# MONOGRAPH

PREPARED BY THE MONOGRAPHS TASK FORCE OF THE AMERICAN SOCIETY FOR HEALTHCARE RISK MANAGEMENT

## How to use & understand

# statutes, regulations, guidelines, interpretations & model guidance

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ONE NORTH FRANKLIN, CHICAGO, IL 60606 ASHRM 312.422.3980 WWW.ASHRM.ORG

## INTRODUCTION

The health care field is the subject of a host of federal statutes, regulations, guidelines, interpretive information, and model guidance. At the state level there is also a considerable number of statutes and regulations that have an impact on the delivery of health care services.

This monograph puts in perspective these federal and state materials. Learning how to read such legal information can facilitate the design and implementation of risk management systems. A flow chart is incorporated here to depict the spectrum of laws and other tools that guide the delivery of health care. In the end, rather than be an imposing and daunting challenge to understand, the outcome can be development of risk management systems that use this information as a blueprint for success.

## UNDERSTANDING THE SYSTEM BEHIND STATUTES

Legislative assemblies enact statutes before they become laws. Such laws do not take effect upon the passage of a legislative bill that generates new legislation. Rather, in most democracies there is a system of checks and balances that provides for a "second look" at legislation. At the federal level in the United States, this role is fulfilled by the President. The President "signs" the law to give it full effect. At the state level, this role is fulfilled by the governor. In other countries, a parliamentary system might include a prime minister who signs into law a piece of legislation passed by an assembly.

In a constitutional system, the authority to enact legislation is described in the constitution. In the United States, the Constitution delineates the authority vested in the federal government and the powers reserved to the states. Congress is empowered to enact legislation at the federal level. Each state has its own constitution that describes the scope of authority vested in a state legislature.

## WHAT IS A STATUTE?

A statute is legislative enactment that has been signed into law. A statute either directs someone to take action, grants authority to act in certain situations, or to refrain from doing so. Statutes are not self-enforcing. Someone must be authorized to do so to take action. A statute may authorize the Department of Health and Human Services to take action, and it is up to the department to implement the law.

## HOW TO READ A STATUTE

Reading or "interpreting" a statute is something of an art. Judges spend years interpreting or construing the "meaning" or application of a law. Getting to the true meaning may come down to a turn of a phrase, the use of a particular verb, or reference back to the written proceedings of Congress or a legislative committee. The same is true at the state level and in other democratic countries.

Notwithstanding what transpires at the appellate court level, each individual is expected to act within the scope of the law. This is the practical side of statutory interpretation. If an environmental law prohibits the dumping of chemical wastes in protected areas, it is axiomatic that such behavior is acting "against" the law. It does not require someone to interpret the fine points of a statute.

Even where the law is less than straightforward, there are certain practical steps that can help risk management professionals understand how to read a statute. These steps include:

**1. Look at the title of the statute.** The body of the law should reflect what is encapsulated in the title of the legislation. For example, if the title reads "Licensure of Nurse Midwives," the body of the law should describe what is involved in licensing nurse midwives.

**2. Look at the preamble.** Legislature often will provide a statement that describes the purpose for the law. This is very useful, especially in trying to understand how to give effect to the law.

**3. Look at the definitions.** Many statutes begin with a section of definitions. Caution should be exercised, however, especially if the law reads*, "For purposes of Sections 1.1.0 through 1.1.8, the definition of 'authorization' means … ."* Such statutory construction is a warning that the definition has limited application. It does not apply to Sections 1.1.9 through the end of the statute. Whether on purpose or as a result of an oversight, sometimes the legislation does not include definitions for the sections that have been carved out from the application of the overarching explanation of the terms. At other times, the definitions are intended to apply to all the sections of the statute. In reading through a statute, however, one may find a section that reads, *"For purposes of this section the term 'authorization' means*" or it may read "*Notwithstanding the provision [definition] in 1.1, the term 'authorization' means… .*" When this type of statutory construction is used, the intent is to provide a section-specific definition or exception to the overall use of the term.

**4. Look at the "action" statement in the statutory section.** Determine if the statutory provision requires you to *take action, refrain from a particular action* or *authorizes you to embark upon a particular activity*. For example, a provision in a nurse practice act may state, "Only those who have successfully passed the state licensure examination and who possess the prerequisite educational background may use the title "RN" after his or her surname." Another version might state, "It is an offense for anyone to use the title "RN" in this state who is not duly licensed to do so." Some protective legislation offers an example of the requirement to take action: "All physicians shall report known or suspected cases of elder abuse to the Department of Social Services." In some instances, a statute grants a caregiver discretionary authority. For example, in some parental notification provisions, a section might state that, "The attending physician may notify the minor's parents of the care provided to the patient, giving due regard to the circumstances of the case."

