patients more than the limiting charge established for physicians' services.

Excluded providers may not receive Medicare payment either as participating or non-participating providers.

You may see advertisements offering to help you convert your practice into a "boutique," "concierge," or "retainer" practice. Many such solicitations promise to help you work less, yet earn more money. **If you are a participating or non-participating physician, you may not ask Medicare patients to pay a second time for services for which Medicare has already paid.** It is legal to charge patients for services that are not covered by Medicare. However, charging an "access fee" or "administrative fee" that simply allows them to obtain Medicare-covered services from your practice constitutes double billing.

Case Example of a Physician Violating an Assignment Agreement by Charging Beneficiaries Extra Fees

•A physician paid $107,000 to resolve potential liability for charging patients, including Medicare beneficiaries, an annual fee. In exchange for the fee, the physician offered: (1) an annual physical; (2) same- or next-day appointments; (3) dedicated support personnel; (4) around-the-clock physician availability; (5) prescription facilitation; (6) expedited and coordinated referrals; and (7) other amenities at the physician's discretion. The physician's activities allegedly violated the assignment agreement because some of the services outlined in the annual fee were already covered by Medicare.

II. Physician Relationships With Fellow Providers: Physicians, Hospitals, Nursing Homes, Etc.

Any time a health care business offers something to you for free or at below fair market value, you always should ask yourself, "*Why?*" For example, if a DME supplier offers to give you cash or to pay for your summer vacation, you should suspect that the supplier is trying to induce you to refer your patients to that vendor. If a laboratory offers to decorate your patient waiting room, you should suspect that it is trying to induce you to send your lab business its way.

For more information on physician relationships with:

fellow providers, see OIG's "Compliance Program Guidance for Individual and Small Group Physician Practices" available at http://oig.hhs.gov/authorities/docs/physician.pdf;

hospitals, see OIG's "Supplemental Compliance Program Guidance for Hospitals" available at http://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf; and

nursing homes, see OIG's "Supplemental Compliance Program Guidance for Nursing Facilities" available at http://oig.hhs.gov/fraud/docs/complianceguidance/nhg_fr.pdf.

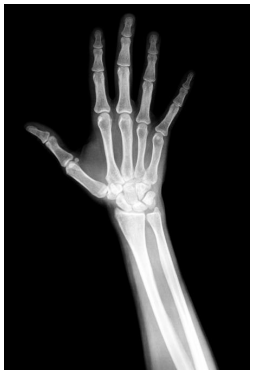
Physician Investments in Health Care Business Ventures

Some have observed that physicians who invest in health care business ventures with outside parties (*e.g.*, imaging centers, labs, equipment vendors, or physical therapy clinics) refer more patients for the services provided by those parties than physicians who do not invest. Maybe this disproportionate utilization partly reflects the physicians' belief in the value of the services or technology, prompting the investments in the first place. However, there also is a risk that the physicians' belief in the value of the services or technology is less a cause than an effect of the investment interest. The physician investors' disproportionate utilization may be motivated partly by the physicians' ability to profit from the use of the ancillary services. These business relationships can sometimes unduly influence or distort physician decisionmaking and result in the improper steering of a patient to a particular therapy or source of services in which a physician has a financial interest. **Excessive and medically unnecessary referrals waste Government and beneficiary money and**

can expose beneficiaries to harm from unnecessary services. Many of these investment relationships have serious legal risks under the AKS and Stark law.

If you are invited to invest in a health care business whose products you might order or to which you might refer your patients, you should ask the following questions. If the answer is "yes" to any of them, you should consider carefully whether you are investing for legitimate reasons.

- ? Are you being offered an investment interest for a nominal capital contribution?
- ? Will your ownership share be larger than your share of the aggregate capital contributions made to the venture?
- ? Is the venture promising you high rates of return for little or no financial risk?
- ? Is the venture or any potential business partner offering to loan you the money to make your capital contribution?
- ? Are you being asked to promise or guarantee that you will refer patients or order items or services from the venture?
- ? Do you believe you will be more likely to refer more patients for the items and services provided by the venture if you make the investment?
- ? Do you believe you will be more likely to refer to the venture just because you made the investment?
- ? Will the venture have sufficient capital from other sources to fund its ongoing operations?



For more information on physician investments, see:

OIG's Special Fraud Alert entitled "Joint Venture Arrangements" available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html;

OIG's Special Advisory Bulletin on contractual joint ventures available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf; and

OIG's "Supplemental Compliance Program Guidance for Hospitals" available at http://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf.

Case Examples Involving Kickbacks for Referrals and Self-Referrals

• Nine cardiologists paid the Government over $3.2 million for allegedly engaging in a kickback scheme. The cardiologists received salaries under clinical faculty services agreements with a hospital under which, the Government alleged, they did not provide some or any of the services. In exchange, the cardiologists referred their patients to the hospital for cardiology services. Two of the physicians also pled guilty to criminal embezzlement charges involving the same conduct.

•A physician paid the Government $203,000 to settle allegations that he violated the physician self-referral prohibition in the Stark law for routinely referring Medicare patients to an oxygen supply company he owned.

Physician Recruitment

A hospital will sometimes provide a physician with a recruitment incentive to induce the physician to relocate to the hospital's geographic area, become a member of its medical staff, and establish a practice that helps serve that community's medical needs. Often, such recruitment efforts are legitimately designed to fill a "clinical gap" in a medically underserved area to which it may be difficult to attract physicians in the absence of financial incentives. However, as you begin planning your professional future and perhaps receiving recruitment offers, you need to be aware that in some communities, especially ones with multiple hospitals, the competition for patients can be fierce. Some hospitals may offer illegal inducements to you, or to the established physician practice you join in the hospital's community, to gain referrals. This means that the competition for your loyalty can cross the line into illegal arrangements for which *both you and the hospital* can be liable.

Recruitment arrangements are of special interest to graduating residents and fellows. Within very specific parameters specified in the Stark law and subject to compliance with the AKS, hospitals may provide relocation assistance and practice support under a properly structured recruitment arrangement to assist you in establishing a practice in the hospital's community. Alternatively, a hospital may pay you a fair market value salary as an employee or pay you fair market value for specific services you render to the hospital as an independent contractor. However, the hospital may not offer you money, provide you free or below-market rent for your medical office, or engage in similar activities designed to influence your referral decisions. **You should admit your patients to the hospital best suited to care for their particular medical conditions or to the hospital your patient selects based on his or her preference or insurance coverage.** As noted, if a hospital or physician practice seperately or jointly is recruiting you as a new physician to the community, you may be offered a recruitment package. But, you may not negotiate for benefits in exchange for a promise—implicit or explicit—that you will admit your patients to a specific hospital or practice setting unless you are a hospital employee. You should seek knowledgeable legal counsel if someone with whom you are entering into a relationship requires you to admit patients to a specific hospital or practice group.

Tips for Medical Directors

If you choose to accept a medical directorship at a nursing home or other facility, you must be prepared to assume substantial professional responsibility for the care delivered at the facility. As medical director, patients (both your own patients and the patients of other attending physicians) and their families count on you, and State and Federal authorities may hold you accountable as well. To do this job well, you should:

- actively oversee clinical care in the facility;
- lead the medical staff to meet the standard of care;
- ensure proper training, education, and oversight for physicians, nurses, and other staff members; and
- identify and address quality problems.

Case Examples of Medical Directorship Issues

• A physician group practice paid the Government $1 million and entered into a 5-year Corporate Integrity Agreement to settle alleged violations of the AKS, FCA, and Stark law related to medical directorships with a medical center. Allegedly, the agreements were not in writing, the physicians were paid more than fair market value for the services they rendered, and the payment amounts were based on the value of referrals the physicians sent to the medical center.

