Chapter 4

Legal and Regulatory Environment

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LEARNING OBJECTIVES

After studying this chapter, you should be able to do the following:

1. Understand how legal and regulatory issues shape and define good financial management of a healthcare organization.
2. Appreciate the consequences of failing to manage the finances of a healthcare organization without regard for the complex and ever-changing array of laws and regulations that are unique to this industry.
3. Identify the major components of a corporate compliance plan, including the establishment of internal controls relating to the finances of an organization.
4. Recognize when and how to involve legal counsel on a Medicare or Medicaid reimbursement issue or other financial matter that has regulatory compliance implications or would otherwise require you to seek legal advice before making a decision.
5. Be aware of the most important aspects of the Patient Protection and Affordable Care Act of 2010 (Health Care Reform Act) as it relates to financial management in the post-reform environment.
6. Identify the most common federal regulatory issues such as fraud and abuse, Stark, HIPAA privacy and security, EMTALA, and IRS requirements for tax-exempt organizations as well as less common concerns that arise under the antitrust laws, Red Flag Rules, and state insurance regulations.
7. Be prepared to respond to a compliance audit or investigation, particularly when the subject of that inquiry includes financial records.

REAL-WORLD SCENARIO

Claudio Bravo, the CFO of Sinking Springs Regional Hospital (SSRH), has been asked by the hospital's CEO, Doris Devine, to help her prepare a presentation to SSRH's board of directors seeking approval of a major restructuring of the hospital's cardiovascular service line. For several years SSRH has been losing market share to its competitors because of perceived quality issues and the growing disloyalty of cardiologists on its medical staff. Devine believes that SSRH needs to do "something bold" to reverse this trend and improve the hospital's performance. While attending a conference in Las Vegas, Devine heard a

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well-known consultant explain how to pay doctors for their exclusive use of a hospital as long as it is done in the context of a quality improvement program.

To his credit, Bravo is skeptical of any arrangement that pays doctors for their referrals, but he was told by Devine that this "concept" has already been approved by the U.S. Department of Health and Human Services Office of Inspector General so he does not need to run it by SSRH's legal counsel. Devine has given Bravo an outline of a service line management program that would do the following: (1) Cardiology Care, Inc. (CCI), a group of nine cardiologists, would be paid a base fee of $1.5 million annually to improve the quality of cardiovascular care at SSRH, plus various incentive payments for increased volumes in the operating room and catheterization lab, increased revenues from diagnostic tests, and improved public opinion of the SSRH; (2) CVS Associates, P.C. (CVS), the primary cardiovascular surgery group in the region, would be paid $500,000 for each additional surgeon it recruits to handle the expected increase in inpatient volumes; (3) all of SSRH's employed primary care physicians would be required, as a condition of their employment, to refer their patients to CCI as the service line manager; and (4) up to $4.5 million in funds from a refinancing of SSRH's tax-exempt debt would be used to purchase new technology for the heart program.

Bravo decides to do some due diligence on CCI and CVS before beginning work on the board presentation. He learns from Sidney Slade, the business manager of CCI, that her company has been under a corporate integrity agreement with the Office of Inspector General for 3 years due to Medicare billing problems at another hospital. Slade also tells Bravo she believes a closer relationship with SSRH would be a "good idea" because the cardiologists' incomes have declined dramatically since she was hired. Slade is worried that her job is at risk and that CCI doesn't have the staff to manage its practice let alone a department of the hospital.

Bravo also contacts Dr. Emil Sikorsky, the lead surgeon at CVS, to see what he knows about Devine's proposal. Sikorsky tells Bravo there's very little SSRH can do to increase its market share because heart surgery volumes are down everywhere. Sikorsky himself would like to be retrained in vascular procedures because he believes "that's the next gold mine." He asks Bravo whether the hospital would be willing to pay for him to enroll in a 6-month fellowship in advanced vascular procedures as long as he promises to come back to SSRH. Bravo says that he will inquire of Devine. Before their conversation ends, Sikorsky asks whether Bravo had heard that the hospital's cardiovascular program is going to be audited next week. Supposedly, SSRH has been found to have (1) a readmission rate on Medicare heart failure patients that is "off the chart" and (2) poor documentation to support why patients are being readmitted with such frequency.

Armed with this new information, Bravo begins developing financial projections for how SSRH would pay for these additional expenditures in its cardiovascular program. The only scenario that would justify this investment in SSRH's heart program is one that achieves market dominance within 3 to 5 years (over 80% of heart patients in SSRH's primary and secondary service areas). Although Bravo believes that is highly unlikely, he prepares a spreadsheet and a Power Point presentation that shows how Devine's proposal will work. He also assumes that with the increased bargaining power of having physicians on board he will be able to negotiate substantially higher rates from managed care payers.

Because Bravo is about to leave for a 2-week vacation, he does not have enough time to have the presentation reviewed by legal counsel before it goes out with the board packet. One of the board members, an attorney in a downtown law firm, receives the presentation and immediately calls his health law partner to ask whether anything in the document could expose the hospital's senior management or directors to civil or criminal penalties.

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PART I. KNOWLEDGE OF THE LAW AND REGULATIONS IS AN ESSENTIAL PART OF HEALTHCARE FINANCIAL MANAGEMENT

LEARNING OBJECTIVE 1

Understand how legal and regulatory issues shape and define good financial management of a healthcare organization.

Developing an Awareness of the Rapidly Changing Legal and Regulatory Environment Is Critical To the Successful Financial Management of a Healthcare Organization

The enactment of the Patient Protection and Affordable Care Act ("Health Care Reform Act," or the "Act")[1] in March 2010 represented a landmark change in the federal law that shapes virtually every financial aspect of the nation's healthcare delivery system. The Act's most significant provisions were designed to address long-standing problems with the availability and affordability of health insurance. Most importantly, the Act sets strict limitations on insurance practices, such as preexisting conditions and lifetime maximum coverage, as well as imposes an individual mandate that all Americans have some form of health insurance.

The Act also sets the stage for systemic changes in how health care is delivered by moving away from fee-for-service payment to a model that rewards healthcare providers who can achieve superior outcomes for their patients. Because the full extent of this legislation will not be known for several years, the content of this chapter will undoubtedly be subject to revision and supplementation over time. Where legal and regulatory changes are already known or anticipated, the text identifies those provisions of the Act that should be considered by the reader in applying the principles that follow.

[1]Patient Protection and Affordable Care Act, Pub. Law No. 111-148 (2010).

LEARNING OBJECTIVE 2

Appreciate the consequences of managing the finances of a healthcare organization without regard for the complex and ever-changing array of laws and regulations that are unique to this industry.

Understanding Regulatory Compliance in a Healthcare Organization

Corporate Compliance Plans

The U.S. Department of Health and Human Services (DHHS) Office of Inspector General (OIG) was established as an independent and objective oversight unit of the DHHS to carry out the mission of promoting economy, efficiency, and effectiveness through the elimination of waste, abuse, and fraud. The OIG strongly recommends adopting a corporate compliance plan because it helps reduce the risk of compliance errors and can limit the liability of directors and management. An effective plan can also reduce liability under the Federal Sentencing Guidelines. A well-written corporate compliance plan helps an organization's employees understand how laws and regulations relate to their jobs and enables management to know that these legal requirements are being followed.

The OIG has said that an effective corporate compliance plan should contain the following elements:

- Adoption of reasonable compliance standards of conduct and procedures. The provider must organize its compliance materials, learn what laws and regulations govern its practices, and put in writing the steps necessary for a high-level compliance officer to be certain that it obeys the law.
- Appointment of a high-level compliance officer. For the plan to be effective, this officer must be someone who can insist on compliance from anyone in the organization, so the compliance officer should be someone at the highest level of management.
- Employee education and systematic compliance training.

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- Development of effective lines of communication. There must be easy access to the compliance officer so that problems can be reported and corrected. There must also be the guarantee that employees can report compliance issues without fear of retaliation. In larger organizations experts suggest a 24-hour hotline so employees can report problems anonymously.
- Consistent and continuous enforcement of compliance standards through well-publicized disciplinary standards. OIG suggests that every plan contain disciplinary standards so there are consequences for serious deviations from the organization's standards of conduct. Disciplinary standards should apply not just for the employee who erred, but also for the supervisor who failed to detect the problem. OIG also suggests that employers use background checks for new employees to ensure they have not been involved in healthcare fraud. OIG maintains a national databank that lists people who have been sanctioned for healthcare fraud.
- Development of auditing and monitoring programs. A monitoring program should include regular reports to the compliance officer and to senior management. For larger organizations this program will probably include compliance audits by internal or outside auditors who are expert in federal billing regulations.
- Development of mechanism for reporting detected violations to the appropriate agency and for correcting the problem prospectively.
- Information about the guidelines for compliance can be found at the OIG website (http://oig.hhs.gov/fraud/complianceguidance.asp).

The Health Care Reform Act requires all healthcare providers participating in Medicare to have a compliance program in place. Although the details of such a required program are not available as of this writing, it is likely that the OIG will promulgate the regulations, so having a plan in place based on OIG suggestions could give providers a head start.

To have an effective compliance plan, all employees must be aware of it. OIG will survey employees when auditing an institution. To develop an effective plan, the first step should be to assess areas of risk facing the organization. For example, although almost any healthcare provider could legitimately worry about tax, antitrust, environmental, employment, intellectual property, confidentiality, licensing, and controlled substance issues, designing an all-encompassing compliance plan is likely to be too difficult to achieve at one time.

The greatest risk for most organizations is erroneous or fraudulent billing. In these cases the first phase of plan development should be to get a snapshot of the organization's billing practices. The risk analysis should usually be made under the supervision of the organization's lawyers.

Problems will develop in an institution when its employee–agents perpetuate frauds that are relatively commonplace, such as billing when inadequately supervising medical residents or spending inadequate time with patients. The facility is culpable unless it has an adequate compliance plan and it did not know or should have known about their employees' behavior.

After the risk areas are identified, a written compliance plan should be developed. The plans are most effective when everyone who is part of the billing process gives his or her input and the values of the individual organization are included in the code of standards. The written plan should then be distributed to all personnel and training should commence.

Once the plan is operative, it is effective only if it includes management support, effective communication, continuous monitoring, and individual accountability. Federal prosecutors have made it clear that simply having an elegant but unused plan on the shelf of the practice manager will be regarded as worse than having no plan at all.

Developing a plan can take anywhere from several months for a small medical practice to about a year for a large hospital. The protection afforded by such a plan makes the investment of time and resources well worth the effort.

LEARNING OBJECTIVE 3

Identify the major components of a corporate compliance plan, including the establishment of internal controls relating to the finances of an organization.

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Internal Control as a Part of Corporate Compliance

As described by the American Institute of Certified Public Accountants (AICPA), "internal control is a process effected by an entity's board of directors, management and other personnel designed to provide reasonable assurance regarding the achievement of objectives in the following categories: reliability of financial reporting, effectiveness and efficiency of operations, and compliance with applicable laws and regulations."[2] This definition emphasizes the fact that internal control is a function of the board, management, and other personnel within the organization. The responsibility for internal control rests squarely on management's shoulders.

The AICPA identifies the five interrelated components of internal control as follows:

- Control environment sets the tone of an organization, influencing the control consciousness of its people. It is the foundation for all other components of internal control, providing discipline and structure.
- Risk assessment is the entity's identification and analysis of relevant risks to achievement of its objectives, forming a basis for determining how the risks should be managed.
- Control activities are the policies and procedures that help ensure management directives are carried out.
- Information and communication are the identification, capture, and exchange of information in a form and time frame that enable people to carry out their responsibilities.
- Monitoring is a process that assesses the quality of internal control performance over time.

Internal control is not the equivalent of corporate compliance, but it should be a key component of a corporate compliance plan. The two work together to ensure that an organization is soundly managed from both a financial and legal perspective.

[2]Thomas A. Ratcliffe, & Charles E. Landes, Understanding Internal Control and Internal Control Services 2, (American Institute of Certified Public Accountants, Inc.) (2009).

PART II. PRIMARY REGULATORY ISSUES CONFRONTING HEALTHCARE ORGANIZATIONS TODAY

LEARNING OBJECTIVE 4

Recognize when and how to involve legal counsel on a Medicare or Medicaid reimbursement issue or other financial matter that has regulatory compliance implications or would otherwise require you to seek legal advice before making a decision.

Medicare Reimbursement

In 1965 Medicare was established as a social insurance program, like Social Security, to provide health insurance coverage for individuals aged 65 and older and for younger people with permanent disabilities. Before 1965 about half of all seniors lacked medical insurance; today, almost all seniors have health insurance coverage under Medicare. Medicare covers approximately 47 million people: 39 million people aged 65 and older and another 8 million people with permanent disabilities who are under age 65. Medicare helps pay for many healthcare services, including hospitalizations, physician services, and prescription drugs. Individuals contribute to Medicare through payroll taxes throughout their working lives and generally become eligible for Medicare when they reach age 65, regardless of their income or health status.