**5. Read statutory provisions in context.** Be careful not to read one section of a statute as being applicable to a circumstance that is addressed in another provision. Many times, statutory craftsmanship provides signals to avoid such misinterpretation. For example, a statutory provision may read, "For purposes of this section" or it may state, "This section is applicable to the following."

**6. Look for exceptions.** Be aware of statutory provisions that create limited application exceptions. For example, the language may read, "*This provision is applicable in all circumstances with the exception of the following ... ."* When this type of statutory construction is used, it in effect creates a number of "carve out" situations in which the provisions of the law do not apply.

**7. Look for effective dates of statutory provisions.** Determine "when" a statutory or statutory section takes effect. Sometimes this information is found at the end of the statute or statutory section. Note, too, that in some states, statutes have built-in expiration dates. This is a form of design that is used to compel state assemblies to evaluate the law with a view to re-enactment or refinement.

**8. Look for severability clauses.** To guard against a court ruling nullifying an entire statute when only one provision is deemed unconstitutional, many statutes include a severability clause. This means that if even if one or more provisions of a statute or ruled unconstitutional, the remainder of the law remains in effect.

## UPDATING STATUTORY INFORMATION

Federal and state statutes can be dynamic documents. Legislative changes occur that change the statute, sometimes repealing or amending specific provisions. In some instances, changes occur as the result of judicial interpretations. A court may rule that a certain provision within a long statute is unconstitutional.

Most risk management professionals do not have the time or resources to track down statutory changes. This can be done by legal counsel. General counsel or panel counsel usually have the resources to provide rapid information to update statutory law.

Statutory change is a signal that careful review is in order for institutional policies, procedures, and practice routines. For example, if a state assembly enacts a new law dealing with psychiatric advance directives, it is important to look at the *application* of the law in operational terms. By the same token, if the highest court in the jurisdiction overturns a provision dealing with the administration of psychotropic medication, applicable policies and procedures must be modified accordingly.

From a practical perspective, there are several strategies to consider:

**1. Establish a process for regular updates.** Develop a service agreement with outside counsel or a practice routine with in-house counsel to provide ongoing statutory updates. Included in this service should be legislative changes and judicial rulings that affect statutory provisions.

**2. Obtain copies of statutory changes.** Many states and the federal government provide online access to statutory changes. This service might also be obtained from in-house or outside counsel.

**3. Update the statutory file book.** Make certain that resource material is current. Rather than have the "old" version behind one tab and the update behind another section, retool the Statutory File Book to reflect only current provisions. This might involve something as simple as cutting and pasting or obtaining a current version of the law.

**4. Evaluate existing policies and procedure.** All policies and procedures should be reviewed to make certain that the content is consistent with any legislative or judicial decisions that resulted in a change in applicable statutory provisions. Working with relevant departments or units, a new policy or procedure may be needed or an existing document may need to be reworked to make it consistent with the revised statutory requirements.

**5. Provide inservice education for staff.** Work with department and unit leaders to provide practice inservice education programs on legislative changes for health care personnel. Thus, if a consent policy and procedure was modified to reflect statutory changes, the core content of the inservice program should be geared to what the caregivers need to know. This sometimes may mean the use of new forms or tools.

**6. Provide updates for leadership.** Many statutory changes have a direct impact on the stewardship of a health care organization. Work with legal counsel to provide a "legislative update" program for the board, senior management and members of health professional staff who are independent contractors such as physicians and licensed independent practitioners. Included in this process should be updates relevant to judicial interpretation of statutory law.

## REGULATORY LAW

Regulations, or rules, are promulgated by administrative personnel to whom legislatures have delegated such responsibilities. At the federal level, the Department of Health and Human Services promulgates regulations/rules that address day-to-day operations of federal health care requirements. The department takes this action based on the authority delegated in enabling legislation.

The federal government and each of the states follow a prescribed course for promulgating regulations. At the federal level, the requirements are set forth in the Administrative Procedures Act (APA). Similar laws are found in each of the states. In essence, the APA maps out how to propose a regulation, or "rulemaking" (Notice of Proposed Rule Making, NPRM), how to solicit public commentary, and how to issue a final rule or regulation. Provision is also made for interim rulemaking and modifications or repeal of regulations.

As in the case of statutory law, rules and regulations are subject to judicial interpretation. Sometimes the judicial intervention is based on procedural considerations. For example, a court might determine that the administrative agency or department failed to adhere to the process required for promulgating a rule under the APA. The result might be a nullification of the rule. In other instances, the legal intervention may be more substantive. A court might determine that, given the scope of enabling legislation, the agency or department exceeded its authority in promulgating a rule or regulation. The net effect would be to nullify the rule or regulation.

## HOW TO READ A REGULATION

As with statutes, there are several practical considerations to keep in mind when reading a regulation:

**1. Read the preamble.** The preamble to an NPRM is a useful tool in understanding the context for a department or an agency promulgating a regulation. The same is true of the preamble that accompanies the final version of the rule or regulation. In the latter situation, the agency or department often provides responses to public commentaries.

