

# one chapter one

## Regulatory and Accrediting Bodies

This chapter focuses on the *Centers for Medicare and Medicaid Services (CMS) Conditions for Participation*, which must be met in order for healthcare organizations to be eligible for Federal funding of services rendered to Medicare and Medicaid recipients. CMS requirements for hospitals can be found in Appendix A “U.S. Code of Federal Regulations.” Appendix B “Centers for Medicare and Medicaid Certification Process” provides an overview of the *CMS Certification Process*. Although there are a plethora of regulatory agencies on the federal, state, and local levels, emphasis is placed on CMS requirements for hospitals.

There are also a variety of accreditation agencies. Again, the emphasis is on the Joint Commission (TJC), which is the largest non-profit accrediting body that requires compliance with CMS requirements in its standards. TJC was the first accrediting body written into the law to be granted *deemed status* to accredit hospitals and other healthcare organizations. Deemed status refers to a provider or supplier that has been accredited by a CMS-approved national accreditation program and, through such accreditation, demonstrates compliance with the applicable conditions of participation, conditions for coverage, conditions for certification or requirements.<sup>1</sup>

A provider may select CMS or another CMS body with deemed status to conduct the accreditation survey and certification process. The various states generally carry out the accreditation survey for CMS if the provider decides not to select an accrediting body with deemed status, such as TJC. It should be noted that CMS also conducts validation surveys to determine

the effectiveness of surveys conducted by other accrediting bodies with deemed status.

The survey is an evaluative process in which a healthcare provider undergoes an examination of its policies, procedures, practices, patient care, and performance to ensure that it meets CMS Conditions for Participation and, where applicable, the standards of the organization chosen by the provider to conduct the survey. TJC in its Hospital Accreditation Standards LD.04.01.01 requires hospitals to comply with laws and regulations that include CMS Conditions for Participation.

The cases presented in each chapter illustrate the importance of complying with the requirements of CMS Conditions of Participation for Medicare and Medicaid reimbursement purposes and, where applicable, if the organization so chooses, the accreditation standards of the surveying body (e.g., TJC). Some healthcare organizations choose to be surveyed by the various states for CMS Conditions of Participation for compliance purposes. It should be emphasized here that healthcare organizations that choose TJC to conduct its accreditation survey must comply with both the CMS Conditions of Participation, as well as, the standards of the TJC. State and local laws are often referred to in the various cases to illustrate how an unfortunate outcome might have been prevented if the laws and regulations that apply to the case had been followed. Laws, rules, regulations, and standards are written to help ensure the quality of care provided to patients and prevent unwanted outcomes.



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### **Regulators Penalize Some Maryland Hospitals for Complication Rates**

One of five Maryland hospitals failed to meet targets set for them by the state for rates of infections, pneumonia, and other complications last year, and most of those medical centers will suffer financial penalties as a result, regulators say.

Nine hospitals in the state will face a combined \$2.1 million cut in their allowed rate increases for the coming fiscal year. Maryland, alone among the states, regulates what hospitals can charge.

Twenty-three hospitals had better-than-average complication rates and will see small bonuses as a result. Scores for all 45 hospitals being tracked are posted online.

*Julie Appleby, Kaiser Health News, February 24, 2011<sup>2</sup>*

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The laws, rules, regulations, and accreditation standards involved in the delivery of health care is dramatically increasing the costs for providers, and yet the insurance industry continues to profit in billions of dollars. One needs only to go to a Marriott hotel in Los Angeles and look *up* from a top

floor window at the towering headquarters of insurance companies to realize where all the money is going and why it is difficult for patients to receive insurance benefits. And after looking at these mammoth structures, one could then visit local hospitals for the sake of comparison. Which buildings are more modern and lavishly built? A picture is worth a thousand words.

## CMS CONDITIONS FOR PARTICIPATION

CMS develops Conditions of Participation (CoPs) and Conditions for Coverage (CfCs) that healthcare organizations must meet in order to participate in the Medicare and Medicaid programs. These minimum health and safety standards are the foundation for improving quality and protecting the health and safety of beneficiaries. CMS also ensures that the standards of accrediting organizations recognized by CMS (through the “deeming” process) meet or exceed the Medicare standards set forth in CoPs and CfCs.

CoPs and CfCs are the minimum health and safety standards that providers and suppliers must meet in order to be Medicare and Medicaid certified. CoPs and CfCs apply to Ambulatory Surgical Centers, Critical Access Hospitals, Home Health Agencies, Hospices, Hospitals, Providers of Outpatient Services, Skilled Nursing Facilities, and a variety of other care providers.<sup>3</sup>

The CoPs for hospitals can be found in the Code of Federal Regulations (CFR 42).




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### Code of Federal Regulations (CFR 42) Public Health

#### CHAPTER IV—CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Part 482—Conditions of Participation for Hospitals

##### Subpart A— General Provisions

##### § 482.1 Basis and Scope

- (a) *Statutory basis.* (1) Section 1861 (e) of the act provides that—
- (i) Hospitals participating in Medicare must meet certain specified requirements; and
  - (ii) The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in the hospital.
- (5b) *Scope.* Except as provided in subpart A of part 488 of this chapter, the provisions of this part serve as the basis of survey activities for the purpose of determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid.
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See Appendix A “U.S. Code of Federal Regulations” for details of conditions of participation that apply to hospitals.

