

1B: Ethics, Privacy, Legal, Regulatory and Financial Issues in Informatics

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Clinical Informatics Subspecialty Delineation of Practice (CIS DoP)

Domain 1: Fundamental Knowledge and Skills (no Tasks are associated with this Domain which is focused on fundamental knowledge and skills)

Clinical Informatics

K001. The discipline of informatics (e.g., definitions, history, careers, professional organizations)
K002. Fundamental informatics concepts, models, and theories
K003. Core clinical informatics literature (e.g., foundational literature, principle journals, critical analysis of literature, use of evidence to inform practice)
K004. Descriptive and inferential statistics
K005. Health Information Technology (HIT) principles and science
K006. Computer programming fundamentals and computational thinking
K007. Basic systems and network architectures
K008. Basic database structure, data retrieval and analytics techniques and tools
K009. Development and use of interoperability/exchange standards (e.g., Fast Health Interoperability Resources [FHIR], Digital Imaging and Communications in Medicine [DICOM])
K010. Development and use of transaction standards (e.g., American National Standards Institute X12)
K011. Development and use of messaging standards (e.g., Health Level Seven [HL7] v2)
K012. Development and use of ancillary data standards (e.g., imaging and Laboratory Information System [LIS])
K013. Development and use of data model standards
K014. Vocabularies, terminologies, and nomenclatures (e.g., Logical Observation Identifiers Names and Codes [LOINC], Systematized Nomenclature of Medicine –Clinical Terms [SNOMED-CT], RxNorm, International Classification of Diseases [ICD], Current Procedural Terminology [CPT])
K015. Data taxonomies and ontologies

K016. Security, privacy, and confidentiality requirements and practices
K017. Legal and regulatory issues related to clinical data and information sharing
K018. Technical and non-technical approaches and barriers to interoperability
K019. Ethics and professionalism
The Health System
K020. Primary domains of health, organizational structures, cultures, and processes (e.g., health care delivery, public health, personal health, population health, education of health professionals, clinical research)
K021. Determinants of individual and population health
K022. Forces shaping health care delivery and considerations regarding health care access
K023. Health economics and financing
K024. Policy and regulatory frameworks related to the healthcare system
K025. The flow of data, information, and knowledge within the health system

Domain 2: Improving Care Delivery and Outcomes

K026. Decision science (e.g., Bayes theorem, decision analysis, probability theory, utility and preference assessment, test characteristics)
K027. Clinical decision support standards and processes for development, implementation, evaluation, and maintenance
K028. Five rights of clinical decision support (i.e., information, person, intervention formats, channel, and point/time in workflow)
K029. Legal, regulatory, and ethical issues regarding clinical decision support
K030. Methods of workflow analysis
K031. Principles of workflow re-engineering
K032. Quality improvement principles and practices (e.g., Six Sigma, Lean, Plan-Do-Study-Act [PDSA] cycle, root cause analysis)
K033. User-centered design principles (e.g., iterative design process)
K034. Usability testing
K035. Definitions of measures (e.g., quality performance, regulatory, pay for performance, public health surveillance)
K036. Measure development and evaluation processes and criteria
K037. Key performance indicators (KPIs)
K038. Claims analytics and benchmarks
K039. Predictive analytic techniques, indications, and limitations
K040. Clinical and financial benchmarking sources (e.g., Gartner, Healthcare Information and Management Systems Society [HIMSS] Analytics, Centers for Medicare and Medicaid Services [CMS], Leapfrog)
K041. Quality standards and measures promulgated by quality organizations (e.g., National Quality Forum [NQF], Centers for Medicare and Medicaid Services [CMS], National Committee for Quality Assurance [NCQA])
K042. Facility accreditation quality and safety standards (e.g., The Joint Commission, Clinical Laboratory Improvement Amendments [CLIA])
K043. Clinical quality standards (e.g., Physician Quality Reporting System [PQRS], Agency for Healthcare Research and Quality [AHRQ], National Surgical Quality Improvement Program [NSQIP], Quality Reporting Document Architecture [QRDA], Health Quality Measure Format [HQMF], Council on Quality and Leadership [CQL], Fast Health Interoperability Resources [FHIR] Clinical Reasoning)
K044. Reporting requirements
K045. Methods to measure and report organizational performance
K046. Adoption metrics (e.g., Electronic Medical Records Adoption Model [EMRAM], Adoption Model for Analytics Maturity [AMAM])
K047. Social determinants of health
K048. Use of patient-generated data
K049. Prediction models
K050. Risk stratification and adjustment
K051. Concepts and tools for care coordination
K052. Care delivery and payment models

Domain 3: Enterprise Information Systems

K053. Health information technology landscape (e.g., innovation strategies, emerging technologies)
K054. Institutional governance of clinical information systems
K055. Information system maintenance requirements
K056. Information needs analysis and information system selection
K057. Information system implementation procedures
K058. Information system evaluation techniques and methods
K059. Information system and integration testing techniques and methodologies
K060. Enterprise architecture (databases, storage, application, interface engine)
K061. Methods of communication between various software components
K062. Network communications infrastructure and protocols between information systems (e.g., Transmission Control Protocol/Internet Protocol [TCP/IP], switches, routers)
K063. Types of settings (e.g., labs, ambulatory, radiology, home) where various systems are used
K064. Clinical system functional requirements
K065. Models and theories of human-computer (machine) interaction (HCI)
K066. HCI evaluation, usability engineering and testing, study design and methods
K067. HCI design standards and design principles
K068. Functionalities of clinical information systems (e.g., Electronic Health Records [EHR], Laboratory Information System [LIS], Picture Archiving and Communication System [PACS], Radiology Information System [RIS] vendor-neutral archive, pharmacy, revenue cycle)
K069. Consumer-facing health informatics applications (e.g., patient portals, mobile health apps and devices, disease management, patient education, behavior modification)
K070. User types and roles, institutional policy and access control
K071. Clinical communication channels and best practices for use (e.g., secure messaging, closed loop communication)
K072. Security threat assessment methods and mitigation strategies
K073. Security standards and safeguards
K074. Clinical impact of scheduled and unscheduled system downtimes
K075. Information system failure modes and downtime mitigation strategies (e.g., replicated data centers, log shipping)
K076. Approaches to knowledge repositories and their implementation and maintenance
K077. Data storage options and their implications
K078. Clinical registries
K079. Health information exchanges
K080. Patient matching strategies
K081. Master patient index
K082. Data reconciliation
K083. Regulated medical devices (e.g., pumps, telemetry monitors) that may be integrated into information systems
K084. Non-regulated medical devices (e.g., consumer devices)
K085. Telehealth workflows and resources (e.g., software, hardware, staff)