•Two orthopedic surgeons paid $450,000 and $250,000 to settle allegations related to improper medical directorships with a company that operated a diagnostic imaging center, a rehabilitation facility, and an ambulatory surgery center. The company allegedly provided the physicians with valuable compensation, including free use of the corporate jet, under the medical directorship agreements, which required the physicians to render limited services in return. The agreements with the physicians allegedly called for redundant services and served to encourage the physicians to refer their patients to the facilities operated by the company.

III. Physician Relationships With Vendors

Free Samples

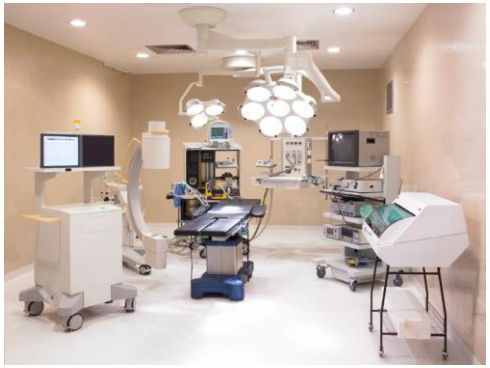
Some physicians welcome visits from pharmaceutical salespeople, while other physicians prefer not to directly engage with industry representatives. If you decide to make your practice accessible to salespeople, you probably will be offered product samples. Many drug and biologic companies provide physicians with free samples that the physicians may give to patients free of charge. **It is legal to give these samples to your patients for free, but it is illegal to sell the samples.** The Government has prosecuted physicians for billing Medicare for free samples. Opinions differ on whether sampling practices ultimately increase or decrease patients' long-term drug costs. If you choose to accept samples, you will need reliable systems in place to safely store the samples and ensure that samples are not commingled with your commercial stock.

Case Example Involving Drug Samples

•Several urologists pled guilty to charges of conspiracy, paid restitution in the tens of thousands of dollars, and received sanctions against their medical licenses for billing Medicare for injectable prostate cancer drugs they received for free from two pharmaceutical companies. The pharmaceutical companies paid $1.4 billion for their part of the alleged scheme to give urologists free samples and encourage them to bill Medicare at an inflated price. The pharmaceutical companies also provided urologists with additional inducements to use their drugs over the competitor's products, including drug rebates, education grants, volume discounts, free goods, and debt forgiveness.

Relationships With the Pharmaceutical and Medical Device Industries

Physician-industry collaboration can produce important medical advances. However, some pharmaceutical and device companies have used sham consulting agreements and other arrangements to buy physician loyalty to their products. Such illegal arrangements induce physicians to prescribe or use products on the basis of that loyalty to the company or to get more money from the company, rather than because it is the best treatment for the patient.



As a practicing physician, you may have opportunities to work as a consultant or promotional speaker for the drug or device industry. For every financial relationship offered to you, evaluate the link between the services you can provide and the compensation you will receive. Test the propriety of any proposed relationship by asking yourself the following questions:

- ? Does the company *really* need *my* particular expertise or input?
- ? Does the amount of money the company is offering seem fair, appropriate, and commercially reasonable for what it is asking me to do?
- ? Is it possible the company is paying me for my loyalty so that I will prescribe its drugs or use its devices?

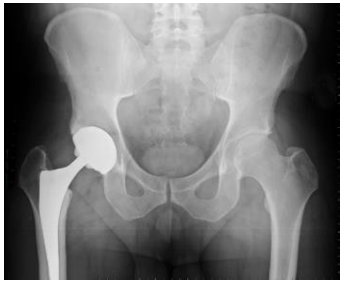
A good discussion that assists in distinguishing between legitimate and questionable industry relationships is located in the OIG's "Compliance Program Guidance for Pharmaceutical Manufacturers" available at http://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf.

If your contribution is your time and effort or your ability to generate useful ideas and the payment you receive is fair market value compensation for your services without regard to referrals, then, depending on the circumstances, you may legitimately serve as a *bona fide* consultant. **If your contribution is your ability to prescribe a drug or use a medical device or refer your patients for particular services or supplies, the proposed consulting arrangement likely is one you should avoid as it could violate fraud and abuse laws.**

For example, if a drug company offers to pay you and a hundred other "thought leaders" to attend a conference in the Bahamas without requiring preparatory work on your part or information about your expertise in the field (other than the fact that you are a licensed physician), you should be suspicious that the company is attempting to influence you to prescribe its drug.

Case Example of Kickbacks in the Device Industry

•Four orthopedic device manufacturers paid $311 million to settle kickback and false claims allegations that the companies bribed surgeons to recommend their hip and knee surgical implant products. The companies allegedly would award physicians with vacations, gifts, and annual "consulting fees" as high as $200,000 in return for the physicians' endorsements of their implants or use of them in operations. Many of the individual orthopedic surgeons at the receiving end of the kickbacks are the subject of ongoing investigations by the Government. One orthopedic surgeon recently paid $650,000 to resolve allegations that the surgeon accepted payments from device manufacturers to use their hip and knee implants.



Transparency in Physician-Industry Relationships

Although some physicians believe that free lunches, subsidized trips, and gifts do not affect their medical judgment, research shows that these types of perquisites can influence prescribing practices. Recent pharmaceutical company settlements with the Department of Justice and OIG require "transparency" in physician-industry relationships, whether by requiring the pharmaceutical company to provide the Government with a list of physicians whom the company paid and/or by requiring ongoing public disclosure by the company of physician payments. **The public will soon know what gifts and payments a physician receives from industry.** The Patient Protection and Affordable Care Act of 2010 requires drug, device, and biologic companies to publicly report nearly all gifts or payments they make to physicians beginning in 2013.

Academic institutions also may impose various restrictions on the interactions their faculty members or affiliated physicians have with industry. These and other considerations may factor into your decision about whether you want to conduct industry-sponsored research; serve as a consultant or director for a drug, biologic, or device company; apply for industry-sponsored educational or research grants; or engage in other relationships with industry.

Both the pharmaceutical industry (through PhRMA) and the medical device industry (through AdvaMed) have adopted codes of ethics for their respective industries regarding relationships with health care professionals. Both codes are available online.

Conflict-of-Interest Disclosures

Many of the relationships discussed in this brochure are subject to conflict-of-interest disclosure policies. Even if the relationships are legal, you may have an obligation to disclose their existence. Rules about disclosing and managing conflicts of interest come from a variety of sources, including grant funders, such as States, universities, and the National Institutes of Health, and from the Food and Drug Administration (FDA) when data are submitted to support marketing approval for new drugs, devices, or biologics. To "manage" your conflicts of interest, consider the conflicts policies that affect your professional activities, candidly disclose any industry money subject to these policies, and adhere to restrictions on your activities. If you are uncertain whether a conflict exists, ask someone. You always can apply the "newspaper test" and ask yourself whether you would want the arrangement to appear on the front page of your local newspaper.

Continuing Medical Education

After finishing your formal graduate medical training, you will assume greater responsibility for your continuing medical education (CME) to maintain State licensure, hospital privileges, and board certification. Drug and device manufacturers sponsor many educational opportunities for physicians. **It is important to distinguish between CME sessions that are educational in nature and sessions that constitute marketing by a drug or device manufacturer.** Industry satellite programs that occur concurrently with a society meeting are generally promotional, even if the primary speaker is a physician who is well known in the field. You should be circumspect about a discussion that focuses on a particular brand drug or device, as opposed to all the treatment alternatives for a specific condition.

For example, if speakers recommend use of a drug to treat conditions for which there is no FDA approval or use of a drug by children when FDA has approved only adult use, you should independently seek out the empirical data that support these recommendations. **Note that although physicians may prescribe drugs for off-label uses, it is illegal under the Federal Food, Drug, and Cosmetic Act for drug manufacturers to promote off-label uses of drugs.**

Advertisements and other promotional materials for drugs, biologics, and medical devices must be truthful, not misleading, and limited to approved uses. FDA is requesting physicians' assistance in identifying misleading advertisements through its Bad Ad Program. If you spot advertising violations, you should report them to FDA by calling 877-RX-DDMAC (877-793-3622) or by emailing badad@fda.gov.

