Certified Professional in Healthcare Quality (CPHQ)

Chapter Review

Chapter 7: Legislation Initiatives

November 1st 2017

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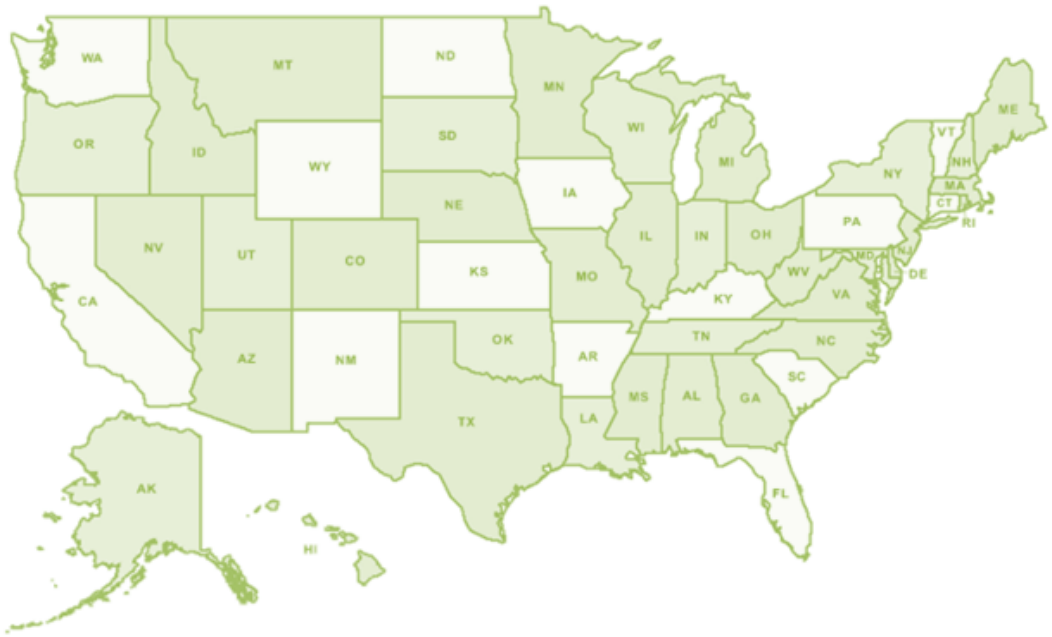
QUALITY Reporting Services

Objectives

Chapter 7: Legislation Initiatives

1. Assist the organization in maintaining awareness of statutory and regulatory requirements (i.e. OSHA, HIPPA, etc.)

2. Recognize quality initiatives impacting reimbursement (i.e. pay for performance/value-based purchasing, etc.)



Corporate Liability in the U.S.

Accountability & Liability Pressures

Liability: is being "legally responsible for something". There are four main types of liability:

- Contractual Liability: obligates the practitioners or organization to perform according to what is promised or advertised.
- Tort Liability: is legal responsibility for civil wrongs, including invasion of privacy, lack of consent, defamation of character, fraud and deceit, assault and battery, and negligence/malpractice.
- Corporate Liability: replaced charitable immunity as the doctrine dictating healthcare organizations' legal responsibility to patients.
  - Vicarious Liability: assumes organizational liability for the negligent acts of its employees and of "ostensible agents". Holds organizations liable for the professional conduct of licensed independent practitioners and other workers who are not employees (but may be under contract) when a patient associates the professional/worker with the organization is not privy to contractual arrangements.
- Criminal Liability: is legal responsibility for actions in violations of criminal law and punishable by fine or imprisonment.

Torts

Tort cases stem from a failure of “duties” noted in the previous slide. There are three types of Torts:

1. Intentional Tort – is a civil wrong that occurs when the person engages in intentional conduct that results in damages to another
2. Negligence: is a careless conduct that results in damages to another. It is failure to follow the degree of care that would be followed by a reasonable prudent person in order to avoid foreseeable harm.
3. Strict Liability: also known as absolute liability, results from cases of defective products or services.

Negligence

The elements required for a person to establish negligence are:

1. There was a presence of duty
2. There was a failure to act (breach of duty) according to the required standards of conduct/care
3. There was proximate causation of harm
4. The harm was caused by the breach of duty

All four of these elements must be in place for the actions to be called negligent.