Domain 4: Data Governance and Data Analytics

K086. Stewardship of data
K087. Regulations, organizations, and best practice related to data access and sharing agreements, data use, privacy, security, and portability
K088. Metadata and data dictionaries
K089. Data life cycle
K090. Transactional and reporting/research databases
K091. Techniques for the storage of disparate data types
K092. Techniques to extract, transform, and load data
K093. Data associated with workflow processes and clinical context
K094. Data management and validation techniques
K095. Standards related to storage and retrieval from specialized and emerging data sources
K096. Types and uses of specialized and emerging data sources (e.g., imaging, bioinformatics, internet of things [IoT], patient-generated, social determinants)
K097. Issues related to integrating emerging data sources into business and clinical decision making
K098. Information architecture
K099. Query tools and techniques
K100. Flat files, relational and non-relational/NoSQL database structures, distributed file systems
K101. Definitions and appropriate use of descriptive, diagnostic, predictive, and prescriptive analytics
K102. Analytic tools and techniques (e.g., Boolean, Bayesian, statistical/mathematical modeling)
K103. Advanced modeling and algorithms
K104. Artificial intelligence
K105. Machine learning (e.g., neural networks, support vector machines, Bayesian network)
K106. Data visualization (e.g., graphical, geospatial, 3D modeling, dashboards, heat maps)
K107. Natural language processing
K108. Precision medicine (customized treatment plans based on patient-specific data)
K109. Knowledge management and archiving science
K110. Methods for knowledge persistence and sharing
K111. Methods and standards for data sharing across systems (e.g., health information exchanges, public health reporting)

Domain 5: Leadership and Professionalism

K112. Environmental scanning and assessment methods and techniques
K113. Consensus building, collaboration, and conflict management
K114. Business plan development for informatics projects and activities (e.g., return on investment, business case analysis, pro forma projections)
K115. Basic revenue cycle
K116. Basic managerial/cost accounting principles and concepts
K117. Capital and operating budgeting
K118. Strategy formulation and evaluation
K119. Approaches to establishing Health Information Technology (HIT) mission and objectives
K120. Communication strategies, including one-on-one, presentation to groups, and asynchronous communication
K121. Effective communication programs to support and sustain systems implementation
K122. Writing effectively for various audiences and goals
K123. Negotiation strategies, methods, and techniques
K124. Conflict management strategies, methods, and techniques
K125. Change management principles, models, and methods
K126. Assessment of organizational culture and behavior change theories
K127. Theory and methods for promoting the adoption and effective use of clinical information systems
K128. Motivational strategies, methods, and techniques
K129. Basic principles and practices of project management
K130. Project management tools and techniques
K131. Leadership principles, models, and methods
K132. Intergenerational communication techniques
K133. Coaching, mentoring, championing and cheerleading methods
K134. Adult learning theories, methods, and techniques
K135. Teaching modalities for individuals and groups
K136. Methods to assess the effectiveness of training and competency development
K137. Principles, models, and methods for building and managing effective interdisciplinary teams
K138. Team productivity and effectiveness (e.g., articulating team goals, defining rules of operation, clarifying individual roles, team management, identifying and addressing challenges)
K139. Group management processes (e.g., nominal group, consensus mapping, Delphi method)



Knowledge Statements from the DoP

K016. Security, privacy, and confidentiality requirements and practices

K017. Legal and regulatory issues related to clinical data and information sharing

K019. Ethics and professionalism

K023. Health economics and financing

K029. Legal, regulatory, and ethical issues regarding clinical decision support

K115. Basic revenue cycle

Key Topics

- International codes of practice and ethical codes relevant to clinical informatics.
- US legal and regulatory rulings most relevant to clinical informatics.
- Oversight of clinical computing activities by local bylaws and compliance groups.
- General principles of capital and operating budgeting as they pertain to clinical information systems
- General principles of managerial accounting
- Key financial concepts used in financial planning for clinical information systems

Ethical and Legal Considerations

International Codes and Principles

US Ethical Codes

US Law



Codes and Principles

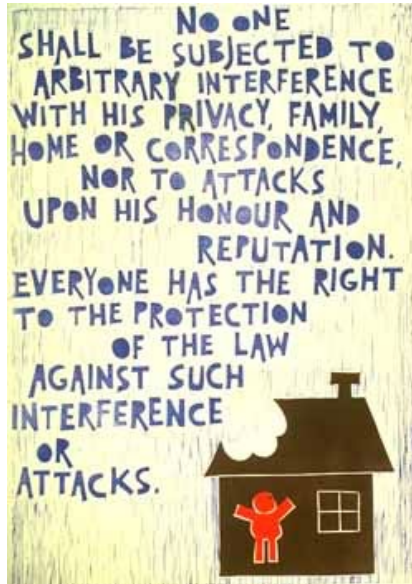
International

- Article 12 Universal Declaration of Human Rights
- Hippocratic Oath
- European Convention on Human Rights

US

- Code of Fair Information Practice
- Belmont Report and the Common Rule
- Conflict of Interest

Universal Declaration of Human Rights



Article 12

No one shall be subjected to arbitrary interference with his **privacy**, family, home or correspondence, nor to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks.

<https://www.un.org/en/universal-declaration-human-rights/index.html>



Hippocratic Oath

Whatever I see or hear in the lives of my patients, whether in connection with my professional practice or not, which ought not to be spoken of outside, I will keep secret, as considering all such things to be private.



Translated by Michael North, National Library of Medicine, 2002.

https://www.nlm.nih.gov/hmd/greek/greek_oath.html



Code of Fair Information Practice

1. There must be no personal data record-keeping systems whose very existence is secret.
2. There must be a way for a person to find out what information about the person is in a record and how it is used.
3. There must be a way for a person to prevent information about the person that was obtained for one purpose from being used or made available for other purposes without the person's consent.
4. There must be a way for a person to correct or amend a record of identifiable information about the person.
5. Any organization creating, maintaining, using, or disseminating records of identifiable personal data must assure the reliability of the data for their intended use and must take precautions to prevent misuses of the data.