If you are invited to serve as faculty for industry-sponsored CME, ask yourself the following questions:

- ? Does the sponsor *really* need *my* particular expertise or input?
- ? Does the amount of money the sponsor is offering seem fair and appropriate for the educational value I will add to the presentation?
- ? Is it possible the sponsor is paying me for my loyalty so that I will prescribe its drugs or use its devices?
- ? Does the sponsor prepare a slide deck and speaker notes, or am I free to set the content of the lecture?

Compliance Programs for Physicians

Establishing and following a compliance program will help physicians avoid fraudulent activities and ensure that they are submitting true and accurate claims. The following seven components provide a solid basis upon which a physician practice can create a voluntary compliance program:

1. Conduct internal monitoring and auditing.
2. Implement compliance and practice standards.
3. Designate a compliance officer or contact.
4. Conduct appropriate training and education.
5. Respond appropriately to detected offenses and develop corrective action.
6. Develop open lines of communication with employees.
7. Enforce disciplinary standards through well-publicized guidelines.

With the passage of the Patient Protection and Affordable Care Act of 2010, physicians who treat Medicare and Medicaid beneficiaries will be required to establish a compliance program.

For more information on compliance programs for physicians, see OIG's "Compliance Program Guidance for Individual and Small Group Physician Practices" available at http://oig.hhs.gov/authorities/docs/physician.pdf.

Where To Go for Help

When you are considering whether or not to engage in a particular billing practice; enter into a particular business venture; or pursue an employment, consulting, or other personal services relationship, it is prudent to evaluate the arrangement for potential compliance problems. The following is a list of possible resources that can help you.

- Experienced health care lawyers can analyze your issues and provide a legal evaluation and risk analysis of the proposed venture, relationship, or arrangement.

- The Bar Association in your State may have a directory of attorneys in your area who practice in the health care field.
- Your State or local medical society may be a good resource for issues affecting physicians and may have listings of health care lawyers in your area.
- Your specialty society may have information on additional risk areas specific to your type of practice.
- CMS's local contractor medical directors are a valuable source of information on Medicare coverage policies and appropriate billing practices. The contact information for local contractors is available at http://www.cms.gov/MLNGenInfo/30_contactus.asp.
- CMS's "Medicare Physician Guide: A Resource for Residents, Practicing Physicians, and Other Health Care Professionals" available at http://www.cms.gov/MLNProducts/downloads/physicianguide.pdf, provides an overview of the Medicare program and information on Medicare reimbursement and payment policies.
- The OIG's Web site, available at http://oig.hhs.gov, provides substantial fraud and abuse guidance.
- As discussed above, OIG issues Compliance Program Guidance documents that include compliance recommendations and discussions of fraud and abuse risk areas. These guidance documents are available at http://oig.hhs.gov/fraud/complianceguidance.asp.
- OIG issues advisory opinions to parties who seek advice on the application of the AKS, CMPL, and Exclusion Authorities. Information on how to request an OIG advisory opinion and links to previously published OIG advisory opinions are available at http://oig.hhs.gov/fraud/advisoryopinions.asp.
- CMS issues advisory opinions to parties who seek advice on the Stark law. Information on how to request a CMS advisory opinion and links to previously published CMS advisory opinions are available at http://www.cms.gov/PhysicianSelfReferral/95_advisory_opinions.asp.

What To Do If You Think You Have a Problem

If you are engaged in a relationship you think is problematic or have been following billing practices you now realize were wrong:

- Immediately cease filing the problematic bills.
- Seek knowledgeable legal counsel.
- Determine what money you collected in error from your patients and from the Federal health care programs and report and return overpayments.
- Unwind the problematic investment.
- Disentangle yourself from the suspicious relationship.
- Consider using OIG's or CMS's self-disclosure protocols.

OIG Provider Self-Disclosure Protocol

The OIG Provider Self-Disclosure Protocol is a vehicle for physicians to voluntarily disclose self-discovered evidence of potential fraud. The protocol allows providers to work with the Government to avoid the costs and disruptions entailed in a Government-directed investigation. For more information on the OIG Provider Self-Disclosure Protocol, see http://oig.hhs.gov/fraud/selfdisclosure.asp.

Case Examples of Physician Liabilities Resolved Under the OIG Provider Self-Disclosure Protocol

•A Minneapolis physician paid $53,400 and resolved liability for violating his Medicare assignment agreement by charging patients a yearly fee for services, some of which were covered by Medicare.

• A Florida physician paid $100,000 and resolved liability related to referring patients to a lab owned by his brother.

• A neurosurgery practice paid $10,000 and resolved liability for employing an individual who was excluded from participation in the Federal health care programs.

What To Do If You Have Information About Fraud and Abuse Against Federal Health Care Programs

If you have information about fraud and abuse against Federal health care programs, use the OIG Fraud Hotline to report that information to the appropriate authorities. The Hotline allows the option of reporting anonymously.

Phone:	1-800-HHS-TIPS (1-800-447-8477)
Fax:	1-800-223-8164
Email:	HHSTIPS@oig.hhs.gov
TTY:	1-800-377-4950
Mail:	Office of Inspector General Department of Health & Human Services Attn: HOTLINE P.O. Box 23489 Washington, DC 20026

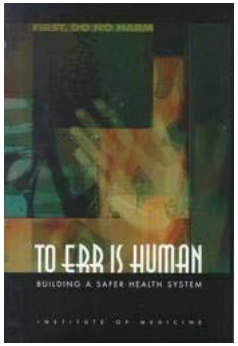
For additional information about the Hotline, visit the OIG Web site at http://oig.hhs.gov/fraud/hotline/.

Medical Staff Education
Zero Harm – Safety Tools for All

Clinton Memorial Hospital
RegionalCare Hospital Partners

Today's Objectives

1. Share with you what we mean by "building and sustaining our patient safety culture"
2. Provide an understanding of how and why people experience error in complex systems
3. Introduce you to our RegionalCare safety behaviors and safety tools



Death By Numbers

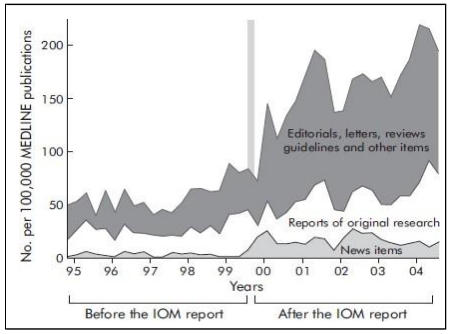
44,000 to 98,000 patient deaths per year from medical errors

To Err is Human, Institute of Medicine (1999)

A Lot of Talk

Patient safety publications before and after the IOM report, *To Err is Human*

Quality & Safety in Health Care (2006)



To Err is Human – To Delay is Deadly

Ten years later, a million lives lost, billions of dollars wasted

"Based on our review of the scant evidence, we believe that preventable medical harm still accounts for more than 100,000 deaths a year… the Centers for Disease Control and Prevention (CDC) estimates that hospital-acquired conditions alone kill 99,000 each year…

In this report, we give the country a failing grade on progress…"

Consumers Union (2009)

Published Cases

Memorial HEALTH

- 89% reduction in 2 years
- $ 10 M savings first year
- $ 11 M savings second year

CLINICAL ADVISORY BOARD
Clinical Strategy Watch
Advisory.com News in Review
March 24, 2005
Vol. 3, Issue 6
PATIENT SAFETY
Care quality: MHUMC stems preventable errors through hospitalwide efforts