Regulatory & Legal Hints

All federal laws, regulations, final rules, and interim rules are published in the Federal Register. They can be found through the following government website. Under the section, “Federal Register Publications and Online Services” is a link to the Federal Register 2.0 (www.ofr.gov).

- The most current issues are in a shortcut bar across the top of the webpage.
- New documents are available for review and comment can be found at www.regulations.gov
- For a list of Case Law Resources and a U.S. Historical Review of laws involving healthcare, please refer to pages 380-385 of the ‘Healthcare Quality Handbook’

Polling Question(s)

Question #1, #2, #3, and #4

Legal Foundations for Quality Practice

Medicare & Medicaid

Medicare and Medicaid are two governmental programs that provide medial and health-related services to specific groups of people in the united States.

- CMS developed and administers the Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) that healthcare organizations must meet in order to begin and continue participating in the Medicare and Medicaid programs.
  - These health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries.

Medicare

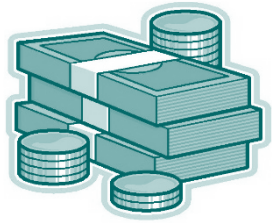
- The Medicare program is an insurance program financed through taxes paid by employees and employers. The primary purpose of the program is to provide a health care safety net for individuals retired from the workforce.
- Medicare has four parts: A, B, C, and D.
  - Part A: is the insurance for hospitalization, skilled nursing, certain home health services and other services. It is available without cost to the individuals who paid Medicare taxes.
  - Part B: medical insurance, there is a monthly premium and enrollees must be eligible to receive Medicare Part A.
  - Part C: known as the Medicare + Choice or Medicare Advantage plans, these plans are additional coverage plans obtained from private insurance agencies to pay for things not included in Medicare Parts A and B.
  - Part D: a prescription drug plan purchases from private insurance agencies, it requires a premium and deductibles. The purpose is to cover the gap when Medicare does not cover the cost of medications.

Medicaid

- The Medicaid system is a federal-state assistance program rather than an insurance program like Medicare.
- In most states the program is offered to those individuals and families meeting certain low- or no-income criteria who generally own no property, through home ownership is permitted in some states.
  - Employment is not necessarily a determinant, but many who receive Medicaid have at least one person in the household who is working.
- Medicaid eligibility includes children, parents, pregnant women, seniors, and people with disabilities who need the health coverage to get healthy and stay healthy.
- Generally, Medicaid coverage has no co-payment requirements, deductibles, or premiums, and there is freedom of choice of provider, though eligibility requirements may be complex.

Prospective Payment System (PPS)

A method of reimbursement that provides healthcare providers – facilities and licensed independent practitioners – with a pre-negotiated fixed set of payment rates for each type of patient or group of services. The payment rate remains unchanged regardless of operating costs.



- PPS was designed to make reimbursements for care in a predetermined, fixed amount.
- CMS has created separate PPS for acute care hospitals, home health agencies, hospice, hospital outpatient, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, skilled nursing facilities, and federally qualified health centers.
- A fee schedule is a complete listing of fees used by Medicare to pay doctors or other providers/suppliers.
  - This comprehensive listing of fee maximums is used to reimburse a physician and/or other providers on a fee-for-service basis.
  - CMS develops fee schedules for physicians, ambulance services, clinical laboratory services, and durable equipment, prosthetics, orthotics, and supplies.

Quality Improvement Organization (QIO)

- Formerly known as Professional Standards Review Organization (PSRO) – physician sponsored and established to assure services provided to Medicare and Medicaid patients worked and employed concurrent utilization review, including admission and continued stay review.
  - The primary purpose of the original PSRO program was quality-protected cost containment.
- The current QIO program is dedicated to improving health quality for Medicare beneficiaries – to improve the effectiveness, efficiency, economy, and quality of services delivered to Medicare beneficiaries.
  - Part of the U.S. Department of Health and Human (HHS) Services' National Quality Strategy for providing better care and better health at lower cost.