**2. Look at the definitions.** Take notice of any definitions that are limited to specific regulations or subsets of a regulation.

**3. Look at the operative terms.** Understand if the regulation requires specific actions, prohibits certain actions, or provides latitude in implementation of the content of the regulation.

**4. Look for exceptions.** Sometimes a regulation has a general application and then a subsequent subsection or provision carves out an exception.

**5. Look for effective dates.** Make certain that it is clear "when" the regulation takes effect for your health care organization.

**6. Look for cross-references.** Beware of sections or subsections that cross-reference to another provision in the regulations.

## USING REGULATORY INFORMATION

At the federal level, regulatory information first appears in a public document called the Federal Register. Similar registers or bulletins are found at the state level. Important preamble information can be found in this document. Once a regulation or rule is final, it is incorporated into the federal or state code of regulations.

It is sometimes easier to read amendments to an existing regulation in the Federal Register than it is to see it ensconced in the Code of Regulations. The reason is that the changes are highlighted in the Federal Register. The same is true of a state register or bulletin. Therefore, it is useful to retain a copy of the Federal Register version of the amended rule to read alongside the final Code of Regulations.

For risk management professionals, there are some practical steps to consider in reading a regulation:

**1. Obtain updates of regulations.** The Federal Register and the Code of Federal Regulations are easily accessed on the Internet. Bookmark the Web site and browse the site daily or weekly for changes. One way of obtaining this information is to go to http://www.access.gpo.gov/su_docs/aces/aces140.html

**2. Compare operational policies and procedures with revised regulations.** If a regulation is modified, consider how it will impact the policies and procedures of the health care organization. If a change is needed in policy and procedure, use institutional processes to make necessary refinements.

**3. Obtain legal guidance.** Many times, a regulation necessitates legal interpretation. Use legal guidance at the outset to make certain that policies, procedures and practice routines will be consistent with the regulation.

**4. Obtain legal updates.** As with statutory changes, seek legal updates for judicial interpretations of regulations. This update may reflect a decision nullifying the regulation or interpreting the application of it.

**5. Provide in-service education.** Offer inservice education for health care personnel with respect to new or modified regulations that affect daily operations. If policies and procedures are modified to reflect regulatory change, the inservice program should emphasize these modifications.

**6. Provide updates for leadership.** If a regulation is promulgated or modified, provide leadership with an education program regarding what they need to know about the new requirements.

**7. Be prepared to address regulatory-accreditation inconsistencies.** Sometimes, an accreditation body may issue a standard that is inconsistent with a regulation promulgated by a department or agency. If the health care organization is using accreditation as a means for obtaining Medicare or Medicaid certification, a choice must be made whether to accede to the regulatory or to the accreditation standard. If the choice is made to follow Medicare or Medicaid, the health care organization might be noncompliant with the accreditation provision. Health care organizations must make a deliberate choice. Since federal funding often provides a large amount of money to a health care organization, the choice is apt to be one in which compliance with the Conditions of Participation for Hospitals in Medicare and Medicaid will take precedence over the position embraced by the accreditation organization. Documenting the rationale for this position may be useful in convincing the accreditation organization to reconsider its perspective.

## GUIDELINES AND MODEL GUIDANCE

From time to time, a government agency or department will issue guidelines to explain the meaning or application of a regulation. On occasion, these guidelines are geared to regulatory personnel to assist them in applying the rule to a given situation. Termed "interpretive guidelines," the content gives the health care organization an excellent vantage point in understanding how the government views the regulation.