Encompassing approximately 12% of the federal budget and 20% of total national health expenditures, Medicare is a significant part of the growth of both federal spending and healthcare spending in the United States. Medicare is administered by the DHHS Centers for Medicare & Medicaid Services (CMS).

Medicare offers a number of programs for its beneficiaries, including health facility coverage, reimbursement of doctor's fees, and prescription coverage. Additionally, Medicare offers a managed care plan, Medicare Advantage, that bundles a number of these offerings.

- *Part A. Hospital Insurance:* Most people do not pay a premium for Part A because they or a spouse already paid for it through their payroll taxes

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while working. Medicare Part A helps cover inpatient care in hospitals, including critical access hospitals, and skilled nursing facilities but not custodial or long-term care. It also helps cover **hospice** care and some home health care. Beneficiaries must meet certain conditions to get these benefits.

- *Part B. Medical Insurance:* Most people pay a monthly premium for Part B. Medicare Part B helps cover doctors' services and outpatient care. It also covers some other medical services that Part A does not cover, such as some of the services of physical and occupational therapists and some home health care. Part B helps pay for these covered services and supplies when they are medically necessary.
- *Medicare Supplemental Insurance or "Medigap Policies":* Medicare Parts A and B are commonly referred to as the "original Medicare plan." A Medigap policy is health insurance sold by private insurance companies to fill the "gaps" in original Medicare plan coverage. Medigap policies help pay some of the healthcare costs that the original Medicare plan does not cover. Insurance companies are permitted to sell only "standardized" Medigap policies. Generally, an eligible beneficiary with a Medigap policy will have Medicare Part A and Part B. The beneficiary will have to pay the monthly Medicare Part B premium and a premium to the Medigap insurance provider.
- *Part C. Medicare Advantage:* Medicare Advantage Plans are managed care health plan options that are part of the Medicare program. Eligible beneficiaries who join one of these plans generally get all their Medicare-covered health care through that plan. Coverage can include prescription drug coverage. Medicare Advantage Plans include one of the following:
  - Medicare health maintenance organization
  - Preferred provider organizations
  - Private fee-for-service plans
  - Medicare special needs plans
- Eligible beneficiaries who join a Medicare Advantage Plan use the health insurance card they receive from the plan for their health care. In most of these plans, generally there are extra benefits and lower copayments than in the original Medicare plan. However, beneficiaries may have to see doctors or go to hospitals that participate in the plan.
- To join a Medicare Advantage Plan, a beneficiary must have Medicare Part A and Part B and pay a monthly Medicare Part B premium to Medicare. Additionally, a beneficiary may also pay a monthly premium to a Medicare Advantage Plan for the extra benefits offered through the plan. A beneficiary who joins a Medicare Advantage Plan will not have any deductibles, copayments, or other cost sharing under their Medicare Health Plan. Accordingly, a beneficiary would not need a Medigap policy.
- *Part D. Prescription Drug Coverage:* Beginning on January 1, 2006, the Medicare prescription drug coverage was available to everyone with Medicare. Part D coverage may help lower prescription drug costs and help protect against higher costs in the future. Medicare Prescription Drug Coverage is insurance offered through private companies. Beneficiaries choose a drug plan and pay a monthly premium.

Certification of Provider of Item or Service

Institutional providers, physicians, nonphysician practitioners, and other healthcare suppliers must enroll in the Medicare program to be eligible to receive Medicare payment for covered services provided to Medicare beneficiaries. The Medicare enrollment application is used to collect information about the institutions and other providers and suppliers and to secure the necessary documentation to ensure the organization is qualified and eligible to enroll in the Medicare program.

The usual process for becoming a certified Part A institutional **Medicare provider** is as follows:

1. The applicant completes and submits the Medicare enrollment application to its designated Medicare fee-for-service contractor.
2. The fee-for-service contractor reviews the application and makes a recommendation for approval or denial to the applicable CMS Regional Office.
3. Once the fee-for-service contractor makes a recommendation to approve enrollment, the state agency or, if applicable, a CMS-recognized accrediting organization conducts a survey. Based on the survey results the state agency

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makes a recommendation for approval or denial (a certification of compliance or noncompliance) to the CMS Regional Office.

4. The CMS Regional Office makes the final decision regarding program eligibility. The CMS Regional Office also works with the Office of Civil Rights to obtain the necessary Civil Rights clearances. If approved, the provider must typically sign a provider agreement.

In Part B, "participation" means a Part B noninstitutional provider agrees to always accept assignment of claims for all services furnished to Medicare beneficiaries. By agreeing to always accept assignment, the provider accepts Medicare-allowed amounts as payment in full and does not collect more than the Medicare deductible and coinsurance from the beneficiary. Unlike many private insurance plans, the Social Security Act requires providers to submit claims for Medicare beneficiaries whether they participate or not.

The participating provider application should be submitted simultaneously with the Medicare enrollment form. Providers that choose to participate receive 5% higher reimbursement than those who do not participate. Medicare payments are issued directly to the physician/supplier because the claims are always assigned, and claim information is forwarded to Medigap insurers.

Payment for the Item or Service

For Part A inpatient institutional care such as hospital and nursing home care, Medicare uses the "inpatient prospective payment system." A prospective payment system is one in which the healthcare institution receives a certain payment for each episode of care provided to a patient, regardless of the actual amount of care used. The amount of the payment is based on the value of a certain diagnosis as determined by CMS in the form of **diagnosis-related groups (DRGs)**. DRGs make up a classification system that groups similar clinical conditions (diagnoses) and the procedures furnished by the hospital during the stay. Related therapeutic outpatient department services provided within three days before admission are included in the payment for the inpatient stay and may not be separately billed. Since October 1, 2007, a new DRG system, called Medicare Severity-DRG, has been used to better account for severity of illness and resource consumption for Medicare beneficiaries.

In addition to the base-rate per DRG payments, hospitals can receive additional outlier payments for extremely costly procedures, for the cost of graduate medical education if the hospital has an approved program, and for treating a disproportional share of low-income patients, as well as for the use of certain new technology. Payments may be reduced if a patient has a short length of stay and is transferred to another hospital.

Outpatient hospital services are reimbursed through Part B, in accordance with the "outpatient prospective payment system." In most cases the unit of payment under the outpatient prospective payment system is the individual service or procedure. Services are assigned to ambulatory payment classifications (APCs) based on similar clinical characteristics and similar costs. The payment rate and copayment calculated for an APC apply to each service within the APC.

Most services are paid separately, including, but not limited to, most surgical, diagnostic, and nonsurgical therapeutic procedures; blood and blood products; most clinic and emergency department visits; and some drugs and biologicals. Within each APC, payment for ancillary and supportive items and services is packaged into payment for the primary independent service. Separate payments are not made for a packaged service, which is considered an integral part of another service that is paid under the outpatient prospective payment system. Some examples of usual packaged services are routine supplies, anesthesia, operating and recovery room use, implantable medical devices, inexpensive drugs under a per day drug threshold packaging amount ($65 in 2010), guidance services, and imaging supervision and interpretation services.

Medicare Part B pays for physician services based on the Medicare Physician Fee Schedule, which lists the more than 7,000 covered services and their payment rates. Physician services include office visits, surgical procedures, and a range of other diagnostic and therapeutic services.

The fee schedule assigns relative value units to each outpatient healthcare service. The Medicare reimbursement for a physician calculation includes the relative value unit for the procedure, relative value units for the practice expense, a geographical adjustment factor for geographical variations in payments, and a conversion factor.

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LEARNING OBJECTIVE 5

Be aware of the most important aspects of the Patient Protection and Affordable Care Act of 2010 (Health Care Reform Act) as it relates to financial management in the post-reform environment.

Effect of Healthcare Reform

Under the Health Care Reform Act, there will be important changes in how the federal government pays for health care provided to Medicare beneficiaries. In addition to measures designed to reduce fraud and waste in the current payment system, the Act also provides for demonstration projects that test different reimbursement structures such as "bundled payments" and other risk-sharing arrangements among providers. A single bundled payment would be made for a continuum of inpatient hospital services, physician services, outpatient hospital services, and post–acute care services for an episode of care that begins three days before a hospitalization and spans 30 days after discharge. If bundled payment structures become the norm, relationships among institutional providers, physicians, outpatient clinics, and post–acute care providers such as skilled nursing and home health care will require a much higher level of integration and cooperation than exists in the current system.[3]

Medicaid Reimbursement

The Medicaid program was established by Congress in 1965 and covers health and long-term care services for many of the sickest and poorest Americans. In 2005 Medicaid covered 59 million people, including one-fourth of U.S. children. Without Medicaid, most of its beneficiaries would join the nearly 46 million uninsured. Like Medicare, Medicaid is a major source of healthcare financing and coverage. It is the main source of financing for long-term care, paying 40% of the national bill for both nursing home care and long-term care. Additionally, Medicaid is the largest source of public funding for mental health care. Safety-net hospitals and health centers that care for the uninsured and many of the low-income population depend on Medicaid. However, as opposed to Medicare, Medicaid is administered at the state level.

Eligibility Determinations

Agencies in each state administer Medicaid under the oversight of CMS. Although participation is voluntary, all states participate in Medicaid. States have broad authority to define eligibility, benefits, provider payment, and other aspects of their programs subject to basic minimum requirements required under federal law. Consequently, Medicaid operates as a distinct program in each state, the District of Columbia, and the U.S. Territories. These variations and the demographic differences among the states result in variations of covered populations from state to state.

Federal law requires each state to cover certain "mandatory" groups to receive the federal match. Mandatory groups include pregnant women, children under age 6 with family income below 133% of the federal poverty level, children ages 6 to 18 below 100% federal poverty level, parents below states' July 1996 welfare eligibility levels (often below 50% federal poverty level), and most elderly and persons with disabilities receiving Supplemental Security Income, for which income eligibility equates to 74% federal poverty level for an individual. Adults without dependent children, no matter how poor they are, are categorically excluded from Medicaid under federal law unless they are disabled or pregnant.

Coverage of Item or Service

Medicaid covers the health services typically covered by private insurance to address the many different healthcare needs of its diverse enrollees and their limited ability to afford care out-of-pocket. Medicaid also covers many additional services, such as dental and vision care, transportation, and long-term care services. Some covered benefits, such as services provided by federally qualified health centers, reflect the unique role certain institutions play in furnishing heath care services to the low-income population. To control costs, states use numerous tools to manage utilization, such as prior authorization and case management.

As with eligibility, state Medicaid programs must cover certain "**mandatory services**" specified under federal law to receive any federal matching funds.

[3]Patient Protection and Affordable Care Act, Pub. Law No. 111-148 § 2704 (2010).

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Medicaid services are covered subject to medical necessity, as determined by the state Medicaid program or a managed care plan that is under contract to the state. Federal law also permits states to cover many services that are designated as "optional services," such as prescription drugs, which all states cover, and personal care services.

Provider Payment Rates

Each state has its own Medicaid reimbursement methodology. CMS reviews state plan reimbursement methodologies for services provided under the state plan for consistency with federal statutes and regulations. These laws require that states "assure that payments are consistent with efficiency, economy and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area."[4]

In general, CMS reviews state payment methodologies and supporting documentation to ensure that the state plan methodology may be audited and is comprehensively described and that payment rates are economic, efficient, and sufficient to attract willing and qualified providers. In addition, the law requires that Medicaid payments to qualified hospitals, nursing facilities, intermediate care facilities for the mentally retarded (ICF/MRs), and clinics not exceed a reasonable estimate of the amount that Medicare would pay for equivalent services in the aggregate within state-owned or –operated, non–state-owned or –operated, and private facilities.

Disproportionate Share Hospital Payments

Medicaid makes special payments to hospitals that serve a disproportionate share of low-income and uninsured patients. Approximately 6% of Medicaid spending is attributable to supplemental payments to hospitals that serve a disproportionate share of low-income and uninsured patients. Known as "DSH" payments, they help support the safety-net hospitals that provide substantial uncompensated care to this population.

Medicaid State Financing. The federal government matches state spending on Medicaid. States are entitled to these federal matching dollars, and there is no funding cap, allowing federal funds to flow to states based on actual need. Through this system the federal government and the states share the cost of funding the Medicaid program.

Federal law provides that the state must ensure adequate funding for the nonfederal share of expenditures from state or local sources for the amount, duration, scope, or quality of care and services available under the state plan. Recognized sources of the state share of Medicaid payments include legislative **appropriations** to the single state agency, intergovernmental transfers, certified public expenditures, and permissible taxes and provider donations. Before approval of a state plan amendment, CMS must verify that the source of the state share meets applicable statutory and regulatory requirements to authorize federal financial participation for the covered services.

