Chapter 4
The Laws and Regulations Governing Hospitals and Healthcare Entities

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Introduction

American healthcare systems, hospitals, clinics, and other points of healthcare delivery are subject to a myriad of laws and regulations promulgated by federal, state, agency, and local entities. In general, regulation is largely intended to best ensure that patients receive safe, high-quality care, in facilities that are operated in a clean and safe fashion, by appropriately trained and supervised employees. Healthcare entities are subject to HIPAA, HITECH, EMTALA, HCQIA, Anti-Kickback and Stark, false claims, CLIA, OCR, human resources laws, and other regulation addresses in detail elsewhere in this text [see Chaps. 12, 13, 25, and 27]. The resultant administrative burden to healthcare entities is substantial and adds not only to the cost of American healthcare at every level from the entities' operations, compliance programs, and governmental oversight and enforcement. At the present time, it is estimated that health systems, hospitals, and post-acute care providers (PACs) must comply with approximately 630 discrete federal regulatory requirements across nine domains, exclusive of intermittent compliance requirements such as antitrust and land use regulations; these include 341 hospital-related requirements and 288 PAC-related requirements. The American Hospital Association has described the array of regulations as "regulatory overload" and has estimated that the annual administrative cost of regulatory compliance to health systems, hospitals, and PACs and hospitals is approximately $39 billion [1]. The pace at which new rules and regulations are adopted and the sheer volume or verbiage of information within each rule make compliance challenging. The AHA also notes that an average

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size community hospital must dedicate 59 full-time equivalents (FTEs) of person power to regulatory compliance, of which more than 25% are physicians and nurses; the regulation of PACs is more complex, requiring on average an additional 8.1 FTEs to ensure compliance. The average-sized hospital spends nearly $760,000 to meet Meaningful Use (MU) administrative requirements annually, devotes 4.6 FTEs, more than 50% of whom are clinical staff, and spends approximately $709,000 annually on the administrative aspects of quality reporting [1].

The First Hospitals

The first institutions devoted specifically to the care of the injured, sick, and infirm were military hospitals which date to ancient antiquity, generally providing more comfort and care than treatment. Perhaps the earliest known civilian, or public, hospitals date to Sri Lanka to a period between 100 BC and 150 AD, described in the Sanskrit encyclopedia of medicine, the Compendium of Caraka. The Academy of Gondishapur was established as a hospital and center for medical education at Gundeshapur in Persia in the year 271 AD [2]. Early Christian and Islamic Hospitals were devoted to the care of lepers and the blind. In ancient Greece, temples dedicated to the healer-god Asclepius were organized as centers of medical learning, care, and healing, frequently in the course of religious rituals and rites. A large number of hospitals were built in Italy during the thirteenth century, especially in Milan and Florence. Between years 1414 and in 1444, in Italy, the Padua hospital "San Francesco Grande" was founded with the specific purpose of caring for the sick and subsequently became an institution for the advancement of medical research and teaching.

Medieval "hospitals" were based in the notion of social charity. The societal obligation to care for its less-fortunate fellow citizens is a global construct found throughout history. Societies and cultures, united in such interest, raised resources necessary for the care of the disadvantaged through tithes (a proportion of one's produce or earnings collected as a tax to support a religious organization) or through voluntary charitable contributions. Charitable care, through community donations of food, orphanages, and "poorhouses" were not specifically organized for the purpose of caring for the sick, but rather to care for those who could not care for themselves, the homeless, the orphaned, the infirm, the elderly, and the sick. In England, medieval and Tudor-era laws established a legal duty to care for the disadvantaged. In general, benevolent care was provided through religious institutions, generally organized at the level of local congregations or parishes. With the advancement of medical science and training, medical rather than comfort goals became the focus of hospitals, which then also evolved into medical schools providing teaching and apprenticeships.

The evolution of hospitals in the Western world from charitable guesthouses to centers of scientific excellence has been influenced by a number of social and

cultural developments which include changes in our understanding of disease, economics, geographic location, religion and ethnicity, socioeconomics, scientific and technological progress, and the perceived needs of society and the population [3]. Thus, "modern medicine is one of those extraordinary works of reason: an elaborate system of specialized knowledge, technical procedures, and rules of behavior. ... From a relatively weak, traditional profession of minor economic significance, medicine has become a sprawling system of hospitals, clinics, health plans, insurance companies, and myriad other organizations employing a vast labor force. ... The history of medicine has been written as an epic of progress, but it is also a tale of social and economic conflict over the emergence of new hierarchies of power and authority, new markets, and new conditions of belief and experience" [4].

The first hospitals in the USA were probably the Bellevue Hospital (established in 1736 as the New York City Almshouse) and the Pennsylvania Hospital (jointly established in 1751 by Dr. Thomas Bond and Benjamin Franklin with the intent of caring "for the sick-poor and insane who were wandering the streets of Philadelphia") [5].

Benjamin Franklin was instrumental in the founding of Pennsylvania Hospital in 1751 [6]. Nonetheless, throughout the eighteenth and even into the early twentieth centuries in America, physicians' offices were within their own homes, from where healthcare to the sick was delivered primarily at home; physicians visited patients at their homes where they performed surgery and deliveries at their homes and cared for the sick. Families and neighbors, as laypersons, would participate in the care of the sick and provide support to the families of the afflicted [7]. With the development of industrialization and urbanization and the accompanying shifts in social structure, in the early eighteenth century, almshouses or poorhouses were established to shelter and treat the indigent ill; and with the recognition of contagion, government-operated pesthouses segregated those who are at risk of spreading diseases such as cholera or tuberculosis. General care was provided to the sick, but there was little ability or attempt to treat or cure. Therefore the role of physicians at such institutions was merely peripheral. Thus, for most of the nineteenth century, hospitals were places where the poor and the "insane" were sent to die. Moreover, almshouses were not intended strictly to provide medical care since they also provided custodial care to the poor and destitute [8]. The vast majority of the care provided at such institutions was by nurses and not physicians. Although such institutions were supported through the philanthropy of the wealthy and by religious organizations and to a lesser extent government funding, the wealthy did not utilize such institutions for their own healthcare; since the conditions were generally deplorable, the physicians were generally unskilled, and there was little hope of healing. Rather, the wealthy continued to be either cared for at home or at hospitals owned and established by more prominent physicians [9].

Nonetheless, scientific advances in asepsis, radiology, and pharmacology provided the framework for the early hospitals. Developments in medical science and technology both led to a widespread hope that some diseases could be cured and a need for more formal education for physicians. The germ theory of disease was published by Koch in 1861; in 1879 Toussaint identified bacteria in chicken, and in

1880 Pasteur identified bacteria as the cause of spread for infections. In 1847, the American Medical Association (AMA) was established as a professional membership organization for physicians. Simultaneously, in 1847, Semmelweis proposed that handwashing was effective in reducing infections in obstetrical patients, and in 1867 Lister published his work on antiseptic techniques using disinfectants. In 1895 Roentgen took the first medical X-ray of his wife's hand, and soon afterward radiology became an accepted diagnostic technique. In the early twentieth century, through the establishment of a more standardized medical education, hospitals slowly became more accepted across socioeconomic classes, and the reputation of providers improved [10]. Through these developments, hospital infections dramatically dropped and became safer and more accepted places for medical care. Hospitals became centers for clinical teaching and by the turn of the twentieth century were recognized as places where medical care was provided for the entire community. Hospitals in the USA began to gain increasingly more credibility and respectability; by 1910, there were over 4000 acute bed hospitals in the USA.

The early education of physicians in the USA was largely by apprenticeship and later through small private medical schools with limited faculty and non-standardized curricula. Prior to the widespread implementation of educational reforms, medical training was highly variable and often considered inadequate [11]. The Carnegie Foundation for the Advancement of Teaching, commissioned in the Flexner Report, published in 1910, challenged the state of medical education at the time and provided a foundation for more standard criteria for the accreditation of medical schools, criteria for student admissions, standardization of curricula, and testing [12].

In 1929, the Great Depression caused almost all privately financed hospital construction in the USA to cease; and between the years 1928 and 1938, nearly 800 hospitals closed, compounding access to healthcare. Subsequently, during the 1930s and 1940s, the ownership of the hospitals changed from physician-owned to church-related and government-operated. Charity remained a cornerstone for early hospitals which were largely established and operated by religious organizations such as the Catholics, Jesuits, Methodists, and Baptists. However, wealthy donors were also instrumental in establishing hospitals such as the Massachusetts General Hospital and Johns Hopkins often as a means of both providing medical education and as a source of prestige.

State Regulation of Hospitals and Healthcare Facilities

The source of the states' power to regulate healthcare institutions is the "police power" derived from the Tenth Amendment of the US Constitution wherein states retain the "powers not delegated to the United States…" [13]. Thus, states are granted, by default, necessary powers to establish and enforce laws protecting the welfare, safety, and health of the public. The state also derives the authority to

regulate healthcare through the enforcement of the federal-state Medicaid program; however, the states' authority under Medicaid is subject to federal authority.

In 1946, the Hospital Survey and Construction Act, better known as the Hill-Burton Act, was enacted by the US Congress and authorized federal grants, loans, and loan guarantees to assist states and communities in constructing acute care general hospitals, special hospitals, nursing homes, public health centers, and rehabilitation facilities [14]. In its original form, the Act established a 5-year program authorizing $75 million annually for hospital construction. In order to be eligible for Hill-Burton funds, a hospital could be organized as either a public or not-for-profit entity. As a condition of funding, recipient facilities contracted, for a period of 20 years, to be available to "all persons residing in the territorial area" of the facility and to make available "a reasonable volume of hospital services to persons unable to pay therefor" – two obligations termed, respectively, the "community service" and "uncompensated care" components of the Act. Thus, the Hill-Burton Act indirectly established the first American program to fund healthcare to underserved areas.

In response to rising healthcare costs, the Social Security Amendment of 1972 contained Section 1122, legislation intended as an oversight mechanism requiring states that participated in the Medicare capital reimbursement program to review and submit recommended capital expenditures to the Secretary of Health, Education, and Welfare for prior approval [15]. New York was the first state to enact a CON law in 1964. Congress enacted the National Health Planning and Resources Development Act's ("NPHRDA") Certificate of Need (CON) program in 1975 [16], in effect a precursor to the future state-based CON laws. The NHPRDA required states to create State Health Planning and Development Agencies (SHPDA) to further develop and administer state-based CON programs and is therefore considered to represent the federal legislation which effectively required states to adopt CON laws. The NHPRDA was repealed in 1986; however, states continued to administer their CON statutes. CON laws are variably in effect in 36 states.