## STATE OPERATIONS MANUAL

The *Observation* section of the *State Operations Manual for the Survey Protocol, Regulations and Interpretive Guidelines for Hospitals* is quoted next to assist the reader in obtaining a general sense of how the survey process is conducted. For the complete set of guidelines, see the web link provided at the end of the following quote:

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### Observations

Observations provide first-hand knowledge of hospital practice. The regulations and interpretive guidelines offer guidance for conducting observations. Observation of the care environment provides valuable information about how the care delivery system works and how hospital departments work together to provide care. Surveyors are encouraged to make observations, complete interviews, and review records and policies/procedures by stationing themselves as physically close to patient care as possible. While completing a chart review, for instance, it may be possible to also observe the environment and the patients, as far as care being given, staff interactions with patients, safety hazards, and infection control practices. When conducting observations, particular attention should be given to the following:

- Patient care, including treatments and therapies in all patient care settings
- Staff member activities, equipment, documentation, building structure, sounds and smells
- People, care, activities, processes, documentation, policies, equipment, etc., that are present that should not be present as well as those that are not present that should be present
- Integration of all services, such that the facility is functioning as one integrated whole
- Whether quality assessment and performance improvement (QAPI) is a facility-wide activity, incorporating every service and activity of the provider and whether every facility department and activity reports to, and receives reports from, the facility’s central organized body managing the facility-wide QAPI program
- Storage, security, and confidentiality of medical records

A surveyor should take complete notes of all observations and should document: the date and time of the observation(s), location, patient identifiers, individuals present during the observation, and the activity being observed (e.g., therapy, treatment modality).

A surveyor should have observations verified by the patient, family, facility staff, other survey team member(s), or by another mechanism. For example, when finding

an outdated medication in the pharmacy, ask the pharmacist to verify that the drug is outdated.

In addition, a surveyor should integrate the data from observations with data gathered through interviews and document reviews.

Surveyors must not examine patients by themselves, although in certain circumstances, in order to determine a patient's health status and whether appropriate health care is being provided, especially to ensure a patient's welfare where he/she appears to be in immediate jeopardy, it is permissible and necessary to examine the patient. After obtaining permission from the patient, the surveyor should request that a staff member of the facility examine the patient in the surveyor's presence. The health and dignity of the patient is always of paramount concern. A surveyor must respect the patient's right to refuse to be examined.

[http://www.cms.gov/manuals/downloads/som107ap\\_a\\_hospitals.pdf](http://www.cms.gov/manuals/downloads/som107ap_a_hospitals.pdf)

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## ACCREDITATION AGENCIES

The accrediting bodies that follow are a few examples of those that have been awarded deemed status with CMS. DNV is one of the more recent bodies to receive deemed status. TJC was the first to be written into law.

### **DNV Healthcare Inc.**

The Centers for Medicare and Medicaid Services (CMS) has granted DNV Healthcare Inc. deemed status to conduct accreditation surveys. DNV Healthcare is a division of Hovik, Norway-based Det Norske Veritas, which was established in 1864 as an inspector of ships but which now conducts reviews for many other industries.

The prestigious DNV Accreditation symbol signifies adherence both to CMS CoPs and to ISO 9001 quality management system under one, seamless program named National Integrated Accreditation for Healthcare Organizations (NIAHO).<sup>4</sup> NIAHO requires surveys on an annual basis and is designed to drive quality transformation into the core processes of running a hospital.

### **TJC**

TJC is a not-for-profit independent organization dedicated to improving the quality of health care in organized healthcare settings.

**1965** Congress passed the Social Security Amendments of 1965 with a provision that hospitals accredited by the *Joint Commission on*

*Accreditation of Hospitals* (then known as JCAH but, today, is named *the Joint Commission* or TJC) would be deemed in compliance with most of the Medicare Conditions of Participation for Hospitals and, thus, would be eligible to participate in the Medicare and Medicaid programs.

**1972** The Social Security Act was amended to require that the Secretary of the U.S. Department of Health and Human Services (DHHS) validate JCAH findings. The law also required the Secretary to include an evaluation of JCAH's accreditation process in the annual DHHS report to Congress.<sup>5</sup>

TJC currently accredits over 19,000 healthcare organizations and programs in the United States. The major functions of TJC include developing organizational standards, awarding accreditation decisions, and providing education and consultation to healthcare organizations. TJC surveys hospitals on an unannounced triennial basis.

## **HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT**

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Public Law 104-191) was designed to protect the privacy, confidentiality, and security of patient information. HIPAA standards are applicable to all health information in all of its formats (e.g., electronic, paper, verbal), and they apply to both electronically maintained and transmitted information. HIPAA privacy standards include restrictions on access to individually identifiable health information and to the use and disclosure of that information, and they set requirements for such administrative activities as training, compliance, and enforcement of HIPAA mandates.

## **THE PATIENT PROTECTION AND AFFORDABLE CARE ACT**

The Patient Protection and Affordable Care Act (PPACA), was passed by Congress and signed into law by the President in March 2010. Its design and purpose is to provide better health security by putting into place comprehensive health insurance reforms that hold insurance companies accountable, lower healthcare costs, guarantee more choice, and enhance the quality of care for all Americans. The battle continues as to the costs of implementing this Act in its entirety. The reader can locate more detailed information on this Act at <http://democrats.senate.gov/pdfs/reform/patient-protection-affordable-care-act-as-passed.pdf>

## REGULATORY CONFLICTS OF INTEREST ABOUND



### Food Inspection Is Often Flawed

The voluntary quality control system widely used in the nation's \$1 trillion domestic food industry is rife with conflicts of interest, inexperienced auditors, and cursory inspections that produce inflated ratings, according to food retail executives and other industry experts.

Recent outbreaks of salmonella illness . . . have focused new attention on weaknesses in the decades-old system, which relies on private-sector auditors hired by food makers.

. . . But experts agree that the inspections often do not translate into safer products for consumers.

"It's a business strategy, not a public health strategy," . . .

Suppliers "will hunt down the fastest, cheapest, easiest and least-intrusive third-party auditors that will provide the certificate" that will allow them to sell their product . . . until that model flips, there will continue to be a false sense of security in terms of what these systems offer."

*Lena H. Sun, The Washington Post, October 22, 2010*

The mission of accrediting bodies is to improve the quality of care rendered in hospitals through its survey process. Accrediting bodies are dependent upon the hospitals it surveys/inspects to reimburse it for the costs of those surveys. This means they need to maintain satisfied clients, and in so doing, a conflict arises. How credible can a survey be when the accrediting body is dependent on the organizations it surveys for financial survival and the organizations being surveyed are dependent on the accrediting body for financial survival? Further, hospitals evaluate the performance of the surveyors. The survival of the surveyor in his or her job is dependent upon good evaluations from the contracting hospitals. Conflicting interests here encourage surveyors/inspectors to be careful about what he/she scores due to fear of retaliation by both the organizations surveyed and the accrediting body.

