

Law and Ethics In Neurocritical Care

A Practical Guide for Managing Clinical Complexities

by the
Neurocritical Care Society



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DEDICATIONS

For my loving parents, who have laid the foundations for all that I do; and, for my loving wife Doris who is my constant guiding light, my support, and without whom none of this could have been accomplished.

James E. Szalados

As with nearly everything else in my life, I dedicate this book to my loving husband, Brandon Seigler, PhD, EdS, MAT. He is an endless source of inspiration, motivation, support, patience, guidance, kindness, joy and love.

Wendy Wright Seigler

To the many patients and physicians struggling with ethical dilemmas over the years, and to my family who has always grounded me in practicality.

Wade S. Smith

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The material and perspectives herein deal primarily with the laws and the legal system in the United States and are not intended in any way to represent a worldwide subject view.

The laws governing health care are derived from federal and state laws which are subject to modifications and changes. Many areas of law are state-specific, and providers must consult the laws of the state in which they practice. The information presented herein may not reflect new and evolving legal developments.

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PREFACE

The complexity of clinical care in our rapidly changing neurocritical care units presents regular opportunities for legal and ethical conundra. Providers practicing in the sub-specialty of neurocritical care, and its allied and parent specialties, are regularly challenged with real time decision-making that have legal and ethical implications, and more-importantly, actual or potentially reasonable solutions.

The complexities of law and medicine make it impossible to know the answers to every clinical dilemma. In addition, expert legal opinion is frequently difficult to obtain in real-time. One practical approach is to maintain sufficient situational awareness so as to 'know when you don't know.'

The vision behind this textbook is to offer a problem-based review of legal and ethical concepts in a very unique format. At present, there is no comparable published product which presents legal and ethical concepts in a condensed, concise, yet comprehensive manner. Legal and ethical concepts are presented here in a generally 2-page format, with carefully selected references and suggested reading to guide further study. Each brief chapter has been authored by subject matter experts with subsequent editorial and peer review. The format of this text is ideally suited for a curriculum in legal medicine or clinical ethics and is applicable to a manner and level of practitioners in clinical care. Moreover, the text is applicable to all neurology and neurocritical care specialties including neurointensivists, neurosurgery, neurointerventionalists, neurohospitalists, and rehabilitation specialists. The text is ideal for all members of the care team including physicians, advanced practice providers, pharmacists, nurses, therapists, and trainees.

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First, we thank all the contributing authors, many of whom are mentors, trusted colleagues and valued friends. Your educational backgrounds, clinical experiences and thoughtful reflections and perspectives added depth to this book that was not otherwise achievable.

Next, we thank the Neurocritical Care Society Educational Products Committee for oversight, feedback and organization of this ambitious endeavor. Specifically, staff members Sara Memmen and Becca Stickney were at our sides providing continuous organizational and moral support. We also thank Dr. Karen Hirsh for keeping us on track. Furthermore, the Neurocritical Care Society continues to be a home for all of us who passionately strive to provide the highest quality of care for critically ill neuroscience patients as a part of a dedicated multidisciplinary team, and we are grateful for the enrichment, education and community it has added to our lives.

The editors also thank Samuel D. Hodge, Jr., JD, for expert peer review of these materials. Professor Hodge teaches both law and anatomy at Temple University and serves as mediator and neutral arbitrator with the Dispute Resolution Institute.

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SECTION I: LAW

Ch. I-1 The American Legal System

James Szalados, MD, Esq

ISSUE: You wish to understand the American system of law. What must you know?

THE FEDERAL AND STATE SYSTEMS OF GOVERNMENT AND LAWS

Law becomes necessary and operative whenever individuals or entities interact within a modern society. Laws form guideposts in Society and serve four general purposes: (a) the setting of standards for acceptable behaviors in society; (b) the maintenance of social order; (c) the provision of a mechanism and structure for dispute and conflict resolution; and, (d) the protection of liberties and rights. Laws and the legal system must be perceived as reasonable, fair, and impartial with the goal of providing justice. The American social contract rests sufficient power within the government so as to provide for law and order within American society while simultaneously preserving individual freedoms to the greatest extent possible. Since the law is, to some extent, predictable, attorneys and counsel can research the laws regarding a proposed plan or issue and advise clients through legal opinions to minimize the risks of future liability.