Certificate of Need (CON) laws are state regulatory mechanisms which, in brief, require that a state oversight or health planning agency approves the construction of healthcare facilities, expansion of facilities, and plans for major capital expenditures or service line expansions. CON laws generally intend to ensure access to healthcare resources, promote healthcare quality, control statewide healthcare costs through the avoidance of needlessly duplicative services, and ensure that services are aligned with the community need. Although New York State enacted the first CON program in the USA in 1964 as the state's Metcalf-McCloskey Act, the current CON program is a product of the National Health Planning and Resources Development Act of 1974 which, inter alia, withheld federal funds from states that did not adopt CON laws. In 1986 Congress repealed the federal CON act, thereby eliminating federal incentives to states to maintain their CON programs. Subsequently, 15 states abolished their CON regulations; however, at present, 35 states and Washington DC continue to operate their CON programs.

The term "reasonable volume" was not defined until 1979, where "not less than the lesser of (i) three percent of its operating costs for the most recent fiscal year for which an audited financial statement is available or (ii) ten percent of all Federal

assistance provided to or on behalf of the facility, adjusted by a percentage equal to the percentage change in the national Consumer Price Index for medical care between the year in which the facility received assistance or 1979, whichever is later, and the most recent year for which a published index is available" [17].

At the present time, there are approximately 300 Hill-Burton healthcare facilities nationwide; however, several states (such as Alaska, Indiana, Minnesota, Nebraska, Nevada, Rhode Island, Utah, and Wyoming) have no Hill-Burton healthcare facilities [18]. In the wake of the COVID-19 pandemic, 22 states with existing CON laws repealed or suspended them all or in part, for indeterminate periods of time. Individual state statutes provide additional regulatory authority over the healthcare institutions within that state.

The Joint Commission (on Accreditation of Healthcare Organizations)

The history of standardization of the quality of patient care in hospitals is widely credited to begin with a surgeon, Dr. Ernest Codman, who, in 1910, advocated that hospitals should be able to track the outcomes of every patient treated to determine if that treatment was effective and that reasoning led to the establishment of the American College of Surgeons. In 1917 following the Conference on Hospital Standardization, the American College of Surgeons formally established the Hospital Standardization Program, and in 1918, the College published a "Standard on Efficiency" in the Bulletin. The perceived need to extend the Hospital Standardization Program to include the American Hospital and medical arena soon became costly, and in 1951, the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association united with the American College of Surgeons to form the Joint Commission on Accreditation of Hospitals (JCAH). The Canadian Medical Association withdrew in 1959 to pursue its own standardization program, Canadian Council on Hospital Accreditation, and in 1970 published its Accreditation Manual for Hospitals. In 1965, the Medicare Act included a provision that hospitals accredited by the Joint Commission were "deemed" to be in compliance with most of the Medicare Conditions of Participation (COP) for Hospitals and therefore were considered to meet the requirements for participation in the Medicare and Medicaid programs [19]. In 1987 the JCAH was renamed as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). In 2007 the JCAHO simplified its name to The Joint Commission (THC). Effective as of 2010, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) removed the Joint Commission's statutorily guaranteed accreditation authority for hospitals as it's related to COP [20]. Nonetheless, despite statutory deference to accreditation by THC, CMS continues to require accreditation by a CMS-approved accrediting

organization or review by a state survey agency as a fundamental element of the Medicare COP [21].

THC continues to dominate the healthcare institution accreditation filed and accounts for greater than 80% of the accreditation market as the accrediting agency of choice for nearly all major hospital systems. To a large extent, THC domination is consumer-driven, based on marketing; it is also costly [22]. The effectiveness of THC accreditation as a surrogate for overall quality of care at any institution continues to be debated [23, 24]. For example, Barnett et al. found that patients admitted to hospitals during TJC survey weeks have significantly lower mortality than during non-survey weeks, particularly in major teaching hospitals [25]; and Lam et al. found no evidence to indicate that patients choosing a hospital accredited by The Joint Commission confer healthcare benefits over choosing a hospital accredited by another independent accrediting organization [26].

THC accreditation is awarded upon successful completion of an onsite survey conducted by trained surveyors who assess an institution's compliance to predetermined and published standards. THC accreditation is generally awarded for a 3-year period; however, laboratory accreditation is a 2-year award.

In addition to TJC, numerous other American organizations perform accreditation and establish standards with respect to healthcare delivery, including the National Committee for Quality Assurance (NCQA), the American Medical Accreditation Program (AMAP), the American Accreditation HealthCare Commission/Utilization Review Accreditation Commission (AAHC/URAC), the Accreditation Association for Ambulatory HealthCare (AAAHC), the Foundation for Accountability (FACCT), and the Agency for Healthcare Research and Quality (AHRQ). Furthermore, a newer accrediting organization, Det Norske Veritas and Germanischer Lloyd (DNV GL), also performs annual onsite inspections and accredits hospitals as well as specialized hospital programs such as stroke care.

As an alternative to Joint Commission accreditation, CMS-approved accreditation, an acceptable substitute accreditation is through a survey conducted by a respective state survey agency, usually through the state Department of Health. Through a state survey venue, surveyors assess a hospital's compliance with the Medicare Conditions of Participation (CoP) for all services, areas, and locations covered by the hospital's provider agreement under its CMS Certification Number (CCN) in accordance with the CMS State Operations Manual (SOM) which outlines the CMS policies. For example, in New York State, the Division of Hospitals and Diagnostic and Treatment Centers (D&TCs) is under the statutory authority of Article 28, Section 3401 of the Public Health Law (PHL), and Title 10 of the New York Codes of Rules and Regulations (NYCRR), Section 405 which, in part, issues and oversees each facility's Operating Certificate, the hospital license issued by the NYS Department of Health (DOH). In the State of New York, licensed acute care hospitals are therefore sometimes referred to as "Article 28 facilities" each identified by a unique number, the Permanent Facility Identifier (PFI), assigned to each hospital or clinic by the DOH. State health departments will also investigate complaints, issue citations, request a Plan of Correction (POC), and maintain a state database containing, for example, the demographic data of each hospital and the

number of complaint investigations completed during the previous year. Thus, specific compliance of hospitals with Medicare CoPs are actually monitored on behalf of the federal government by the respective state agency that licenses hospitals.

Classification of Healthcare Institutions

The notion of healthcare facilities has evolved from the simple designation of "hospitals" into a large array of institutions which have evolved with time to respond to patient and community needs and changes in healthcare markets, payment and reimbursement models, and federal and state regulations, laws, and mandates. In turn, with the evolution of various subtypes of healthcare instructions, the economic models, payment structure, and the regulatory landscape are adapted so as to maintain structural and quality oversight. Present-day hospitals are classified in many ways using a variety of criteria, for example, acuity or length of stay, number of beds, financial organization, ownership and control, academic status, or specialization. Examples of such designations may include, for example, public versus private, general versus specialty (i.e., pediatrics, veterans, women's health, psychiatric or mental health), for-profit versus not-for-profit, short-term versus long-term acute care hospitals, and academic versus community hospitals. Public hospitals are funded and owned by local, state, or federal governments. Private hospitals are owned by investors with a goal of profit, often concentrating services to one or a few service lines such as plastic surgery, cardiology, or neurosurgery. Increasingly, individual hospitals are a part of a healthcare system. The American Hospital Association (AHA) reports that 67% of AHA member hospitals are part of health systems, the majority consisting of three to ten hospitals [27]. Nonetheless, the definition of what constitutes a healthcare system is highly variable; for example, the Dartmouth College Center of Excellence defines a health system as an organization that consists of either at least one hospital plus at least one group of physicians (must include at least three primary care physicians) or more than one group of physicians; the National Bureau of Economic Research (NBER) Center of Excellence defines a health system based on the nature of the relationships between two or more healthcare provider organizations: (1) organizations with common ownership, (2) contractually integrated organizations (e.g., accountable care organizations), and (3) informal care systems, such as common referral arrangements; and the RAND Center of Excellence defines a health system as two or more healthcare organizations that are affiliated through shared ownership or a contractual relationship for payment and service delivery [28]. When a healthcare system also provides a form of insurance services to patients, it becomes an Integrated Delivery Network (IDN), which is then a formal system of providers and sites of care that provides healthcare services and a health insurance plan to a patient population. An IDN may vary in the scope of services it offers but can include, for example, acute care services, long-term health services, specialty clinics, primary care, and home care services, together with a plan of health insurance.

At the turn of the twentieth century, hospitals were unregulated entities, which, together with physician's offices, represented the cottage industry which was healthcare at the time. The earliest attempts at developing uniform standards for the organization and operation of hospitals were developed by the American College of Surgeons (ACS), first published as the "Minimum Standard" set circa 1918. The Minimum Standard requirements both challenged and changed the landscape of hospitals, medical staff, and teaching programs. In 1946 the Hospital Survey and Construction (Hill-Burton) Act required states to establish minimum standards for hospitals that were constructed through aid provided by the Act. In 1951 the ACS partnered with the American College of Physicians, AHA, and the American Medical Association (AMA) to form the Joint Commission on Accreditation of Hospitals (JCAH). The JCAH was created in 1951 to develop minimum health and safety standards for hospitals and subsequently to provide a uniform structure and methodology for the survey, review, and accreditation of US hospitals. In 1987, JCAH became the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) based on its extended oversight of long-term care facilities, ambulatory healthcare, home care, hospice care, mental healthcare, and managed care organizations; and in 2007 the name was subsequently shortened to The Joint Commission (TJC). Nonetheless, widespread state oversight, regulations, and licensing standards for hospitals did not begin until the 1950s. Medicare was signed into law in 1965, at which time there remained wide variation in the application of Joint Commission on Accreditation of Hospitals (JCAH) standards and a substantial number of US hospitals were not participating in the voluntary accreditation program administered by JCAH. Thus, the 1965 amendments to the Social Security Act which established Medicare also contained certain minimum requirements for hospitals, the Conditions of Participation (CoPs) which were first developed in 1965 by the Bureau of Health Insurance (BHI) of the Social Security Administration's Medicare Bureau.

CMS defines a "hospital" as "an institution primarily services in providing, by or under the supervision of physicians, inpatient diagnostic and therapeutic services or rehabilitation services". Facilities must meet the federal statutory definition of a hospital to participate in Medicare as a hospital, with the specific requirement that the hospital be primarily engaged in providing inpatient care. Hospitals must then meet CMS CoPs to be recognized by CMS as a hospital.