Inspections within the food service industry are somewhat similar to the hospital accreditation survey process.

- Food makers often know when inspectors will audit their facilities, and they vigorously prepare for those inspections. This was also true with hospitals until several years ago when TJC, for example, decided to conduct unannounced surveys. This change occurred mostly because of criticism from its own surveyors, the public, and even some of the surveyed organizations.

- Most food makers score high on their inspections, and yet they still have outbreaks and recalls. Until several years ago, TJC scored hospitals, but they have discontinued the scoring process, in part due to criticism from surveyors and healthcare providers. Because of the competition between hospitals, surveyors had been pressured by the organizations they inspected to give high scores. Large billboards on Florida highways advertised scores of 100, yet in actuality, those hospitals may have provided no better quality of care than a hospital that had scored an 80.
  - (1) One small town hospital advertised in a newspaper that it scored 100 on its TJC survey. The same hospital had no full-time emergency department physician. An uncle's niece said, "I would not take my dog to that hospital. They killed my mom."
  - (2) Bob's dad was having difficulty breathing, and Bob convinced him to go to the emergency department of a hospital that sported a score of 98. The emergency department physician, after examining an X-ray of the patient, told Bob, "It's people like your dad that drive up the costs of health care. By the way, your dad is okay." Even though Bob was disturbed by the physician's first remark, he went home pleased that his dad had been given a clean bill of health. Unfortunately, the hospital called Bob's dad the next day to say that he should see his family doctor because he had a suspicious lesion on his lung. It was cancer, and he has since passed away.
  - (3) Addy was at a hospital with a score of 99. She had colon cancer and, after surgery, was told she would be on a soft diet. Shortly thereafter, Addy was served pork chops at mealtime, so she queried her nurse about this and explained that she had been told she would receive a soft diet. The nurse responded that the diet could not be changed and that until she got a soft diet order from the physician, Addy would have to remain on a regular diet, which of course meant that Addy had to go without eating.
  - (4) Annie had continual headaches for more than a year. The doctor had diagnosed migraines and said they were stress-related. More than 2 years later, a brain scan was finally ordered, and it revealed Annie had had a brain tumor. She has since passed away.
  - (5) Nancy went to her doctor's appointment. The doctor said, "Please lay down on the examining table." She reached for the doctor's hand for help in easing down onto the table. The doctor did not extend a helping hand. When the exam was over, Nancy again reached for the doctor's hand. The doctor looked away from her and said, "You got down by yourself, you can get up by yourself."

- (6) The anesthesiologist who attended Auntie (a happy, elderly lady) during anesthesia said to Auntie's daughter Susie that he had not seen Auntie's medical files. He was not aware of her diagnoses (hiatal hernia, asthma . . .) and test results (e.g., EKG). He said to the daughter, "If I had seen all of the test results, I would have administered a local anesthetic instead of a general anesthetic." Auntie had to be placed on a ventilator because she developed pneumonia after surgery, and she was eventually transferred to a nursing home. Three days later, during Susie's third visit to her mother at the nursing home, the daughter noticed alarming signs that her mother might be dying, so she hurried to the nursing station and reported this. The nurse who went to the room with Susie asked, "How do you know she is dying?" Susie said, "Look at her feet, they are purple." The nurse then took Auntie's blood pressure, which was too low, but the nurse seemed unconcerned about the reading or about Auntie's extreme restlessness. Susie said to the nurse, "My mother is dying. I see you gave her morphine. You are never supposed to give her morphine unless she is on a ventilator." (They had given her morphine and a relaxant medication.) At that point, the nurse began preparing a bath for Auntie and ordered food for her. Susie cried out, "I am not a freaking nurse, but I know my mother is dying, and here you are figuring to give her a bath and feed her." The nurse again said, "How do you know she is dying?" Susie again said, "Look, her feet are purple, and I can tell by the way she's breathing." Auntie passed away shortly thereafter.
- As with hospitals, the food companies typically pay food industry inspectors, creating a conflict of interest for inspectors who might fear they will lose business if they don't hand out high ratings.

The industries presented earlier raise some disturbing issues. For instance, there is a blatant conflict of interest for the various inspecting agencies and for those entities they are inspecting, and this places public health at risk in order to benefit the bottom line of those agencies and healthcare providers. The question arises: should someone regulate the regulators? But even if so, one must ask at what point standards and regulations become important enough that caregivers understand them and adhere to them. It is likely that managers and caregivers would agree there is inconsistency in knowing what the standards and expectations are, interpreting them consistently—and in scoring them.



### Continuous Stream of New Laws and Regulatory Requirements

Although regulations are generally enacted out of public concern—as well as legal and ethical reasoning—the continuous flow of new regulations often create new problems even as they help resolve earlier ones. For example, do HIPAA regulations that aim to protect patient privacy also affect patient care negatively? Two anonymous opinions are provided next.

#### *Con*

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Ever since hospitals started increasing their compliance to HIPAA regulations, a lot of subtle and not-so subtle changes have been taking place in the way patient information is communicated (at least at the hospitals I have rotated at). Patient names are now often reduced to initials on checkout sheets. At the ER, a patient's chief complaints are no longer noted on the board. No one is allowed to photocopy any progress notes or order sheets containing patient information anymore. While I feel strongly that patient confidentiality is very important and should be protected within reason, I also feel that some of the regulations are getting out of hand, making it much more difficult for residents, students, and others involved in patient care to share important communications, even within a closed system. It seems that these regulations are hell-bent on blindfolding and gagging healthcare workers in an effort to protect confidentiality at the expense of clear communication between colleagues about important patient issues.