U.S laws are is derived from the common law of the system of English law; however, Louisiana and Puerto Rico derive their state law structure from civil law based on the Napoleonic Code. The American legal system is based on four federal sources of law: (a) constitutional law; (b) administrative law; (c) statutes, and (d) common law, or precedent.

The U.S. Constitution is the basis of the U.S. legal system, and establishes a federal system of government which defines the principles, structures, and processes of that government; more specifically it defines the respective powers and responsibilities of the federal and state governments. The U.S. Constitution defines the separation of powers in Articles I through III of the U.S. Constitution and thereby provides for checks and balances between branches of government: (a) the legislative branch of government is vested with both houses of U.S. Congress and defines the power to make federal laws; (b) the executive branch is vested with the power to carry out and enforce laws; and, (c) the judicial branch

whose role it is to interpret the law. Although each branch may enact laws, their respective scope of lawmaking is defined in the Constitution.

The judicial branch of government is the U.S. Supreme Court (SCOTUS). The SCOTUS may hear a case because it involves a constitutional question, or, via appeal from a highest level federal or state court. A constitutional question refers to a legal issue that requires interpretation of the Constitution; these issues usually involve the Bill of Rights, which are the within in the first 10 amendments to the Constitution.

The legislative branch of the federal government refers to federal laws enacted by Congress in the form of statutes. The official compilation and codification of the federal statutes is published in the in the United States Code (U.S.C.). Congress also has the power to appoint federal agencies (such as the Drug Enforcement Agency and the Food and Drug Administration); such agencies are vested with rule-making authority through which they create regulations specific to their subject matter jurisdictions; such rules have the force of law and form a branch of law referred to as administrative law. Rules enacted by agencies are published in the Federal Register (Fed. Reg.) and codified in the Code of Federal Regulations (C.F.R.).

Under the U.S. Constitution, states are charged with all powers not enumerated, or expressly granted to the federal government through the U.S. Constitution. Therefore, the states are vested with a parallel legal structure which includes a state constitution, state legislatures which enact state statutes, state agencies which enact state-specific rules, and state court systems which enforce their own separate body of state laws with associated legal precedents. State constitutions typically reiterate the rights guaranteed under the U.S. Constitution and although state constitutions may establish additional rights, they may not restrict federally guaranteed rights.

CONSTITUTIONAL FREEDOMS

The U.S. Constitution and the Bill of Rights specify individual rights which provide the

framework for procedural and substantive safeguards. Some of the fundamental constitutional rights include: the right to due process (Fifth and Fourteenth Amendments), the right to equal protection under the law, the right to a trial by jury in civil trials (Seventh Amendment), and the right to a lawyer and the right to a speedy trial (Sixth Amendment) among others. Of these, the right to due process, which protects against deprivation of life liberty or property without due process of law is fundamental to the American legal system.

THE ORGANIZATION OF THE AMERICAN COURT SYSTEM

The U.S Court system is organized as a dual court system: the federal and the state judiciaries. The federal court system is organized in the (a) SCOTUS; (b) twelve U.S. Courts of Appeals and the Court of Military Appeals; and (c) 94 U.S. district courts and the specialized courts. Decisions reached in the district courts may be appealed to the courts of appeals, and potentially to the Supreme Court. In order for the Supreme Court to hear a case, it must issue a *writ of certiorari*, for which at least four of the nine Supreme Court justices must agree to hear a case. The 94 federal judicial districts are organized into 12 regional circuits, each of which has a court of appeals. All federal judges are chosen by the President and approved by the Senate. In any appellate process the court to which a case is appealed must determine whether or not the lower court correctly applied the law or made a substantial procedural error. Federal courts have limited subject matter jurisdiction (defined in Article III, Section 2 of the Constitution) including for example, cases relating to constitutional interpretation, matters of federal law, and matters of diversity jurisdiction which cases between citizens of different states, in which the