SENTARA™

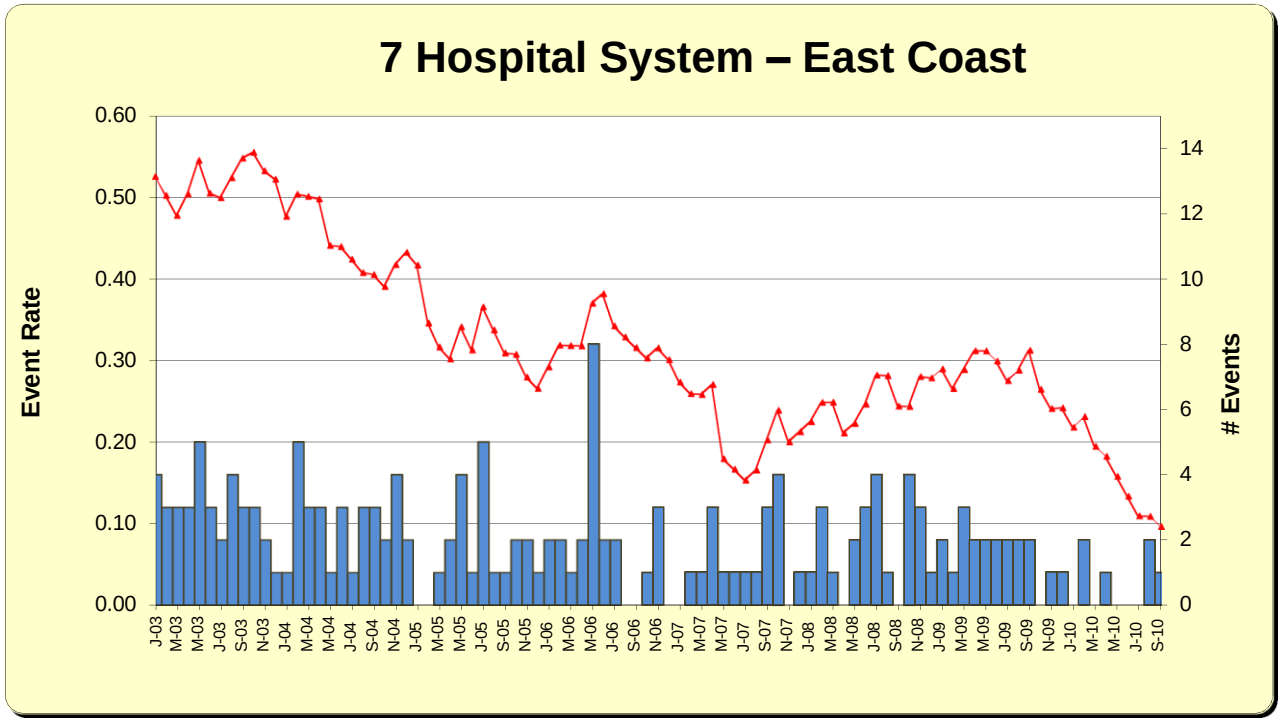
- 50% reduction in 18 months
- AHA Quest for Quality Award 2004
- JCAHO Eisenberg Quality Award 2005