U.S. Dep't. of Health, Education and Welfare, [Secretary's Advisory Committee on Automated Personal Data Systems, Records, computers, and the Rights of Citizens](#) (1973).

Garfinkel S. Database Nation. The Death of Privacy in the 21st Century. Sebastopol: O' Reilly Media, 2001.



Belmont Report and Common Rule

The [Belmont Report on Ethical Principles and Guidelines for the Protection of Human Subjects of Research](#). April 18, 1979

1. Respect for Persons.
2. Beneficence. (1) do not harm and (2) maximize possible benefits and minimize possible harms.
3. Justice.



Federal Policy for the Protection of Human Subjects or the “Common Rule”, published in 1991, codified in separate regulations by 15 Federal departments and agencies

For all participating departments and agencies the Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance.



AMIA Conflict of Interest Policy

A **real or apparent** conflict of interest may arise when a leader has some other interest that might suggest divided loyalty on the part of the leader between obligations to AMIA, on one hand, and to some other organization or cause, on the other. The “other interest” may arise from a transaction between AMIA and a third party, or a leader’s volunteer or paid relationship with a third party, which may compromise their ability to provide unbiased and undivided loyalty to AMIA. **There is no monetary threshold for a COI.** The AMIA COI policies extend to relationship that a spouse, domestic partner, parent or child of an affected individual.

US Law

Bill of Rights

HIPAA

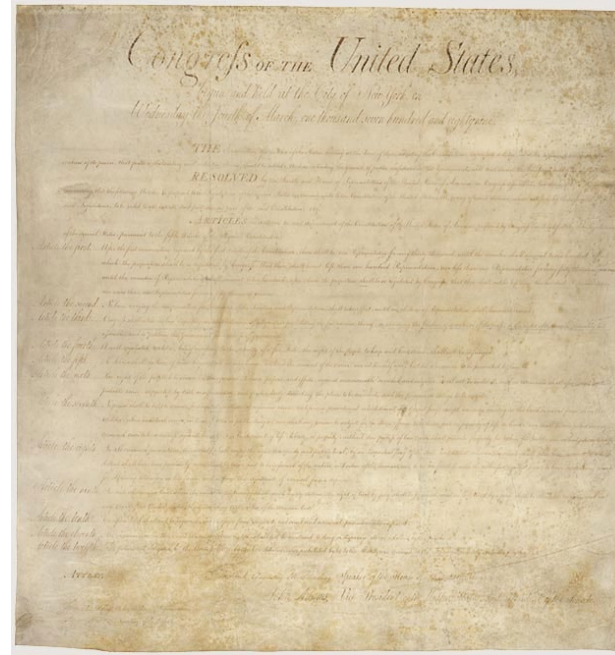
State and local laws

Flows of patient information permitted by law

United States Bill of Rights

Fourth Amendment – Protection from unreasonable search and seizure.

The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.



American Recovery and Reinvestment Act

DIVISION A—APPROPRIATIONS PROVISIONS

TITLE I—AGRICULTURE, RURAL DEVELOPMENT, AND RELATED AGENCIES

TITLE II—COMMERCE, JUSTICE, AND RELATED AGENCIES

TITLE III—DEPARTMENT OF DEFENSE

TITLE IV—ENERGY AND WATER DEVELOPMENT

TITLE V—FINANCIAL SERVICES AND RELATED AGENCIES

TITLE VI—DEPARTMENT OF HOMELAND SECURITY

TITLE VII—INTERIOR, ENVIRONMENT, AND RELATED AGENCIES

TITLE VIII—DEPARTMENTS OF LABOR AND EDUCATION, AND RELATED AGENCIES

TITLE IX—LEGISLATIVE BRANCH

TITLE X—MILITARY CONSTRUCTION AND RELATED AGENCIES

TITLE XI—STATE, FOREIGN OPERATIONS, AND RELATED PROGRAMS

TITLE XII—TRANSPORTATION, HOUSING AND URBAN DEVELOPMENT, AND RELATED AGENCIES

TITLE XIII—HEALTH INFORMATION TECHNOLOGY

TITLE XIV—STATE FISCAL STABILIZATION FUND

TITLE XV—ACCOUNTABILITY AND TRANSPARENCY

TITLE XVI—GENERAL PROVISIONS—THIS ACT

TITLE XVII—MISCELLANEOUS PROVISIONS

TITLE XVIII—MISCELLANEOUS PROVISIONS

TITLE XIX—MISCELLANEOUS PROVISIONS

TITLE XX—MISCELLANEOUS PROVISIONS

TITLE XXI—MISCELLANEOUS PROVISIONS

TITLE XXII—MISCELLANEOUS PROVISIONS

TITLE XXIII—MISCELLANEOUS PROVISIONS

TITLE XXIV—MISCELLANEOUS PROVISIONS

TITLE XXV—MISCELLANEOUS PROVISIONS

TITLE XXVI—MISCELLANEOUS PROVISIONS

TITLE XXVII—MISCELLANEOUS PROVISIONS

TITLE XXVIII—MISCELLANEOUS PROVISIONS

TITLE XXIX—MISCELLANEOUS PROVISIONS

TITLE XXX—MISCELLANEOUS PROVISIONS

TITLE XIII—HEALTH INFORMATION TECHNOLOGY

SEC. 13001. SHORT TITLE; TABLE OF CONTENTS OF TITLE.

(a) SHORT TITLE.—This title (and title IV of division B) may be cited as the “Health Information Technology for Economic and Clinical Health Act” or the “HITECH Act”.