Federal rules and regulations regarding hospitals and healthcare facilities generally apply only to those which participate in federally funded payment programs, generally Medicare ("participating hospitals"), although nonparticipating hospitals may also be reimbursed through federal funds if certain conditions are met. Current federal standards for hospitals participating in Medicare are presented in the Code of Federal Regulations (CFR) as 24 separate CoPs which are presently 75 specific requirements or standards. The Bureau of Eligibility, Reimbursement and Coverage of the Health Care Financing Administration (HCFA) is charged with the responsibility for the review and revision of CoPs. A separate unit within HCFA unit, the Bureau of Health Standards and Quality (HSQB), is responsible for the administration and enforcement of CoP standards. CMS recognizes that it is possible for a hospital to have multiple inpatient campuses and outpatient locations; however, then

the entire healthcare system must be certified since it is not permissible to certify only part of a participating hospital.

Under Section 1861 of the Social Security Act, hospitals that participate in Medicare must meet certain requirements as specified in the Social Security Act with the caveat that the Department of Health and Human Services (DHHS) may impose additional requirements as it deems necessary. Section 1865 of the Social Security Act provides that hospitals accredited by TJC or the American Osteopathic Association (AOA) are automatically '"deemed"' ("deemed status") to meet all the health and safety requirements for participation; although both the federal conditions and the Joint Commission standards also require hospitals to be licensed by their respective states.

Critical Access Hospitals

Congress created the Critical Access Hospital (CAH) designation through the Balanced Budget Act of 1997 [29] in an attempt to reduce the financial vulnerability of rural hospitals and improve access to healthcare in rural settings. The Act also contained the Medicare Rural Hospital Flexibility Program (Flex Program) to support CAHs. In order to be eligible for CAH status, hospitals must in general meet at least the following conditions: (a) 25 or fewer acute care inpatient beds, (b) located more than 35 miles from another hospital, (c) maintain an annual average length of stay of 96 hours or less for acute care patients, and (d) provide 24/7 emergency care services. CAHs are designated by CMS. Financial incentives to CAHs include the following: (1) CAHs are paid for most inpatient and outpatient services to patients at 101% of reasonable costs; (2) Medicare does not include CAHs in the hospital Inpatient Prospective Payment System (IPPS) or the hospital Outpatient Prospective Payment System (OPPS); and (3) Medicare pays CAH services according to Part A and Part B deductible and coinsurance amounts and does not limit most of the 20% CAH Part B outpatient services copayment charges by the Part A inpatient deductible amount [30].

CAHs are eligible for participation in the 340B Drug Pricing Program, based in the Section 340B of the Public Health Service Act which requires pharmaceutical manufacturers participating in Medicaid to provide outpatient drugs at discounted prices to healthcare organizations which serve uninsured and low-income patients [31]. In addition to CAHs, the 340B program is also available to sole community hospitals (SCHs), rural referral centers (RRCs), and public and nonprofit disproportionate share hospitals (DSH). Through participation in the 340B program, these institutions can potentially achieve an average savings of 25 to 50% in pharmaceutical costs.

Medicare Critical Access Hospitals (CAHs) are certified under separate standards [32]. CAHs are a distinct type of provider with their own Medicare CoPs and also reimbursed under a separate payment method [33]. For example, CAHs are reimbursed by CMS for most inpatient and outpatient services to patients at 101%

of reasonable costs; they are not included in the Medicare hospital Inpatient Prospective Payment System (IPPS) or the hospital Outpatient Prospective Payment System (OPPS); and Medicare pays CAH services according to Part A and Part B deductible and coinsurance amounts. Nonetheless, although CAHs are treated distinctly by the CMS for purposes of accreditation and reimbursement, they are entities that are created by state designation [34]. A Medicare-participating hospital must meet the following criteria to be designated by CMS as a CAH:

- Be located in a state that has established a State Medicare Rural Hospital Flexibility program.
- Be designated by the state as a CAH.
- Be located in a rural area or an area that is treated as rural.
- Be located either more than 35 miles from the nearest hospital or CAH or more than 15 miles in areas with mountainous terrain or only secondary roads; OR prior to January 1, 2006, were certified as a CAH based on state designation as a "necessary provider" of healthcare services to residents in the area.
- Maintain no more than 25 inpatient beds that can be used for either inpatient or swing-bed services.
- Maintain an annual average length of stay of 96 hours or less per patient for acute inpatient care (excluding swing-bed services and beds that are within distinct part units).
- Demonstrate compliance with the CAH CoPs found at 42 CFR Part 485 subpart F.
- Furnish 24-hour emergency care services 7 days a week [35].

Nonetheless, a CAH may be granted "swing-bed" approval to provide post-hospital skilled nursing facility-level care in its inpatient beds, and, in addition, a CAH may also operate a psychiatric and/or a rehabilitation distinct part unit of up to ten beds each [35].

Acute Care Hospitals

Although reasonably constant, there has been a slow but steady decline in the number of hospitals over the past decades, for a variety of reasons including insolvency as well as merger and acquisitions. At the time of this writing, based upon the most recent available data, there are approximately 6146 hospitals in the USA (7156 in 1975) with approximately 924,000 hospital beds (1.5 million in 1975), accounting for 34.3 million hospital-reported admissions for year 2018. Hospital care accounts for approximately one-third of all healthcare costs, and the healthcare sector employs more than six million people in the USA [36].

The AHA classifies most hospitals in the USA to be community hospitals; of these, two-thirds are located in large cities. Community hospitals are sub-classified as (1) teaching or (2) non-teaching hospitals. Teaching hospitals are generally affiliated with a medical school, provider training program, or university or college and are active in teaching and training of healthcare professionals, conduct clinical

research, and usually provide complex and specialized care such as trauma, transplant, and a wide array of specialty and subspecialty care [37]. Acute care hospitals are divided into hospitals which provide (1) short-term acute care or (2) long-term acute care. This classification of facilities is jointly governed by the federal and state statutes and regulations.

Short-term acute care hospitals (STACHs) are also referred to as a Short Stay Hospital (SSH). For example, NYS defines "acute care" as "inpatient general routine care provided to patients who are in an acute phase of illness, but not to the degree which requires the concentrated and continuous observation and care provided in the intensive care units of an institution" [38]. An acute care hospital may be defined as "any institution, place, building, or agency providing accommodations, facilities, and services over a continuous period of twenty-four hours or more for observation, diagnosis, or care of two or more individuals not related to the operator who are suffering from illness, injury, deformity, or abnormality, or from any other condition for which obstetrical, medical, or surgical services would be appropriate for care or diagnosis" [39]. For example, Connecticut Public Health Code (PHC) defines a short-term hospital as one "that has facilities, medical staff and all necessary personnel to provide diagnosis, care and treatment of a wide range of acute conditions, including injuries."

On the other hand, a long-term acute care hospital (LTAC, LTCH, or LTACH) is a special type of hospital, certified as an acute care hospital, which is focused on the care of patients with complex acute medical issues which require intense, special treatment for a longer period of time, on average 25 days generally admitted to the LTACH from intensive care, or step-down intensive care, units in SSHs. LTACHs specialize in treating patients who may have more than one serious condition; often these are patients who have three to six concurrent active diagnoses or are patients who have suffered an acute episode on top of several chronic illnesses. Accordingly, LTACHs provide complex care such as mechanical ventilation via tracheostomies, complex respiratory therapy, dialysis, heart failure care, sepsis care with a need for long-term antibiotics, complex wound care, and subacute brain trauma care [40]. The diagnostic codes (DRGs) for such diagnoses, where the stay is prolonged, will generally result in an outlier payment to the STACH due to extensive resource consumption; however, that outlier payment will usually not be sufficient to compensate the STACH for the added costs of care, resulting in a loss to the institution both as a real loss (reimbursement lower than the cost of care) and also an opportunity cost (potential shortage of acute care beds for non-outliers). LTACHs are designed to deliver care for medically complex patients who were initially admitted to an STACH, at a lower overall cost than would be possible if the patients received their entire care in STACHs for the same duration. LTACHs may be affiliated with healthcare systems and hospitals or be managed by corporations or privately. LTACHs are different from Long-term care (LTC) facilities, which do not provide acute acre, are primarily custodial, and are discussed in detail below.

Long-Term Care Facilities

A Long-term care facility (LTC facility) can be defined as "A facility that provides rehabilitative, restorative, and/or ongoing skilled nursing care to patients or residents in need of assistance with activities of daily living" [41]. LTC facilities are a type of PAC. Long-term care facilities include skilled nursing facilities (SNF), nursing homes, rehabilitation facilities, inpatient behavioral health facilities, and long-term chronic care hospitals. LTC facilities are regulated jointly by CMS [42] and the states. LTC facilities are subject to CMS CoPs and Conditions for Coverage (CfCs).

In 1986 the Institute of Medicine (IOM) published recommendations intended to comprehensively and radically reform the regulations and thereby improve the quality of care provided in nursing homes [43]. These IOM recommendations were largely accepted by Congress, enacted through the Nursing Home Reform Act as part of the Omnibus Budget Reconciliation Act (OBRA) of 1987 and, subsequently, generally implemented by CMS. CMS has regulatory authority and responsibility for federal regulations regarding the CoPs which must be met by nursing homes in order to receive Medicare and Medicaid funding.

Most residents of LTC facilities are elderly, infirm, and likely to have one or more chronic health conditions and the average length of stay (ALOS) for a LTC resident is substantially longer than for acute care facilities. In addition, LTC resident are likely to be dependent on caregivers for activities of daily living (ADLs) such as transferring, eating, bathing, and toileting. In some cases, residents with debilitating injuries or progressive neurologic conditions will require continuous custodial care in a LTC facilty throughout their lifetime. Therefore, although patients in LTC are not acutely ill, they are nonetheless frail and pose significant challenges to caregivers. The recent rapid growth in litigation against LTFs which allege negligence in the care provided to LTC facility residents, despite intense federal and state regulations, suggests persistent quality challenges [44]. A review of nursing home litigation claims by Stevenson and Studdert found that state statutes (49%) and common law causes of action (36%) represented the primary legal bases of claims that more than half of claims nationwide involved deaths, followed in frequency by alleged harms that included pressure ulcers/bed sores, dehydration/weight loss, and emotional distress. Notably, suit was brought most frequently by children of nursing home residents, followed by residents' spouses and lastly by the residents themselves. Lastly, the authors found that 7.9% of claims reached trial with almost and that on national average 46.2% resulted in verdicts for the plaintiff. Importantly, the authors conclude that, on the basis of the rates and the outcomes of litigation in the nursing home sector, there are likely persistent issues regarding the quality of care in LTC facilities [45]. On the other hand, Studdert et al. later found an inverse relationship between nursing home performance on quality measures and litigation although the risk of litigation was only fractionally lower for the best-performing nursing homes as compared to their worst-performing counterparts [46].