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I haven't had to do anything with patient care under HIPAA, but something had to be done about patient privacy, so I don't know how difficult it is. However, something had to be done about protecting patient privacy. In a university hospital, where I worked in a lab, patient records were often left on carts in the hallway unattended for hours. Conversations about patients were common in the elevators even when it was obvious that some of the occupants were visitors. In a horrifying incident for me, I was molested when I was a patient, and the hospital administrator gave the police my chart! Because the administrator had no legal responsibility to maintain my privacy, she suffered NO repercussions for her devastating actions.

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#### *Commentary*

The regulatory effect on the hospital's bottom line is incalculable. There are conservatively more than 100 regulatory agencies that affect hospital operations. Various attempts have been made to list and describe how many of them overlap. Discussed in this casebook are the regulatory requirements that affect providers participating in Medicare programs, which is a majority of providers.



## Discussion

1. Discuss how the constant flow of regulatory requirements can harm the quality of care provided in the nation's hospitals.
2. Discuss how the constant flow of regulatory requirements can improve the quality of care provided in the nation's hospitals.

Standards and regulations are helpful in establishing the "Standard of Care" expected in a particular case. Standards and regulations are written—and healthcare organizations are required to comply with them—to help minimize the numerous mistakes and injuries that occur on a daily basis in the delivery of patient care.

The intent of laws, rules, and regulations are often broken, misinterpreted, or even applied indiscriminately based on the knowledge and ethical character of the reviewer. The preceding article describes how pervasive conflicts of interest are between inspected agencies and accrediting bodies.



## Accreditation Surveys and State Enforcement of Standards

**Citation:** *Evelyn V. v. Kings County Hosp. Ctr.*, 956 F. Supp. 288 (1997)

The essence of the plaintiffs' claim in this case is that reasonable steps were not taken to ensure that Kings County Hospital complied with established state health standards. The plaintiffs submitted that 42 U.S.C. § 1396a(a)(9) gives them a federal right to such enforcement of state standards. 42 U.S.C. § 1396a(a)(9) states: "A state plan for medical assistance must provide that the State health agency, or other appropriate State medical agency, shall be responsible for establishing and maintaining health standards for private or public institutions in which recipients of medical assistance under the plan may receive care or services."

Kings County Hospital Center had a history of noncompliance with health-care standards. In January and February 1989, Health and Human Services (HHS) requested that the New York State Department of Health (Department of Health) conduct an allegation survey of the hospital. Based on the survey report, HHS concluded that the hospital was not in compliance with five CoPs in Medicare and Medicaid. In April 1989, HHS advised the hospital that a complete Medicare survey would be conducted by the Department of Health, after which the hospital would be expected to submit a plan for correction. HHS warned that if the hospital were unable to achieve compliance with the Medicare conditions, termination action would be pursued.

Before conducting the complete Medicare survey, the Department of Health settled its state enforcement action with the hospital. On April 19,

1989, the hospital agreed to pay a fine and to implement a detailed plan of correction.

In June 1989, the Department of Health conducted the requested survey of the hospital. The hospital was found to be out of compliance with seven CoPs in Medicaid and Medicare. Efforts were undertaken by the hospital to correct the cited deficiencies. The Department of Health conducted a follow-up survey in August 1989, and based on its report, HHS concluded that the hospital had attained compliance with all CoPs in Medicare and Medicaid, except those relating to physical environment. HHS accepted the hospital's long-range plan for correction of environment deficiencies. It did, however, advise the hospital that it would no longer be deemed eligible for Medicare and Medicaid participation based on its TJC accreditation. Rather, it would be closely monitored by the Department of Health. Department of Health monitoring reports from September, October, and November 1989 indicate that although the hospital was still experiencing compliance difficulties, significant improvements were being made.

The Department of Health did not conduct, nor does it appear that HHS requested, any comprehensive survey of the hospital in 1990. During that year, the Department of Health investigated 29 specific complaints about the hospital's care and conditions. On-site investigations resulted in the issuance of 11 statements of deficiencies requiring corrections.

From January 7 to January 18, 1991, the Department of Health conducted a federal monitoring survey at the hospital. Based on findings that the hospital was out of compliance with five conditions for participation in Medicare and Medicaid, HHS notified the hospital on March 19, 1991, that its "participation in the Medicare program is being terminated as of May 19, 1991." The hospital was advised that the termination order would be rescinded if it brought itself back to condition-level compliance before the scheduled termination date.

On April 5, 1991, the hospital submitted to the Department of Health a plan of correction and a request for resurvey. The resurvey revealed that although problems had not been completely eliminated, the hospital had managed to achieve condition-level compliance with all federal standards for participation in Medicare and Medicaid except those relating to physical environment. On May 1, 1991, the Department of Health recommended to HHS that the hospital be permitted to continue to participate in the Medicare and Medicaid programs. HHS agreed and, on May 8, 1991, notified the hospital that it was rescinding its previous termination decision. The hospital was warned that, because it had not demonstrated the ability to sustain the

corrective action outlined in the plan submitted in 1989, the time frames in the April 1991 submission would be closely monitored, and the facility would remain under state survey jurisdiction.

A few days later, on May 10, 1991, the Department of Health issued a report finding that the deficiencies noted at the hospital in the January 1991 survey constituted violations of both state and federal standards. A formal enforcement action was commenced. Negotiations to settle this action were interrupted when the death of a stabbing victim at the hospital raised further questions about the hospital's delivery of care. The Department of Health conducted an investigation into the victim's treatment at the hospital and, in the fall of 1991, cited the hospital for further violations of state health standards.

In October 1991, the Department of Health conducted another federal survey of the hospital and again found several serious departures from federal and state standards. HHS again threatened to terminate the hospital from participation in the Medicare and Medicaid programs, and the Department of Health formally cited the hospital for violations, demanding a plan of correction by November 22, 1991.