amount in controversy exceeds \$75,000. However, Federal courts may decide cases based on state law in diversity matters. In the U.S. Courts of Appeals, there are no juries, no witnesses are called, and no evidence is examined; attorneys present their appeals arguments before three or more judges. Under the Supremacy Clause of the Constitution, federal decisions represent *stare decisis* to state courts within the deferral jurisdiction. Finally, there are a variety of federal special courts which include courts of military appeals, courts of veteran's appeals, tax courts, patent law courts, bankruptcy courts, courts of probate, territorial courts, and the courts of the District of Columbia. Federal courts have exclusive jurisdiction over bankruptcy cases involving personal, business, or farm bankruptcy; therefore, a bankruptcy case cannot be filed in state court. Prosecutorial authority in the federal system is granted to the office of the U.S. Attorney for the district in question.

The state courts are also organized by level; the state district or trial courts, the state courts of appeal, and the state supreme courts. The nomenclature of the courts may vary by state, although the process remains the same. Matters appealed from the state supreme courts may be appealed to the SCOTUS. Prosecutorial authority for matters of state law is granted to the Office of the state Attorney General. Local state matters are prosecuted by the Office of the District Attorney. In addition, there are a variety of city and town courts, administrative courts, divorce and custody courts, traffic courts, and small claims courts, for example.

REFERENCES/SUGGESTED READING

Schantz WT. The American legal Environment. Individuals, Their Business, and Their Government. West Publishing Co., St Paul MN, 1976.

Ch. I-2 Source of Law**Wendy Wright, MD, JM****ISSUE: A legal question arises during the course of treatment.**
Where do health care laws come from?**WHAT IS “THE LAW?”**

A law is a binding custom or practice that is enforced by a controlling authority. In the United States, that controlling authority is the federal, state or local government. Enforcement is by way of government-imposed penalties, such as fines or restrictions of certain actions. The entire body of such customs or practices can be referred to as “the law.” In general, laws are written by legislative bodies, carried out by the executive branch of government, and interpreted by the judiciary. Broadly considered, the role of the law in society is to make rules and settle disputes in order to advance principles of justice.

GOALS OF THE LAW

Laws promote order, stability, and continuity. Through the passage of laws, a society will reflect its own sense of “right” and “wrong.” Laws set an expectation for social norms, such that a person can depend on these standards when choosing their actions. Precedent, which is when a judicial decision followed by a judge is applied to future similar cases, allows people to reliably predict how they will be treated in similar circumstances. Precedent also saves time, in that society does not need to re-write the rules every time a dispute arises. It is important that the laws advance the goals of justice, including fairness, impartiality, and equal protection. The government should not impose penalties without affording the accused party due process.

Laws also serve to promote public policy. This is more of a function of social usefulness, rather than right or wrong. Public health law, for example, deals with the authority of the government to improve the health of the population within societal norms. This includes consideration of limits on the government’s power over the people.

PARADOX OF BEING BOTH FREE AND GOVERNED

Recall from principles of basic civics that the Federal Government did not create the

individual states, but rather the states created the Federal Government. This was because the states recognized that there were things that the Federal Government could do better than the individual states, such as coin money and enter into treaties. Since the original states were hesitant to give up their power to the central government, they took two key approaches to avoid centralizing power: federalism and separation of powers.

FEDERALISM

Federalism dictates that certain powers are retained for the states. These powers are prohibited from being controlled by Congress. As such, the U.S. Constitution stipulates that any powers not enumerated as being specific to the federal government belong to individual states.

SEPARATION OF POWERS

Under the principal of the separation of powers, the framers of the Constitution split government functions into three parts, each of which would provide checks and balances over the other. In general, the legislative branch (Congress) makes the laws (Article I), the executive branch (the President) executes (carries out and enforces) the laws (Article II), and the judicial branch interprets the laws via the process of adjudication (Article III). Highest judicial authority belongs to the Supreme Court of the United States. Some will point to the administrative agencies as the “fourth branch” of government. Administrative agencies have legislative, executive and adjudicative powers, but are functionally part of the executive branch. Administrative agencies are covered in a separate chapter (See Ch. I-3).