Medicaid Administrative Claiming. Federal law directs payment of Federal Financial Participation at different matching rates, for amounts "found necessary by the Secretary for the proper and efficient administration of the State plan."[5] The Secretary of the DHHS is the final arbiter of which activities fall under this definition. Claims held under this authority must be directly related to the administration of the Medicaid program. In addition, payment may only be made for the percentage of time spent actually attributable to Medicaid-eligible individuals.

CMS has approved cost allocation plans from states that include the following types of administrative costs necessary for the proper and efficient administration of the State plan:

- Medicaid eligibility determinations
- Medicaid outreach
- Prior authorization for Medicaid services
- Medicaid Management Information System development and operation
- Early and periodic screening, diagnostic and treatment administration
- Third-party liability activities
- Utilization review
- Medicaid financial operations and reporting

[4]42 U.S.C. § 1396(a)(30)(A).

[5]42 U.S.C. § 1396b.

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Medicare Appeals

Medicare Beneficiary Appeal Rights

A **Medicare beneficiary** has the right to appeal any decision about the beneficiary's Medicare services regardless of the coverage plan. If Medicare does not pay for an item or service provided to the beneficiary or if the beneficiary is not given an item or service the beneficiary believes he or she should receive, they can appeal.

An enrollee in original Medicare can appeal a Medicare denial of payment or underpayment for an item or service received. Appeal rights are printed on the back of the Explanation of Medicare Benefits or Medicare Summary Notice that is mailed to the beneficiary. The notice also explains why the bill was not paid and the appeal steps.

Appeal Rights Under Medicare Managed Care Plans

An enrollee in a Medicare managed care plan can appeal a denial of payment or a disallowance of service that should be covered or provided. If a fast decision is requested, the plan must answer the appeal within 72 hours. The Medicare managed care plan must describe the appeal process in writing. If a plan does not decide in favor of the beneficiary, the appeal is reviewed by an independent organization that works for Medicare, not for the plan.

Appeal Rights Under Medicare Prescription Drug Plans

A Medicare prescription drug plan enrollee can appeal a plan sponsor's decision not to provide or pay for a Part D prescription drug that the enrollee believes the plan sponsor should provide or pay for. The word "provide" includes such things as authorizing prescription drugs, paying for prescription drugs, or continuing to provide a Part D prescription drug that the enrollee has been receiving. The Medicare prescription drug plan must inform the enrollee in writing how to request an appeal.

A standard appeal must be answered by the plan sponsor within seven calendar days after receiving the request. An enrollee or the enrollee's physician can request an expedited 72-hour appeal if the enrollee's health could be seriously harmed by waiting up to seven calendar days for a decision. If the plan sponsor does not decide in favor of the enrollee, that decision can be appealed to an independent organization that works for Medicare, not for the plan sponsor.

Supplier Appeals for Part B Reimbursement

Once an initial claim determination is made there are five levels of appeal to protect providers, physicians, and other suppliers. Physicians and other suppliers who do not take assignment on claims have limited appeal rights. Beneficiaries may transfer their appeal rights to nonparticipating physicians or other suppliers who provide the items or services and do not otherwise have appeal rights. All appeal requests must be made in writing.

Appeals Process

Medicare offers five levels in the Part A and Part B appeals process. The levels, listed in order, are as follows:

1. Redetermination by a financial institution, carrier, or Medicare Administrative Contractor (MAC): A redetermination is an examination of a claim by the financial institution, carrier, or MAC personnel who are different from the personnel who made the initial determination. The appellant (the individual filing the appeal) has 120 days from the date of receipt of the initial claim determination to file an appeal. A minimum monetary threshold is not required to request a redetermination.
2. Reconsideration by a qualified independent contractor (QICs): A party to the redetermination may request a reconsideration if dissatisfied with the redetermination. A QIC conducts the reconsideration. The QIC reconsideration process allows for an independent review of medical necessity issues by a panel of physicians or other healthcare professionals. A minimum monetary threshold is not required to request a reconsideration.
3. Hearing by an administrative law judge (ALJ): If at least $130 remains in controversy after the QIC's decision, a party to the reconsideration may request an ALJ hearing within 60 days of receipt of the reconsideration. Appellants must also send notice of the ALJ hearing request to all parties to the QIC reconsideration and verify this on the hearing request form or in the written request.

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4. Review by the Medicare Appeals Council within the Departmental Appeals Board ("the Appeals Council"): If a party to the ALJ hearing is dissatisfied with the ALJ's decision, the party may request a review by the Appeals Council. There are no requirements regarding the amount of money in controversy. The request for Appeals Council review must be submitted in writing within 60 days of receipt of the ALJ's decision and must specify the issues and findings that are being contested.
5. Judicial review in U.S. District Court: If at least $1,260 is still in controversy after the Appeals Council's decision, a party to the decision may request judicial review before a U.S. District Court judge. The appellant must file the request for review within 60 days of receipt of the Appeals Council's decision. The Appeals Council's decision contains information about the procedures for requesting judicial review.

LEARNING OBJECTIVE 6

Identify the most common federal regulatory issues such as fraud and abuse, Stark, HIPAA privacy and security, EMTALA, and IRS requirements for tax-exempt organizations as well as less common concerns that arise under the antitrust laws, Red Flag Rules, and state insurance regulations.

Fraud, Abuse, and Penalties

Fraud consists of intentional acts of deception, whereas abuse involves improper acts that are inconsistent with standard practice and may result in overpayment or over-utilization. Fraud and abuse can take many forms. Providers may bill for services not delivered or not medically necessary. Double billing for a single procedure can occur, as can improper "upcoding" to receive a higher reimbursement rate. Kickbacks for referrals or medical procedures are another frequently cited form of fraud.

The Medicare program involves claims for services submitted by thousands of providers on behalf of more than 44 million beneficiaries. The cumulative effect of even small overpayments can translate to significant program losses because of the number of claims and providers involved. The Health Care Fraud and Abuse Control Program, under the joint direction of the U.S. Attorney General and the Secretary of the DHHS, acting through the OIG, was designed to coordinate federal, state, and local law enforcement activities with respect to enforcing laws to minimize healthcare fraud and abuse.

Criminal Statutes

A number of criminal statutes address false or fraudulent representations made to, and false claims filed with, Medicare or other federally funded healthcare programs. The Medicare and Medicaid Anti-Fraud and Abuse Amendments provide criminal penalties for making false statements of material fact in a claim made for Medicare or Medicaid payment and for failing to disclose or conceal an event affecting the right to receive a benefit or payment.[6] In addition, the Anti-Fraud and Abuse Amendments provide criminal penalties for improper use of Medicare or Medicaid benefits, presenting claims by unlicensed physicians, and advising a person to transfer assets to gain Medicaid eligibility.

In addition to the direct criminal statutes, criminal mail or wire fraud also apply to the use of mail or wire for the purpose of a scheme or plan to defraud or for obtaining money or property by means of false or fraudulent representations.[7] The Racketeer Influenced and Corrupt Organizations Act prohibits a person from receiving income from a pattern of activity including committing an enumerated act (such as mail or wire fraud) at least twice in 10 years.[8] Further, criminal money laundering is the act of knowingly engaging in a monetary transaction in criminally derived property of a value greater than $10,000 and derived from specific unlawful activity (such as mail or wire fraud or any act or activity constituting an offense involving a federal healthcare offense).[9]

Finally, a person may not knowingly and willfully falsify, conceal, or cover up by trick, scheme, or device a material fact, or make any materially false, fictitious,

[6] 42 U.S.C. § 1320a-7b.
[7] 18 U.S.C. §§ 1341 & 1343.
[8] 18 U.S.C. §§ 1961 *et seq.*
[9] 18 U.S.C. §§ 1956-1957.

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or fraudulent statements or representations, or make or use a materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry.[10] Such false statements are also criminal acts. These various criminal laws illustrate that Medicare fraud can result in a variety of criminal charges. In addition, the Anti-Kickback Statute includes criminal penalties and is discussed in more detail below.

False Claims Act

The False Claims Act (FCA) is the federal government's primary civil remedy for improper or fraudulent claims.[11] Although the FCA applies to all federal programs, not just to public healthcare benefits, it increasingly has been applied in health care, due in part to the large dollar amounts involved. Under the FCA healthcare providers who knowingly make false or fraudulent claims to the government are fined $5,500 to $11,000 *per claim* plus up to three times the amount of the damages caused to the federal program. Large fines can quickly accrue, because providers routinely submit thousands of claims to the government each year. For example, on March 10, 2000, the Department of Justice filed claims under the FCA seeking recovery of over $1 billion from Vencor Inc., a long-term healthcare provider, for its alleged knowing submission of false claims. The Department of Justice alleged that Vencor was engaged in improper billing practices, claims for services not rendered, provision of medically unnecessary services, misrepresenting eligibility or credentials, and substandard quality of care.

To violate the FCA specific intent to defraud the government is not required; the government need only establish that the claim submitted is false and that it was submitted knowingly. Thus, the FCA prohibits activity that does not fall under the traditional definition of fraud, which requires actual knowledge and the intent to defraud. In addition, an amendment to the FCA was passed in 2009 that defines a claim under the FCA as a claim for payment made either directly to the government or to a government contractor. As a result, where, for example, a physician group bills a hospital for services provided, if those services are ultimately paid for by Medicare, such a bill is available for prosecution under the FCA. As with most other civil actions, the government must establish its case by presenting a preponderance of the evidence rather than by meeting the higher burden of proof that applies in criminal cases.

To prove that a healthcare provider has submitted a false claim knowingly, the government must establish that the person submitted the claim with actual knowledge, in deliberate ignorance, or with reckless disregard for the claim's truth or falsity. The FCA is not intended to apply to honest mistakes and negligence. Yet, those doing business with the government are obligated to make at least limited inquiries as to the accuracy of the claims they submit.

Qui Tam Actions

FCA claims may be brought against an entity not only by the Department of Justice or other governmental organization but also by an individual. When such an action is brought by an individual, it is referred to as a "*qui tam*" action, and the individual is referred to as a "relator." ***Qui tam*** actions are also known as "whistleblower" suits. In a *qui tam* action a relator with personal knowledge of a fraud brings the suit against a defendant on behalf of the government. The knowledge with which the relator brings a *qui tam* action must not be public knowledge but information that would not otherwise be available without the *qui tam* suit.

The relator in a *qui tam* action does not need to have been personally harmed by the alleged false claim. However, the relator receives a certain percentage of any award or settlement amount. Once a relator files a *qui tam* action, the government has the option of joining the action as a plaintiff. If the government joins, the relator is entitled to between 15% and 25% of any award or settlement, depending on the assistance provided. If the government decides not to join, the relator is entitled to between 25% and 30% of any award or settlement. By granting a relator a percentage of a successful *qui tam* action, the FCA provides individuals with incentive to assist the government in identifying fraud, especially where insider knowledge is required to identify such acts.

Kickbacks and Self-Referrals

The Anti-Kickback Statute (AKS) and the Stark Physician Self-Referral Law (Stark Law) are two important fraud and abuse authorities. They are among

[10] 18 U.S.C. § 1035.

[11] 31 U.S.C. §§ 3729 *et seq*.

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the most important regulatory restrictions and must be considered when structuring business relationships between healthcare entities. Violations of these laws can result in nonpayment of Medicare claims, civil monetary penalties, exclusion from the Medicare program, and liability under the FCA, discussed above. Submitting a claim to Medicare when the provider has violated AKS or the Stark Law is a false claim, because claims include a certification that the provider is in compliance with Medicare laws and regulations. In addition, violation of AKS can result in criminal penalties, including imprisonment and fines.

Unfortunately, AKS and the Stark Law include much uncertainty, in part because the regulations governing their implementation change so frequently. Both AKS and the Stark Law have relatively short statutory language, and then significant regulations adding safe harbors and exceptions, and specifying details left unclear in the statute. Therefore, following rule-making procedures, the OIG can change the AKS regulations, and the CMS can change the Stark Law regulations without any action of Congress.

Implementation of AKS and Stark Law is difficult because the requirements often conflict with the economic interests of the parties structuring the relationship. In addition, both AKS and the Stark Law have a complex web of exceptions, safe harbors, and interpretation from the OIG and CMS in the form of commentary to the rules, advisory opinions, and other published guidance.

AKS and the Stark Law are federal statutory and regulatory schemes addressing entities with relationships to Medicare and Medicaid. In addition, many states have their own version of anti-kickback and physician self-referral prohibitions, varying in complexity and coverage, addressing relationships between healthcare entities either reimbursed by Medicaid, other state-payor, or in some cases limit relationships regardless of payment source. Because of length constraints state law is not addressed in this chapter.