Federal Oversight: CMS (Medicare and Medicaid)

The increasing availability of healthcare, the growth in the population, changes in lifestyle, and the costs of new technology created debate over access. Reinhardt and Relman framed the debate as follows:

> We have a crisis in the private sector because employers can't continue adding the rising costs of their employees' health insurance to the price of their products without becoming non-competitive in world markets. And we have a crisis in the public sector because the government, having made a commitment to provide care for the poor and the elderly, is no longer willing to pay the bills, and local taxpayers are unwilling to pick up the slack. So, I don't think you help the public understanding of our dilemma by asserting that there is no "crisis." The problem is that we want to have our cake and eat it too. We want more and better health care, but we don't have a system of paying for it that distributes the cost equitably or assures equal access for all citizens [47].

A Brief Overview of Medicare

Private health insurance in America became accepted in the 1930s and 1940s (9% of the population had some form of private health insurance in 1940) and by 1950 more than half of the population (more than 40 million people) had some form of private insurance [48]. Legislative proposals for national health insurance appeared in 1943, 1945, and 1947, initially under the Roosevelts and subsequently under Truman, although such proposals did not pass into legislation. In 1965, President Johnson signed into law the bill that led to Medicare and Medicaid. Medicare [49] was established as a federally funded program to help provide healthcare for Americans age 65 and older. The original Medicare program included Part A (hospital insurance) and Part B (medical insurance), and the budget for Medicare in 1965 was approximately $10 billion. Medicare coverage became effective in 1966; and 19 million individuals enrolled in Medicare the first year of the program. Medicare eligibility requires the participant to have paid into the system through payroll taxes. Medicare is composed of four parts, titled A, B, C, and D. Part A provides coverage for inpatient hospital, skilled nursing, hospice, and home services. Part B provides coverage for physician, laboratory, outpatient, preventive care, and other similar services. Medicare Part C or Medicare Advantage is a combination of parts A and B. Part D provides coverage for prescription medications.

In 1972, President Nixon enacted legislation to expand Medicare coverage to include individuals under the age of 65 with long-term disabilities and individuals with end-stage renal disease (ERSD) requiring dialysis or kidney transplantation. The Omnibus Reconciliation Act of 1980 expanded home health services and created Medigap, Medicare supplement insurance. In 1982, hospice services for the terminally ill were added to existing Medicare benefits. Arguably, as an indirect product of access to healthcare, American life expectancy increased from an average of 70.2 years in 1965 to 78.8 years in 2012 [50].

Congress created the Medicare Part C program through the Balanced Budget Act of 1997. The Children's Health Insurance Program (CHIP) was also created in 1997 and provided health insurance and preventive care to, at the time, 11 million, or 1 in 7, uninsured children largely from uninsured working families whose earnings disqualified them from Medicaid eligibility. Today, all of the 50 states, the District of Columbia, and the territories have enacted CHIP plans.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), private health plans approved by Medicare, became known as Medicare Advantage Plans sometimes termed "Part C" or "MA Plans" and also laid the foundation for a prescription drug benefit designed for seniors and people with disabilities on Medicare. Thus, the MMA subsequently expanded Medicare to include an optional prescription drug benefit, termed "Part D" which took effect in 2006.

In March of 2020, President Trump enacted a coronavirus emergency stimulus package, called the CARES (Coronavirus Aid, Relief, and Economic Security) Act, to provide expanded coverage expands for treatment and services for those affected by COVID-19. The CARES Act also broadened reimbursement for telehealth services; Medicare certification for home health services provided by physician assistants, nurse practitioners, and certified nurse specialists; and increased Medicare payments for COVID-19-related hospital stays and durable medical equipment.

A Brief Overview of Medicaid

In 1960, Congress established the Kerr-Mills program (Public Law 86-778) which enabled federal grants to the states to pay for medical services for the medically indigent elderly. In 1965, the Child Health and Medical Assistance Act was submitted for consideration to the 1965 federal legislative program. The Medical Assistance Program (Title XIX) commonly known as Medicaid was enacted as Title XIX of the Social Security Amendments of 1965 (Public Law 89-97), jointly funded by the states with federal matching funds, provides medical assistance to certain categories of the poor regardless of age and the chronically ill. Through the Medicaid program, low-income children have gained access to vaccinations and preventive and primary care; and elderly patients unable to afford Medicare premiums or long-term care have alternative options for healthcare. Medicaid eligibility for low-income families was linked to Aid to Families with Dependent Children (AFDC).

The growth in Medicaid enrollment and hospital caseload prompted states to develop alternative financing mechanisms, such as disproportionate share hospital (DSH) payments to help fund the state share of Medicaid spending at the hospital level. The Omnibus Budget Reconciliation Act of 1981 (OBRA-81) required states to provide hospitals with DSH payments to hospitals with higher Medicaid volumes.

Medicaid enrollment grew from 4 million in 1966 to exceed 33 million in 2000; throughout the same time period, per enrollee grew from $200 to more than $6000 per enrollee per year. From less than $1 billion in 1966, Medicaid expenditures exceeded $200 billion in fiscal year (FY) 2000 [51]. Together, Medicare and

Medicaid serve nearly 25% of Americans and finance about $1 in every $3 that the nation spends on healthcare [52].

The Centers for Medicare & Medicaid Services (CMS)

In 1965, at the inception of Medicare and Medicaid, the responsibility for the administration of Medicare fell under the Social Security Administration (SSA), and the administration of Medicaid fell under the aegis of the Social and Rehabilitation Service (SRS); both are organized under the Department of Health, Education, and Welfare (HEW). In 1977, the administrative responsibility for both Medicare and Medicaid programs was merged through the creation of the Health Care Financing Administration (HCFA) under the oversight of HEW. In 2001, the Centers for Medicare & Medicaid Services (CMS) was formally organized under the Department of Health and Human Services (DHHS). Although CMS is based in Maryland, it also has ten regional offices throughout the USA: in Boston, New York, Philadelphia, Atlanta, Dallas, Kansas City, Chicago, Denver, San Francisco, and Seattle.

In addition to CMS, important divisions of the HHS include the Office for Civil Rights which has administrative oversight for and enforcement authority over the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009; the Office of Inspector General (OIG) which provides oversight and enforcement of violations of Medicare and Medicaid Integrity (false claims, Stark, self-referral) and also for the Centers for Disease Control and Prevention, the National Institutes of Health, and the Food and Drug Administration; the Office of the National Coordinator for Health Information Technology; the National Institutes of Health (NIH); and the Food and Drug Administration (FDA).

Key Federal Regulations Affecting Acute Care Facilities

In addition to local and federal rules, regulations, laws, and ordinances which govern healthcare entities, additional important federal regulations and programs include:

Constitutional Authority over Healthcare

The US Constitution does not make mention of the words “health,” “healthcare,” or “medical care,” and the US Constitution does not explicitly address either the right to healthcare or its regulation. The scope of Congressional powers is enumerated in

the Constitution. The authority of Congress legislate in the areas of health and healthcare derives from the enumerated powers set forth in Article I, Section 8 of the Constitution which states, in part, that "[t]he Congress shall have Power to lay and collect Taxes, ... to ... provide for the ... general Welfare of the United States."

The Commerce Clause of the US Constitution states that "Congress shall have the Power… to regulate Commerce… among the several States…" [53]. Constitutional constructions of the Commerce Clause have resulted in expanded federal powers to regulate public health issues. Supreme Court interpretations of the Commerce Clause empowered the US Congress to regulate labor, agriculture, manufacturing, and education. The federal government has the resources to survey the population's health status and health needs, set policies and standards, pass laws and regulations, support biomedical and health services research, help finance and deliver personal healthcare services, and provide technical assistance and resources to state and local health systems [54].

Moreover, a legal doctrine called the "dormant Commerce Clause" may not only empower Congress to act, but it can also bar state and local actions that could interfere with interstate commerce even when Congress has not acted. Thus, in effect, there is no constitutional provision to prohibit Congress from regulating inactivity when exercising its enumerated powers. Of course, legislation enacted under the Commerce Clause must be rationally related to a legitimate constitutional end, which in the case of healthcare is founded in the general welfare, conversely healthcare and health.

Since the Commerce mandate provides a reasonable foundation for Congressional regulation of healthcare, it bolstered through the Necessary and Proper Clause which provides that Congress shall have the authority "to make all Laws which shall be necessary and proper for carrying into Execution the foregoing Powers."

Administrative Procedure Law: Agency Structure and Function

Under the US Constitution, two distinct principles, separation of powers and due process, resulted in the development of the nondelegation doctrine, the theory that one branch of government may not delegate its own constitutionally authorized power to another. However, with the need for administrative efficiency in an increasingly complex world, the courts found a contrast between the delegation of authority between branches of government and the delegation of authority to a public agency. Supreme Court Chief Justice Marshall recognized in the 1825 ruling in *Wayman v. Southard*, that, although Congress may not delegate powers that "are strictly and exclusively legislative," it may delegate "powers which [it] may rightfully exercise itself" [55]. The Court recognized that the administration of the law requires exercise of discretion and that "in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives" [56].

Article I, Section I, of the US Constitution provides that all legislative power is vested in Congress; however, Congress may delegate legislative power to an administrative agency. Although the Constitution does not recognize agencies, the US Supreme Court accorded legitimacy to federal administrative agencies and empowered them to enact rules, regulations, and standards that are binding to the same extent as statutes enacted by Congress. Thus, delegation of powers, under US constitutional law, represents the transfer of a specific authority by one of the three branches of government (executive, legislative, and judicial) to another branch or to an independent agency. Justice Marshall distinguished between "important" subjects, "which must be entirely regulated by the legislature itself," and subjects "of less interest, in which a general provision may be made, and power given to those who are to act under such general provisions, to fill up the details" [55]. Through the delegation of powers doctrine, a regulatory agency is established by Congress, empowered by statute to exercise quasi-legislative authority over a specific segment of economic activity, such as healthcare, technology, communications, or transportation. The US Congress, for example, has created government agencies to which it has delegated authority to promulgate and enforce regulations pursuant to law. Agencies are thus empowered with quasi-legislative functions, executive functions, and quasi-judicial functions which allow them to regulate and oversee areas of administrative law, regulatory law, secondary legislation, and rulemaking. Regulatory agencies are empowered with broad powers to oversee activities within their designated field of jurisdiction, to enact laws and regulations, to investigate violations, and to enforce compliance [57].

The Administrative Procedure Act (APA) [58] is a federal statute which prescribes the processes by which agencies may propose and enact regulations, emphasizing transparency and public input at each stage of rule enactment. The statute which confers authority to an agency is termed an "enabling statute." Under the APA, administrative functions are categorized as either formal or informal rulemaking or adjudication, all of which have binding effects on the field which is being regulated.

The term "rulemaking" refers to the "agency process for formulating, amending, or repealing a rule" [59]. The rulemaking process first requires publication of proposed rules in the Federal Register, followed by a prescribed period of public notice and opportunity for comment, and subsequent publication of the final rule. A rule is defined to mean "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency" [60]. Finally, agencies must annually publish a "regulatory plan" or "work plan" in the Federal Register subsequently compiled within the Code of Federal Regulations (CFR).