(b) TABLE OF CONTENTS OF TITLE.—The table of contents of this title is as follows:

TITLE XIII—HEALTH INFORMATION TECHNOLOGY

TITLE XIV—STATE FISCAL STABILIZATION FUND

TITLE XV—ACCOUNTABILITY AND TRANSPARENCY

TITLE XVI—GENERAL PROVISIONS—THIS ACT

TITLE XVII—MISCELLANEOUS PROVISIONS

TITLE XVIII—MISCELLANEOUS PROVISIONS

TITLE XIX—MISCELLANEOUS PROVISIONS

TITLE XX—MISCELLANEOUS PROVISIONS

TITLE XXI—MISCELLANEOUS PROVISIONS

TITLE XXII—MISCELLANEOUS PROVISIONS

TITLE XXIII—MISCELLANEOUS PROVISIONS

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TITLE XXVII—MISCELLANEOUS PROVISIONS

TITLE XXVIII—MISCELLANEOUS PROVISIONS

TITLE XXIX—MISCELLANEOUS PROVISIONS

TITLE XXX—MISCELLANEOUS PROVISIONS

“HITECH” Act

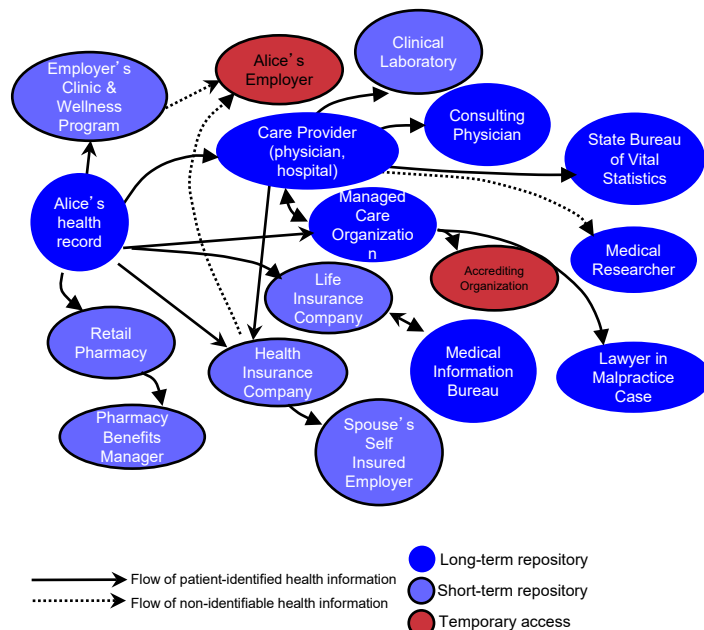
TITLE IV—MEDICARE AND MEDICAID HEALTH INFORMATION TECHNOLOGY; MISCELLANEOUS MEDICARE PROVISIONS

TITLE VI—BROADBAND TECHNOLOGY OPPORTUNITIES PROGRAM

TITLE VII—LIMITS ON EXECUTIVE COMPENSATION



Flows of Alice's Health Information



Source: [For The Record](#), Institute of Medicine, 1997

ISBN: 0-309-05697-7, 288 pages, 6 x 9, hardback (1997). National Research Council

Model and Context for Security and Privacy

- Threat assessment
- Asset list
- Policy
- Education
- Technical measures

Privacy Protections within EHRs

- It is very difficult to predict which clinician will need to view which record.
- Most US hospitals use policy and audits to protect against access to records for which physicians have no professional relationship.
- Sanctions occur for inappropriate access

43240 EPIC		unknown		Patient selected from Patient Lookup form.			U	2/21/14	15:27:30
43241 EPIC		unknown		Appointment desk accessed for patient			U	2/21/14	15:27:31
43242 EPIC		unknown		A report with patient data accessed.			U	2/21/14	15:27:32
43243 ORCA		Rehabilitation Medicine	Care Provider	Tab Access Discharge Readiness			H	2/21/14	15:27:34
43244 ORCA		UW Contact Center	Clinical Care	Chart Access			H	2/21/14	15:27:39
43245 ORCA		UW Contact Center	Clinical Care	Tab Access Chart Default			H	2/21/14	15:27:39
43246 ORCA		UW Contact Center	Clinical Care	Tab Access Discharge Readiness			H	2/21/14	15:27:40
43247 ORCA		UW Rehab Medicine	Clinical Care	Tab Access Form Browser			H	2/21/14	15:28:02
43248 ETEBRY		HMC Pharmacy	PharmT				H	2/21/14	15:29:44
43249 ETEBRY		HMC Pharmacy	PharmT				H	2/21/14	15:30:10
43250 ETEBRY		HMC Pharmacy	PharmT				H	2/21/14	15:30:12
43251 ETEBRY		HMC Pharmacy	PharmT				H	2/21/14	15:30:19
43252 ETEBRY		HMC Pharmacy	PharmT				H	2/21/14	15:30:20
43253 ETEBRY		HMC Ambulatory Pharmacy	Pharm				H	2/21/14	15:30:54
43254 ORCA		UW Rehab Medicine	Clinical Care	Tab Access Clinical Notes			H	2/21/14	15:31:25
43255 ORCA		HMC Ambulatory Pharmacy	Pharmacy	Tab Access Chart Default			H	2/21/14	15:31:55
43256 ORCA		HMC Ambulatory Pharmacy	Pharmacy	Chart Access			H	2/21/14	15:31:55
43257 ORCA		HMC Ambulatory Pharmacy	Pharmacy	Tab Access Medication List			H	2/21/14	15:31:59
43258 ORCA		HMC Ambulatory Pharmacy	Pharmacy	Tab Access - Status / Plan Summary			H	2/21/14	15:32:02
43259 ETEBRY		HMC Ambulatory Pharmacy	Pharm				H	2/21/14	15:32:24
43260 EPIC		HMC ANTICOAGULATION-PHARMACY		Patient selected from Patient Lookup form.			U	2/21/14	15:34:18
43261 EPIC		HMC ANTICOAGULATION-PHARMACY		Patient Station accessed for patient.			U	2/21/14	15:34:18
43262 EPIC		HMC ANTICOAGULATION-PHARMACY		A Registration/ADT workflow initiated.			U	2/21/14	15:34:19
43263 EPIC		HMC ANTICOAGULATION-PHARMACY		Reg: Coverage FC forms Covered Through Information			U	2/21/14	15:34:21
43264 EPIC		HMC ANTICOAGULATION-PHARMACY		Reg: Coverage FC forms HTML Summary subcomponent			U	2/21/14	15:34:21



Clinical Computing Systems and the Law

- The importance of authentication and authorization
- Concept of non-repudiation
- Patient billing is based on codes, and codes have to be based on Medical Record documentation.
- Audit trails, document version history
- Close cooperation with compliance and general counsel



30(b)6 witness

- This particular rule is designed to allow a party to serve a notice of deposition or subpoena upon another party without designating a particular person to testify but to “describe with reasonable particularity the matters for examination.”
- CMIOs may serve as 30(b)6 witnesses as experts in electronic health records and other topics as called by plaintiff or defense teams in litigation

<https://www.law.cornell.edu/rules/frcp>





True or False

The HITECH Act refers to sections of the Affordable Care Act that provide financial incentives for meaningful use of certified electronic health records.