The original states further split the power of the Congress, which performs legislative functions, into two parts. The making of laws was seen as the most powerful function of government, and the framers of the Constitution equated power with the potential for oppression. With this

division, two different bodies, the House of Representatives and the Senate, representing diverse constituencies, must come together to agree on laws. Therefore, if you have ever felt that Congress is moving too slowly, it was designed that way from the outset to avoid unnecessary restrictions on liberty.

The separation of powers reverberates through state governments. States have their own legislatures, an executive (Governor), and judiciary (headed by state supreme courts).

FRAMEWORK OF LAW

The highest source of law in the U.S. is the Constitution; no law may violate this document. The Constitution provides a general framework for the structure of the government. The government, in turn, is the body that makes, implements, enforces, and interprets the law.

Each state also has a constitution, which lays out the framework for the structure of the state government. The common wisdom is encapsulated in the colloquialism that the state exists to “educate, medicate and incarcerate.” As this phrase indicates, it is the state (and sometimes local) government that is primarily expected to attend to the needs of its inhabitants. However, this common wisdom has started to break down as the Federal Government becomes increasingly involved in health care issues. This mixing of federal, state and local authority is sometimes called “marble cake federalism,” in contrast to the classic federalism symbolism of a layer cake.

If state laws and federal laws conflict, the federal law usually has supremacy, assuming the U.S. Constitution grants the power in question to the Federal Government in the first place. State and federal court systems are different, each with its own jurisdiction (the types of cases a court can hear). For example, federal courts will hear disputes that have to do with federal law, such as questions of constitutional rights. Occasionally, there is cross over from a state to a federal court. Medical malpractice cases are generally carried out in state courts, unless the plaintiff and defendant are from different states, in which case the federal court system may be the

appropriate venue. When conflict exists between state supreme courts, the Supreme Court of the United States settles the dispute.

WHERE DO LAWS COME FROM?

Sources of law include:

- U.S. Constitution and state constitutions
- Statutes from Congress or state legislatures
- Regulations from administrative agencies
- Ordinances passed by municipal bodies, such as a city council, to govern issues not already covered by federal and state governments (such as zoning and safety regulations)
- Common law, which is forged through disputes brought in individual court cases and shaped by judicial opinion

HEALTH LAW

Health Law is an expansive area of law, including law that impacts the health care industry. This broad category includes federal, state and local legislation, regulation and adjudication. Health law itself has become highly subspecialized, spanning topics from business associations to end-of-life decision making. Three priorities of health law include quality, access and cost. Much of health law (other than medical malpractice) is administrative law, which is discussed in Ch I-3.

STATE LAWS

As stated previously, states traditionally had most of the powers to regulate health care. Many of these powers have been maintained, regardless of the increasing influence of the Federal Government. For example, states regulate professional licensing, which allows them to define the practice of medicine in that state. Other important state powers include insurance regulation, administration of Medicaid services, and oversight of medical malpractice disputes.

INFLUENCE OF NON-GOVERNMENT ENTITIES ON HEALTH CARE

Motivators for hospital policies, organizational structure and quality initiatives can come from sources other than

government. Quality and advancement can be driven by competitive forces within the health care market, as patients become more savvy consumers. Additionally, there are private organizations that are used by the government to carry out regulatory responsibilities, most notably The Joint Commission. The Joint Commission accredits hospitals that meet its standards; the Centers for Medicare and Medicaid Services (CMS) uses this accreditation process to “deem” the hospital as certified to receive Medicare payments. In some states, accreditation by The Joint Commission also means that the hospital is effectively licensed by the state.

Medical practice is also heavily influenced by private professional societies and certification bodies. Professional societies may issue guidelines and practice parameters. If clinicians do not follow them, they are not breaking the law, *per se*, but they may run the risk of falling below the standard of care, and may face negative consequences. Certifying bodies can describe the expected skill set of a board-certified clinician, raising the bar for the standard of care provided by that clinician.