Anti-Kickback Statute

AKS states that no person may offer or request, give, or receive remuneration in exchange for a referral for a good or service that may be reimbursed under a federal healthcare program (e.g., Medicare).[12] Note that at least one district court has held that a referral does not need to actually be made: "the Government need only prove that the money was paid in exchange for the promise of referrals."[13] In addition, AKS prohibits both the payment and the receipt of such kickbacks. AKS applies to all healthcare providers and any other person that may fall under its prohibition, as compared with the Stark Law, which is limited to physicians.

"Remuneration" under AKS is interpreted broadly. It is clear when, for example, an imaging provider hands cash to a physician in exchange for a promise to refer patients for magnetic resonance imaging that remuneration has been given in exchange for referrals. However, remuneration can be given or received in the form of free or discounted goods or services. For example, a hospital providing office space to a physician for below-market rent in exchange for referrals from that physician is also considered remuneration in exchange for referrals. As a result, healthcare providers should take care to ensure that all financial arrangements are consistent with *fair market value*. The concept of fair market value arises in most AKS safe harbors to ensure that improper remuneration is not given either by above-market compensation (i.e., extra cash) or below-market compensation (i.e., improper discount).

AKS is intent based, so to violate the statute a person must have the intent to give or receive remuneration for referrals. However, even if the physician performs some service for the money received, the potential for unnecessary drain on Medicare remains. If the payments were intended to induce a provider to refer for services, the statute was violated, even if the payments were also intended to compensate for professional services.[14] AKS is violated if *one purpose* of the payment is to induce referrals.[15] The one purpose does not even need to be the main purpose; one court found that "the issue of sole versus primary reason for payments is irrelevant since any amount of inducement is illegal."[16] Therefore, any intent to induce referrals would fulfill the requirements under AKS.

[12] 42 U.S.C. § 1320a-7b(b).

[13] *United States v. Picciotti*, 40 F. Supp. 2d 242, 248 (D.N.J. 1999).

[14] *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985)

[15] *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989).

[16] *U.S. ex rel. Pogue v. Diabetes Treatment Centers*, 565 F.Supp.2d 153, 162 (D.D.C. 2008).

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AKS includes a few statutory exceptions, including bona fide employment. It is indicative of the breadth of AKS that an exception for employment was made. According to the statutory language, a bona fide employee may be compensated in any otherwise-legal manner. It is important to note that the Stark Law is not so liberal in exceptions to employment and places some requirements on physician employment (discussed below).

The OIG has identified various payment practices that, although potentially capable of inducing referrals of business under Medicare and Medicaid, are essentially harmless or efficient and therefore should not be viewed as kickbacks for purposes of criminal prosecution or civil remedies. The resulting regulations, often referred to as the "safe harbor rules," are intended to give guidance and comfort to providers who engage in certain narrowly prescribed business practices that Congress did not intend to prohibit by AKS and, in some instances, should be encouraged by the federal government.[17]

There are 25 safe harbors identified by the OIG. Some commonly used are the safe harbors for space rental, equipment rental, and personal services agreements between healthcare entities and/or providers. For each of these arrangements, the safe harbor requires that the arrangement be in writing, for a term of at least 1 year, that the compensation be set in advance, and that the compensation be consistent with fair market value and be commercially reasonable. As discussed above, the OIG wants to make sure that, for example, a hospital is leasing a magnetic resonance imaging facility to a physician practice for its fair market value and not leasing it for "bargain basement" prices in exchange for referrals from the physicians to the hospital. In addition, there are safe harbors for investment in healthcare entities, certain **discounts** for products, and for waiver of coinsurance or deductibles, among others. These safe harbors each contain a number of requirements to meet before an arrangement is protected.

If an arrangement fully complies with a safe harbor, AKS is not violated. Failure of an arrangement to comply with a safe harbor can mean one of three things: (1) the arrangement is not intended to induce the referral of business reimbursable under Medicare or Medicaid, so there is no violation of AKS or need for a safe harbor; (2) the arrangement could be a clear statutory violation and also not qualify for safe harbor protection and therefore at high risk for prosecution; or (3) the arrangement may violate the statute in a less serious manner although not be in compliance with a safe harbor provision. The degree of the risk depends on an evaluation of the many factors that are part of the decision-making process regarding case selection for investigation and prosecution.

The OIG has the primary responsibility for enforcing AKS. In addition it its audit function, the OIG issues advisory opinions at the request of various parties, which lend guidance to the statutes and regulations that make up AKS. The OIG also implements a self-disclosure protocol, under which a party who has violated AKS (or other Medicare law) can report the wrongdoing in exchange for lenient treatment. However, there is no guarantee of leniency, and the Department of Justice is informed of all self-disclosures made to the OIG.

Stark Law

The Stark Law prohibits a physician from referring a patient for certain "designated health services" to an entity with which the physician has a "financial relationship." In addition, a provider may not bill Medicare for a claim based on a prohibited referral.[18] Unlike AKS, the Stark Law does not include an intent requirement. In addition, the Stark Law only applies to referrals made by physicians.

The Stark Law was premised on the assumption that a physician may not make the best medical decision for a patient where the physician has economic ties to a related for-profit business. If the physician's self-interest impacts decision making, care may be compromised. In addition, healthcare costs may be increased by referring for services that may not be medically necessary as well as by a prearranged referral source.

To understand the Stark Law, a clear understanding of the definitions in the basic rule is needed. A "financial relationship" is defined to include investment or ownership interests and compensation relationships. In addition, the definition of financial relationship includes both direct and indirect relationships. Therefore, referrals may be prohibited between a physician and a hospital where a physician has an impermissible contractual relationship with a physician group that shares a parent entity with the hospital.

[17] 42 C.F.R. § 1001.952.

[18] 42 U.S.C. § 1395nn.

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"Designated health services" is specifically defined to include the following:

- Clinical laboratory services
- Physical therapy, occupational therapy, and speech-language pathology services
- Radiology and certain other imaging services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices
- Home health services and supplies
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

Excluded from "designated health services" are those services reimbursed as part of a composite rate, unless the service itself is reimbursed as a composite rate above (e.g., home health and inpatient hospital services).

Violation of the Stark Law can result in denial of payment of Medicare claims, refunds of amounts collected in violation of the Stark Law, civil monetary penalties of up to $15,000 for each claim that a person knows or should know was made in violation of the Stark law, and three times the amount of the improper collection. Finally, where a claim is submitted in violation of the Stark Law, the FCA is also implicated, as discussed above.

By regulation, CMS has stated that it will not impose penalties if an arrangement involves temporary noncompliance. This is a specific exception that only applies where an arrangement met an exception to Stark Law for at least 180 consecutive calendar days, the financial relationship fell out of compliance for reasons beyond the control of the entity, and the arrangement does not violate AKS. The Stark regulations specifically provide that any claims paid improperly due to a violation of the Stark Law shall refund all amounts on a timely basis.

Although the Stark Law prohibition is broad, there are a number of statutory and regulatory exceptions.[19] For physicians practicing as part of a group practice, there is an "in office ancillary exception" that allows a physician to refer for services within the group practice. However, the group practice must meet the Stark Law's complicated definition of "group practice," the physician or another member of the group practice must personally furnish or directly supervise the furnishing of the services, the services must be provided in a specific location, and the services must be billed by the referring physician or group practice.

Compensation-related exceptions, like AKS safe harbors, generally focus on ensuring relationships are consistent with fair market value and commercially reasonable and ensure that compensation does not vary on the volume or value of referrals. There are exceptions for renting office space and renting equipment, each with a number of specific requirements. Importantly, the equipment rental exception was recently changed to disallow "per-click" compensation. Therefore, an equipment rental relationship may not be compensated on a per use basis but must be used for certain prearranged blocks of time to meet the Stark exception.

In addition, there are exceptions for personal services and bona fide employment, and both exceptions have a number of requirements. Unlike AKS, which only requires bona fide employment to meet an exception, the Stark Law employment exception requires that the employment be for identifiable services, compensation be consistent with fair market value, and not take into account the volume or value of referrals. Such limitation does not prohibit productivity bonuses if the bonuses are based on services performed personally by the employee.

PRIVACY OF HEALTHCARE INFORMATION UNDER HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was enacted to improve the Medicare and Medicaid programs and the efficiency and effectiveness of the healthcare system by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information.[20]

The American Recovery and Reinvestment Act of 2009 contains the Health Information Technology for Economic and Clinical Health Act (HITECH Act), which authorizes significant investment in health information technology and expands the provisions

[19]42 C.F.R. §§ 411.350 *et seq*.

[20]Pub. Law No. 104-191, 110 Stat. 1936 (1996).

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of HIPAA.[21] Notably, the HITECH Act establishes mandatory federal breach reporting requirements for HIPAA-covered entities and their business associates as well as personal health record vendors and companies that service them and extends many HIPAA privacy and security requirements directly to business associates.

The DHHS issued regulations regarding electronic transactions (the "Transaction Standards"), which were effective on October 16, 2002[22]; standards for privacy of individually identifiable health information (the "Privacy Standards"), which were effective on April 14, 2003[23]; security standards for the protection of electronic protected health information (PHI; the "Security Standards"), which were effective April 20, 2005[24]; and standards for notification of breach of unsecured PHI (the "Breach Notification Standards"), which were effective on September 23, 2009.[25] As of this writing, additional regulations are still outstanding pursuant to the HITECH Act, which will further expand HIPAA requirements.

Overview of HIPAA

HIPAA rules and regulations apply to "covered entities." Covered entities by statutory definition include healthcare providers, health plans, and healthcare clearinghouses. "Healthcare provider" refers to any provider of healthcare services as defined in relevant Medicare provisions and to any other person or organization that furnishes, bills, or is paid for healthcare services or supplies in the normal course of business. "Health plan" is defined broadly to include any individual or group plan that provides or pays the cost of medical care. "Healthcare clearinghouse" is defined as a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements. Billing companies are an example of a healthcare clearinghouse.

The regulations also affect business associates of covered entities. A business associate is a person (or other entity) to whom the covered entity discloses PHI to enable that person to carry out or assist with the performance of a function for the covered entity or to perform the function on behalf of the covered entity. Examples of business associates include independent contractors or other persons or entities receiving information for the purposes noted above, including lawyers, accountants, auditors, consultants, and billing firms.

The Privacy Standards specify that covered entities may not disclose PHI to business associates without "satisfactory assurances" that the business associate complies with relevant standards. Satisfactory assurances include certain contractual language that must be included in all contracts between the covered entities and the business associates. Accordingly, covered entities would need to consider HIPAA provisions when drafting contracts with independent contractors.

Covered entities are also required to take "reasonable steps" to ensure that business associates are in compliance with the Privacy and Security Standards. Such steps are important, because a covered entity is liable for the misdeeds of a business associate if it knew, or should have known, of those misdeeds.

Any violation of a HIPAA Standard by a covered entity or a business associate is subject to criminal and civil penalties. Under the HITECH Act a state's attorney general may bring a civil action on behalf a resident whose interests are threatened or harmed by a HIPAA violation.

It is a criminal offense for a person to knowingly (1) use or cause to be used a unique health identifier, (2) obtain individually identifiable health information relating to an individual, or (3) disclose individually identifiable health information to another person. Upon conviction the person shall be (1) fined not more than $50,000, imprisoned not more than 1 year, or both; (2) if the offense is committed under false pretenses, be fined not more than $100,000, imprisoned not more than 5 years, or both; and (3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than $250,000, imprisoned not more than 10 years, or both.

If criminal penalties are not appropriate, the Office for Civil Rights for CMS could assess civil penalties. Table 4–1 shows the four categories of violations and the four corresponding tiers of penalties, all subject to a $1.5 million upper limit for all violations of an identical provision during a calendar year.

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[21]Pub. Law No. 111–5, 123 Stat. 115 §§13400 *et seq.* (2009).

[22]45 C.F.R. Parts 160 and 162.

[23]45 C.F.R. Parts 160 and 164, Subparts A and E.

[24]45 C.F.R. Parts 160 and 164, Subpart C.

[25]45 C.F.R. Parts 160 and 164, Subpart D.

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Table 4–1 Categories of Civil Violations and Penalties for HIPAA Standards Violations

Violation Tier	*Penalty*
Did not know of violation, and with reasonable diligence would not have known of violation.	For each violation, not less than $100 or more than $50,000.
Violation due to reasonable cause, and not willful.	For each violation, not less than $1,000 or more than $50,000.
Violation due to willful neglect but corrected within 30 days of knowledge of violation.	For each violation, not less than $10,000 or more than $50,000.
Violation due to willful neglect and not corrected within 30 days of knowledge of the violation.	For each violation, not less than $50,000.