Advocate Health Care

"Can Your Nurses Stop a Surgeon?"
Hospitals & Health Networks, September 2007

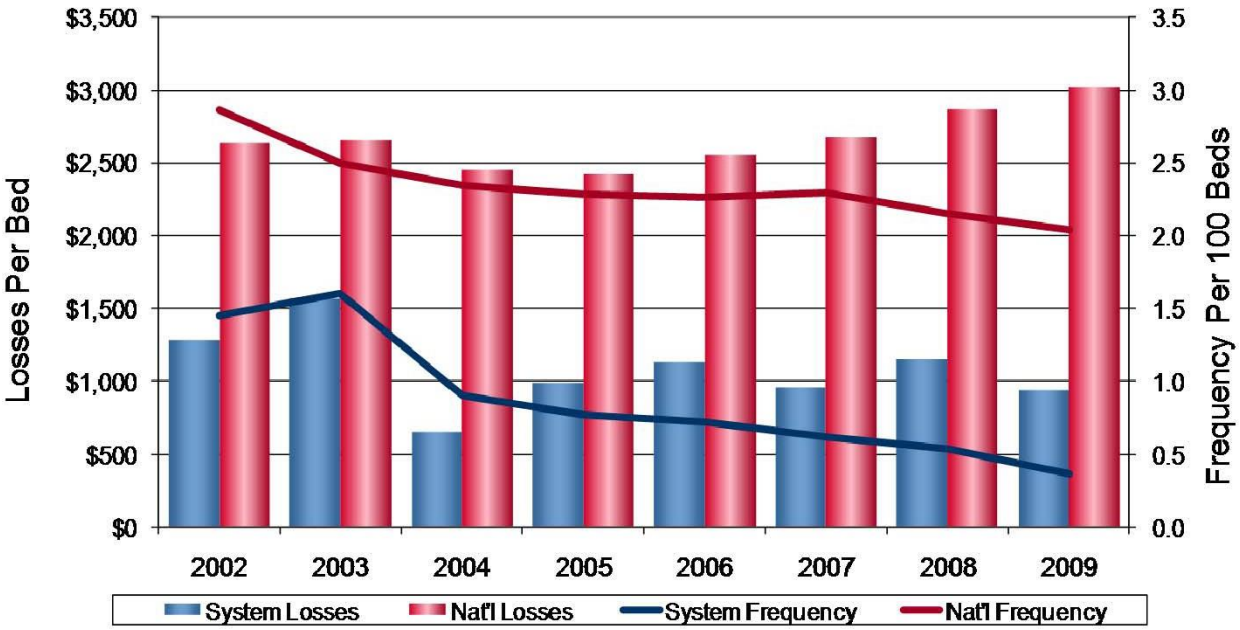
Example Serious Safety Event Rate

January 2003 – September 2010

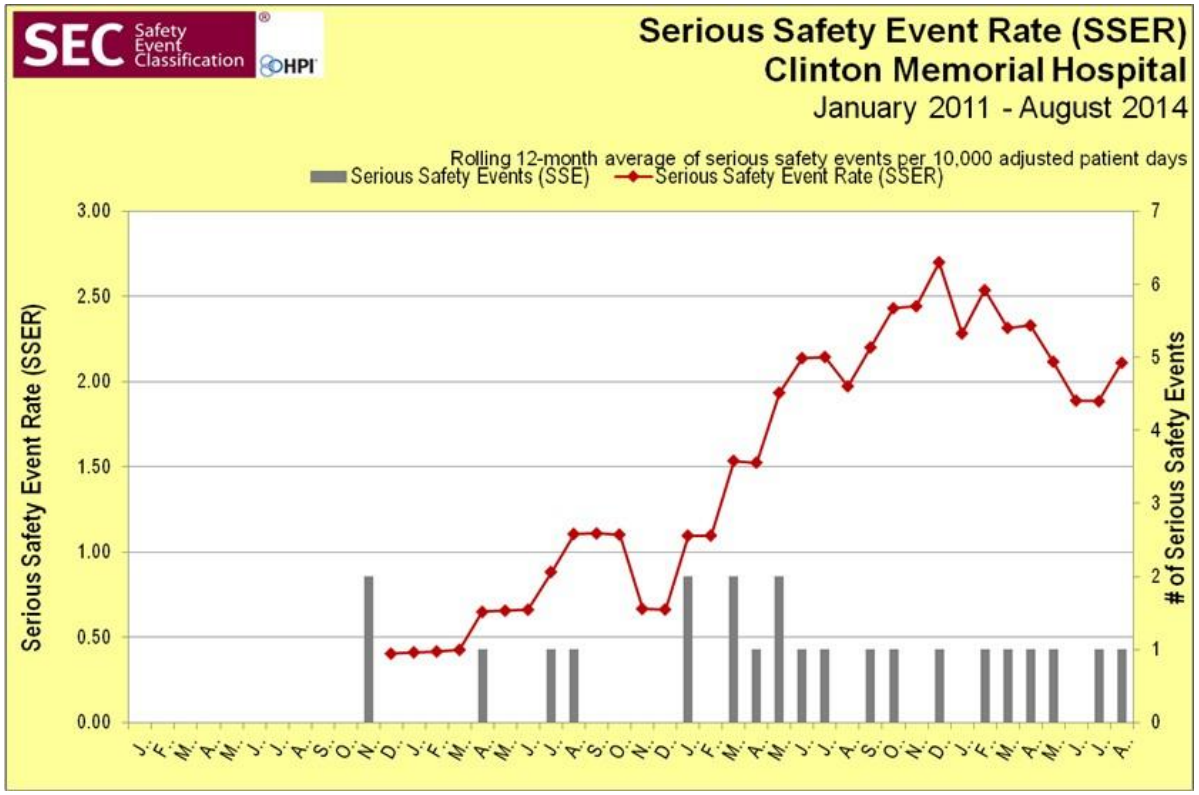


Finance's Interest in Safety

Multi-Hospital East Coast System

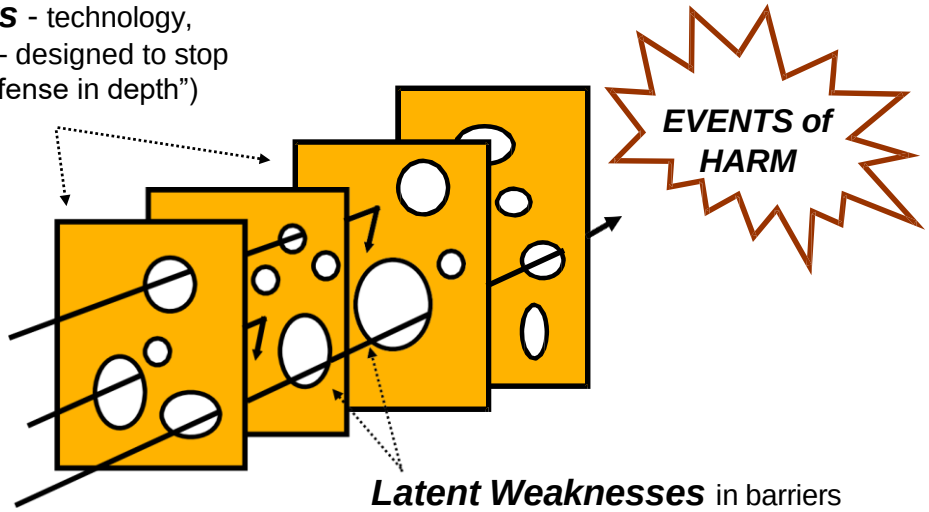


National Data Source: ASHRM Hospital Professional Liability & Physician Liability 2009 Benchmark Analysis


SEC Safety Event Classification
HPI
Serious Safety Event Rate (SSER)
Clinton Memorial Hospital
January 2011 - August 2014
Rolling 12-month average of serious safety events per 10,000 adjusted patient days
Serious Safety Events (SSE)
Serious Safety Event Rate (SSER)
Serious Safety Event Rate (SSER)
# of Serious Safety Events
3.00
2.50
2.00
1.50
1.00
0.50
0.00
7
6
5
4
3
2
1
0
J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J A

Anatomy of a Safety Event

Multiple Barriers - technology, processes, and people - designed to stop active errors (our "defense in depth")



Active Errors by individuals result in initiating action(s)

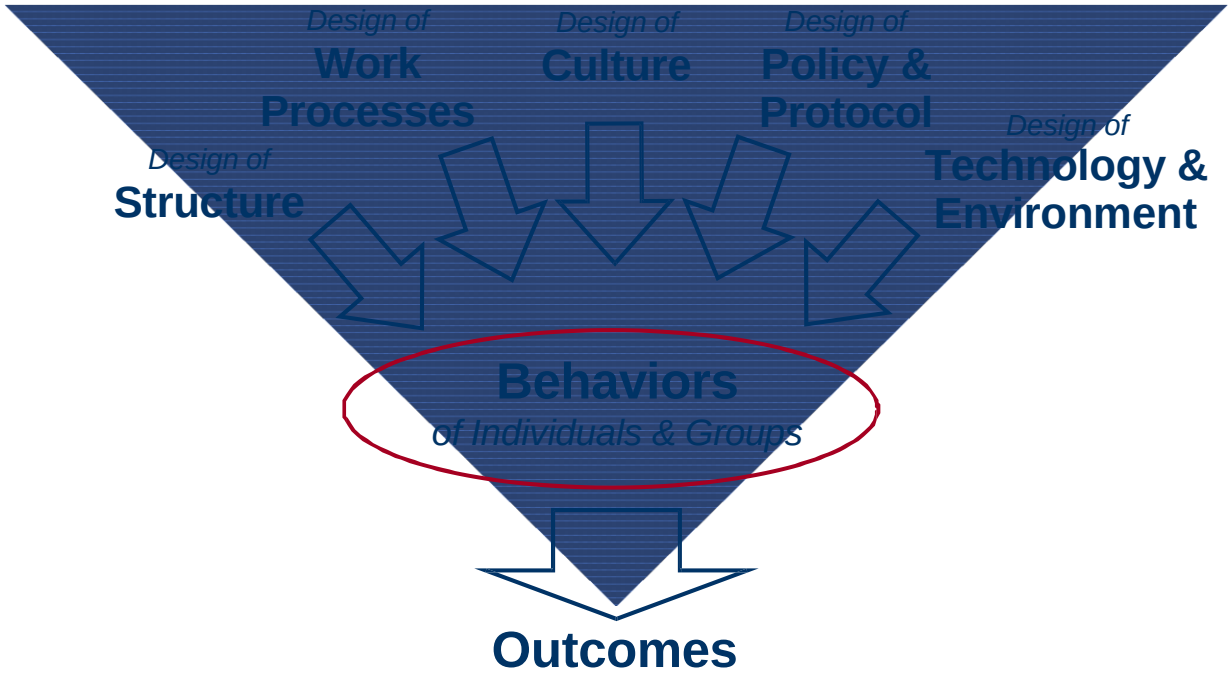
Latent Weaknesses in barriers

PREVENT
The Errors

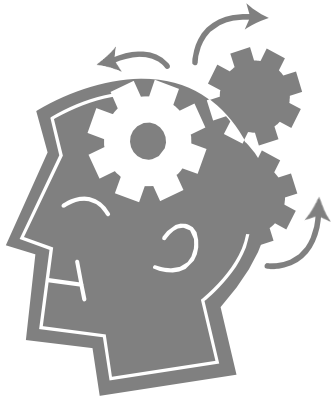
DETECT & CORRECT
The System Weaknesses

From James Reason, *Managing the Risks of Organizational Accidents*, 1997

Shaping Behaviors at the Sharp End



As Humans, We Work in 3 Modes



Skill-Based Performance

"Auto-Pilot Mode"

Rule-Based Performance

"If-Then Response Mode"

Knowledge-Based Performance

"Figuring It Out Mode"

Skill-Based Performance

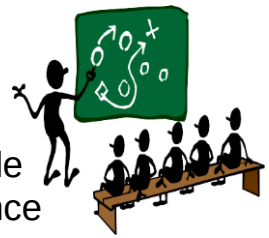
What You're Doing At The Time

Very familiar, routine tasks that you can do without even thinking about it – like you're on auto-pilot

Errors We Experience	Error Prevention Strategy
Slip – *Without intending to*, you do the wrong thing **Lapse** – *Without intending to*, you fail to do what we meant to do **Fumble** – *Without intending to*, you mishandle or blunder an action or word	**Stop and think before acting**

3 in 1,000 acts performed in error
(pretty reliable!)