True or False




The HITECH Act refers to sections of the Affordable Care Act that provide financial incentives for meaningful use of certified electronic health records.

FALSE. The HITECH Act is part of ARRA, not ACA



CMS Guidelines for Use of Macros

Reimbursement is closely tied to documentation, whether on paper, through dictation or using an EHR




Guidelines for Teaching Physicians, Interns, and Residents

General Documentation Guidelines

Both residents and teaching physicians may document physician services in the patient's medical record. The documentation must be dated and contain a legible signature or identity and may be:

- Dictated and transcribed;
- Typed;
- Hand-written; or
- Computer-generated.



A macro is a command in a computer or dictation application in an electronic medical record that automatically generates predetermined text that is not edited by the user. The teaching physician may use a macro as the required personal documentation if he or she personally adds it in a secured or password protected system. In addition to the teaching physician's macro, either the resident or the teaching physician must provide customized information that is sufficient to support a medical necessity determination. The note in the electronic medical record must sufficiently describe the specific services furnished to the specific patient on the specific date. If both the resident and the teaching physician use macros only, this is considered insufficient documentation.



Letter from Secretaries Sebelius and Holder



September 24, 2012

American Hospital Association
Richard Umdbenstock
President and Chief Executive Officer
325 Seventh Street, N.W.
Washington, DC 20004

Federation of American Hospitals
Charles N. Kahn, III
President and Chief Executive Officer
750 9th Street, NW, Suite 600
Washington, DC 20001-4524

Association of Academic Health Centers
Steve Wartman
President and Chief Executive Officer
1400 Sixteenth Street, NW, Suite 720
Washington, DC 20036

Association of American Medical Colleges
Darrell G. Kirch, M.D.
President and Chief Executive Officer
2450 N Street, NW
Washington, DC 20037-1126

National Association of Public Hospitals and Health Systems
Bruce Siegel, MD, MPH
President and Chief Executive Officer
1301 Pennsylvania Avenue, NW
Suite 950
Washington DC 20004

Dear Chief Executive Officers:

As leaders in the health care system, our nation's hospitals have been at the forefront of adopting electronic health records for use in coordinating care, improving quality, reducing paperwork, and eliminating duplicative tests. Over 55 percent of hospitals have already qualified for incentive payments authorized by Congress to encourage health care providers to adopt and meaningfully use this technology. Used appropriately, electronic health records have the potential to save money and save lives.

However, there are troubling indications that some providers are using this technology to game care is not just bad patient care; it's illegal. These indications include potential "cloning" of medical records in order to inflate what providers get paid. There are also reports that some hospitals may be using electronic health records to facilitate "upcoding" of the intensity of care

This letter underscores our resolve to ensure payment accuracy and to prevent and prosecute health care fraud. A patient's care information must be verified individually to ensure accuracy; it cannot be cut and pasted from a different record of the patient, which risks medical errors as well as overpayments. The Centers for Medicare and Medicaid Services (CMS) is specifically reviewing billing through audits to identify and prevent improper billing. Additionally, CMS is initiating more extensive medical reviews to ensure that providers are coding evaluation and management services accurately. This includes comprehensive coding reports from many facilities. CMS has the authority to address inappropriate increases in coding intensity in its payment rules, and CMS will consider future payment reductions as warranted.

We will not tolerate health care fraud. The President initiated in 2009 an unprecedented Cabinet-level effort to combat health care fraud and protect the Medicare trust fund, and we take those responsibilities very seriously.

Law enforcement will take appropriate steps to pursue health care providers who misuse electronic health records to bill for services never provided. The Department of Justice, Department of Health and Human Services, the FBI, and other law enforcement agencies are monitoring these trends, and will take action where warranted. New tools provided by the health care law authorize CMS to stop Medicare payments upon suspicion of fraud and to mine data to detect it in the first place. These efforts have contributed to record-high collections and prosecutions. Prosecutions in 2011 were 75 percent higher than in 2008. That said, we will continue to escalate our efforts to prevent fraud and pursue it aggressively when it has occurred.

The nation's hospitals share our goal of a health system that offers high quality, affordable care. We thank you for your relentless work toward this goal which can be better achieved once all Americans have privacy-protected electronic health records. The health information technology incentive program promotes electronic health records that go beyond documentation and billing and towards meaningful use as a foundation for new payment and delivery models. The Affordable Care Act has accelerated the spread of such models like Accountable Care Organizations, patient-centered homes, and value-based purchasing which shift the incentives away from volume and towards value. As we phase-in electronic health records, though, we ask for your help in ensuring that these tools are not misused or abused.

Sincerely,

Kathleen Sebelius
Secretary
U.S. Department of Health & Human Services

Eric H. Holder, Jr.
Attorney General
U.S. Department of Justice





The HIPAA Security Rule

- A. Requires awareness and compliance of security professionals but does not extend to the general workforce.
- B. Requires protection against published and known security threats only
- C. Defines confidentiality, integrity and availability
- D. Does not cover availability of electronic PHI
- E. Pertains to transmission and storage but not impermissible use of e-PHI



The HIPAA Security Rule

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ANSWER: C. A good resource is <https://www.hhs.gov>. The HIPAA Security rule states that covered entities ensure confidentiality, integrity and availability of e-PHI and requires that entities ensure compliance by their workforce.

TJC (JCAHO) IM Standards

Patient-Specific information

- 6.1 The hospital has a complete and accurate medical record for every individual assessed, cared for, treated or served.
- 6.2 Records contain patient-specific information, as appropriate, to the care, treatment, and services provided.
- 6.3 The medical record thoroughly documents operative or other high risk procedures and the use of moderate or deep sedation or anesthesia.

TJC IM Standards

Information Management Planning

- 1.1 The hospital plans and designs information management processes to meet internal and external information needs.

Confidentiality and Security

- 2.1 Information privacy and confidentiality are maintained.
- 2.2 Information security, including data integrity, is maintained.
- 2.3 The hospital has a process for maintaining continuity of information.

TJC IM Standards

6.4 For patients receiving continuing ambulatory care services, the medical record contains a summary list of all significant diagnoses, procedures, drug allergies, and medications.

6.5 Designated qualified personnel accept and transcribe verbal orders from authorized individuals.

6.6 The hospital can provide access to all relevant information from a patient's record when needed for use in patient care, treatment and services.