Among 1,117 healthcare executives responding to an annual American Health Information Management Association survey,[26] 40% reported being fully compliant with HIPAA Privacy and Security Standards as of April 2006, whereas 85% reported being greater than 85% compliant with the Standards. About 21% had written security policies and procedures in place, and 17% had actually implemented such policy and procedures. About 12% had hired data security officers. The most frequent security breaches are from within a covered entity's organization.

Privacy Standards

In general, the Privacy Standards were designed to accomplish three broad objectives:

- Define and limit the circumstances in which entities use and disclose PHI
- Establish certain individual rights regarding PHI
- Require covered entities to adopt administrative safeguards to protect the confidentiality and privacy of PHI

Although the law does not require the collection or electronic transmission of any health information, it does require that the standards be followed anytime transactions are conducted electronically.

PHI is defined as health information used or disclosed by a covered entity in any form (electronic, paper records, oral communications) that identifies an individual and relates to the individual's past, present, or future physical or mental health or condition; the provision of health care to the individual; or the past, present, or future payment for the provision of health care to the individual.

The HIPAA Privacy Standards prohibit covered entities from using or disclosing individually identifiable health information that is or has been transmitted or maintained electronically, except in certain circumstances. Unlike many medical records statutes, this requirement is not limited to the record in which the information appears but rather applies to the information itself. Thus, any information that has been transmitted by fax, telephone, computer, electronic handheld device, or any other electronic means is protected by the HIPAA Standards thereafter in whatever form it might appear, including oral communications.

Under the Privacy Standards, an individual has rights over his or her health information, including the right to request restrictions on certain uses and disclosures of PHI, the right to receive confidential communications of PHI, the right to inspect and copy PHI, the right to amend PHI, and the right to receive an accounting of disclosures of PHI. An individual also has a right to adequate notice of the covered entity's legal duties with respect to PHI. This notice is provided through the ubiquitous "Notice of Privacy Practices" one receives from healthcare providers. This notice contains a statement of the individual's rights with respect to PHI and a brief description of how the individual may exercise these rights.

A covered entity may not use or disclose PHI, unless permitted or required by the HIPAA Standards. A covered entity is permitted to use or disclose PHI to the individual; for treatment, payment, or healthcare operations, including disclosures to business associates; pursuant to and in compliance with a valid patient

[26]The State of HIPAA Privacy and Security Compliance 3 (Am. Health Info. Mgmt. Ass'n ed., 2006).

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authorization; as required by law; or, under certain circumstances, if the PHI is stripped of information that may identify the patient. Further, a covered entity is required to disclose PHI to an individual by request and when required by the Secretary of DHHS to conduct certain investigations. With few exceptions, when using or disclosing PHI or when requesting PHI from another covered entity, a covered entity must make reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request.

HIPAA and the HITECH Act provisions supersede contrary provisions of state law. A law is contrary where a covered entity would find it impossible to comply with both the state and federal requirements or the state law provision stands as an obstacle to the accomplishment and execution of the full purposes and objectives of the administrative simplification provisions of HIPAA. HIPAA and the HITECH Act do not supersede a contrary state law provision if the Secretary of DHHS determines that it is not contrary, if such provision addresses controlled substances, or if the provision relates to the privacy of individually identifiable health information and the state law is more stringent than HIPAA. Further, HIPAA and the HITECH Act cannot invalidate or limit the authority established by any law for the reporting of disease, injury, child abuse, birth, or death; for public health surveillance; or for public health investigations or interventions. HIPAA and the HITECH Act also may not limit the ability of a state to regulate health plans. Therefore, organizations subject to the provisions of HIPAA and the HITECH Act must determine which relevant state laws are contrary to HIPAA and the HITECH Act. Most state laws will not be deemed contrary to HIPAA and the HITECH Act and will likely continue to apply.

Security Standards

Covered entities must comply with the Security Standards with respect to e-PHI. Compliance requires the covered entity to:

- Ensure the confidentiality, integrity, and availability of all e-PHI the covered entity creates, receives, maintains, or transmits
- Protect against any reasonably anticipated threats or hazards to the security or integrity of such information
- Protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required under the Privacy Standards
- Ensure compliance with HIPAA by its workforce

The Security Standards require a covered entity to comply with specific administrative safeguards, physical safeguards, technical safeguards, and organizational requirements, and to implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, or other requirements of the Security Standards. Under the HITECH Act business associates must also comply with all but the organizational requirements of these provisions. Although compliance with each element is important, the technical safeguards deserve particular attention.

Technical safeguards refer to the technology, and policy and procedures regarding technology, that protect e-PHI and control access. The technical safeguards include mandatory standards for access controls, audit controls, data integrity, person or entity authentication, and transmission security.

The access controls standard requires implementation of technical policies and procedures for electronic information systems that maintain e-PHI to allow access only to those persons or software programs that have been granted access rights. The required implementation specifications include assignment of a unique name and/or number for identifying and tracking user identity and the establishment (and implementation as needed) of procedures for obtaining necessary e-PHI during an emergency. The addressable implementation specifications include implementation of electronic procedures that terminate an electronic session after a predetermined time of inactivity and implementation of a mechanism to encrypt and decrypt e-PHI.

The audit controls standard requires implementation of hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use e-PHI. The data integrity standard requires implementation of policies and procedures to protect e-PHI from improper alteration or destruction. The addressable implementation specification requires assessing the implementation of electronic mechanisms to corroborate that e-PHI has not been altered or destroyed in an unauthorized manner.

The person or entity authentication standard requires implementation of procedures to verify that a person or entity seeking access to e-PHI is the one

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claimed. The transmission security standard requires implementation of technical security measures to guard against unauthorized access to e-PHI that is being transmitted over an electronic communications network. The addressable implementation specifications include implementation of security measures to ensure that electronically transmitted e-PHI is not improperly modified without detection until disposed of and implementation of a mechanism to encrypt e-PHI whenever deemed appropriate.

THIRD-PARTY PAYER CONTRACTS

Patients generally do not pay out of pocket for their healthcare services and supplies. Therefore, every healthcare provider needs to be able to seek reimbursement from the **third-party payer** that is responsible for the patient's healthcare costs. There is a variety of payers, as well as a variety of products payers' offer, that healthcare providers may encounter. It is important to understand the differences and regulatory structures through which payer agreements are regulated.

Payers may be public or private. The most significant public payers are Medicare and Medicaid, which are discussed above. In addition, the State Children's Health Insurance Program, the armed services health plan, and Federal Employees Health Benefits Program are all examples of public payers.

Private payers offer products in the form of insurance, in which the payer collects premiums to finance health benefits. The insurance plan then bears the risk and pays the provider for a beneficiary's healthcare services based on the rules of the plan. Other times, an insurance company or other third-party administrator may administrate a program for a self-funded employer or other organization. Self-funded plans are employers or other organizations that collect the premiums, bear the risk, and are liable for the cost of beneficiaries' healthcare services to the providers but pay the administrator to process claims.

Payers often have any number of products available to employers and beneficiaries. The products fall into one of the following categories.

Traditional Indemnity or Fee-for-Service

Early hospital and medical plans offered by insurance companies paid either a fixed amount for specific diseases or medical procedures (schedule benefits) or a percentage of the provider's fee. The patient received medical care and was responsible for paying the provider. If the service was covered by the policy, the insurance company was responsible for reimbursing the patient based on the provisions of the insurance contract. Health insurance plans that are not based on a network of contracted providers or that base payments on a percentage of provider charges are still described as indemnity or fee-for-service plans. These plans are less common.

Managed Care

Managed care products are based on a panel or network of contracted healthcare providers. **Preferred provider organizations** contract with providers to secure certain rates but also reimburse a certain smaller percentage of healthcare services provided by out-of-network providers. Exclusive provider organizations only reimburse providers within the network. Both preferred provider and exclusive provider organizations reimburse providers on a fee-for-service basis, either as a percentage of costs or pursuant to a negotiated fee schedule. Managed care network plans often include:

- A set of selected providers that furnish a comprehensive array of healthcare services to enrollees
- Explicit standards for selecting providers
- Formal utilization review and quality improvement programs

Health Maintenance Organizations

A **health maintenance organization** (HMO) is a type of **managed care organization** that provides healthcare coverage that is fulfilled through a specific closed network. An HMO covers only care rendered by those doctors and other professionals who have agreed to treat patients in accordance with the HMO's guidelines and restrictions. Providers may be employees of the HMO ("staff model"), employees of a provider group that has contracted with the HMO ("group model"), or members of an independent practice association ("IPA model"). HMOs may also use a combination of these approaches. HMOs reimburse providers on a capitated basis, meaning that the **provider network** receives a fixed fee for each patient, and the risk that the patient will use more or fewer resources is therefore shifted to the providers.

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Self-Insured Plans

Self-insured plans are health plans sponsored by an employer or organization offered to employees or members through which the employer or organization retains the risk associated with the plan. Self-insured plans often enter into an administrative services only arrangement for administration of the plan with an insurance company or third-party administrators. The administrative services only arrangement ensures that the risk stays with the self-insured group; the insurance company or third-party administrator merely provides certain claims, billing, medical management, and/or other administrative services. Self-insured plans may include any of a variety of products described above, including indemnity plans, preferred provider organizations, or HMOs.

State Law

In general, insurance is regulated at the state level. Each state has its own specific laws regulating health insurance plans. The activities of the organization determine the different licensure requirements. For example, private payers that are risk-bearing entities are subject to the licensure requirements of the state insurance department. In addition, selling a specific insurance product in a state likely requires state licensure for that product by the insurance department. Finally states often require specific third-party administrator licensure where entities provide administrative services only.

States may have a variety of laws regulating payer plans and payer–provider agreements. For example, "any willing provider" laws require a managed care organization to enter into an agreement with any provider who meets the requirements of that network or product. Some states require continuity of care provisions, which require providers to treat a patient either for a fixed period of time or for the duration of an illness, regardless of whether benefits through the managed care organization have been terminated. States may also require a managed care organization or HMO to cover emergency services, even if provided out of network under a closed-network policy.

Certain state laws enforce protections for providers against certain acts of managed care organizations. For example, a payer may be required to disclose medical review criteria and other policies and procedures to providers. Payers may be subject to "prompt pay" laws, requiring that "clean claims," or claims made consistent with payer requirements, are paid within a certain period of time. States may also disallow managed care organizations from requiring providers from participating in all plans rather than just those plans in which the provider chooses to participate.

Federal Law

Self-insurance plans are regulated by the Employee Retirement Income Security Act of 1974 (ERISA).[27] Plans subject to ERISA must include certain mandated benefits and other requirements that protect members of the self-funded plan. ERISA preemption, areas where the federal ERISA law preempts state insurance law, is subject to complex rules that have been evolving over time through court cases. ERISA provides three standards used to determine the extent of preemption:

1. If a state law "relates to" a self-funded plan governed by ERISA, then the federal ERISA preempts state law.
2. State laws "regulating insurance" avoid ERISA preemption.
3. Self-funded employee benefit plans are not considered insurance companies by states, so state insurance laws do not apply to such plans.

LEARNING OBJECTIVE 7

Be prepared to respond to a compliance audit or investigation, particularly when the subject of that inquiry includes financial records.

LEGAL AUDITS AND INVESTIGATIONS

A legal audit or investigation is a complete review of an organization's legal obligations where violation of the obligations could result in the imposition of civil or criminal sanctions. A healthcare organization is exposed to many areas of risk where legal audits and investigations, as part of a robust and comprehensive

[27] 29 U.S.C. § 1001 *et seq.*

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compliance program, should occur on a routine and ongoing basis. Some of the more notable areas of the law under which audits and investigations may occur include the FCA, Medicare and Medicaid laws, HIPAA, ERISA, and federal and state self-referral and anti-kickback laws.

Legal audits and investigations are formalized and structured processes that result in reliable reports that an organization and/or an outside investigational agency can rely on to determine whether any laws or regulations have been violated and if so, the extent of liability and potential harm. Only if an investigation or audit is conducted under the direction of an attorney, or by an attorney, will the attorney–client privilege or work product doctrine apply to the interviews, records, and reports produced by the investigation or audit. Accordingly, it is essential to structure the audit or investigation to meet the elements of the attorney–client privilege and work product doctrine. Engaging outside counsel, as opposed to inside counsel, to direct or conduct the audit or investigation enhances the claim of attorney–client privilege and work product doctrine.

From the beginning of the audit or investigation it should be expressly documented, preferably by the governing body, that the purpose of audit or investigation is to secure legal advice for the organization. Counsel should be empowered to direct all aspects of the audit or investigation, and all employees should be directed to cooperate fully and exclusively with counsel. Further, all reports and records should be marked "private and confidential," "attorney–client privilege," and "attorney work product" as appropriate and maintained in a segregated and secure file system. Finally, all audit and investigation reports issued by counsel should reflect counsel's legal advice and risk assessment to improve the likelihood of maintaining protections of the attorney–client privilege and work product doctrine.