Rule-Based Performance



What You're Doing At The Time

Responding to a situation by recalling and using a rule that you learned either through education or experience

Errors You Experience	Error Prevention Strategy
Used the wrong rule – You were taught or learned the wrong response for the situation	**Educate about the right rule**
Misapplied a rule – You knew the right response but picked another response instead	**Think a *second* time**
Non-compliance – Chose not to follow the rule (usually, thinking that not following the rule was the better option at the time)	**Reduce burden, increase risk awareness, improve coaching**

1 in 100 choices made in error
(not too bad!)

Knowledge-Based Performance

What You're Doing At The Time

Problem solving in a new, unfamiliar situation.
You come up with the answer by:

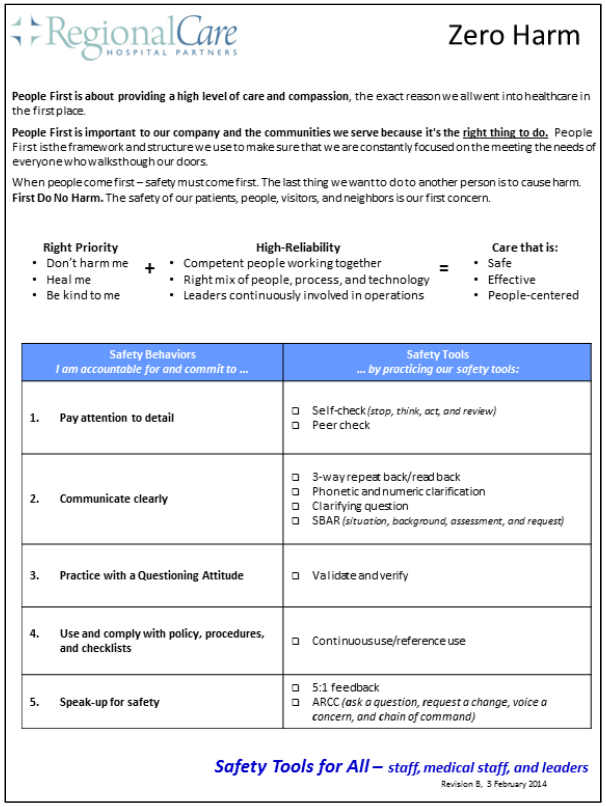
- Using what we do know
- Taking a guess
- Figuring it out by trial-and-error

Errors You Experience	Error Prevention Strategy
You came up with the wrong answer (a mistake)	**STOP and find an expert who or that knows the right answer**

30-60 of 100 decisions made in error
(yikes!)

Safety as Our Core Value

A Powerful Driver of Individual Decision Making



RegionalCare HOSPITAL PARTNERS

Zero Harm

People First is about providing a high level of care and compassion, the exact reason we all went into healthcare in the first place.

People First is important to our company and the communities we serve because it's the right thing to do. People First is the framework and structure we use to make sure that we are constantly focused on the meeting the needs of everyone who walks though our doors.

When people come first – safety must come first. The last thing we want to do to another person is to cause harm. **First Do No Harm.** The safety of our patients, people, visitors, and neighbors is our first concern.

Right Priority		High-Reliability		Care that is:
• Don't harm me • Heal me • Be kind to me	+	• Competent people working together • Right mix of people, process, and technology • Leaders continuously involved in operations	=	• Safe • Effective • People-centered

Safety Behaviors *I am accountable for and commit to ...*	Safety Tools *... by practicing our safety tools:*
1. **Pay attention to detail**	❑ Self-check *(stop, think, act, and review)* ❑ Peer check
2. **Communicate clearly**	❑ 3-way repeat back/read back ❑ Phonetic and numeric clarification ❑ Clarifying question ❑ SBAR *(situation, background, assessment, and request)*
3. **Practice with a Questioning Attitude**	❑ Validate and verify
4. **Use and comply with policy, procedures, and checklists**	❑ Continuous use/reference use
5. **Speak-up for safety**	❑ 5:1 feedback ❑ ARCC *(ask a question, request a change, voice a concern, and chain of command)*

Safety Tools for All – staff, medical staff, and leaders

Revision B, 3 February 2014

1. Pay attention to detail
   - ❑ Self-check
   - ❑ Peer check
2. Communicate clearly
   - ❑ 3-way repeat back
   - ❑ Phonetic and numeric clarification
   - ❑ Clarifying question
   - ❑ SBAR
3. Practice with a Questioning Attitude
   - ❑ Validate and verify
4. Use and comply with policy, procedures, and checklists
5. Speak-up for safety
   - ❑ 5:1 feedback
   - ❑ ARCC

1. Pay Attention to Detail

What should we do?

Focus our attention before we act

Why should we do this?

- To avoid unintended slips or lapses
- To reduce the chance that we'll make an error when we're under time pressure or stress

Safety Tools:

Self Checking *using* STAR (Stop Think Act Review)

Peer Checking

Self Checking Using STAR

Stop

Pause for one second to focus attention on task

Think

Visualize the act and think about what is to be done

Act

Concentrate and perform the task

Review

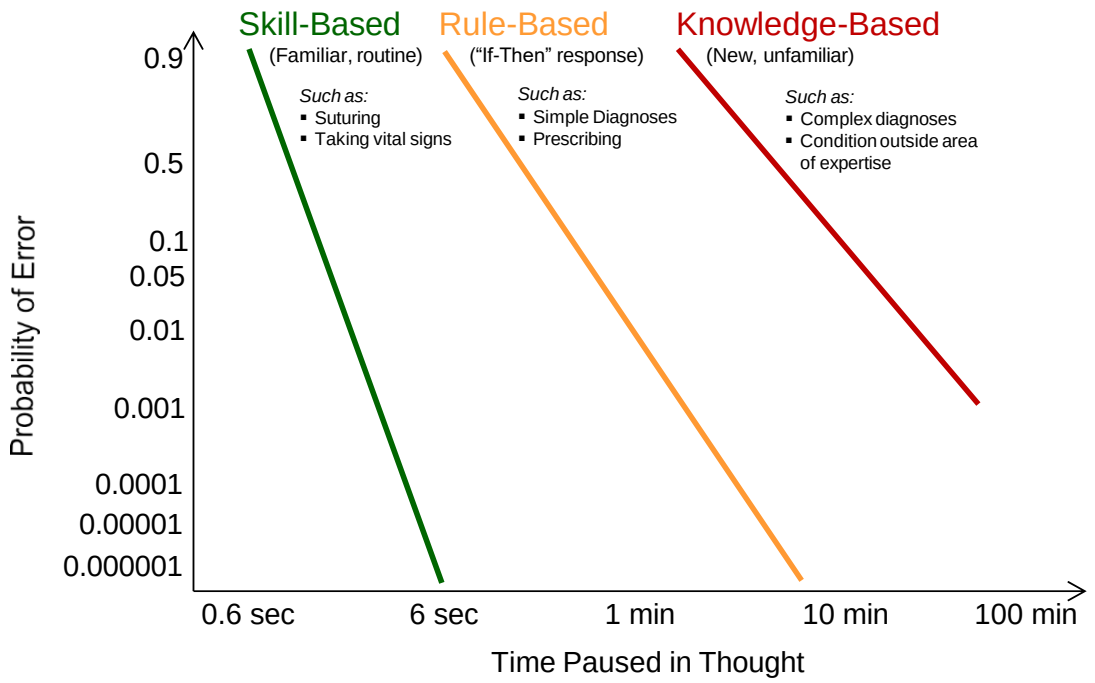
Check for the desired result

Self Checking

The most effective way to avoid slips and lapses.

It takes **one second** to do and reduces the probability of making an error by a factor of 10 or MORE!