Medical Records Committee

- Oversight to meet goals of information management.
- Oversight for implementation of regulations
- Oversight for meeting accreditation standards.
- Policy and Procedure approval
- Understanding of record and systems functionality and impact on information flow.
- Advisory and direction in areas of
 - System functionality and workflow
 - Appropriate Entries into the record
 - Chart Completion
 - Forms management
- Audits and Quality review with action steps.



Health Information Management

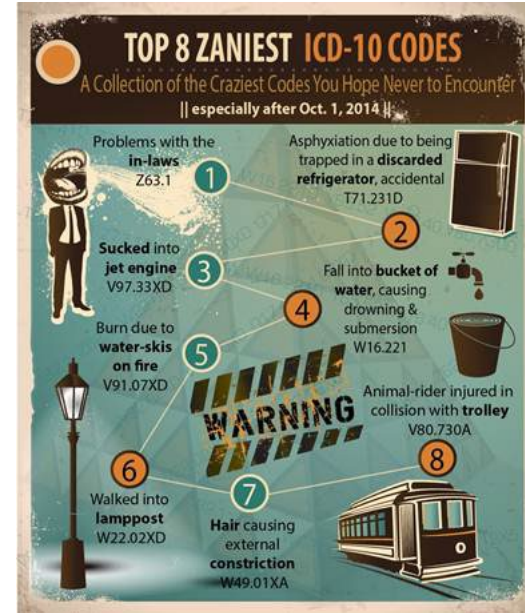
- Hospital leaders have overall responsibility for managing information.
- Hospital Bylaws, Rules & Regulations establishes the Medical Records Committee, and professional staff record responsibilities.
- Hospital Policy & Procedures guide hospital operations.
- Regulatory Bodies – State & Federal
 - State: Division of Health,
 - Federal: CMS; Medicare, HIPAA
 - Accreditation – Joint Commission (on Accreditation for Healthcare Operations) (TJC)



Key Operations

Coding and the analysis of coded data are key operations

- Clinical Classification Systems
- There are many other recognized classification systems
- ICD-10 and CPT (HIPAA standard)
 - Billing and Payment for healthcare services
 - Research
 - Turns data into useful information for process improvement, quality and patient safety



HIM Key Operations

Release of Information (ROI)

- Disclosures to outside organizations must meet all HIPAA, state and federal disclosure regulations.
- Dept. handles all incoming requests for records.
- Determine and prepare records to be disclosed according to regulations.

Master Patient Index and Encounters

- Every patient has one medical record number.
- Every patient visit has an encounter.

HIM Credentials and Certifications

Coding Certifications

Privacy Certifications

Health Information Credentials

- RHIA (Registered Health Information Administrator)
- RHIT (Registered Health Information Technician)

Clinical Decision Support and the Law

Protecting Access to Medicare Act (2014) requires that ordering clinicians consult appropriate use criteria (AUC) through a qualified clinical decision support mechanism when requesting advanced imaging services (ie, SPECT/PET MPI, CT, and MR) on outpatients and nonemergent emergency room for the furnishing provider to receive payment approval from CMS.

FDA and ONC regulation—see References

Key Topics

- General principles of capital and operating budgeting as they pertain to clinical information systems
- General principles of managerial accounting
- Key financial concepts used in financial planning for clinical information systems

Definitions, 1

Capital budgeting: Planning process for expenditure of relatively large sums on long-term assets such as replacing worn out assets with new ones and developing new business opportunities. [Tiffen 2007]

Operating budgeting: A detailed projection of all estimated income and expenses based on forecasted revenue during a given period (usually one year). a complete operating budget consists of not only a projected profit and loss statement but also a supporting cash flow statement, as well as a balance sheet. [Rollins]

Definitions, 2

Depreciation: To lower the price or estimated value of [Webster], particularly of a long-term asset that has diminishing value over time.

Net present value: The difference between the present value of all cash inflows and the present value of all cash outflows; used to determine whether or not a project is an acceptable investment. [Garrison, 1994].

Principles of Managerial Accounting

- Managerial accounting is concerned with **providing information to managers**, in contrast to financial accounting, which is concerned with providing information to stockholders and others outside an organization.
- Includes accounting information (budgets, performance reports for controlling), tools for organizing and directing and decision making.
- There are many differences between financial and managerial accounting.

Garrison, 1994



Managerial Accounting, in Contrast to Financial Accounting:

- Focuses on providing data for managers
- Places more emphasis on the future
- Places more emphasis on non-monetary data
- Emphasizes segments of an organization rather than just the organization as a whole.
- Is not governed by generally accepted accounting principles

Garrison, 1994



Principles of Managerial Accounting Tools

- Fixed and variable costs
- Profit and loss (P&L) statement
- Operating leverage
- Cost-volume-profit analysis



Budget Types

Statistics. Calculates the budget needed for various "what-if" scenarios.

Revenue. revenue receipts of government and the expenditure met from these revenues

Cash. A prediction of future cash receipts and expenditures for a particular time period

Expense. Includes spending data items.

Operating

Capital

Time Value Analysis

Future value of
lump sum

Present value
of lump sum

Net present value is the value of the sum of future cash flows presented in today's dollars.