The Department of Health resurveyed the hospital in early December 1991 and issued its report to HHS on December 6, 1991. On December 16, 1991, HHS decided once again to rescind its termination of the hospital from the Medicare and Medicaid programs, finding that in the resurvey the hospital had managed to demonstrate condition-level compliance with all requirements except physical environment.

On February 3, 1992, the Department of Health advised the hospital that it was amending the pending state enforcement action to add the deficiencies cited during the October 1991 survey. This action was settled on July 10, 1992. The hospital again agreed to implement a plan of correction. To monitor the hospital's compliance with the plan of correction, the Department of Health was to conduct monitoring visits in October 1992, February 1993, and July 1993. Soon after the October 1991 Department of Health survey, the hospital was surveyed by TJC to determine whether the hospital should be reaccredited. In January 1992, TJC notified the hospital that it was recommending against accreditation. TJC ultimately permitted the hospital to operate with conditional accreditation.

In October 1992, the Department of Health conducted its first monitoring visit of the hospital pursuant to its July 1992 order of settlement with the hospital. The hospital was cited for numerous specific and general violations. The Department of Health demanded that the hospital provide a plan for correction.

In January 1993, the Department of Health conducted a comprehensive state and federal survey of the hospital. Although numerous deficiencies were cited, HHS did not take any action against the hospital. On March 17, 1993, the hospital submitted a plan to the Department of Health to correct the noted deficiencies. Parts of the plan were deemed unacceptable, prompting resubmissions by the hospital in June and July 1993. In July 1993, the Department of Health conducted a monitoring visit of the hospital. Various deficiencies were again noted. In August 1993, the Department of Health accepted the hospital's most recent plan for correction.

In November 1994, the hospital was scheduled to be reviewed by TJC. Having run the hospital for some time with only conditional accreditation, management understood that the institution would have to pass TJC review or lose its accreditation and its status as a Medicare and Medicaid provider. To assist the hospital in preparing for the review, New York City's Health and Hospitals Corporation arranged for a mock survey to be conducted in May 1994. In July 1994, the results were announced: numerous problems still existed. Some changes in management were made and the Health and Hospitals Corporation authorized a one-time allocation of over \$1 million to the hospital to address various needs that would be pertinent to TJC review. These efforts proved successful and TJC again accredited the hospital.

In moving for summary judgment in their favor, the defendants submitted that the plaintiffs failed to state a claim because 42 U.S.C. § 1396a(a)(9) does not confer the right to enforcement of state standards, and even if the court were to find such an enforceable federal right, their actions suffice to satisfy their legal obligations.

As evidence that the state agencies were failing to meet their obligations pursuant to 42 U.S.C. § 1396a(a)(9) with respect to the hospital, the plaintiffs pointed to the various surveys of the hospital over the years revealing noncompliance with health standards. The Department of Health surveyed the hospital to ensure compliance with both federal and state law. 42 U.S.C. § 1395aa(a), expressly referred to in § 1396a(a)(9), provides for the Secretary of HHS to contract with state health agencies to certify those institutions qualifying for Medicaid participation. This law states

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The Secretary shall make an agreement with any State which is able and willing to do so under which the services of the State health agency or other appropriate State agency (or the appropriate local agencies) will be utilized by him for the purpose of determining whether an institution therein is a hospital or skilled nursing facility, or . . . a home health agency, or . . . a hospice program or . . . a rural health clinic, [or] a rural primary care hospital, . . . or a comprehensive outpatient rehabilitation facility. . . .

To the extent that the Secretary finds it appropriate, an institution or agency which such a State (or local) agency certifies is a hospital, skilled nursing facility, rural health clinic, comprehensive outpatient rehabilitation facility, home health agency, or hospice program (as those terms are defined in section 1395x of this title) may be treated as such by the Secretary.

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Further, 42 U.S.C. § 1395aa(c) provides for the Secretary of HHS to use state health agencies to conduct surveys of hospitals participating in the Medicaid program. It states

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The Secretary is authorized to enter into an agreement with any State under which the appropriate State or local agency which performs the certification function described in subsection (a) of this section will survey, on a selective sample basis (or where the Secretary finds that a survey is appropriate because of substantial allegations of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect health and safety of patients), hospitals which have an agreement with the Secretary under 1395cc of this title and which are accredited by the Joint Commission on Accreditation of Hospitals. The Secretary shall pay for such services in the manner prescribed in subsection (b) of this section.

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42 C.F.R. § 488.26(c)(1) describes the survey process as the means to assess compliance with federal health, safety, and quality standards.

The Secretary of HHS entered into an agreement with the Department of Health to perform the certifications and surveys provided for in these statutes and regulations. It was expressly recognized in the agreement that, in performing its contractual duties, the State acted on behalf of the Secretary.

As a general rule, institutions accredited as hospitals by TJC are deemed qualified to participate in Medicare and Medicaid. The Secretary of HHS may, however, request a state agency such as the Department of Health to conduct a validation survey to determine whether an accredited hospital does meet Medicare and Medicaid participation standards. The Secretary of HHS may also request that the Department of Health conduct allegation surveys when HHS receives information indicating that a hospital may be out of compliance with the conditions for participation in Medicaid and Medicare and that it conduct monitoring surveys to determine if past noted deficiencies have been corrected. Survey reports are submitted to HHS, which makes the final determination as to whether a hospital may continue to participate in the Medicare and Medicaid programs.

Accreditation survey reports constitute recommendations to the Health Care Financing Administration. Based on these recommendations, HHS takes appropriate action. If a survey reveals that a hospital is not in

compliance with one or more federal standards, its ability to continue participating in Medicare and Medicaid programs depends on its submission of an acceptable plan of correction for achieving compliance within a reasonable period of time acceptable to the Secretary of HHS. Ordinarily, a deficient hospital is expected to bring itself into compliance with federal conditions within 60 days, but the Secretary of HHS may grant additional time when appropriate. Where noncompliance is acute or persistent, the Secretary of HHS is empowered to terminate a hospital from participation in Medicare and Medicaid programs. The parties agree that such termination would effectively shut down a public hospital, because it could not operate without federal funds.