The substantive standard for rulemaking by an agency is that the rules and regulations must not be arbitrary or capricious and they must fall within the scope of statutory authority granted to the agency by Congress. The APA describes the

necessary procedures for agency rulemakings and adjudications, as well as standards for judicial review of final agency actions, and the DHHS, of which CMS is a part, is bound by the rulemaking process [61]. In general, the standard for judicial review of an agency's rulemaking presents a formidable barrier to a substantive legal challenge. In estate of Smith v. Heckler, the Tenth Circuit Court of Appeals held that the "judiciary is not a 'super agency' controlling the affairs of an agency which is part of another branch of government" [62]. State legislatures empower state agencies under the respective state Administrative Procedures Acts of the individual states.

Regulatory agencies have statutory authority to function with oversight, but their actions are also subject to legal review. Controversies arising from agency actions are adjudicated in Administrative Courts, by administrative law judges. Nonetheless, controversies generally favor agencies since courts accord deference agencies, with the presumption that agencies have sought and used specialized knowledge regarding the technical aspects of the issues that they regulate. Agencies frequently work with panels of experts during the rulemaking process to define problems and regulate them.

The US Supreme Court has promulgated three standards of judicial deference to agency decisions: (1) under *Chevron v. NRDC* [63], courts will defer to agency interpretations of their enabling statutes unless they are unreasonable on their face; (2) under *Auer v. Robbins* [64], courts defer to an agency's interpretations of its own regulations, even in the case of ambiguity; and (3) under *Skidmore v. Swift* [65], courts do not unconditionally defer to an agency's interpretation, but rather give varying amounts of deference in recognitions of that agency's expertise within a specific subject matter.

The classic legal test to guide the analysis of whether a court should defer to a ruling made by an agency in its interpretation of its enabling statute is derived from Chevron,[1] in which the court's opinion developed a two-part framework of review:

> First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue, the court does not simply impose its own construction on the statute . . . Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.

Federal (CMS) and state regulators function as administrative agencies and are therefore bound by the procedural requirements of the Administrative Procedures Act [66].

[1] See Chevron, *supra.*

Diagnosis-Related Groups and the Prospective Payment System

Fee-for-service (FFS) reimbursement for healthcare services provided by physicians represented a long-standing industry norm, especially within the private healthcare sector. With greater access under the Medicare and Medicaid programs, the rising costs of healthcare served as an impetus for cost containment strategies. Health maintenance organizations (HMOs) were incepted ion the 1960s. Under the HMO model, the HMO receives a flat per person per month amount for which it provides all necessary health. The fee cap was thought to provide an incentive to providers to provide diagnostic and treatment services as efficiently as possible. In 1985, HCFA began to encourage the development of health maintenance organizations (HMOs) to provide Medicare coverage to enrolled beneficiaries.

The Medicare risk program became operational in 1985 under the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982 (Public Law 97-248) and allocated responsibility to HMOs for the provisions of Medicare-covered services to beneficiaries in return for a capitated payment. In addition to the objective of cost control, additional goals of the HMO program included the following: (1) more efficient healthcare with improved healthcare quality and (2) to provide Medicare beneficiary access to the same range of choices of healthcare delivery systems available to the non-Medicare population. At its inception, HCFA set the capitation payment to an HMO, on behalf of an enrolled beneficiary, at 95% of HCFA's actuarial estimate of the average amount that HCFA would spend in FFS reimbursements on a typical Medicare beneficiary a particular geographically defined county [67].

The Medicare Inpatient Prospective Payment System (IPPS) was introduced in 1983. The IPPS classified each patient's hospital admission into a diagnostic category (DRG) on the basis of the documentation in the medical record which translates into an International Classification of Diseases (ICD) nomenclature; then, extraction of additional data from the record is used to define a Medicare Severity-Adjusted Diagnosis-Related Group (MS-DRG) based on data including (a) the principal diagnosis, (b) complications and comorbidities (secondary diagnoses), (c) surgical procedures required during the admission, (d) age, (e) gender, and (f) discharge destination (routine, transferred, or expired). The assignment of an MS-DRG is calculated by computer through the use of a program known as the "grouper" designed for use by hospitals and Medicare Administrative Contractors (MACs). Using the MS-DRG, CMS pays hospitals by a predetermined fee schedule, although allowances are made for patients who incur exceptionally length of stay or costs ("outliers"). Each MS-DRG is assessed annually by CMS for its relative weight, which is indexed to the relative costs for treating patients with that MS-DRG during the prior year; this ratio is published annually in the Federal Register for each MS-DRG. The average MS-DRG weight for a hospital's Medicare admission is referred to as the Case Mix Index (CMI) which indicates the severity of illness for a hospital's patient population. In 2007, CMS revised its method of calculating relative weights, so as to base relative weights on allocated costs instead of charges.

DRG reimbursement affects only facility, not professional fee reimbursement. Traditionally, Medicare reimbursement was based on a payment methodology of a provider's customary, prevailing, and reasonable charges. In 1989, the Omnibus Budget Reconciliation Act (OBRA) of 1989 implemented the Medicare fee schedule which effectively changed the basis for physician reimbursement from charges to relative values that reflected the costs of resources consumed during patient care for a specific condition. The basis for Medicare reimbursement became the relative value unit (RVU) based on three categories of resources: (a) physician work, (b) practice expense (PE), and (c) malpractice (MP) expense. The Medicare Physician Payment Schedule also incorporates, and annually updates, geographic adjustments to reflect the variations in the costs of furnishing services in a specific geographic area using three factors: (a) the resource-based relative value scale (RBRVS), (b) the geographic practice cost indexes (GPCI), and the monetary conversion factor.

Hospital Readmissions Reduction Program (HRRP)

Readmissions after inpatient hospitalizations are common, costly, and in many cases potentially preventable. In 2009, a review of Medicare beneficiaries observed that 19.6% patients were readmitted within 30 days of discharge, and Medicare was paying more than $17 billion annually on unplanned rehospitalizations [68]. The Hospital Readmissions Reduction Program (HRRP), an initiative required under Section 3025 of the Affordable Care Act (2012), is a Medicare value-based purchasing (VBP) program that requires the Secretary of the Department of Health and Human Services (HHS) to implement a reduction in payments, or impose financial penalties, upon hospitals with excess readmissions for defined conditions or procedures: (1) acute myocardial infarction (AMI), (2) chronic obstructive pulmonary disease (COPD), (3) heart failure (HF), (4) pneumonia, (5) coronary artery bypass graft (CABG) surgery, and (6) elective primary total hip arthroplasty and/or total knee arthroplasty (THA/TKA) [69]. In addition, the twenty-first Century Cures Act directs CMS to assess a hospital's performance relative to other similar hospitals. The intent of the HRRP is to improve communication and care coordination between hospitals, caregivers, and patients so as to improve discharge planning, reduce avoidable readmissions, improve the quality of hospital care, and decrease utilization costs due to readmissions. As of 2017, of the participating sites, the CBOs demonstrated lower readmission rates and Medicare Part A and Part B expenditures as compared with comparable nonparticipants [70].

A "readmission" is defined as the admission of a patient to the same hospital from which the patient was discharged or to another hospital within a time period specified by the Secretary from the date of the patient's discharge.

At present, CMS includes the following six condition−/procedure-specific 30-day risk-standardized unplanned readmission measures in the program: (1) acute myocardial infarction (AMI), (2) chronic obstructive pulmonary disease (COPD), (3) heart failure (HF), (4) pneumonia, (5) coronary artery bypass graft (CABG)

surgery, and (6) elective primary total hip arthroplasty and/or total knee arthroplasty (THA/TKA) [71]. Those hospitals with relatively high readmission rates for patients with these conditions have Medicare payments adjusted by the greater of a "ratio" or a "floor adjustment factor." Hospitals are also mandated to publish their hospital readmission rates on the Hospital Compare website.

Readmissions or rehospitalizations among Medicare beneficiaries have been repeatedly demonstrated to be prevalent and associated with poor quality of care outcomes and significant financial costs [72]. Historical data has shown that nearly 20% of all Medicare discharges had a readmission within 30 days [68], 12% of readmissions are potentially avoidable, and that prevention of as few as 10% of these readmissions could save Medicare $1 billion [73]. The Community-based Care Transitions Program (CCTP), created under Section 3026 of the ACA, launched in 2012, was developed as a system to test models for improving care transitions and reducing readmissions.

The Hospital Value-Based Purchasing (VBP) Program

Intuitively, in any enterprise costs can generally be trimmed without impacting quality; however, beyond a point, costs begin to impact quality. The goal of value-based care is the advancement of healthcare quality while increasing patient access and while keeping reimbursement constant. CMS developed several models of value-based care, each with a phase-in period, first associated with incentive payments and subsequently with penalties for nonperformance. Value-based purchasing (VBP) is a program that increases the accountability of healthcare providers for both the cost and quality of care.

The Hospital VBP Program was established to reward acute care hospitals with incentive payments, as payment adjustments under the Inpatient Prospective Payment System (IPPS) as an incentive for achieving higher quality of care provided in the inpatient hospital setting. The Hospital VBP Program incentivizes the (1) elimination of or reducing the incidence of healthcare errors' adverse events, (2) adoption of evidence-based care standards and protocols in order to obtain the best outcomes for Medicare patients, (3) the incentivization of hospitals to develop processes to improve patient experience (patient satisfaction scores), (4) improved transparency of care quality, and (5)

a recognition that hospitals that provide high-quality care at a lower cost to Medicare should be rewarded for performance [74]. VBP programs depend on three main factors: the external environment, provider characteristics, and program features. The external environment of VBP includes factors such as the regulatory environment, payment policies, patient treatment preferences, and compliance with prescribed care. Provider characteristics important to VBP include structure of the healthcare system, leadership commitment, the organizational culture, available resources and capabilities (including information technology), and demographics of the population served. Program features which impact VBP include the targeted

patient population, program goals, the metrics used, financial incentives, and risk structure [75].

In 2015, based on early success, DHHS announced their intent to tie 85% of all traditional Medicare payments to quality or value by 2016 and 90% of payments by 2018. With the passage of the Accountable Care Act, a voluntary program of "pay-for-reporting" evolved into the "pay-for-performance" (P4P) Physician Quality Reporting System (PQRS) program which instead imposed penalties for not reporting quality data [75]. P4P was later extended to performance-based penalties and bonuses through implementation of the Value-Based Payment Modifier (Value Modifier) [76].