The United States Constitution

WHERE DO I FIND “THE LAW”

How many times have you heard the question, “Is that even legal?” uttered in the ICU? Studying law and finding sources of law have some parallels to medicine. Like medicine, the law evolves. Many questions are still the subject of debate and depend heavily on the facts of the case. Like medicine, it is hard to find a source of truth that meets one’s needs. Imagine turning to a neurology book to try to find “the answer” to a clinical question. Textbooks (like this one) describe principles and offer suggestions for approaching an issue, but are no substitute for an educated, trained, licensed professional who knows how to approach the relevant literature and can piece together a comprehensive understanding of each particular case. For more information on legal resources, see Ch. I-50.

REFERENCES/SUGGESTED READING

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Ch. I-3 Administrative Law in Health Care

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ISSUE: My professional society has asked members to comment on a proposed CMS rule.

What is the role of administrative law in health care?

WHAT IS ADMINISTRATIVE LAW?

Administrative law deals with the processes, procedures and details of the workings of government. These elements allow legislation to transform from policy directive into functional system of governance. Administrative law includes the laws that define the authority, structure, and function of administrative agencies, as well as the regulations (also called rules, or actions that agencies produce by issuing administrative laws) and adjudications (also called orders), which carry the force of law.

WHAT IS AN ADMINISTRATIVE AGENCY?

Administrative agencies fulfill a vital role in government. They are governmental entities that fill in the gaps needed to put legislative statutes into action. They are created by the U.S. Constitution and by enabling legislation written by the U.S. Congress (or state counterparts). Sometimes called the “fourth branch” of government, administrative agencies are technically part of the executive branch of government and, therefore, help to carry out (“execute”) laws. The structure and function of an administrative agency are set forth in the Administrative Procedures Act of 1946 (APA).

WHAT DO ADMINISTRATIVE AGENCIES DO?

Administrative agencies have as much or as little power as they are authorized to have by their enabling statutes. They can perform legislative functions, in that they can pass regulations, backed by the force of law. They can also issue documents that do not have the force of law, such as memos, guidance documents and interpretative documents. Congress tends to delegate authority to the administrative agencies if Congress lacks the time and/or the subject matter expertise to effectuate the finer details of the law. For example, Congress passed the Patient

Protection and Affordable Care Act in 2010, but the creation of Affordable Health Benefits Exchanges is left to the regulatory agencies.

Administrative agencies also have adjudicative powers in that they may issue orders. Orders tend to be relevant to individual persons or entities, so they are more like judgments before a court and do not necessarily bind other parties. They can be formal or informal, and sometimes administrative agency hearings are mandatory alternatives to the court system. For example, a person who is denied supplemental security income (SSI) may request a hearing in front of an administrative law judge.

Administrative agencies can also investigate compliance infractions and prosecute enforcement actions. When specifically authorized to do so, an agency may file civil lawsuits or initiate criminal prosecution. Examples include fraud and abuse enforcement. These functions are most like those undertaken by the executive branch; therefore, administrative agencies can undertake functions similar to all three branches of government (legislative, judicial and executive), but only if so authorized via delegation from Congress.

AGENCY RULEMAKING

The process for agency rulemaking is determined by the APA. In order for an administrative agency to pass a regulation, they first must be delegated the authority to do so by an enabling statute. The rulemaking process can be formal or informal. Formal rulemaking is reserved for decisions that need to be made “on the record after opportunity for an agency hearing.” Informal rulemaking is more common and is referred to as “notice and comment” rulemaking. Despite being called “informal,” this process is still very detailed, as described in the APA. In brief, the agency publishes a proposed rule in the Federal Register (which is the

official journal of the Federal government, published Monday through Friday, excluding holidays) and then takes comments from the general public for a specified period of time (usually 60 days). The agency may decide to make clarifications or revisions based on public comments. The final regulation, backed by the force of law, is published in the Federal Register and will be incorporated into the Code of Federal Regulations.

WHAT ARE THE ADVANTAGES OF ADMINISTRATIVE AGENCIES?