The audit and investigation team, led by or conducted by counsel, should include members who are independent of physicians and line management; have access to existing audit and healthcare resources, relevant personnel, and all relevant areas of operation; can present written evaluative reports on compliance activities to the CEO, governing body, and members of the compliance committee on a regular basis; and specifically identify areas where corrective actions are needed. Although it is important that the team include employees of the organization, those team members should not be involved with a review of an area over which they are responsible. Additionally, the team may include consultants with specific content knowledge of clinical areas, accounting, or billing and coding. For purposes of retaining attorney–client privilege, any outside consultants preparing reports or records should be engaged by counsel.

Once chartered by the governing body or senior management and counsel is engaged, an audit or investigation begins with the preparation of a detailed audit plan. The audit plan identifies all areas and subject matter to be reviewed and the specific areas of interest to the audit team.

An audit or investigation may use a variety of techniques, including site visits; interviews with management operations, coding, claims processing, patient care, and other related reviews; questionnaires developed to solicit impressions of a broad cross-section of the organization's employees and staff; reviews of related medical and financial records and other source documents; reviews of written materials and documentation prepared by the different divisions of the organization; and **trend analysis**, or longitudinal studies, that seek deviations, positive or negative, in specific areas over a given period.

Violations of an organization's compliance program or failures to comply with applicable federal or state law may threaten an organization's status as a reliable, honest, and trustworthy provider capable of participating in federal healthcare programs. Detected but uncorrected misconduct can seriously endanger the mission, reputation, and legal status of the organiza-tion. Accordingly, if an audit or investigation identifies areas of suspected noncompliance, counsel should advise the governing body or senior management of the legal risks and an appropriate course of action that may include further investigation, specific remedies to mitigate harm, and perhaps an immediate referral to criminal and/or civil law enforcement authorities.

TAX EXEMPTION ISSUES FOR HEALTHCARE ORGANIZATIONS

Nonprofit healthcare organizations are a significant part of the healthcare industry. Although there are state-specific laws that exempt certain organizations from state tax, state exemption usually follows when an organization is exempt from federal tax. The most common way for a healthcare organization to qualify

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for exemption under the federal tax system is under § 501(c)(3) of the Internal Revenue Code.[28] The Internal Revenue Service (IRS) not only enforces the Code but provides guidance to assist in understanding the rules surrounding tax-exempt organizations.

Qualification as a § 501(c)(3) Organization

There are two advantages to qualifying as a tax-exempt organization under § 501(c)(3) rather than a different section of the Code. First, § 501(c)(3) organizations are eligible for tax-exempt financing. Second, donors who make contributions to § 501(c)(3) organizations can deduct the donation to the fullest extent permitted under the Code.

Organizations may qualify as § 501(c)(3) if they are charitable, religious, educational, or scientific in nature. The IRS has found that the "promotion of health" is a charitable purpose.[29] Therefore, most § 501(c)(3) healthcare organizations qualify as organizations by being both organized and operated for charitable purposes.

To be organized for charitable purposes, an organization must include limits in its articles of incorporation by enumerating the charitable purposes and disallowing all but an insubstantial part of its activities any activities that are (1) not in furtherance of the charitable purposes, (2) attempting to influence legislation, (3) influencing or participating in a political campaign of a candidate for public office, or (4) have objectives that characterize it as an action organization. Further, the organization must be required to distribute its assets upon dissolution to one or more exempt purposes.

A § 501(c)(3) organization must also comply with the operational requirements of § 501(c)(3). The organization must meet four requirements:

1. Primary purpose: An organization must engage "primarily" in activities that accomplish one or more exempt purposes, and no more than an insubstantial part of its activities can be toward a nonexempt purpose.
2. Private inurement: The net earnings of an organization may not "inure" to the benefit of private shareholders or individuals.
3. Public benefit: The organization must serve a public rather than a private interest and may not be operated for the benefit of private interests, such as individuals, the creator, shareholders, or other persons controlled by such private interests.
4. Lobbying or political activities: No substantial part of an organization's activities may constitute the carrying on of propaganda or attempting to influence legislation or participate in a political campaign on behalf of any candidate for public office.

Public Charity Versus Private Foundation

Organizations with § 501(c)(3) status are either public charity or private foundation organizations. Being a private foundation has a number of disadvantages. For example, private foundations are taxed on investment income and have certain restrictions on how their funds may be spent and invested. In addition, tax deductions on individual contributions to private foundations are more limited than those to public charities. Finally, private foundations must file additional reports not required of public charities.

Every § 501(c)(3) organization is considered a "private foundation" unless it fits within one of the specific forms of "public charity."[30] A § 501(c)(3) organization may meet public charity requirements as a result of its status, if such organization is a church, a hospital, an educational organization, or a governmental unit. In addition, an organization qualifies as a public charity if it is "publicly supported"—that is, if it normally receives at least one-third of its total support from the government and/or public donations. Finally, if a § 501(c)(3) organization is not publicly supported and does not meet a status requirement, it may be a public charity only where it is operated exclusively for the benefit of one or more organizations that independently qualify as a public charity and is operated, supervised, or controlled by such organization.

As noted above, hospitals with § 501(c)(3) status automatically qualify as public charities. In regulations, the IRS has defined "hospital" to include not only traditional inpatient hospitals but also rehabilitation institutions, outpatient clinics, or community mental health or drug treatment centers if the principal purpose or function is the providing of hospital care or the treatment of any physical or mental disability or condition,

[28] 26 U.S.C. § 501(c)(3).

[29] Rev. Rul. 69-545, 1969-2 C.B. 117.

[30] 26 U.S.C. § 509.

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whether on an inpatient or outpatient basis, provided that the cost of such treatment is deductible to the patient. However, a hospital in this context does not include long-term care facilities that do not provide medical services or healthcare management companies.[31]

Charity Care

As stated above, the IRS has found that the "promotion of health" is a charitable purpose. In addition, the tax-exempt organization does not need to provide a direct benefit to all members of the community, but the organization must ensure that the group of potential beneficiaries of the organization is not so small that there is no benefit to the community. This "community benefit" standard is further defined by the IRS to include a hospital that operates an emergency room open to everyone regardless of means or healthcare coverage and that provides nonemergency hospital care to everyone in the community able to pay for such care.[32]

The IRS has not historically required nonemergency charity care as a requirement for a hospital's tax-exempt status. However, for other healthcare entities or a hospital without an emergency department, the IRS has indicated that a charity care policy is an important factor in determination of the organization's tax-exempt status.

In addition, the community benefit standard also includes who controls the operations of the organization. Specifically, who sits on the organization's board of directors, whether the hospital has an open medical staff policy, whether it accepts and treats Medicare and Medicaid patients, and whether it uses surplus funds to improve facilities, equipment, and patient care and to provide health-related education, training, and research are fundamental to the community benefit analysis.

Beginning in 2010 and 2011 the Health Care Reform Act imposes new requirements on nonprofit hospitals related to charity care requirements.[33] Specifically, nonprofit hospitals will be required to (1) engage in a mandated triennial community health-needs assessment and related plan to address the community's needs, (2) maintain written financial assistance and emergency care policies, (3) charge uninsured patients only the lowest rate charged to insured patients for emergency or other medically necessary care, and (4) make reasonable efforts to determine whether a patient is eligible for the above financial assistance policy before engaging in extraordinary measures for collection.

The new rules apply to any "hospital organization," defined as any organization that operates a facility that is required to be licensed or registered as a hospital under state law, as well as any organization that the Secretary of the Treasury Department determines provides hospital care as the principal basis for its tax exemption. For a "hospital organization" that operates more than one hospital facility, the organization must meet the new requirements separately for each facility and will lose § 501(c)(3) status with respect to any facility that does not separately meet the new requirements.

Unrelated Business Income Tax

If a § 501(c)(3) organization realizes income from activities outside of its specific exempt functions, it may have to pay tax on that amount, referred to as unrelated business income tax (UBIT). UBIT prevents tax-exempt organizations from unfairly competing with for-profit entities in the marketplace.

UBIT is imposed on income to a tax-exempt organization from an unrelated trade or business.[34] An unrelated trade or business exists where three factors are met:

1. The activity constitutes a trade or business, generally meaning the sale of goods or services in exchange for income.
2. The activity is regularly carried on, meaning that it is conducted in a manner comparable with competing for-profit taxable entities. An activity is not regularly carried on if it only occurs once per year.
3. The activity is not substantially related to the exempt purposes of the organization. An activity is substantially related where there is a substantial causal relationship between the activity and the exempt purpose. The IRS has found that just because an activity is a source of funding for an exempt purpose does not make it substantially related.

[31]Treas. Reg. § 1.170A-9(c)(1).

[32]Rev. Rul. 69-545, 1969-2 C.B. 117.

[33]Patient Protection and Affordable Care Act, Pub. Law No. 111-148 § 9007 (2010).

[34]26 U.S.C. §§ 511-14.

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Certain activities are specifically excluded from the definition of "unrelated trade or business" under the Code. Specifically, a trade or business in which substantially all work is performed by volunteers, carried on for the convenience of an organization's members, students, patients, officer, or employees; the sale of goods, substantially all of which are **donations**; certain entertainment or trade show activities; and a few other very narrow exceptions.

A tax-exempt healthcare organization's income is *not* subject to UBIT if the income is in the form of **dividends**, interest, royalties, certain rent of real property, gain from the sale of noninventory property, or research income. Tax-exempt organizations must report UBIT on their annual Form 990 filings with the IRS, discussed below. In addition, excessive UBIT could lead to loss of tax-exempt status. Generally, an organization should be concerned where more than one-fourth of its total revenues are derived from unrelated trade or business activities.

The IRS has specifically commented on a number of business activities in which healthcare organizations commonly participate. For example, the IRS has found that both pharmacy sales and laboratory tests performed by a tax-exempt healthcare organization are substantially related to exempt purposes and therefore income is exempt from taxes, where sales are to, or tests performed for, patients. However, sales to nonpatients are subject to UBIT. The IRS defined patients as people who are (1) admitted as inpatients, (2) treated at the entity's outpatient facilities, (3) referred to an outpatient facility for diagnosis or treatment, (4) refilling prescriptions received during treatment as a patient, (5) receiving medical services as part of a hospital-administered home care program, or (6) receiving medical services in a hospital-affiliated extended care facility.

In addition, the IRS generally has found that cafeterias, gift shops, and parking facilities at tax-exempt hospitals are substantially related to the hospital's exempt purpose. However, management or consulting to unrelated entities generally results in unrelated taxable income. Income from billing services may or may not be taxable, based on the facts.

Form 990

Tax-exempt § 501(c)(3) healthcare organizations are required to file an annual disclosure form with the IRS called a Form 990. Information provided to the IRS on the Form 990 is open for public inspection, with the exception of the organization's contributors. The organization must make available its three most recent Form 990s for inspection and copying at certain offices of the organization. In addition, Form 990-T, the annual return form for UBIT, is subject to the same public disclosure requirements as the Form 990 information return.[35]

The Form 990 has evolved over the years, through statutory changes, input through public comment, and based on information gathered by the IRS when auditing tax-exempt organizations. In December 2007 the IRS issued a significantly redesigned Form 990, which has individualized schedules depending on the type of tax-exempt organization. The new Schedule H, specific to healthcare organizations, requires more detail regarding how the organization is satisfying the community benefit standard, discussed above.

An organization that is required to file a Form 990 but fails to do so is penalized $20 per day or $100 per day if the organization has annual gross receipts exceeding $1 million. In addition, if the IRS makes a written demand for filing a Form 990 on reasonable, future date after one failure to file, the individuals responsible for the failure to meet the second deadline will be personally liable for $10 per day of continued failure.[36]

RED FLAGS RULE

On November 9, 2007, the Federal Trade Commission (FTC), the federal bank regulatory agencies, and the National Credit Union Administration jointly published a final rule on Identity Theft Red Flags.[37] This rule, promulgated pursuant to the Fair and Accurate Credit Transactions Act of 2003, requires financial institutions and creditors to develop and implement written "identity theft prevention programs." The programs must provide for the identification, detection, and response to patterns, practices, or specific activities—known as "red flags"—that could indicate identity theft. Although the final rule became effective on January 1, 2008, full compliance with the rule is not required until December 31, 2010.

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[35] 26 U.S.C. §§ 6033 & 6104.

[36] 26 U.S.C. § 6652.

[37] 16 C.F.R. § 681.1 *et seq*.