The Hospital VBP Program incentivizes performance through measures of quality, efficiency, patient experience, and safety. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) was signed into law in 2015 and created the Quality Payment Program that created the Merit-Based Incentive Payment System (MIPS); repealed the long-standing, unsuccessful Sustainable Growth Rate (SGR) formula for Medicare; and allocated bonus payments for participation in eligible alternative payment models (APMs) [77].

Hospital VBP indicators include (a) the elimination or reduction of adverse event, (b) the adoption of evidence-based care standards and protocols in order to obtain optimal patient outcomes, (c) the development of processes which improve patient experience, (d) methods to increase the transparency of care quality, and (e) recognition of those hospitals which provide high-quality care at a lower cost [78]. The quality domain measures are weighted each year; for the year 2020, (i) clinical outcomes (25%), (ii) person and community engagement (25%), (iii) safety (25%), and (iv) efficiency and cost reduction (25%).

The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015

The Medicare Access and CHIP (Children's Health Insurance Program) Reauthorization Act of 2015 replaced the Sustainable Growth Rate formula as a means of updating Medicare physician compensation. MACRA revised the reimbursement formula for physicians and providers under the Quality Payment Program (QPP) which linked Medicare Part B payment to measures of quality and resources use and adoption of Certified EHR Technology (CEHRT). The Merit-Based Incentive Payment System (MIPS) was a key component of the MACRA Quality Payment Program (QPP) which was more popular for the first performance year. Under MIPS, the Meaningful Use (MU) Medicare incentive program, Physician Quality Reporting System (PQRS), and the Value-Based Modifier (VBM) program will be consolidated into one program. MACRA represents a financial incentive for hospitals to make providers adopt advanced Alternative Payment Models (APMs) allowing hospital-based providers to participate in shared savings and incentives, possibly though a Professional Services Agreement (PSA) although hospitals will

also be in a position to leverage MACRA to incentivize the quality of care provided by employed providers.

Hospital-Acquired Condition (HAC) Reduction Programs

The Hospital-Acquired Condition (HAC) Reduction Program (HACRP) is a Medicare pay-for-performance program. Value-based purchasing is a form of pay-for-performance, which, in turn, is a tiered system of reimbursement based on provider or entity performance as based in established quality metrics [79]. The ACA established the HAC Reduction Program under Section 1886(p) of the Social Security Act to link Medicare payments to healthcare quality in the inpatient hospital setting beginning in 2015. CMS established a scoring methodology used to rank hospitals based upon their performance with respect to risk-adjusted HAC quality measures. The worst-performing hospitals which fall into a rank (scores greater than the 75th percentile of all Total HAC Scores that is in the lowest quartile-based on their HAC score) are subject to a 1% reduction in their total Medicare reimbursements. HACs are divided into two domains: (1) Domain 1 represents the Agency for Healthcare Research and Quality (AHRQ) composite Patient Safety Indicators (PSI) 90 scores, and (2) Domain 2 is composed of the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) measures.

The CMS PSI 90 measure is represented by the following ten CMS PSI component measures [80]:

- PSI 03 – Pressure Ulcer Rate
- PSI 06 – Iatrogenic Pneumothorax Rate
- PSI 08 – Inhospital Fall with Hip Fracture Rate
- PSI 09 – Perioperative Hemorrhage or Hematoma Rate
- PSI 10 – Postoperative Acute Kidney Injury Requiring Dialysis Rate
- PSI 11 – Postoperative Respiratory Failure Rate
- PSI 12 – Perioperative Pulmonary Embolism or Deep Vein Thrombosis Rate
- PSI 13 – Postoperative Sepsis Rate
- PSI 14 – Postoperative Wound Dehiscence Rate
- PSI 15 – Unrecognized Abdominopelvic Accidental Puncture/Laceration Rate

Domain 1 constitutes 35% of the total score and is solely based on the Agency for Healthcare Research and Quality's (AHRQ) Patient Safety for Selected Indicators (PSI) 90 composite measure. The scores for the PSIs from 1–12 are allocated on a 110 basis, where a score of 1 indicates the best performance and a score of 10 indicates the worst performance.

CDC NHSN is represented by the following hospital-associated infections (HAI) measures [80]:

- Central line-associated bloodstream infection (CLABSI)
- Catheter-associated urinary tract infection (CAUTI)

- Surgical site infection (abdominal hysterectomy and colon procedures) (SSI)
- Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia
- *Clostridium difficile* infection (CDI)
- *Total HAC Score*
- *Payment* Reduction Indicator

Domain 2 accounts for the remaining 65% of the total score and consists of an average of two intensive care unit-based nosocomial infections: central line-associated bloodstream infections (CLABSI) and catheter-associated urinary tract infections (CAUTI).

Nonetheless, there is a controversy regarding the effectiveness of the HACRP program since there is data to suggest that minority-serving hospitals are being disproportionately penalized [81] and because of the sensitivity of the HACRP penalties to small changes in performance and correlation of the HACRP score with hospital characteristics also potentially challenges the validity of the HACRP measure and method of risk adjustment [82].

Patient Safety and Quality Improvement Act (PSQIA) of 2005

The Patient Safety and Quality Improvement Act (PSQIA) protects healthcare workers who report unsafe conditions [6]. Legislators created the law to encourage the reporting of medical errors while maintaining patients' confidentially rights. To ensure patient privacy, the HHS levies fines for confidentially breaches. The law also authorizes the Agency for Healthcare Research and Quality (AHRQ) to publish a list of patient safety organizations (PSOs) that record and analyze patient safety data. The Office for Civil Rights (OCR) enforces the law among national healthcare facilities. The regulation implementing the Patient Safety and Quality Improvement Act of 2005 (PSQIA) was published on November 21, 2008, and became effective on January 19, 2009.

Compliance with Healthcare Regulations

Healthcare compliance ("compliance" or "corporate compliance") is a critical administrative function in all highly regulated industries, such as healthcare, banking, charitable not-for-profits, finance, universities, and government contractors. The many government agencies that regulate healthcare will necessarily approaches its regulatory framework based upon its own area of control; for example, the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), the Equal Employment Opportunity Commission (EEOC), and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) will each focus on an area of

regulation – the corporate compliance program must ensure compliance with all regulations. The purpose of a compliance program is to align administrative practices within an institution with the relevant internal and external rules, regulations, law, and policies. Compliance is not only a good practice for legal, ethical, and strategic reasons but is also mandated by law. The Deficit Reduction Act of 2005 § 6032 required all Medicaid providers receiving $5 million a year or more to have an effective compliance program [83]. The HHS Office of Inspector General (OIG) has published guidelines on the development of model corporate compliance programs [84]. Federal Sentencing Guidelines allow for reduced penalties for those organizations which have enacted an "effective" corporate compliance program [85]. The seven components of an effective program as defined in the Guidelines are (1) standards and procedures, (2) oversight responsibilities, (3) employee training, (4) monitoring and auditing, (5) reporting systems, (6) enforcement and discipline, and (7) response and prevention [86].

The governing body (BOD) of a healthcare organization is responsible for the conduct of the organization and bears responsibility for a healthcare organization's compliance or lack of compliance. Thus, the healthcare compliance program necessarily reports directly to the BOD. The oversight and review of compliance program functions by a BOD include the (1) roles of, and relationships between, the organization's audit, compliance, and legal departments; (2) mechanism and process for issue-reporting within an organization; (3) approach to identifying regulatory risk; and (4) methods of encouraging enterprise-wide accountability for achievement of compliance goals and objectives [87].

Antitrust

Antitrust litigation involving hospitals has been common and is increasingly common in the setting of current healthcare market consolidations including practice acquisitions and merger and acquisition activities. In the perspective of antitrust laws, healthcare institutions and medical practices are business firms which are engaged in the economic activity of providing medical services. Modern antitrust law focuses on corporate behavior and not business objective. The Department of Justice (DOJ) notes that "competition in the healthcare industry benefits consumers because it helps contain costs, improve quality, expand choice, and encourage innovation. The Antitrust Division enforces the antitrust laws in healthcare to protect competition and to prevent anticompetitive conduct" [88]. The USA has enacted three major federal antitrust laws: (1) the Sherman Antitrust Act of 1890, (2) the Clayton Act of 1914, and (3) the Federal Trade Commission Act of 1914 [89].

Section 1 of the Sherman Act prohibits all contracts, combinations, and conspiracies that unreasonably restrain interstate commerce and foreign trade, including agreements among competitors to fix prices, rig bids, and allocate customers, practices which are punishable as criminal felonies. Section 2 of the Sherman Act makes it a crime to monopolize any part of interstate commerce. An unlawful monopoly

exists when one firm controls the market for a product or service, and it has obtained that market power, not because its product or service is superior to others, but rather through abusive suppression of competition with anticompetitive conduct. The "rule of reason" is a judicial doctrine of antitrust law which states that a practice is in violation the Sherman Act only if the practice is an unreasonable restraint of trade, based on economic factors.

The Clayton Antitrust Act is a civil (as opposed to criminal) statute which, in Section 7, prohibits mergers or acquisitions that are likely to substantially lessen competition and are likely to increase prices for consumers. The Robinson-Patman Act [90] is a federal law which was enacted in 1936 as an amendment to the Clayton Act to prevent price discrimination in interstate commerce or the charging of different prices to equally-situated distributors, when the effect of such sales is to reduce competition and may give favored customers an advantage in the market unrelated to their actual efficiency. The Robinson-Patman Act has been invoked, generally unsuccessfully, against health maintenance organizations (HMOs) because of a broad exception to the prohibition against price discrimination when one of the sales is made to any of certain entities listed in the Nonprofit Institutions Act. The Celler-Kefauver Act further amended the Clayton Antitrust Act through prohibition of practices that would reduce market as a result of the asset acquisitions, or mergers, to prevent vertical and conglomerate mergers that would limit competition. The Federal Trade Commission Act created the Federal Trade Commission and as a civil statute reiterated the prohibition against unfair methods of competition in interstate commerce, intended to monitor and regulate any "unfair or deceptive" trade practices. The FTC and the Department of Justice are the enforcers of antitrust laws in the USA.

The Hart-Scott-Rodino Act requires certain types of mergers and consolidations, where party acquiring has total assets or annual net sales of more than $100 million and the acquired party has total assets or annual net sales of more than $10 million, to be reported to the FTC or the Department of Justice (DOJ) before the transaction occurs [91].

The Emergency Medical Treatment and Active Labor Act

In 1986, the Emergency Medical Treatment and Active Labor Act (EMTALA) [92] was enacted by Congress as part of the Consolidated Omnibus Reconciliation Act (COBRA) with the intent of both ensuring access to emergency medical care and to deter the then-prevalent practice of "patient dumping" [93] by which uninsured patients were transferred from private to public hospitals, solely for financial reasons, without consideration of their medical stability. Although EMTALA applies only to facilities which participate in Medicare, it thus applies to over 98% of all US hospitals.