Quality Improvement Network (QIN)

- The QIN is a division of the QIO, referred to QIN-QIO and it's purpose is to provide healthcare organizations education, outreach, and sharing practices that have working in other areas.
  - Utilize data to measure improvement, and will work with patients, familiars, and community partners through communication and collaboration.
  - Also focus on targeted health conditions and priority populations to reduce the incidence of healthcare-acquired conditions.
  - The activities under the QIO are referred to as "Scopes of Work" SoW. The activities conducted within their contracts typical run for three years, but recently changed to five years

Accountable Care Organizations (ACOs)

- Groups of doctors, hospitals, and other healthcare providers, who work together to give coordinated high quality care to their patients, at lower costs.
- Medicare currently offers three ACO programs:
  - Medicare Shared Savings Program: is a program that helps Medicare fee-for-service program providers become an ACO and share the savings. The Shared Savings Program aims to improve patient outcomes and increase value of care by providing better care for individuals, better health for populations, and lowering growth in expenditures.
  - Advance Payment ACO Model: is a supplementary incentive program for selected participants in the Shared Savings Program. Selected participants receive upfront and monthly payments, which they can use to make important investments in their care coordination infrastructure.
  - Pioneer ACO Model: is a program designed for early adopters of coordinated care who already have experience in coordinating care for patients across care settings. These provider groups can then move more rapidly from a shared savings payment model to a population-based payment model.

Polling Question(s)

Question #5, #6, #7, #8, #9, and #10

Legal Foundations for Patient Protection

Patient Self-Determination Act (PSDA)

- A law that requires that providers develop policies and procedures addressing a patient's right to refuse treatment and to execute an "advance directive" in accordance with individual state laws.
- There are six requirements of the law:
  1. Written policies and procedure for living wills and durable power of attorney
  2. Written information to adult patients concerning their rights
  3. Documentation in the medical record concerning existence of advance directive
  4. Care not to be conditioned on whether or not the patient signed an advance directive
  5. Insurance compliance with advance directives, once executed
  6. Provide education for staff and the community on issues concerning advance directives

Health Insurance Portability & Accountability Act (HIPPA)

- Was enacted by the U.S. Congress in 1996 and was a major health insurance reform bill. It requires health plans to certify compliance with standards and healthcare rules, and other items.

Polling Question(s)

Question #11 and #12

Legislation Impacting Organizational Activities

Corporate Compliance

- Chief Compliance Officer (CCO) is responsible to establish and oversee processes necessary to prevent or quickly identify any inaccurate billing practices or actual misbehavior that might result in errors being investigated as fraudulent practice by the Office of Inspector General (OIG).
  - Quality professionals and Risk Management professionals are likely candidates for this role.
  - In smaller organizations, the Quality professional will also have the Compliance responsibilities in a combined position.
- The definition of compliance is to act in accordance with another's command, request, rule, or wish.
  - In healthcare, this translates to providing billing, reimbursing, and monitoring services according to the laws, regulations, administrative rules and guidelines governing the organization.

Compliance Programs

The best resource for compliance program templates and guidance is on the Office of Inspector General website (www.oig.hhs.gov)

- OIG Compliance Program Guidance:
  - The plan must be unique to the individual entity's needs, exposures, and resources and to its particular corporate structure, mission, and employee composition.
  - Canned or generic compliance programs are not acceptable to OIG.
  - The Health Care Compliance Association is the professional organization to assist with this aspect of the compliance role.
    - It offers training, certification, and publications committed to improving the quality and recognition of the healthcare compliance industry (https://www.hcca-info.org).

Elements of Compliance

The OIG's document defines a comprehensive compliance program consisting of seven mandatory elements.

1. Conducting internal monitory and auditing
2. Implementing compliance and organizational standards
3. Designating a Compliance Officer (not general counsel or CFO) who reports directly to the CEO and governing board
4. Conducting appropriate training and education
5. Responding appropriately to detected offenses and developing corrective action
6. Developing open lines of communication
7. Enforcing disciplinary standards through well-publicized guidelines

Compliance Information

Three initial documents for a Healthcare Quality Professional to review are noted below:

- *Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors,* OIG, and American Health Lawyers Association
  - https://oig.hhs.gov/fraud/docs/complianceguidance/040203CorpRespRsceGuide.pdf
- *Corporate Responsibility and Health Care Quality – A Resource for Health Care Boards of Directors,* OIG, and American Health Lawyers Association
  - https://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf
- *Practical Guidance for Health Care Governing Boards on Compliance Oversight,* OIG, Association of Healthcare Internal Auditors, American Health Lawyers Association and Health Care Compliance Association
  - *https://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf*

Compliance Systems

Healthcare quality professionals should be familiar with two key systems:

- The National Practitioner Data Bank (NPDB)
  - Was established in 1987 and authorizes the government to collect information concerning sanctions taken by state licensing authorities and entities against healthcare practitioners. In 1990, Congress amended the law by broadening the language to include any negative action or finding by these authorities, not just sanctions.
- The Healthcare Integrity and Protection Data Bank (HIPDB).
  - Was created to also combat fraud and abuse in health insurance and health care delivery. It is a national data collection program for the reporting and disclosure of certain final adverse actions taken against healthcare practitioners, providers, and suppliers. It collects information regarding licensure and certification actions, exclusions from participation in federal and state healthcare programs, healthcare-related criminal convictions and civil judgements, and other adjudicated actions or decisions as specified in regulation.

Compliance Laws

Healthcare quality professionals will want to become familiar with the following three laws and regulations among the many that CMS oversees:

- Clinical Laboratory Improvement Amendments (CLIA): In 1988, CLIA established quality standards for all laboratories (regardless of where the test was performed) to ensure the accuracy, reliability, and timeliness of patient test results.
  - CLIA regulations are stratified based on the complexity of the test method: waived complexity; moderate complexity, including the subcategory of provider-performed microscopy; and high complexity. The regulations specify quality standards for laboratories performing moderate- and/or high-complexity tests and require waived laboratories to enroll in CLIA and follow manufacturers' instructions (CMS, 2012a).
- Health Insurance Portability and Accountability Act (HIPAA): HIPAA provides federal protections for personal health information and provides patients with rights
- Emergency Medical Treatment and Active Labor Act (EMTALA): Any hospital participating in Medicare and offering emergency services must provide a medical screening examination (MSE) when a request is made for examination or treatment for an emergency medical condition (EMC), including active labor, regardless of an individual's ability to pay. The hospital is then required to provide stabilizing treatment for patients with EMCs. If a hospital is unable to stabilize a patient within its capability, or if the patient requests, an appropriate transfer should be implemented (CMS, 2012b).

Compliance Resources

CMS works along with the Centers Disease Control (CDC) and the Federal Drug Administration (FDA) to assure clinical lab quality. The CDC's responsibilities for the national CLIA program include:

- Providing analysis, research, and technical assistance
- Developing technical standards and laboratory practice guidelines, including standards and guidelines for cytology
- Conducting laboratory quality improvement studies
- Monitoring proficiency testing practices
- Developing and distributing professional information and educational resources
- Managing the Clinical Laboratory Improvement Advisory Committee (CLIAC)

Additional Compliance Laws

- Safe Medical Devise Act (SMDA) and FDA Safety and Innovation Act (FDASIA): requires reporting within ten (10) work days of any information that reasonably suggests that a medical devise has caused, or may have caused, or contributed to a death, serious illness, or serious injury, either to the FDA or the manufacturer.
  - A device user facility is defined as a hospital, ambulatory surgical facility, nursing home, outpatient treatment facility, or outpatient diagnostic facility, which is NOT a physician's office.
  - A medical device is any item (other than a drug or biologic) used to diagnose, treat, or prevent a disease, injury or other condition.
  - Serious illness or injury means either life-threatening, or resultant permanent impairment, and/or required medical or surgical intervention to prevent permanent impairment.
- Federal Occupational Safety and Health Act (OSHA): requires employers to establish occupational safety and health programs and ensure safe and healthy working conditions for employees. Assuring safe and healthful workplaces by setting and enforcing standards, and providing training, outreach, education and assistance.

Polling Question(s)

Question #13, #14, #15, #16, #17, #18, and #19

THANK YOU!

Questions ? ? ?

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Answer Key

1. C	11. A
2. A	12. A
3. B	13. B
4. A	14. C
5. B	15. A
6. B	16. B
7. A	17. C
8. B	18. A
9. C	19. B
10. A	