In addition to conducting federally requested surveys, the Department of Health also uses on-site surveys to assess hospitals' compliance with state standards of care. Should deficiencies be detected with respect to these standards, hospitals are required to submit plans of correction, which are reviewed through follow-up surveys. Where appropriate, the Department of Health can commence an enforcement proceeding against a deficient hospital, with possible penalties ranging from a fine to revocation of a hospital's operating certificate and closure.

### *Issue*

Does 42 U.S.C. § 1396a(a)(9) confer on the plaintiffs a federal right enforceable through 42 U.S.C. § 1983 to have the New York State Department of Social Services and the New York State Department of Health take reasonable steps to ensure that hospitals operating as Medicaid providers comply with state standards of operation?

### *Holding*

Because the plaintiffs have no federal right to state enforcement of state standards of health care at hospitals participating in the Medicaid program, summary judgment was granted in favor of the defendants.

### *Reason*

The court had to determine if this case really involved a federal right, as opposed to a claimed violation of federal law. The problem in this case was in deciding precisely what it is Congress mandated in § 1396a(a)(9) for the benefit of Medicaid recipients. Congress requires state Medicaid plans to provide for a state health agency to be responsible for establishing and

maintaining health standards for institutions that operate as Medicaid providers. The parties agree that the New York plan provides for the Department of Health to serve this statutory function. They agree that the Department of Health has established standards for state hospitals. Where the parties disagree is in their interpretation of the statute's requirement with respect to maintaining health standards. A thing is "maintained" when it is kept "in a state of repair, efficiency, or validity," when it is "preserve[d] from failure or decline" [Webster's Third New International Dictionary 1362 (1986)]. The defendants submitted that the statute thus obligated them to review their health standards and, when necessary, update them to ensure that they remain valid and consistent with current medical practice. The plaintiffs submitted that the statutory obligation is broader—that reasonable efforts must be made to ensure that state hospitals participating in the Medicaid program operate in compliance with established state standards. The court rejected the plaintiffs' construction.

The court noted that, although § 1983 has been used as a vehicle to enforce federal rights embodied in federal regulations as well as statutes, it would be quite remarkable for Congress to federalize a whole body of unspecified state rules and regulations and thereby make the state's enforcement of its own standards a federal right that parties could pursue through private § 1983 actions. The language of § 1396a(a)(9) does not suggest such a sweeping congressional intent. The statute requires simply that a state agency be responsible for establishing and maintaining health standards for participating institutions. An agency can maintain appropriate standards for institutions without having any enforcement powers over those institutions. Few fields have changed as rapidly in this century as medicine. Surgical procedures, professional training requirements, medication protocols, and methods for handling and storing blood have all evolved considerably, such that standards considered exemplary when § 1396a(a)(9) was first enacted would not be deemed adequate today. Congress wished to ensure that states did not view their § 1396a(a)(9) obligation as static. Rather, they would be expected to maintain, review, and update the health standards they established to ensure that they remained consistent with modern medical practice.

If Congress had wished to mandate enforcement of the state standards, it could easily have expressed this intent by drafting § 1396a(a)(9) to require maintenance of health standards at all institutions, rather than simply for participating institutions. As the parties have noted, when the federal government did wish to impose an enforcement obligation on the states with respect to standards for nursing homes, this was plainly expressed. 42 U.S.C.

§ 1396a(a)(26) requires states to have “medical review teams” conduct “periodic inspections” of such facilities. From 1978 to 1994, 42 C.F.R. § 449.33(5)(iii) required states to review the reports of such medical teams “as they reflect on health and safety requirements and as necessary take appropriate action to achieve compliance or withdraw certification.” No such survey or compliance obligation has ever been imposed on states with respect to hospitals.

The plaintiffs submitted that it made no sense that Congress simply wished to require state agencies to promulgate standards and update them from time to time without also contemplating their enforcement. The legislative history reveals that Congress did contemplate local enforcement of state standards, but it did not mandate such enforcement. A senate report indicated that Congress wished to encourage states to improve healthcare standards while interfering as little as possible in a state’s actual articulation or supervision of those standards. Congressional expectations and hopes do not create unambiguous federal rights enforceable through § 1983.

The overall scheme for review of hospitals participating in Medicare and Medicaid is also at odds with the plaintiffs’ claim of a federal right to sue state defendants to compel enforcement of state healthcare standards with respect to hospitals. There is no federal requirement that state agencies ever survey hospitals to assess compliance with their own standards. Instead, the focus of the statute and regulations is on the promulgation and enforcement of federal standards. It is the Secretary of HHS who has sole responsibility for promulgating federal health, safety, and quality standards applicable to hospitals participating in Medicare and Medicaid programs [see 42 U.S.C. § 1395x(e)(9)] and who is charged with enforcing these standards by threatening termination.

The focus of this statutory and regulatory scheme on the responsibilities of the Secretary of HHS for the promulgation and enforcement of federal standards of health care necessarily supports the conclusion that a state agency satisfies its § 1396a(a)(9) obligations to “establish and maintain” local standards for healthcare providers simply by promulgating and then updating these standards. In this way, Congress certainly hoped to encourage better standards of local health care and even their enforcement. Sensitive to differences in regional capabilities, Congress did not create a federal right to any particular state standard or to any level of local enforcement. The core responsibility for ensuring that Medicare and Medicaid providers meet some minimum standard of care remains exclusively with the federal government.



## Discussion

1. What was the court's reasoning for not granting the plaintiffs a federal right enforceable through 42 U.S.C. § 1983 to have the New York State Department of Social Services and the New York State Department of Health take reasonable steps to ensure that hospitals operating as Medicaid providers comply with state standards of operation?
2. What are the implications for hospitals that lose their accreditation?