Advantages of administrative agencies include the following abilities:

- To address a larger body of finer details that needs to go into law than what Congress is able to do, based on subject matter expertise, time, and staffing
- To promptly take new circumstances into account when updating rules and regulations (compared to Congress, which must pass entirely new legislation)
- To provide forward looking guidance (compared to going through a court proceeding, which can only provide guidance after a dispute)
- In their adjudicatory function, to decide disputes efficiently and with a higher degree of subject matter expertise than a traditional court, which frees up judicial resources for other cases

WHAT ARE THE DISADVANTAGES OF ADMINISTRATIVE AGENCIES?

Disadvantages of administrative agencies include:

- Agencies are subject to bias of their own; “agency capture” occurs when regulatory employees that work very closely with industry act based on the preferences of the industry rather than interests of the public
- Agencies allow legislators to avoid responsibility for decisions
- Agencies may abuse broad delegations of power

WHICH FEDERAL ADMINISTRATIVE AGENCIES ARE INVOLVED IN HEALTH CARE?

Several administrative agencies play a role in health care delivery, but the most notable is the Department of Health and Human Services (HHS). The Secretary of HHS is a cabinet-level political appointee who reports directly to the President. Amongst its eleven operating divisions are:

- Agency for Healthcare Research and Quality (AHRQ)
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Office of Civil Rights (OCR)
- Office of Inspector General (HHS-OIG)

Since health care has an extensive scope and impact, there are many other federal agencies that oversee certain aspects of health law. For example, the Occupational Safety and Health Administration (OSHA) is part of the U.S. Department of Labor; and the Federal Bureau of Investigations (FBI), which partners with divisions of HHS to investigate fraud and abuse claims, is part of the Department of Justice (DOJ). Also housed within the DOJ is the Drug Enforcement Agency (DEA), through which clinicians must be licensed in order to prescribe certain medications.

There are also independent administrative agencies, including familiar names like the Central Intelligence Agency (CIA) and the National Aeronautics and Space Administration (NASA). Independent regulatory agencies are housed within the executive branch of government, but do not answer directly the President in order to minimize political influence. Some independent agencies, like the Federal Emergency Management Agency (FEMA) and the Securities and Exchange Commission (SEC) have involvement in health-related issues, such as hazard mitigation and investigation of fraud, respectively.

CMS

The Centers for Medicare and Medicaid Services (CMS) is a large government agency that is governed by a complex body of statutes and regulations. Previously known as the Health Care Financing Administration (HCFA), CMS is charged with overseeing Medicare. It also works with state governments and local contractors to oversee Medicaid and the Children's Health Insurance Program (CHIP). Other responsibilities of CMS include oversight of quality standards for long-term care facilities and clinical laboratories.

WHO OVERSEES ADMINISTRATIVE AGENCIES?

Systems of checks and balances apply to the administrative agencies. Congressional supervision is achieved by limiting the initial delegation of power to the agency, by oversight hearings (when needed), and finally, by the ability to override agency actions by statutes (when desired). Federal courts can review agency action, as described in the APA, but they often defer to agency expertise. Many of the agency heads report to the President. In this way, agencies are accountable to the will of the people, in that the President can be voted out of office if the citizens of the United States wish to change the direction of administrative policy.

STATE ADMINISTRATIVE AGENCIES

States also have administrative agencies that address state-specific issues including public health and education. These state agencies function very much like federal agencies. They have law making powers in that they may issue regulations if delegated to do so by the state legislature. State agencies may not contradict the rules and regulations of their federal counterparts. Most states have adopted legislation similar to the APA, which directs agency structure and function.

State agencies are often created to handle issues pertinent to health administration and may include departments of public health, state licensing bodies, and county medical examiners. Insurance regulation is a function of the state (rather than federal) government, so state insurance departments, often overseen by an insurance commissioner reporting to the

governor, have a large role in health care delivery.

HOW CAN I STAY INFORMED ABOUT THE ACTIONS OF ADMINISTRATIVE AGENCIES?

Professional and state medical societies can often be a helpful source of information about agency action and proposed rulemaking. One may go directly to the source and look through the Federal Register at www.federalregister.gov. A way to stay engaged in the process is to contribute comments to proposed rules. You can search through www.regulations.gov by subject matter, and by rules for which comments are being taken.

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