Time Reliability Correlation



Source: R E Hall, et al. "Post Event Hunan Decision Errors: Operator Action Tree/Time Reliability Correlation," NUREG-CR-3010, November 1982

Peer Check

Take advantage of working together

- Check the accuracy of each other's work
- Identify slips and lapses
- Point out unusual situations or hazards

Individual reliability is limited:

1 defect per 1,000 opportunities (or 0.001)

Peer Checking multiplies the error probability:

0.001 x 0.001 =

1 defect per one million

<u>Key to Successful Peer Checking</u>

Be willing to check others AND be willing to have others check us

2. Communicate Clearly

What should we do?

Ensure that we hear things correctly and understand things accurately

Why should we do this?

To prevent wrong assumptions and misunderstandings that could cause us to make wrong decisions

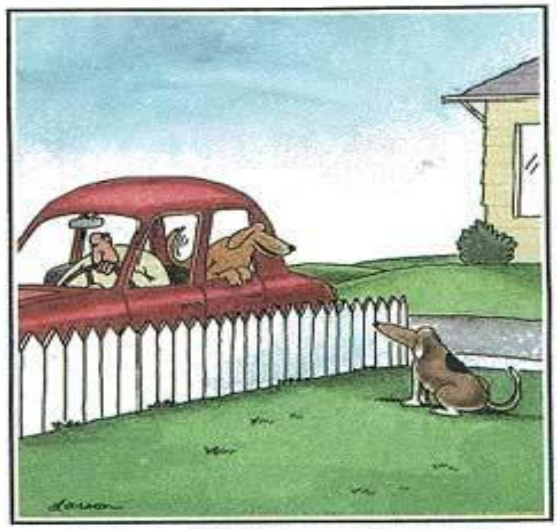
Safety Tools:

3-Way Repeat Backs & Read Backs

Clarifying Questions

Phonetic & Numeric Clarifications

SBAR



"Ha ha ha, Biff. Guess what? After we go to the drugstore and the post office, I'm going to the vet's to get tutored."

3-Way Repeat Back

Sender initiates communication using Receivers Name. Sender provides an order, request, or information to Receiver in a clear and concise format.

Receiver acknowledges receipt by a repeat-back of the order, request, or information.

Sender acknowledges the accuracy of the repeat-back by saying, **That's correct!** If not correct, Sender repeats the communication.

A Safety Phrase:
"Let me **repeat that back**…"

3-Way Read Back

The same thing as a 3-Way Repeat Back, BUT…

Receiver documents the information, request, or order and reads it back.

Don't rely on your memory…

write it whenever you receive critical information that might be difficult to remember.

This is *so critical* that The Joint Commission requires this for communication of critical test results, verbal orders and telephone orders.

Ask Clarifying Questions

Ask one to two clarifying questions:

- In all high risk situations
- When information is incomplete
- When Information is not clear

Asking clarifying questions can reduce the risk of making an error by $2\frac{1}{2}$ times!

Why…

To make sure that you really understand what's being communicated so that you don't make a decision based on a wrong assumption.

How…

Phrase your questions in a manner that will give an answer that improves your understanding of the information.

A Safety Phrase:
"Let me ask a **clarifying question**…"

Phonetic Clarifications

For *sound alike words*, say the letter followed by a word that begins with the letter. For example:

A	Alpha	**J**	Juliet	**S**	Sierra
B	Bravo	**K**	Kilo	**T**	Tango
C	Charlie	**L**	Lima	**U**	Uniform
D	Delta	**M**	Mike	**V**	Victor
E	Echo	**N**	Novembe r	**W**	Whiskey
				X	X-Ray
F	Foxtrot	**O**	Oscar	**Y**	Yankee
G	Golf	**P**	Papa	**Z**	Zulu
H	Hotel	**Q**	Quebec		
I	India	**R**	Romeo		

Numeric Clarifications

For sound alike numbers,
say the number and then say the digits

15…that's one-five

50…that's five-zero

45…that's four-five

425…that's four-two-five

4 to 5…that's the range four dash five

And **always** use leading zeroes – as in 0.9

SBAR Briefing Format

When you need to communicate about a problem or issue that needs resolution…

Situation

- Who you're calling about, the immediate problem, your concerns

Background

- Review of pertinent information: procedures, patient condition

Assessment

- Your view of the situation: "*I think the problem is…" or "I'm not sure what the problem is"*
- Urgency of action: *"the patient is deteriorating rapidly - we need to do something"*

Recommendation

- Your suggestion to or request of the other person

3. Practice with a Questioning Attitude

What should we do?

Use good judgment at all times

to ensure our actions are the best.

Why should we do this?

- Reduces the chance that we'll make a mistake in a high-risk situation
- Helps ensure that work activities are stopped when uncertain and unsafe conditions are identified

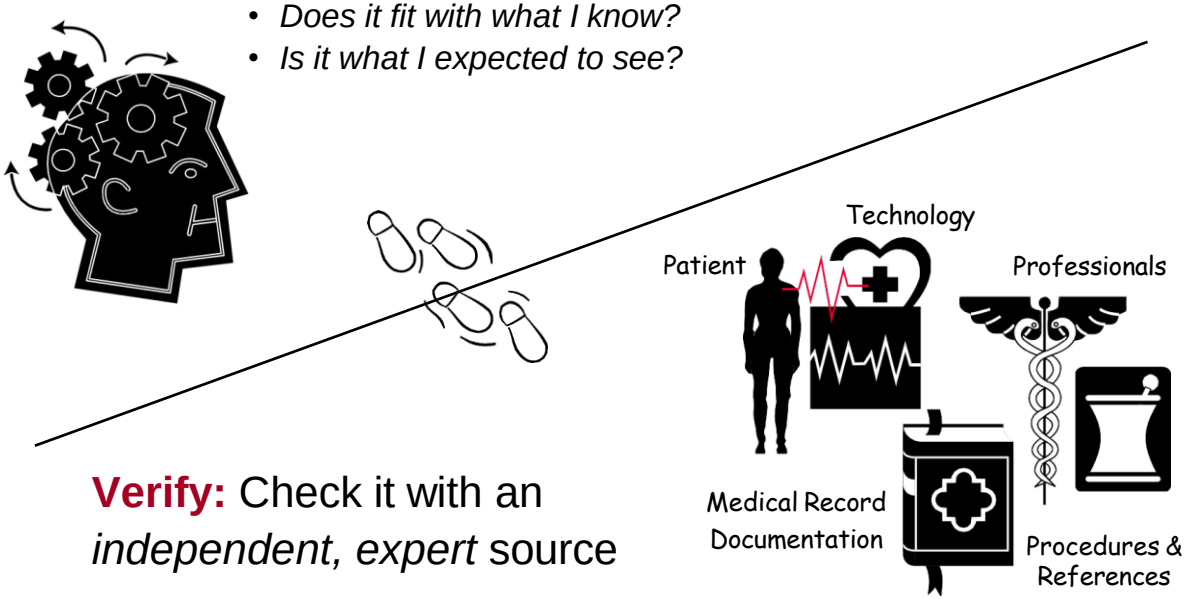
Safety Tool:

Validate & Verify

Validate & Verify Technique

Validate: Does it make sense to me?

- *Does it fit with what I know?*
- *Is it what I expected to see?*



Verify: Check it with an *independent, expert* source

4. Use And Comply With Policy, Procedures, And Checklists

What should we do?

- Know the correct policy, procedure, action, or checklist
- Perform according to specifications

Why should we do this?

- They help us perform tasks consistently, efficiently, correctly, and safely and avoid reliance upon memory.

Safety Tool:

Continuous Use / Reference use

Policy/Procedure/Checklist Compliance

Continuous Use

- For Procedures that are:
  - Safety critical
  - Complex
  - Performed infrequently
- Read the entire protocol before taking any action.
- Ensure that the entire team understands all the steps
- Use tool/checklist/job aid each and every time.