## TJC Reports: Privileged Communications

**Citation:** *Humana Hosp. Corp. v. Spears-Petersen*, 867 S.W.2d 858 (Tex. Ct. App. 1993)

The underlying suit in this petition involved a plaintiff, Ms. Garcia, who was scheduled to undergo an epidural steroid injection but was administered a lumbar epidural steroid injection instead by the defendant, Dr. Garg. The plaintiff sued Dr. Garg on the basis of negligence, lack of informed consent, battery, and fraud. She also sued Humana Hospital Corporation (Humana) for negligence in credentialing, supervising, and monitoring Dr. Garg's clinical privileges. The plaintiff's attorney requested documents from Humana, including reports prepared by TJC.

TJC is a voluntary organization that surveys various healthcare organizations for the purpose of accreditation. The organization's governing body consists of members representing such organizations as the American Medical Association, the American College of Physicians, and the American Hospital Association.

Humana objected to releasing TJC reports and filed for a protective order preventing disclosure. TJC reports contained recommendations describing the hospital's noncompliance with certain of its published standards. Humana argued that TJC reports are privileged information under Texas statute. Under Texas law, the records and proceedings of a medical committee are considered confidential and are not subject to a court subpoena. The plaintiff argued that TJC is not a medical committee as defined in the Texas statute. The hospital's chief operating officer, Mr. Williams, testified that TJC surveys and accredits hospitals across the country. The accreditation is voluntary, and the hospital chooses to have the accreditation survey. During the survey, TJC looks at certain standards it has developed for hospitals to abide by in maintaining quality care. The hospital's executive committee is charged in its bylaws with keeping abreast of the accreditation process. Humana argued that release of TJC's recommendations would do

more than “chill” the effectiveness of such accreditation—no prudent hospital would discuss or release any information to TJC knowing that it could be used against it in malpractice suits. *Id.* at 861. Humana argued further that even if the information was privileged, it had already been disclosed to a third party, the hospital, thus waiving its rights to nondisclosure. The trial court denied Humana’s motion for a protective order that, if granted, would have permitted it to withhold from discovery any information pertaining to credentialing, monitoring, or supervision practices of the hospital regarding its physicians. Humana appealed.

### ***Issue***

Were TJC Accreditation reports considered privileged?

### ***Holding***

The Court of Appeals of Texas held that the accreditation reports were privileged because (1) TJC was a “joint committee” as created by statute creating a privilege from discovery for hospital review committee deliberations, (2) the disclosure of TJC’s reports to the hospital did not result in waiver of the privilege, and (3) the reports reflected a deliberative process by TJC and were therefore privileged.

### ***Reason***

The purpose of privileged communications is to encourage open and thorough review of a hospital’s medical staff and operations of a hospital with the objective of improving the delivery of patient care. The plaintiff argued that TJC is not a medical committee as defined in the Texas statute. The court of appeals found that

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the determinative factor is not whether the entity is known as a “committee,” or a “commission,” or by any other particular term, but whether it is organized for the purposes contemplated by the statute and case law. We think it is clear from the evidence we have detailed that the Joint Commission is a joint committee made up of representatives of various medical organizations and thus fits within the statutory definition. . . . Further, it is organized, as are the various in-house medical committees that indisputably come within the statute, for the laudable purposes of improving patient care. Both the statute and case law recognize that the open, thorough, and uninhibited review that is required for such committees to achieve their purpose can only be realized if the deliberations of the committee remain confidential. *Id.* at 862.

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As to TJC's disclosing its report to the hospital, the

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only disclosure . . . was to the hospital as the intended beneficiary of the committee's findings. The only disclosure made to the outside world was the accreditation certificate, which merely declares that the hospital has been awarded accreditation by the Joint Commission. *Id.* at 862.

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### Discussion

1. How might TJC's new "public disclosure policy" to make available certain information to the public affect the "privilege" of other information surrounding the accreditation process (e.g., interviews, notes, minutes, and reports)?
2. Does privilege from discovery extend to all documents maintained in the normal course of business?



### Failure to Report Patient Incident

**Citation:** *Westin v. Shalala*, 845 F. Supp. 1446 (D. Kan. 1994)

#### Facts

On December 17, 1984, Ms. Grundmeier, a patient in a nursing facility, was found unconscious and wedged between the mattress and the bedrail in her room. After emergency resuscitation, she was airlifted to a hospital, where she died later that same day.

On November 18, 1985, a grand jury convened and returned an indictment against Ms. Westin in her capacity as the nursing facility's administrator. The indictment charged Ms. Westin with one felony and four misdemeanors.




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### The Colorado Department of Health, Pursuant to the Code of Colorado

Regulations at 6 CCR 1011-1 ch. V § 4.5.4, require that

. . . accidents and incidents resulting in possible patient injury shall be reported on special report forms. The report shall include date, time, and place of incident; circumstances of the occurrence; signature of witness; time doctor was notified; physician's report; and signature of person making the report. A copy of the report shall be filed in the patient's medical record.

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Despite these requirements, no incident report was prepared.

On March 13, 1990, upon motion of the district attorney, the court dismissed the case against Ms. Westin. On May 24, 1991, the Inspector General notified Ms. Westin that she was going to be excluded for 5 years from participation in Medicare and any state healthcare program because of her conviction of a criminal offense relating to the neglect or abuse of patients. Ms. Westin appealed the Inspector General's decision to the Department of HHS, Departmental Appeals Board (DAB), and an administrative law judge (ALJ) sustained the exclusion imposed. Ms. Westin appealed, and the DAB, Appellate Division, affirmed the ALJ's decision. Ms. Westin appealed Appellate Division's decision, claiming there was not sufficient evidence to support the exclusion of her from participating in the Medicare program.

### **Issue**

Was there substantial evidence to support an order excluding Ms. Westin from participation in the Medicare program?

### **Holding**

The United States District Court for the District of Kansas held that there was substantial evidence to support an order excluding Ms. Westin from participation in the Medicare program.