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The Rule applies to "financial institutions" and "creditors." It is important to look closely at how the Rule defines those terms because they apply to groups that might not typically use those words to describe themselves. Whether a business or organization is a financial institution or creditor is not based on the line of work but whether the business activities fall within the definitions in the law. The Rule gives examples of businesses and organizations that probably are covered, but the list is not exhaustive.

Entities Subject To the Rule

The Rule defines a "financial institution" as

- A state or national bank
- A state or federal savings and loan association
- A mutual savings bank
- A state or federal credit union
- Any other entity that directly or indirectly holds a "transaction account" belonging to a consumer

Transaction accounts are deposits or accounts from which a consumer can make payments or transfers to third parties. The FTC's jurisdiction extends to state-chartered credit unions and other institutions that hold transaction accounts—for example, mutual funds that offer accounts with check writing or debit card privileges or other businesses that offer accounts where consumers can make payments or transfers to third parties.

Under the Rule the definition of "creditor" is broad and includes businesses or organizations that regularly provide goods or services first and allow customers to pay later. Examples of groups that may fall within this definition are utilities, accountants, and other professionals, telecommunications companies, and healthcare providers. The definition also covers businesses or organizations that regularly grant loans, arrange for loans or the extension of credit, or make credit decisions. Examples include finance companies, mortgage brokers, and automobile dealers or retailers that offer financing or collect or process credit applications for third-party lenders. In addition, the definition includes anyone who regularly participates in the decision to extend, renew, or continue credit, including setting the terms of credit. For example, a third-party debt collector who regularly renegotiates the terms of a debt is a creditor under the Rule.

Compliance Issues

The Rule begins at the point where data security ends. An identity thief typically uses the personal information of another to get goods or services from unsuspecting businesses and has no intention of paying the bill. Companies with procedures to look for and respond to the "red flags" that an identity thief is trying to use someone else's information can mitigate losses to businesses and frustration to the victims of identity theft.

Under the Rules a healthcare provider is considered a "**creditor**." A creditor is required to (1) periodically conduct a risk assessment to determine whether it offers or maintains covered accounts; (2) establish a written identity theft prevention program that is designed to detect, prevent, and mitigate identity theft in connection with the opening of a covered account or any existing covered account (the "Program"); and (3) administer the Program. The regulations require that a Program be appropriate to the size and complexity of the creditor and the nature and scope of its activities and include reasonable policies and procedures to (1) identify relevant red flags for the covered accounts, (2) detect red flags that have been incorporated into the Program, (3) respond appropriately to any red flags that are detected to prevent and mitigate identity theft, and (4) ensure the Program is updated periodically to reflect changes in risks to customers and to the safety and soundness of the creditor from identity theft.

Penalties

The FTC can seek both monetary civil penalties and injunctive relief for violations of the Rule. Where the complaint seeks civil penalties, the U.S. Department of Justice typically files the lawsuit in federal court, on behalf of the FTC. Currently, the law sets $3,500 as the maximum civil penalty per violation. Each instance in which the company has violated the Rule is a separate violation. Injunctive relief in cases like this often requires the parties being sued to comply with the law in the future and provide reports, retain documents, and take other steps to ensure compliance with both the Rule and the court order. Failure to comply with the court order could subject the parties to further penalties and injunctive relief.

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ANTITRUST IN HEALTH CARE

The purpose of antitrust laws is to promote a competitive, free marketplace; these laws are intended to protect the public from the adverse effects of monopoly power. The federal government and virtually all state governments have antitrust laws, which reflect a public policy principle that a competitive marketplace protects consumers, restrains private economic power, and generally produces the best allocation of quality goods and services at the lowest prices.

The three main sources of federal antitrust law are the Sherman Act, the Clayton Act, and the Federal Trade Commission Act. Section 1 of the Sherman Act prohibits all conspiracies or agreements that restrain trade.[38] Section 7 of the Clayton Act prohibits all mergers and acquisitions of stock or assets that may substantially lessen competition or that tend to create a monopoly.[39] Section 5 of the Federal Trade Commission Act prohibits unfair methods of competition.[40]

Sherman Act

As interpreted by the courts, Section 1 of the Sherman Act applies to agreements that unreasonably restrain trade, which may include agreements or conspiracies to fix prices, divide market territories or groups of customers, boycott other firms, or use coercive tactics with the intent and effect of injuring competition.

The Sherman Act applies to virtually all businesses in the country, including healthcare providers. As of this writing, the insurance industry is a significant exception to antitrust law, although the House of Representatives has passed a bill to repeal the exception. The Sherman Act condemns any conduct that causes inefficiencies resulting in higher prices or lower quality of services to the ultimate consumer. Most business practices that are condemned under the Sherman Act are justified from a business standpoint but deemed illegal because they "unreasonably" restrain trade (i.e., the anticompetitive effect of the business practices outweigh their probusiness justifications). An example of such a practice would be a "noncompete" clause prohibiting the seller of a business from ever engaging in a similar business activity. Although such a noncompete clause is justified on business grounds for the buyer, the clause's provision could unreasonably restrain trade. Noncompete clauses are generally accepted if they are geographically and temporally reasonable. Some practices, however, are condemned because there are no acceptable justifications for the conduct. An example of such a practice is an agreement among competitors to fix prices.

Price-fixing concerns arise in the healthcare setting where physician organizations (POs), physician hospital organizations (PHOs), or other networks of otherwise unaffiliated healthcare providers negotiate with payers as a group. Keep in mind, where healthcare providers are all owned by the same parent, sharing price information is always acceptable. However, otherwise independent providers negotiating as a unit without meeting certain requirements is considered price fixing and violates antitrust law. From an antitrust perspective, these providers may be viewed as competitors that are jointly setting the price they will charge for their services. However, there are a number of contexts in which POs and PHOs can legally assist providers with negotiating payer agreements, which are discussed further below.

Enforcement of antitrust laws is jointly shared by the Department of Justice and the FTC, and the agencies have largely overlapping jurisdiction. Over the years the agencies have developed expertise in particular industries or markets. For example, the FTC devotes most of its resources to certain segments of the economy, including those where consumer spending is high: health care, pharmaceuticals, professional services, food, energy, and certain high-tech industries like computer technology and Internet services. When issuing guidance the agencies have historically come to an agreement on how to enforce a certain area of antitrust law.

A merger or joint venture between two or more hospitals may be investigated by either the Department of Justice or FTC under the Clayton Act. These agencies have established a procedure for deciding, on the basis of staff expertise, prior dealings with the parties involved, and caseload, which agency investigates a particular merger or joint venture. Although either agency may investigate a merger or joint venture for civil violations, once criminal conduct is suspected, the case is referred to the Department of Justice. Private parties and state attorney generals may also sue to block mergers or joint ventures under either the Sherman or Clayton Act.

[38] 15 U.S.C. § 1.

[39] 15 U.S.C. § 18.

[40] 15 U.S.C. § 45.

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Some actions by providers, such as agreements among firms to fix prices or divide markets, are on their face antitrust violations and are called "per se" violations. Actions not considered per se violations are evaluated under the "rule of reason."

The Hart-Scott-Rodino Antitrust Improvements Act of 1976 requires that parties notify both FTC and Department of Justice of certain mergers, acquisitions, joint ventures, or tender offers before consummation of the agreements.[41] This filing requirement applies to all parties engaged in such activities, including hospitals, and covers agreements in which the acquiring entity has net sales or total assets of at least $100 million and the entity being acquired has assets of at least $10 million. Based on information provided in these filings, the Department of Justice and FTC decide whether to allow the proposed merger to proceed or to open a preliminary investigation. If the preliminary investigation indicates that a potential violation exists, FTC or Department of Justice may issue a second request for additional information to review before deciding whether to challenge the proposed merger or collaboration as a potential violation of antitrust laws.

Reviews of mergers might include interviews of competitors and analysis of the marketplace. When weak competitors are interviewed by the Department of Justice, however, they are often cowed by the specter of the larger competitor that could be either their future partner or a monolith ready to put the weaker sister out of business. Other providers might be inclined to give unwarranted opposition because they do not want the increased competition.

In August 1996 the Department of Justice and FTC issued their current guidelines, *Statements of Antitrust Enforcement Policy in Health Care*, outlining general enforcement policies regarding certain types of practices of healthcare providers. The 1996 *Statements* specify how agencies will apply the antitrust laws to nine types of conduct of hospitals, physicians, nursing homes, and other providers, such as joint purchasing, information exchange, and formation of PHOs.

The ninth policy statement applies to any organization composed of various types of providers that combine to jointly offer healthcare services, including POs and PHOs. According to the statement, if members of the network offer only complementary or unrelated services, they do not compete and there are no antitrust concerns. If the network is formed by a group composed of competing providers, however, the antitrust agencies are concerned that the network may interfere with competition and with the market efficiencies that competition protects. To address these concerns, the antitrust agencies identified ways in which PHOs and others may be structured to create incentives for providers to operate efficiently even in the absence of competition.

One way in which sharing competitive information within a network is acceptable under antitrust principles is when participating providers share "substantial" financial risk, referred to as "financial integration." The antitrust agencies regard these providers as risk sharing if the compensation each receives through the network depends on the overall performance of the network as a whole. For example, a network may negotiate capitated payer agreements with HMOs because the network is provided a flat amount per beneficiary and as a result bears the financial risk when providing services. Alternatively, a PHO could receive a fixed amount for a "package" of complex or extended services delivered by its participating providers, even though services may require numerous providers and the aggregate cost of furnishing services might vary significantly from patient to patient. For example, a system consisting of a hospital, obstetricians/gynecologists, pediatricians, and anesthesiologists could collectively agree to furnish all necessary prenatal, delivery, and postdelivery services to enrollees for a fixed fee.

As an alternative, the antitrust agencies suggest that a network may be able to adopt and strictly enforce clinical standards that guarantee the efficient delivery of care even in the absence of risk sharing or competition, referred to as "clinical integration." The FTC has approved a number of existing clinically integrated networks through a series of advisory opinions, which have provided guidance as to what exactly is required to jointly negotiate with payers. The lessons learned from these opinions include the importance of evidence-based clinical practice guidelines, including data collection mechanisms for measuring performance; participation and buy-in from all physicians, including primary care and specialists; and that the network not be exclusive and not have market power in the community. With the increased incentives for adopting electronic health records, some PHOs and POs have used the opportunity to begin adopting the data collection systems to implement the required systems for analyzing network participant performance

[41] 15 U.S.C. § 18a.

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against clinical standards toward implementing a fully clinically integrated panel.

Where there is neither financial integration nor clinical integration, a network may not jointly contract for its providers, for example, for a general fee-for-service payer agreement. However, the "messenger model" is a means of allowing networks to assist their providers in contracting without joint negotiation. An acceptable messenger model exists where there are significant safeguards against providers sharing rate information with one another. When the network and payer want to enter into an agreement for provider services, the payer suggests a certain compensation level, which the network "messengers" to its providers. Each provider then either accepts the offer or counters with its own offer. In this way the network assists providers with payer contracting, but rate information is not shared in violation of antitrust law.

Clayton Act

Section 7 of the Clayton Act prohibits mergers and acquisitions that may substantially lessen competition "in any line of commerce … in any section of the country."[42] Enacted in 1914 the Clayton Act made price discrimination, tying and exclusive dealing contracts, mergers of competing companies, and interlocking directorates illegal but not criminal.

In 1950 Congress modified Section 7 of the Clayton Act with the Celler-Kefauver Act, proscribing one company from acquiring part or all assets of a competitor where such an action could result in substantially lessening competition or creating a monopoly. In 1980 Congress further modified Section 7 of the Clayton Act, extending its reach to any person subject to FTC jurisdiction, thus adding partnerships and sole proprietorships.

In the 1992 Department of Justice/FTC *Horizontal Merger Guidelines*, the agencies described their enforcement policy relative to the Sherman, Clayton, and FTC Acts and emphasized the need to apply the guidelines to the specific facts of each case. The agencies applied a five-step methodology outlined in the guidelines for analyzing the specific facts of each merger.

The guidelines provide a general analytical methodology used by the agencies in deciding if the agencies will challenge a merger. First, the agencies determine whether the merger will increase concentration in a market already concentrated. If not, then the analysis generally will not proceed any further. However, if so, then the agencies will assess if increased concentration raises anticompetitive concerns. Next, the agencies will consider whether another competitor can make a timely market entry to deter or counteract the competitive concern. Then, the agencies will assess any efficiencies gained, not possible through any other means other than the merger. Finally, the agencies will ask if either merging party probably will fail or absent the merger, resulting in the failing party's assets exiting the market.

The 1996 *Statements of Antitrust Enforcement Policy in Health Care: Statement 1* provides specific guidelines in the healthcare area to prevent antitrust concerns from deterring activities potentially resulting in lower healthcare costs, increased competition, and increased consumer choice by addressing the issue of mergers among hospitals.