Net Present Value formula: $NPV(i, N) = \sum_{t=0}^N \frac{R_t}{(1+i)^t}$



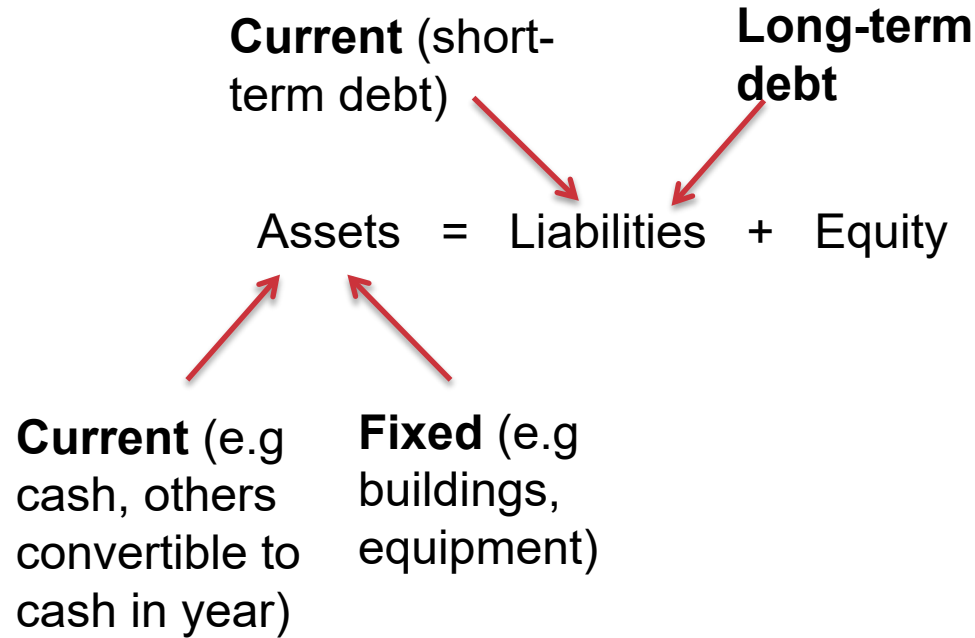
Compounded and Discounted Amounts

The **time value of money** is accounted for by the concept of compounding interest. Because a sum invested today will accrue interest in the future, a fixed sum paid in the future is worth less than the same amount today.

Rate =	0.05	
Year	Compounded Amount	Discounted Amount
0	1.000	1.000
1	1.050	0.952
2	1.103	0.907
3	1.158	0.864
4	1.216	0.823
5	1.276	0.784



Balance Sheet



Income Statement

Operating earnings = Gross Profit – (Operating Expenses + Depreciation)

Cash flow

Cash flow is the amount of cash that changed hands during an accounting period.

True or false:

Cash flow is basically the same thing as profit.

Income Statement

Operating earnings = Gross Profit – (Operating Expenses + Depreciation)

Cash flow

Cash flow is the amount of cash that changed hands during an accounting period.

True or false:

Cash flow is basically the same thing as profit.

ANSWER:

False. A sale may contribute to profit for the year, but may not result in cash until the next year.



Sample IT Budget FY 22

Project	Capital*	Operating*	Capital & Operating Total*
Data Center	\$50.0	\$35.0	\$85.0
Outpatient EHR	\$50.0	\$20.0	\$70.0
Help Desk	\$0.0	\$2.0	\$2.0
End User Devices	\$0.5	\$3.0	\$3.5
Network	\$1.0	\$4.0	\$5.0
TOTAL PROJECT AND PRODUCTION SUPPORT	\$101.5	\$64.0	\$165.5

*\$ in millions

Fiscal year: July 1, 2021 – June 30, 2022

The Costs of HICT

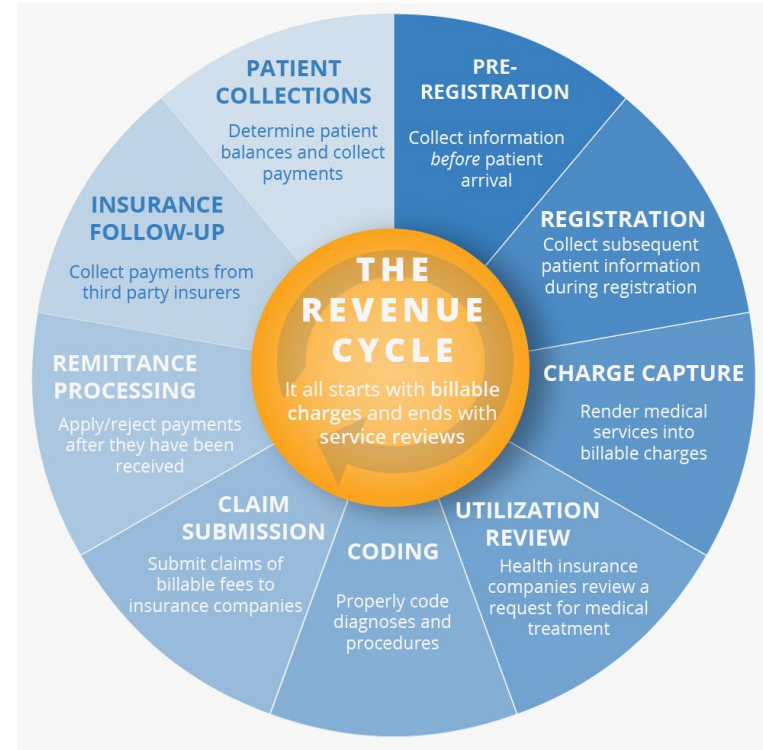
- Implementation
 - Support
 - Training program
 - Build processes
 - Administration
- RDTE (research, development, training, evaluation)
- Maintenance
 - Support/maintenance contracts
 - Application support
 - User support
 - Technical support
 - Upgrades—hardware and software
 - Complying with legal and regulatory requirements



Basic Revenue Cycle

Revenue cycle is the administrative and clinical processes of capture, management and collection of medical service revenue.

Starts with appointment/admission and ends when fully paid for services provided.



Basic Revenue Cycle

- **Appointment/pre-registration**
- **Charge capture:** Information about an episode of care is translated into a medical claims system for billing purposes.
- **Coding:** Codes are applied to a patient's record by coding specialists.
- **Claims submission:** Providers send a claim requesting payment from insurers.
- **Insurer communications:** Communication with insurers to determine patient coverage levels, collect reimbursements and negotiate contracts with insurers.
- **Payment collections:** After insurance reimbursements are received, healthcare facilities bill patients for any remaining balance.
- **Medical service review:** Analysis of clinical treatment data to find ways to lower expenses, maximize resources and improve health outcomes.

<https://healthinformatics.uic.edu/blog/what-is-healthcare-revenue-cycle-management/>



The largest category of hospital expenses for most organizations is:

- A. Pharmaceuticals
- B. Depreciation
- C. Salaries and benefits
- D. Provision for uncollectable accounts