EMTALA-participating hospitals with Emergency Departments (EDs) must screen and treat the emergency medical conditions of all the patents who present

there for care in a nondiscriminiatory manner, regardless of their ability to pay, insurance status, national origin, race, creed, or color. EMTALA imposes three distinct legal duties on Medicare-participating hospitals: (1) the duty to perform a mandatory medical screening examination (MSE) on all patients who present for medical care in order to determine whether an emergency medical condition (EMC) exists; (2) if an EMC is determined to exist, the patient must either be stabilized medically in accordance with the hospitals' capabilities or transferred to another hospital with the requisite capabilities; and (3) hospitals with specialized capabilities or facilities (such as trauma centers or burn units) are required to accept transfers of patients in need of such specialized services if they have the capacity to treat them.

Obligations under EMTALA are considered to arise when an individual first presents to the ED, more specifically, when an individual first arrives on hospital property. However, under some circumstances, EMTALA obligations may be triggered before the patient's actual arrival; for example, in those instances where a patient is en route and the ED has been previously been notified of the patient's pending arrival [94]. EMTALA prohibits a hospital or its staff from delaying a screening examination or the initiation of stabilizing care "in order to inquire about the individual's method of payment or insurance status," although the collection of basic demographic information prior to the MSE is considered acceptable [95]. The term "individual" has been interpreted to refer to any person with a potential EMC who presents for care regardless of whether that person is a Medicare patient or even a US citizen. EMTALA further defines an EMC as "[a] medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expected to result in—(1) [p]lacing the health of the individual . . . in serious jeopardy; (2) [s]erious impairment to bodily functions; or (3) [s]erious dysfunction of any bodily organ part" [96]. The transfer protocol of patients requires that the referring hospital (1) provides ongoing care within its capability until transfer to minimize transfer risks, (2) provides copies of medical records, (3) confirms that the receiving facility has space and qualified personnel to treat the condition and has agreed to accept the transfer, and (4) ensure that the transfer be made with qualified personnel and appropriate medical equipment. In general patients may be reasonably transferred when the treating physician, in his or her best judgment, documents that the benefits of transfer outweigh the risks and accepting facility and provider are identified and the transfer is conducted with appropriate equipment and personnel. In the event that the patient is not transferred, and the hospital instead accepts the patient as an inpatient for further treatment, the obligations under EMTALA are considered met [97].

EMTALA also governs obligations for on-call providers, including generalists and specialists. EMTALA requires healthcare facilities to maintain a list of physicians who are on call, as either treating or consulting physicians. On-call physicians may provide consultation by telephone, video conferencing, or any other reasonable means of communication, and there is no specific requirement that the on-call physician evaluates the patient in person. However, the on-call physician must evaluate

a patient in person if specifically requested to do so; failure to do so is considered a violation under EMTALA [98].

In 2020, during the SARS-CoV-2 virus pandemic, which caused the 2019 Novel Coronavirus Disease ("COVID-19"), the Centers for Medicare & Medicaid Services ("CMS") issued a memorandum waiving certain EMTALA obligations deemed to apply only if the hospital's actions did not discriminate on the basis of a patient's source of payment or ability to pay. The CMS memorandum, issued March 9, 2020, entitled QSO-20-15 (Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications Related to Coronavirus Disease 2019) [99], addressed how hospitals and Critical Access Hospitals could best fulfill EMTALA obligations while continuing to minimize the risk of exposure of ED patients from those already infected with COVID-19. Furthermore, in addition to the QSO, the Secretary of the Department of Health and Human Services ("Secretary") invoked his waiver authority and waived sanctions under EMTALA for certain medical screening exams ("MSEs") and stabilization requirements, effective March 1, 2020 [100]. Specifically, the EMTALA waiver allowed hospitals to:

1. Direct or relocate individuals who come to the emergency department ("ED") to an alternative off-campus site for the MSE, in accordance with a state emergency or pandemic preparedness plan.
2. Effect transfers normally prohibited under EMTALA of individuals with unstable emergency medical conditions ("EMCs"), so long as the transfer is necessitated by the circumstances of the declared emergency for the COVID-19 pandemic, without sanction.

Hospitals have a duty to report EMTALA violations to the CMS. Allegations of EMTALA violations are investigated by the Office of the Inspector General (OIG). Where alleged violations are found, potential penalties include termination of the hospital's and/or physician's Medicare provider agreement and also civil monetary penalties (CMPs or fines) imposed on hospitals and/or physicians. In violation of EMTALA, a hospital may be fined up to $50,000 per violation ($25,000 for a hospital with fewer than 100 beds); physicians may be fined up to $50,000 per violation, and these fines may also extend to on-call physicians. A receiving facility that has suffered a financial loss as a result of another hospital's violation of EMTALA may further bring a suit to recover any damages sustained. The statute of limitations under EMTALA is 2 years, and, under federal law, whistleblowers are protected by law. Moreover, EMTALA violations are not covered by standard malpractice insurance policies, since EMTALA violations in themselves may not represent malpractice, although derivative actions for malpractice stemming from negligent screening examinations or stabilization are possible and actions under negligence or abandonment may also ensue.

EMTALA is now considered one of the most comprehensive laws guaranteeing nondiscriminatory access to emergency medical care, became the de facto national healthcare policy for the uninsured, and now applies to virtually all aspects of patient care in the hospital setting.

Federal Taxation Status of Hospitals

Hospitals may be classified as either "for-profit" or "not-for-profit" entities, a designation separate from whether or not he healthcare entity is indeed profitable or not. Tax exemption is complicated and largely beyond the scope of this discussion however; in general tax exemption status refers to exemption from state and local taxes (such as real estate tax and state corporate tax) and federal corporate income tax. Requirements for exemption from state and local taxes can vary substantially between state localities. In order to qualify for federal tax exemption, a healthcare institution organized under one of the sections of Internal Revenue Code (IRC) § 501 is considered exempt from taxation [101]; and, the (c) designation denotes a not-for-profit or a charitable organization. Of the potential § 501(c) classifications, § 501(c)(3) status is potentially the most desirable since it confers benefits such as the ability to accept tax deductible contributions and the ability to issue tax-exempt bonds. Organizations under § 501(c)(3) must be organized and operated exclusively for one or more of (a) religious, (b) charitable, (c) scientific, (d) testing for public safety, (e) literary, (f) educational, or (g) prevention of cruelty to children or animals. In order to qualify for § 501(c)(3) status, the organization must meet both organizational and operational test requirements. Under the organizational test, the entity's articles of incorporation must specify that the organization is limited to the performance of exempt purposes, and under the operational test, the entity must be operated for the stated exempt purposes.

Hospitals have traditionally been exempt from federal taxation if they are "organized and operated exclusively for... charitable... purposes" which in its initial iteration in 1956 was that not-for-profit hospitals provide free or discounted medical services. Thus, prior to 1969, the IRS specified that to maintain tax-exempt status, hospitals were simply required to provide charity care, although there was latitude to define the amount of care required. In 1969, however, the IRS issued a ruling that created a more ambiguous standard and also eliminated the obligation to provide charity, or uncompensated, care [102]. In order to be considered a "charitable hospital," the entity must meet the general requirements for tax exemption under Internal Revenue Code (IRC) Section 501(c)(3), Revenue Ruling 69-545, and IRC Section 501(r)(1):

> Section 501(c)(3) organizations must be organized and operated exclusively for specific tax-exempt purposes to be exempt from federal income tax. In addition to being a type of organization that is specifically described within Section 501(c)(3), these organizations must also have the following characteristics [103].
>
> **Organizational Test**
>
> An organization must be organized exclusively for one or more exempt purposes. Generally, an organization is organized exclusively for one or more exempt purposes only if its organizational documents:
>
> - Limit the purposes of such organization to one or more exempt purposes.
> - Do not expressly empower the organization to engage, other than as an insubstantial part of its activities, in activities which in themselves are not in furtherance of one or more exempt purposes.
> - Do not expressly empower it to.
> - Devote more than an insubstantial amount of its activities to attempting to influence legislation.

- Participate or intervene in any political campaign on behalf of or in opposition to any candidate for public office.
- Engage in activities which characterize it as an "action" organization.
- The organizational documents must also permanently dedicate the organization's assets to charitable purposes upon dissolution.

Operational Test

The operational test for exemption under Section 501(c)(3) consists of four broad categories:

1. Requirement to operate exclusively for exempt purposes
2. Prohibition against inurement
3. Prohibition against becoming an action organization
4. Prohibition against substantial private benefit

An organization is considered to operate exclusively for one or more exempt purposes if it engages primarily in activities that accomplish one or more exempt purposes as specified in Section 501(c)(3).

Patient Protection and Affordable Care Act (ACA) §9007 further amended the IRC and added §501(r) entitled "Additional Requirements for Charitable Hospitals" [104] that required four elements to meet tax-exempt status: (1) community health needs assessment and implementation strategy; (2) financial assistance policies, including adherence to the hospital's Emergency Medical Treatment and Active Labor Act emergency care obligations (which are expressly identified in the statute); (3) policies related to hospital charges; and (4) policies related to billing and collections [105]. The IRS prescribed penalties for noncompliance including loss of tax-exempt status and a monetary penalty of $50,000 per year for failure to satisfy the community health needs assessment requirements.

Nonetheless, private causes of action by indigent patients who received bills for payment [106] or alleging the illegality of balance billing [107] have not been successful. On the other hand, states have been successful in their attempts to quantify and challenge the level of charity care required to qualify for tax-exempt status under state law. In the Illinois case of *Provena Covenant Med. Cent. v. Dep't. of Revenue*, Provena was alleged to charged uninsured patients "established rates, which were more than double the actual costs of care" while charging privately insured patients or patients enrolled in Medicare or Medicaid discounted rates for the same medical care; Provena was found to have waived $831,724 in actual costs while receiving a benefit of $1.1 million in property tax exemptions. Here the Illinois Supreme Court held that Provena failed to qualify as a tax-exempt hospital for purposes of a state property tax exemption [108].

Healthcare Entity Organization

Hospitals, as incorporated entities, have fairly uniform organizational structures which are composed of diverse employees with multiple layers of accountability. The administrative structure of an accredited hospital is defined by TJC within the Comprehensive Accreditation Manual for Hospitals chapter on "Leadership." Early

guidance from TJC, prior to 1994, included standards and chapters addressing, for example, “Management,” “Governance,” “Medical Staff,” and “Nursing Services”; however, TJC, beginning in 1994 adopted a systemic approach to organizational leadership. Healthcare systems are generally characterized by three groups of leaders: (1) the governing body; (2) the chief executive officer (CEO), chief medical officer (CMO), chief nursing officer (CNO), chief operating officer (COO), chief financial officer (CFO), and other senior managers (which may be referred to collectively as the “C-suite”); and (3) the medical staff leadership. Hospital leadership is accountable to the Board of Directors.