Reference Use:

- For procedures that:
  - Consist of small segments easily performed from memory
  - Not safety critical
  - Not complex or infrequently performed
- Read the entire protocol before taking an action
- Ensure that you understand all the steps before taking any action

5. Speak up for Safety

What should we do?

- Monitor the actions of other team members for the purpose of sharing the workload and reducing or avoiding errors
- Act on a responsibility to protect in a manner of mutual respect – an assertion and escalation technique

Why should we do this?

Help maintain situation awareness

A way of “watching each other’s back”

Helps ensure that work activities are stopped when uncertain and unsafe conditions are identified

Safety Tools:

5:1 feedback

ARCC (**a**sk a question, **r**equest a change, voice a **c**oncern, and **c**hain of command)

Peer Coaching using 5:1 Feedback

Positive Feedback

Encouraging someone to continue practicing an observed behavior

Top Positive Reinforcements

1. Head nod
2. “Yes”
3. “Thank you”

Negative Feedback

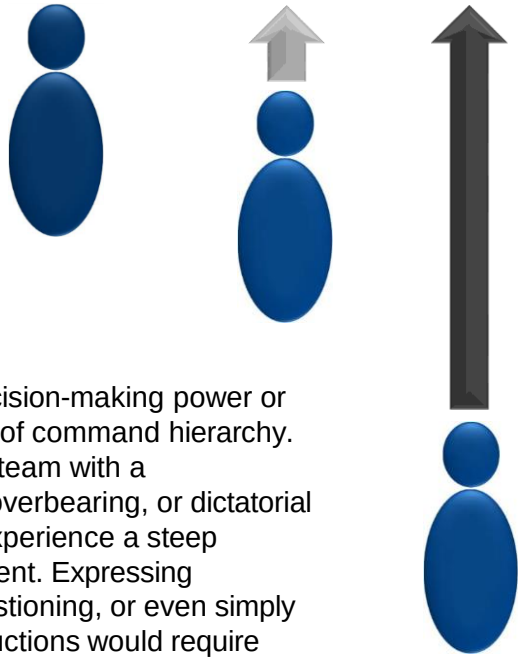
Discouraging someone from continuing to practice an observed behavior

Top Negative Reinforcements

1. Furrowed brow
2. “No”
3. Offering a practice tip

Adapted from *Bringing Out the Best in People*, by Dr. Aubrey Daniels (1994)

Authority Gradient



The ***perceived*** steepness – not necessarily the real – as seen by the ***subordinate***

Balance of decision-making power or the steepness of command hierarchy. Members of a team with a domineering, overbearing, or dictatorial team leader experience a steep authority gradient. Expressing concerns, questioning, or even simply clarifying instructions would require considerable determination…

Most teams require some degree of authority gradient; otherwise roles are blurred and decisions cannot be made in a timely fashion.

AHRQ PSNet patient safety network

HPI®

Challenges in "Speaking Up For Safety"

"*Communication Openness*" Dimension results demonstrate that approximately 37% of staff believe they ***might not be comfortable speaking up*** about something even if a patient might be harmed*

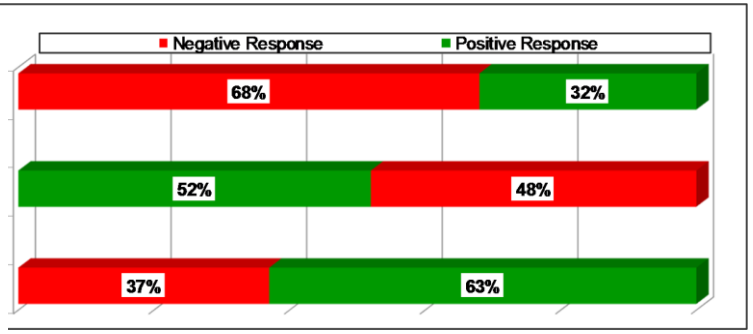
Why?

*Primarily finding difficulty in **asking questions**, **particularly to those in authority** (68% said "sometimes or never")*

Staff feel free to question the decisions of those with more authority

Staff are afraid to ask questions when something doesn't seem right

Staff will freely speak up about things that may negatively affect patient care



*From the 2013 AHRQ Safety Culture Survey

Speak Up for Safety Using ARCC

Something I do to help our team prevent a safety event

Use the lightest touch possible…

Ask a question

Make a **R**equest

Voice a **C**oncern

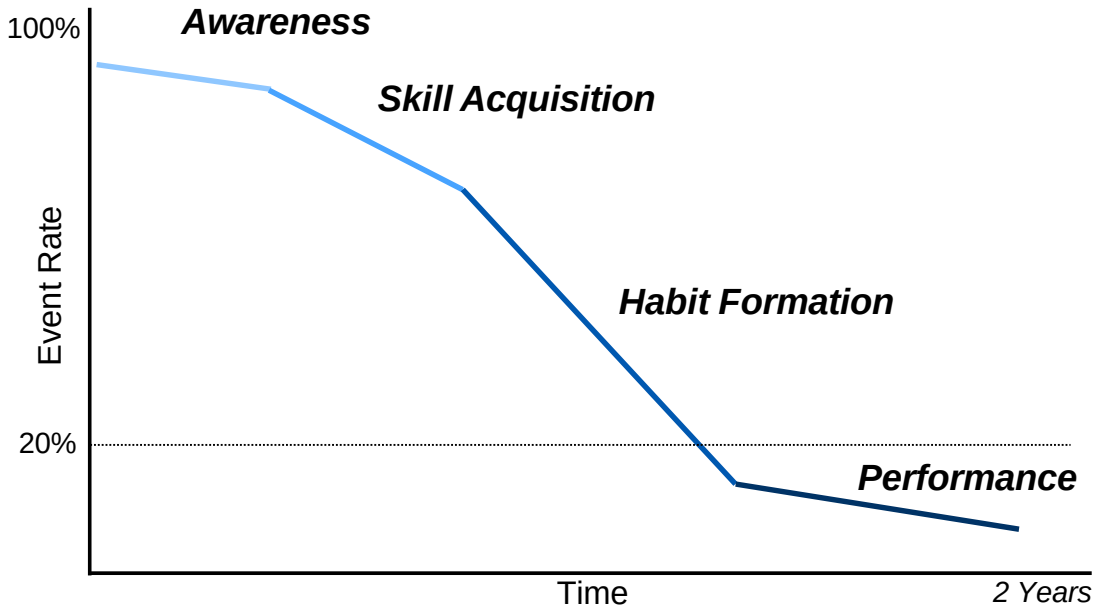
If no success…

Use **C**hain of Command

A Safety Phrase
"I have a **concern**…"

Making it Stick - “It’s Hawthorne Until Habit”

Dr Glenn Bingle, CMO of Community Health Network



Next Steps

- Think about what you will do differently in your work environment as it pertains to patient safety.
- Practice these error prevention techniques-take care of each other!
- Make Clinton Memorial Hospital and your work environment the safest place for our patients.

Thank you for choosing to practice at CMH.

PLEASE GO TO THE FOLLOWING LINKS TO REVIEW THE FOLLOWING ITEMS

MEDICAL STAFF BYLAWS
https://www.cmhregional.com/sites/clinton/assets/uploads/Medical%20Staff%20Bylaws%2012182019.pdf

RULES & REGULATIONS
https://www.cmhregional.com/sites/clinton/assets/uploads/Rules%20&%20Regulations-%20approved%20Nov%2024%202021.pdf

ScionHealth

Clinton Memorial Hospital
New Healthcare Provider Orientation

CERTIFICATE OF COMPLETION

I acknowledge that I have reviewed and completed Clinton Memorial Hospital's Provider Orientation which included general orientation, sepsis education, avoiding Medicare/Medicaid Fraud & Abuse, zero harm training, Medical Staff Bylaws, and Rules & Regulations.

_____
NAME (PRINT)

_____
SIGNATURE

_____
DATE