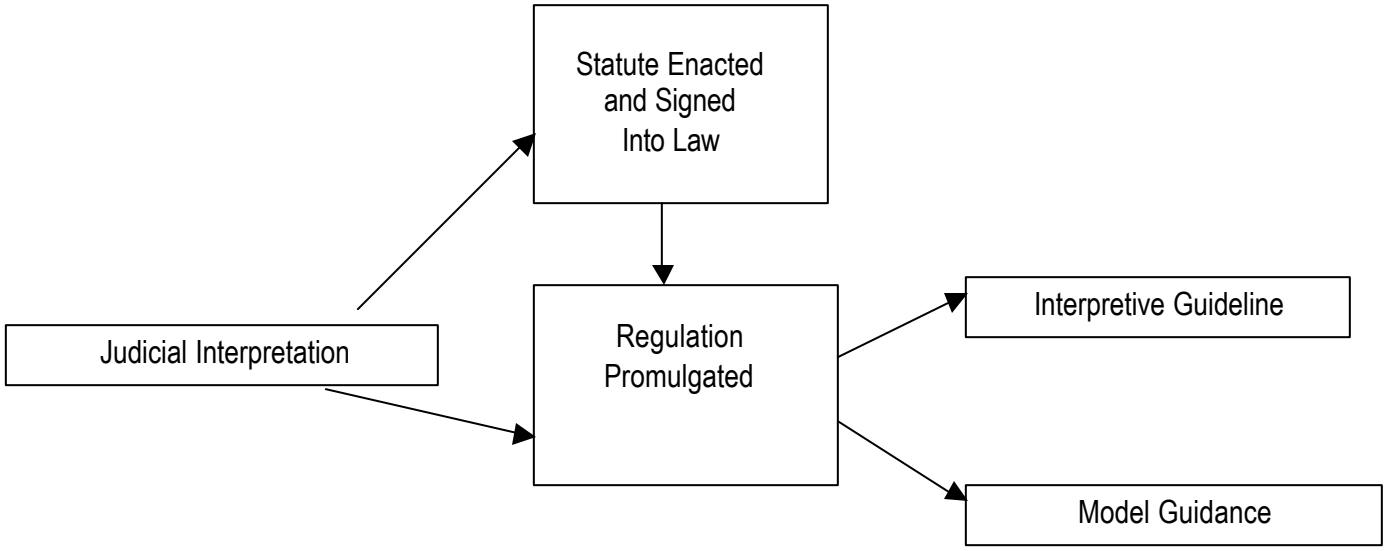
The interpretive guidelines do not have the effect of law. Rather it is like a portal that illuminates how a regulatory body intends to enforce the regulatory requirement.

A difference set of materials – model guidance – is sometimes issued by a regulatory body. It is designed to assist the subject of a regulatory framework in achieving compliance with the requirements. In the health care field, there are examples of such model guidance for corporate compliance. Often published on the Web site of the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services or in the Federal Register, this federal guidance represents the basic expectations to be met in achieving regulatory compliance. Indeed, the model guidance often will encourage the user to do more in terms of being a compliant organization.

The OIG is not the only regulatory body to issue model guidance. The Food and Drug Administration (FDA) also issues model guidance. Like the interpretive guidelines, the model guidance does not have the effect of a statute or regulation. Rather, it is a template for action. It is a tool for developing policies, procedures, and practice routines that track the expectations of regulatory agencies and departments.

## A PROCESS MODEL

The schematic below depicts the process from legislation through regulation to interpretive guidelines and model guidance. The statutory and regulatory requirements are subject to judicial interpretation. It is plausible that a plaintiff may use the model guidance as a tool in establishing a standard of care. The same is true in terms of statutes and regulations. Health care organizations should position themselves to use these requirements, guidelines and guidance in a proactive way to establish practical policies and procedures with a view to avoiding liability or regulatory challenges.




## CONCLUSION

There is an art to the interpretation and application of statutes and regulations. Because these provisions are written in a stylistic manner, it is sometimes difficult to understand the meaning or application of these requirements. To avoid confusion or misunderstandings, it is prudent to obtain legal advice in using these legal tools. Recognizing this fact is an important attribute of the risk management professional.

## WHERE TO FIND THE TOOLS

Many federal agencies and departments provide statutory, regulatory and model guidance on their Web sites. Others also include interpretive guidelines. Similarly, at the state level, there are useful Web sites to explore for such information.

Below are some frequently accessed federal Web sites to utilize in finding statutes, regulations, interpretive guidelines, and model guidance:

**Federal Register:** http://www.access.gpo.gov/su_docs/aces/aces140.html
**Code of Federal Regulations:** http://www.gpo.gov/nara/cfr/index.html
**U.S. Government Official Web Portal:** http://www.firstgov.gov/
**Legislative Information on the Internet:** http://thomas.loc.gov/
**Food and Drug Administration:** http://www.fda.gov/
**Centers for Disease Control and Prevention:** http://www.cdc.gov/
**U.S. Department of Health and Human Services:** http://www.dhhs.gov/
**HHS Office of the Inspector General:** http://www.oig.hhs.gov/
**HHS Office of Civil Rights (OCR):** http://www.hhs.gov/ocr/

## RELATED RESOURCES

**Risk Management Handbook for Health Care Organizations - 3rd Edition** (See Part I – Framework for Health Care Risk Management). 2001. Available from www.ashrm.org or at (800) AHA-2626. Catalog # 178160.

**Health Care Fraud Enforcement and Compliance.** R. Fabrikan, P.E. Kalb, M.D. Hopson and P.H. Bucy. Law Journal Press, New York. 2002.

**United States Health Care Laws & Rules.** P. Pavarini, editor. American Health Lawyers Association - West Group, Washington, D.C. 2002.

**Health Law and Compliance Update.** J. Steiner, editor. Aspen Publishers, New York. 2003.

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**Fay A. Rozovsky,** JD, MPH, DFASHRM, Marsh USA Inc., Richmond, VA
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