The Healthcare Board of Directors (Board)

The Board of Directors (BOD), or the Board of Trustees, is the legally constituted governing body of the hospital, with full responsibility for the financially viable and quality/safety practices of the hospital. The BOD is responsible for the establishment and oversight of the hospital’s bylaws and policies, establishes new policies, and, on the advice of a medical advisory board, appoints senior leadership and medical staff. The BOD can be variable with respect to size and membership, often a reflection of the type and location of the hospital. BODs of for-profit organizations govern on behalf of shareholders, and the primary obligation is to increase shareholder value. On the other hand, nonprofit corporations do not have shareholders, community leaders, legislators, and regulators such as the state Attorney General has the authority to hold board members accountable for actions and inactions. Board members are the fiduciaries with three primary legal duties known as the “duty of care,” “duty of loyalty,” and “duty of obedience.” The duty of care refers to prudent stewardship; the duty of loyalty requires that the fiduciary acts in the best interest of the corporation; and the duty of obedience requires that the member follows applicable laws, regulations, and bylaws, and adheres to the stated corporate mission [see Chap. 29 “Corporate Structure”]. Members of the BOD must maintain confidentiality and carefully manage potential conflicts of interest. In order to perform its functions efficiently and expeditiously, the BOD relies on committees and C-suite status reports. The “balanced scorecard” or “dashboard” concept includes four key dimensions of performance: financial, organizational, executive, and quality [109].

TJC defines the roles of the BOD in Standard LF.01.03.01 as “the body ultimately accountable for the safety and quality of care, treatment, and services… the governing body’s ultimate responsibility for safety and quality derives from its legal responsibility and operational authority for hospital performance. In this context, the governing body provides for internal structures and resources, including staff that supports safety and quality” and lists the elements of performance [110]:

1. The governing body defines in writing its responsibilities.
2. The governing body provides for organization management and planning.
3. The governing body approves the hospital’s written scope of services.

4. The governing body selects the chief executive.
5. The governing body provides for the resources needed to maintain safe, quality care, treatment, and services.
6. The governing body works with the senior managers and leaders of the organized medical staff to annually evaluate the hospital's performance in relation to its mission, vision, and goals.
7. The governing body provides a system for resolving conflicts among individuals working in the hospital.
8. The governing body provides the organized medical staff with the opportunity to participate in governance.
9. The governing body provides the organized medical staff with the opportunity to be represented at governing body meetings (through attendance and voice) by one or more of its members, as selected by the organized medical staff.
10. Organized medical staff members are eligible for full membership in the hospital's governing body, unless legally prohibited.

The effectiveness of a hospital BOD has been shown to be related to hospital financial performance. With respect to financial oversight, a BOD has six core financial responsibilities, to (1) specify financial objectives, (2) review and align the management financial plan with stated objectives, (3) enhance creditworthiness, (4) ensure capital is effectively allocated, (5) monitor financial performance, and (6) verify financial statements [111]. Important financial indicators include cash flow, efficiency, charity care, debt structure, return on investment, operating expenses, profitability, liquidity, creditworthiness, capital structure, and asset activity. Boards must be able to understand the key elements of financial performance and prescribe appropriate corrective or strategic interventions. In addition, financial and performance metrics must be compared with local, regional, and national benchmarks.

Hospital BOD also has a responsibility for hospital quality performance, even as quality performance is increasingly linked to financial performance. In 2007 the Institute for Healthcare Improvement (IHI) developed the "Boards on Board" program, with the intent of engaging BOD leadership in clinical quality. Increasingly, the notion of a "culture of quality" is used to discuss the engagement of senior leadership, specifically including the BOD, in the elements that comprise the safety and quality of care environment. Often, safety, quality, and finance are closely linked. Medical errors are costly and are an increasingly visible competitive metric.

The National Quality Forum (NQF) has also called on hospital BODs to focus on quality [112]. Provonost et al. discuss six principles for governance oversight of hospital quality of care and patient safety: (1) ensure oversight for quality everywhere within the system that care is delivered, (2) create a framework to organize and report the safety and quality-related work and metrics, (3) identify care areas where quality is ambiguous or underdeveloped and ensure reporting and accountability in such areas, (4) create a consolidated quality dashboard to track safety and quality performance, (5) ensure the integrity of the data used to measure and report quality and safety performance, and (6) transparently report performance and create an explicit accountability model [113].

Administration and Executives

The chief executive officer is the chief administrator of the hospital and is responsible to the BOD. In a large hospital, there are many separate departments, each of which is controlled by a department head. The CEO operates an executive leadership team, with second-level executives including the COO, CFO, CMO, and CNO, designations which may variably be referred to as "vice president" of operations, financer, medical affairs, and nursing, respectively. Further, in some cases the CMO/VPMA and CNO/VPN may be referred to as Medical Director and Director of Nursing, respectively.

TJC defines the roles of the chief executive of a hospital in Standard LD.01.04.01 as "a chief executive manages the hospital" and lists the elements of performance as:[2]

1. The chief executive provides for information and support systems.
2. The chief executive provides for recruitment and retention of staff.
3. The chief executive provides for physical and financial assets.
4. The chief executive identifies a nurse leader at the executive level who participates in decision-making.
5. When the chief executive is absent from the hospital, a qualified individual is designated to perform the duties of this position.

In addition to TJC, state statutes address the duties of hospital administrative staff. For example, in NYS, NYCRR Title 10 Section 405.3 lists and details, in part:

> The hospital shall be managed effectively and efficiently in accordance with hospital bylaws and policies and procedures. The daily management and operational affairs of the hospital shall be the responsibility of the chief executive officer.
>
> (a) The chief executive officer shall be responsible for the development, submission and implementation of all plans to correct operational deficiencies identifed by regulatory agencies on a timely basis and shall report to the governing body progress in developing and carrying out plans of correction.
>
> (b) Personnel. The chief executive officer develops and implements personnel policies and practices with regard to at least the following…

Additional hospital executives are responsible for managing the organization, making financial decisions, overseeing business strategy, and indirectly managing the hospital support staff infrastructure.

The Medical Staff

Physicians traditionally have been relatively independent of hospitals and have used them as "workshops" in which to carry out their professional services [4]. The medical staff of a hospital are integral to the healthcare mission; in essence, the medical

[2] See The Governance Institute, supra.

staff define the healthcare entity. The medical staff are composed of the physicians, dentists, podiatrists, psychologists, and advanced practice providers (APPs), often collectively referred to as "providers." APPs are composed of, for example, physician assistants, nurse anesthetists, anesthesiologist assistants, nurse practitioners, and nurse midwives. In a regulatory nomenclature, providers are often referred to as "licensed independent practitioners." An unlicensed person who diagnoses and/or treats a patient through activities that are covered by any of the licenses is considered to be practicing illegally and is "practicing without a license." Laws vary by state, an activity that is illegal in all states. Although the classification of the crime will vary by state and by circumstances, the practice of medicine without a license may be charged as either a misdemeanor or felony offense, punishable by fines and prison terms that range from 1–8 years, depending on the jurisdiction. In addition a person harmed through the unlicensed practice of medicine may sue in civil court for assault/battery and be entitled to restitution as monetary damages and possibly punitive damages.

Physicians and licensed independent practitioners (collectively "the medical staff") bring to the healthcare entity the technical knowledge and training necessary to provide patients with the requisite preventive, diagnostic, and therapeutic medical care that is essential to the hospital mission. In addition, the medical staff are authorized to provide clinical supervision of support staff.

TJC first defined the organized medical staff as a hospital standard in 1951. TJC defines its medical staff leadership as "an organized medical staff that is accountable to the governing body" in TJC Leadership Standard LD.01.05.01. The elements of medical staff performance according to TJC are:

1. There is a single organized medical staff unless criteria are met for an exception to the single medical staff requirement.
2. The organized medical staff is self-governing.
3. The medical staff structure conforms to medical staff guiding principles.
4. The governing body approves the structure of the organized medical staff.
5. The organized medical staff oversees the quality of care, treatment, and services provided by those individuals with clinical privileges.
6. The organized medical staff is accountable to the governing body.

EP 2 requires that the medical staff be self-governing, and EP 6 requires the medical staff to be accountable to the governing body. TJC defines self-governance to include:

- The initiation, development, and approval of medical staff bylaws and rules and regulations
- The approval or disapproval of amendments to the medical staff bylaws and rules and regulations
- The selection and removal of medical staff officers
- The determination, establishment, and enforcement of criteria and standards for membership on the medical staff

- The determination, establishment, and enforcement of criteria for the delegation of oversight responsibilities to practitioners with independent privileges
- The establishment of mechanism for maintaining patient care standards and credentialing and delineation of clinical privileges
- Performance improvement activities

The organized medical staff has a critical role in the oversight of safety and quality through setting of rules, regulations, and internal standards and review of adverse outcomes, credentialing, peer review, and punitive actions. However, smaller community hospitals may face significant challenges with respect to peer review and credentialing by virtue of their limited resources, difficulty in medical staff recruitment, and limited medical staff size [114]. For examples, hospitals that have a Department of Surgery composed of two partners may have difficulty conducting an effective peer review and may restrict competition through control of credentialing in the institution [See also Chap. 7].

The 2009 Comprehensive Accreditation Manual for Hospitals further elaborates on the responsibilities of the medical staff's including, for example:

- Oversight of care provided by physicians and other licensed independent practitioners in the hospital
- A role in graduate medical education programs, when the hospital has one (or more)
- A leading role in performance improvement activities to improve the quality of care and patient safety
- Collection, verification, and evaluation of each licensed independent practitioner's credentials
- Recommending to the governing body that an individual be appointed to the medical staff and be granted clinical privileges, based on his/her credentials
- Participating in continuing education

The relationship between the hospital and the medical staff continues to evolve as physicians and physician practices are increasingly acquired and owned by hospitals; thereby transforming an independent medical staff into medical staff who are employees of the hospital, and therefore, at least partly or potentially, subject to administrative control. The changing physician practice environment has wide-ranging potential implications from voluntary involvement in medical staff governance and duties, medical staff socialization, and even burnout.

Conclusion

Compliance with regulatory mandates is mandatory to healthcare entities. The regulatory and legal environment of healthcare is both de facto complex but is also constantly changing. Therefore, in order to remain compliant with the regulatory mandates that govern healthcare, both fluency with respect to terminology and its

implications and competence with respect to an appreciation of the scope of potential regulatory impact are important. Although few will be able to recite the regulations, it is perhaps more important to appreciate the potential regulations that are applicable to any one circumstance and know where to find the law.

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