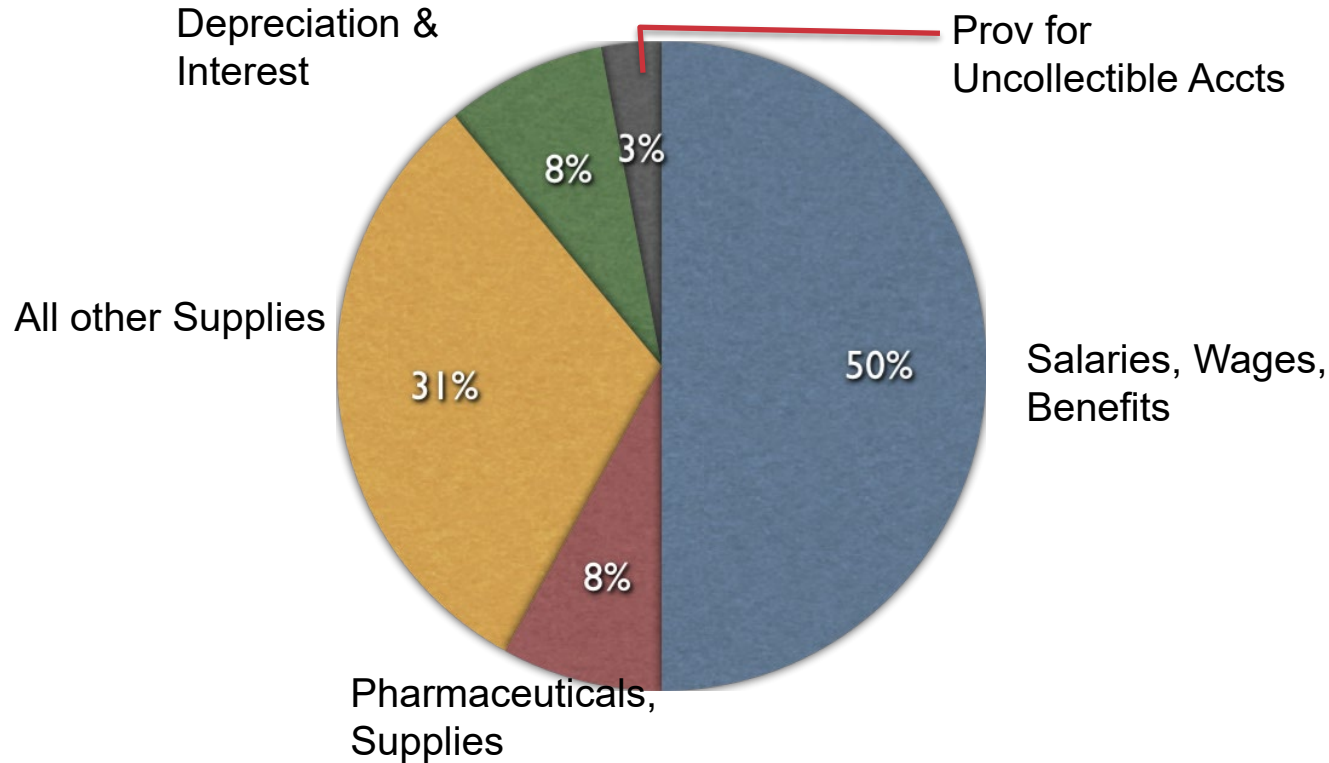
The largest category of hospital expenses for most organizations is:

- A. Pharmaceuticals
- B. Depreciation
- C. Salaries and benefits**
- D. Provision for uncollectable accounts

ANSWER: C. Salaries and benefits are almost always the largest component of expenses.



Hospital Expenses (fictitious example)



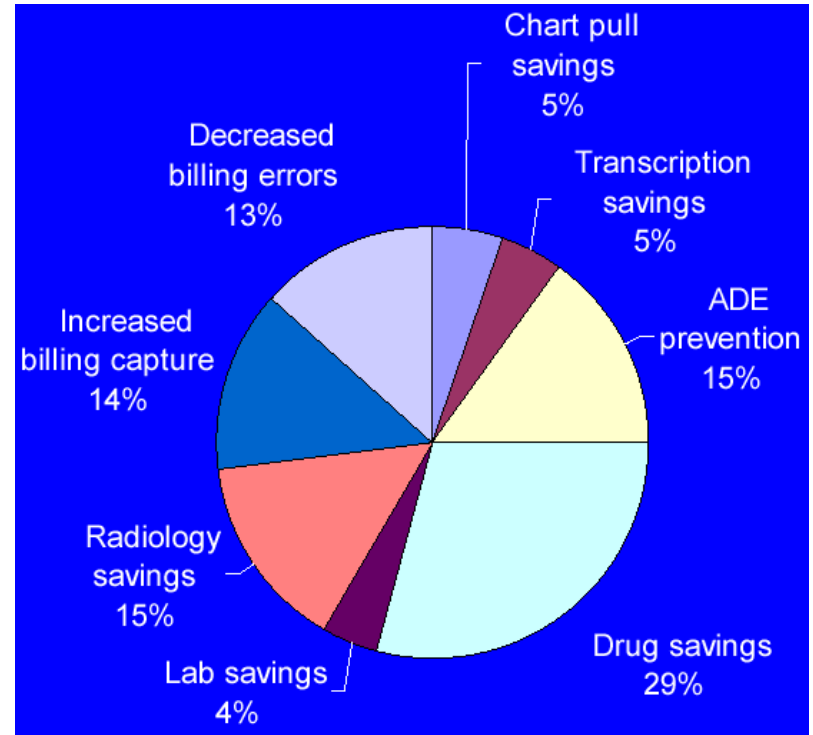
ROI from Clinical Systems

“The adoption of interoperable EMR systems could produce efficiency and safety savings of \$142–\$371 billion.”

[Hillestad, 2005]

“Studies on return on investment in health IT are few, and are unlikely to be rigorously and convincingly performed.”

[Payne, 2013]



[Glaser, NIH, 2002]

Business Case Analysis, Pro Forma Projections

Business Case Analysis is a structured methodology and document that aids decision making for obtaining best value for achieving operational requirements while balancing cost, schedule, performance, and risk by identifying and comparing alternatives including the mission and business impacts (both financial and non-financial), risks, and sensitivities.

Pro forma, Latin for “as a matter of form” or “for the sake of form”, is a method of calculating financial results using certain projections or presumptions. Pro forma financials may not be GAAP (generally accepted accounting principles) compliant but can be issued to the public to highlight certain items for potential investors.

https://www.directives.doe.gov/terms_definitions/business-case-analysis-bca
<https://www.investopedia.com/terms/p/proforma.asp>



Total Cost of Ownership (TCO)

Hardware and software

- Computer, network
- Purchasing research
- Migration
- Risks

Operations

- Infrastructure
- Electricity
- Diminished performance
- Security

Long term expenses

- Replacement
- Future upgrade
- Decommissioning

Consider life cycle of system or project, not just initial purchase or licensing cost

https://en.wikipedia.org/wiki/Total_cost_of_ownership



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