The agencies have suggested that many potential hospital mergers pose little competitive concerns and require less analysis. In fact, some providers argue that the increase in enforcement has been concurrent with the federal governments desire to bring down costs in the healthcare environment. The providers desire to get better payments caused them to band together. Thus, increased enforcement leads to the balance of power being shifted to the payers. To further facilitate competitive analysis, the agencies have created so-called antitrust safety zones in which the agencies will not challenge mergers if the hospitals meet certain requirements.

The agencies have stressed that if the merging hospitals fall outside the safety zone, they may still not challenge the proposed merger and they will apply the five-step analytical process described earlier in the 1992 *Horizontal Merger Guidelines*. After applying this rule of reason analysis, the agencies have not challenged mergers in the following situations: where the merger did not increase market power because of the postmerger presence of strong competitors, where the merged hospitals could achieve cost savings not otherwise possible, and where the merger includes a failing hospital likely to exit the market otherwise. Hospitals falling outside the safety zone can seek agency review by the Department of Justice or the FTC before the merger, for a preliminary determination of the agencies' probability of challenging the mergers.

[42] 15 U.S.C. § 18.

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EMERGENCY MEDICAL TRANSFER AND ACTIVE LABOR ACT

The Emergency Medical Treatment and Active Labor Act (EMTALA) requires all Medicare- or Medicaid-participating hospitals with an emergency department to provide appropriate medical screening to each patient requesting emergency care to determine whehter the patient requires such care.[43] Originally passed by Congress in 1985 as part of the Consolidated Omnibus Budget Reconciliation Act of 1985, EMTALA often is referred to as the "antidumping law" because it prohibits hospitals from transferring an emergency patient to another hospital simply because of the patient's inability to pay.

If emergency care is needed, the statute requires the hospital to medically stabilize the patient (assuming the hospital has the medical capabilities to do so), irrespective of the patient's ability to pay. Hospitals are prohibited from posting payment information in their emergency rooms. Patients who have medical conditions that the hospital is incapable of stabilizing (as certified by a physician) or who ask to be transferred to another facility before the hospital can stabilize their condition must be transferred to another facility in accordance with specific requirements of EMTALA. If after evaluation the patient is found not to have a medical emergency, the hospital's obligation to the patient under EMTALA ends.

EMTALA also requires that a Medicare- or Medicaid-participating hospital ensures that emergency department staff do not engage the patient in discussion regarding his or her financial or insurance information before conducting the medical screening examination and stabilization of the emergency condition. Hospitals may, however, commence normal registration procedures, which may include asking whether the patient carries insurance, as long as such procedures do not delay screening and stabilization.

To avoid EMTALA violations, hospitals should perform the following:

- Require all clinical, administrative, and contract staff to review and understand the EMTALA requirements.
- Ensure that all patients who decide to leave the hospital without receiving treatment or withdraw their request for emergency treatment are offered a medical examination and treatment within the hospital facilities before they leave, and that staff who can identify and stabilize a patient's medical condition always are available in the hospital to provide these services within the limits of the hospital staff's medical capabilities.
- Ensure that all reasonable steps are taken to obtain the patient's written informed consent to refuse any examination or treatment services, and that the patient's medical record contains a description of the examination, treatment, or both as well as documentation of the patient's refusal to receive emergency care.
- Ensure that emergency department staff have reviewed and understand all statutory requirements regarding transfer of patients to another facility.
- Instruct hospital staff to refrain from asking patients to complete financial forms or inquiring about patients' financial or insurance status, even if the patient engages the staff in conversation, until the medical screening examination has been conducted and the patient's emergency medical condition has been stabilized.

[43] 42 U.S.C. 1395dd.

SUMMARY

This chapter has provided a general overview of the laws and regulations that govern the healthcare industry. A financial manager can expect to be confronted by such legal issues and should plan to address them on a regular basis. The Health Care Reform Act of 2010 will usher in a period of even greater regulatory oversight as access to health care is expanded and payment methods are dramatically altered. The failure to understand the importance of these legal requirements can put an organization at significant financial risk and expose individuals to personal liability. Corporate compliance should be considered an essential element of every healthcare organization's culture and the foundation of its financial security.

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ASSIGNMENTS

1. Identify at least three federal statutes that may be implicated by the proposed restructuring of SSRH's cardiovascular service line.

2. How much reliance should a CFO place upon a CEO's assertion that a novel physician-hospital relationship has been approved by DHHS-OIG? How can a CFO be sure that a particular proposal is legally acceptable?

3. How is the Patient Protection and Affordable Care Act of 2010 (the "Health Care Reform Act") likely to reshape financial arrangements between hospitals, physicians, and other providers if Medicare makes a single payment for all care received by a beneficiary from 72 hours before admission to 30 days after discharge from an inpatient facility?

4. If Bravo wanted to see for himself whether SSRH's cardiovascular program was in fact at risk of being found out of compliance with Medicare's conditions of participation, how should he go about getting relevant patient documentation without violating the privacy requirements of HIPAA?

5. Based on his legal concerns about the proposed restructuring, Bravo believes that SSRH would be on firmer legal ground if the relationship with CCI was limited to private pay patients only and if HMO, Inc., a major managed care payor in the market, was also involved in the quality improvement program. Is he right, and why?

6. What suggestions would you have to improve SSRH's corporate compliance program given that Devine's proposal may never have been reviewed by legal counsel before going to the SSRH board?

7. If SSRH implemented a policy that heart failure patients could not be received by the hospital's emergency department unless the patient had first contacted a CCI cardiologist, would EMTALA be implicated? How would you confirm that the hospital is not at risk of an EMTALA violation?

8. What business risk does the Red Flags Rule protect against? Who is covered by the Red Flags Rule? How does a subject entity demonstrate compliance with the Red Flags Rule?

9. Describe "internal control" as it relates to a corporate compliance program. What are the five interrelated components of internal control?

10. Compare and contrast Medicare and Medicaid.

11. Discuss the various types of third-party payors.

12. What are the four operational requirements for a § 501(c)(3) tax-exempt organization?

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SOLUTIONS AND ANSWERS

1. A number of federal statutes may be implicated by the proposed restructuring of SSRH's cardiovascular service line, including (1) the Anti-Kickback Statute, (2) the Stark Law, (3) the False Claims Act, (4) the Internal Revenue Code, and (5) Patient Protection and Affordable Care Act.

2. The CFO should have a novel physician-hospital relationship reviewed by counsel. It is likely that the CEO is referring to an Advisory Opinion in which the OIG has reviewed a specific arrangement and indicated that the arrangement has a low risk for violating the Anti-Kickback Statute based on a certain set of facts. To ensure that SSRH's proposed arrangement has the same low risk as the arrangement approved by the OIG, the SSRH proposed arrangement must meet all of the requirements and have all of the safeguards indicated in the Advisory Opinion. All such arrangements should be reviewed by counsel to minimize risk of the significant civil and criminal penalties possible for any such violation.

3. Under the current Medicare reimbursement system, hospitals are reimbursed one amount for each inpatient admission at a given rate based on the characteristics and diagnosis of the patient. Once the patient is discharged, Medicare reimburses outpatient providers for services to the patient directly per procedure or office visit. Therefore, hospitals and outpatient providers will need to determine how to divide one payment for all services provided throughout the 33 day period, for services provided regardless of provider or location. It is likely that as the Health Care Reform Act is implemented, hospitals and outpatient providers will merge for ease of distribution of reimbursement, but also to more efficiently negotiate how a bundled payment is divided. Finally, post–acute care providers, such as nursing homes and home health providers, will have to work with hospitals and other outpatient providers to negotiate how they will be reimbursed for services provided within the 33 day period for which a bundled payment is provided.

4. Bravo is the CFO of a hospital, which is a covered entity under HIPAA. A covered entity is permitted to use protected health information for healthcare operations. Ensuring that a healthcare service line is in compliance with Medicare's conditions of participation is a part of the healthcare operations of the hospital.

   If Bravo requires outside assistance of a consultant or attorney to determine whether the Medicare conditions of participation are being met, such consultant or attorney would be a business associate under HIPAA. Therefore, before any patient information could be transferred, the consultant and SSRH must execute a business associate agreement ensuring that the protected health information is properly secured in compliance with HIPAA requirements.

5. Although Bravo is technically correct that the Anti-Kickback Statute and the Stark Law apply only where Medicare or another federal healthcare program is paying for healthcare services or items, such a plan is difficult and risky in practice. If CCI is truely limited to private pay patients, the arrangement need not meet the requirements of the Stark Law. The Anti-Kickback Statute need only be considered in the context of whether the arrangement could be used as remuneration in exchange for other referrals of Medicare or Medicaid beneficiaries.

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However, there is always a risk that patients may have Medicare as a secondary payor and the hospital would mistakenly bill Medicare or other government payor for services provided under the CCI arrangement. In addition, if the relationship with CCI includes HMO, Inc. as a third-party payor, it is very likely that HMO, Inc. includes a Medicare Advantage plan, and/or a Medicaid managed care plan, both of which would implicate Stark and the Anti-Kickback Statute. Therefore, limiting a service line to private payors in order to avoid the requirements of the Stark Law and the Anti-Kickback Statute is not the safest way to try to comply with the laws.

6. SSRH's corporate compliance program should require all new arrangements or affiliations with independent physicians or physician groups to be reviewed by counsel, especially when the relationship or affiliation is novel, and when the physicians are in a position to refer to the hospital.

7. EMTALA requires that if emergency care is needed, a hospital with an emergency department must medically stabilize the patient. Therefore, to limit the hospital's risk of an EMTALA violation, the emergency department should ensure that a patient is stable before inquiring whether the patient contacted a CCI cardiologist. SSRH is free to transfer the patient once the patient's condition has been stabilized.

8. The Red Flags Rule protects against the use of stolen identification for the purchase of goods and services. "Financial institutions" and "creditors" are subject to the Red Flags Rule. A healthcare entity is likely a creditor if it permits deferred payment of debt. To demonstrate compliance, an entity subject to the Red Flags Rule must (1) periodically conduct a risk assessment to determine whether it offers or maintains covered accounts; (2) establish a written identity theft prevention program that is designed to detect, prevent, and mitigate identity theft in connection with the opening of a covered account or any existing covered account (the "Program"); and (3) administer the Program. The regulations require that a Program be appropriate to the size and complexity of the creditor and the nature and scope of its activities and include reasonable policies and procedures to (1) identify relevant red flags for the covered accounts, (2) detect red flags that have been incorporated into the Program, (3) respond appropriately to any red flags that are detected to prevent and mitigate identity theft, and (4) ensure the Program is updated periodically to reflect changes in risks to customers and to the safety and soundness of the creditor from identity theft.

9. "Internal control" is a process undertaken by an entity's board of directors, management, and other personnel designed to provide reasonable assurance regarding the achievement of objectives in the following categories: reliability of financial reporting, effectiveness and efficiency of operations, and compliance with applicable laws and regulations. The five interrelated components of internal control are (1) establishing a control environment that sets the tone of an organization; (2) assessment of relevant risks to determine how the risks should be managed; (3) policies and procedures that help ensure management directives are carried out; (4) identification, capture, and exchange of information in a form and time frame that enable people to carry out their responsibilities; (5) monitoring the quality of internal control performance over time.

10. Medicare is a social insurance program that provides health insurance coverage for individuals aged 65 and over and individuals with permanent disabilities. Benefits include hospital insurance, doctor's services, and prescription drug coverage. Medicaid is a safety net insurance program that provides health insurance coverage to poor and very sick individuals. The single largest expenditure under Medicaid is for nursing home care. While Medicare is funded and administered through the federal government, Medicaid is funded by the federal and state governments and is administered by state government.

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11. Generally, third-party payors are either public or private. Public payors include Medicare, Medicaid, the Federal Employees Health Benefit Program, and the State Children's Health Insurance Program. There are specific eligibility requirements for each program and some degree of cost sharing between the government and the individual beneficiary. Private payors are non-governmental entities, regulated by state law, that offer packages of health insurance benefits to businesses and individuals. The types of plans include traditional indemnity fee-for-service plans, managed care plans, health maintenance organizations, and self-insured plans.

12. The four operational requirements for a § 501(c)(3) tax-exempt organization are (1) the organization must engage "primarily" in activities that accomplish one or more exempt purposes, and no more than an insubstantial part of its activities can be toward a nonexempt purpose; (2) the net earnings of an organization may not "inure" to the benefit of private shareholders or individuals; (3) the organization must serve a public rather than a private interest and may not be operated for the benefit of private interests, such as individuals, the creator, shareholders, or other persons controlled by such private interests; and (4) no substantial part of an organization's activities may constitute the carrying on of propaganda or attempting to influence legislation or participate in a political campaign on behalf of any candidate for public office.

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