### **Reason**

There was no requirement that the Secretary of HHS demonstrate that actual neglect or abuse of patients occurred, nor was there a requirement that the individual or entity be convicted of an actual offense of patient neglect or abuse. Under Colorado law, Ms. Westin, as an administrator of a nursing home, was required to (1) report all accidents and injuries "resulting in possible patient injury" to the Colorado Department of Health, and (2) file a copy of that report in the patient's medical record. The evidence was clear from the record that the conviction for failing to report the incident occurred while Ms. Grundmeier was a patient at the nursing facility, and that the conviction was connected to the medical services the nursing facility and its employees provided to Ms. Grundmeier. *Id.* at 1452.



### **Discussion**

1. Do you believe the court was too harsh in its decision to exclude the administrator of the nursing facility from participating in the Medicare program for a period of 5 years? Explain.

2. Why have statutes been enacted that require the reporting of accidents and incidents that result in patient injuries?



### **Breaking State Law—Administering Nitrous Oxide**

**Citation:** *Lowenberg v. Sobol*, 594 N.Y.S.2d 874 (N.Y. App. Div. 1993)

#### ***Facts***

This case arises from a complaint by a dental hygienist against a former employer, Lowenberg and Lowenberg Corporation. The dental hygienist alleged that the defendant allowed the dental hygienists to administer nitrous oxide to patients. Under state law, dental hygienists may not administer nitrous oxide. The Department of Education's Office of Professional Discipline investigated the complaint by using an undercover investigator. The investigator made an appointment for teeth cleaning. At the time of her appointment, she requested that nitrous oxide be administered. Agreeing to the investigator's request, the dental hygienist administered the nitrous oxide. After the procedure was completed, the investigator paid her bill and left the office. There were no notations in the patient's chart indicating that she had been administered nitrous oxide.

The hearing panel found the dental hygienist guilty of administering nitrous oxide without being properly licensed. In addition, the hearing panel found that the dental hygienist had failed to accurately record on the patient's chart that she had administered nitrous oxide. Lowenberg and Lowenberg Corporation were reprimanded and fined \$750 each. The plaintiffs/petitioners, the dental hygienist and Lowenberg and Lowenberg, Corporation commenced proceedings for review of the determination.

#### ***Issue***

Was there sufficient evidence to support a determination that the petitioners engaged in professional misconduct?

#### ***Holding***

The New York Supreme Court, Appellate Division, held that the investigator's report provided sufficient evidence to support the hearing panel's determination that the petitioners had committed professional misconduct by permitting an unlicensed individual to administer nitrous oxide.

**Reason**

The Lowenberg's's actual knowledge of the hygienist's illegal conduct is not a prerequisite to a finding of misconduct based on a failure to supervise. There is adequate support in the record to support a finding that the Lowenberg's conduct was such that it could reasonably be said that he permitted the dental hygienist to perform acts she was not licensed to perform.

**Discussion**

1. What issues does this case raise for healthcare organizations that fail to provide properly licensed personnel in patient care settings, as required by law (e.g., the availability of registered nurses on nursing units)?
2. Do you agree that there was sufficient evidence to support a determination of professional misconduct?

**Code Violation and Revocation of License**

**Citation:** *Henley v. Alabama Bd. of Nursing*, 607 So.2d 56 (Ala. Civ. App. 1992)

**Facts**

A registered nurse sought review of a decision by the State Board of Nursing revoking her license. The board filed a complaint against the nurse alleging that she had violated Ala. Code 1975, § 34-21-25 and § 610-X-8-.05(c)(d) (e) of the Alabama Board of Nursing Administrative Code. These provisions allow the revocation of a nursing license if (1) the licensee is found unfit or incompetent because of the use of alcohol or is addicted to the use of habit-forming drugs to such an extent as to render the licensee unsafe or unreliable; (2) the licensee is mentally incompetent; or (3) the licensee is guilty of unprofessional conduct of a character likely to deceive, defraud, or injure the public in matters pertaining to health care. This complaint was filed after the nurse was subjected to a series of arrests beginning in November 1986, when she was arrested and charged with disorderly conduct and public intoxication.

A hearing officer reviewed the evidence of the allegations and recommended revocation of the nurse's license. The hearing officer's findings of fact and conclusions of law were adapted by the board, and the nurse's license was revoked. That decision was appealed to the trial court, which upheld the decision of the board. The nurse appealed pro se, claiming the evidence did not support revocation of her license.

### **Issue**

Did the evidence of the nurse's arrests and conviction for disorderly conduct and public intoxication support revocation of her license, absent evidence from a treating physician regarding her competence?

### **Finding**

The Alabama Court of Civil Appeals found that the evidence of the nurse's arrests and conviction for disorderly conduct and public intoxication supported revocation of her license, absent evidence from a treating physician regarding her competence.

### **Reason**

Appellate review of administrative actions is limited to determinations of "whether the agency acted within the powers conferred upon it by law and the constitution, whether its decision is supported by substantial evidence, and whether the agency's decision is reasonable and not arbitrary." *Alabama Bd. of Nursing v. Herrick*, 454 So.2d 1041, 1043 (Ala. Civ. App. 1984). The allegations were that the nurse suffered from alcohol addiction and mental incompetency, which rendered her incompetent to assume all of the responsibilities of the practice of nursing. The record contained substantial evidence supporting those allegations, and the nurse presented nothing to sufficiently rebut them.



### **Discussion**

1. What other alternatives might the hospital consider in its disciplinary process?
2. Do you agree with the court's decision? Explain.

## NOTES

1. <http://hospitalcompare.hhs.gov/%28S%28pvan5rfwa0sta1iajui30h45%29%29/staticpages/help/hospital-glossary.aspx?Choice=D>
2. <http://www.kaiserhealthnews.org/Stories/2011/February/24/maryland-hospitals-infection-control.aspx>
3. <https://www.cms.gov/CFCsAndCoPs/>
4. <http://www.dnv.com/industry/healthcare/>
5. [http://www.jointcommission.org/assets/1/18/Joint\\_Commission\\_History\\_20111.PDF](http://www.jointcommission.org/assets/1/18/Joint_Commission_History_20111.PDF)