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 an HCO.
2. Appreciate the consequences of failing to manage the finances of an HCO with 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 (Affordable Care Act, or ACA)[1] as it relates to financial management in the post-reform environment. Describe how the ACA's three pillars—insurance reforms, care delivery system reforms, and financial savings reforms—are changing the American healthcare system.
6. Identify the most common federal regulatory issues, such as fraud and abuse, Stark Law, HIPAA, EMTALA, and IRS requirements for tax-exempt organizations, as well as less common concerns that arise under the antitrust laws and federal and state laws regulating third-party payers.
7. Be prepared to respond to a compliance audit or investigation, particularly when the subject of that inquiry includes financial records.

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

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 for 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 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" had 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 PowerPoint 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.

Also included in Bravo's proposal is a description of two potential new health information technology (HIT) initiatives he received from SSRH's Chief Information Officer Tiffany Technophile. The first proposal is a telemedicine initiative that would enable select SSRH-affiliated providers to conduct remote appointments with their patients via telemedicine. The provider–patient interaction would be housed on the platform of a third-party telemedicine company.

Technophile's second proposal is for the creation of a software application that would allow patients to upload certain physical fitness data that is collected through "wearable" devices (e.g., smartwatches, step monitors, and other activity trackers). Using this data (which would be accessible via the hospital's internal network), SSRH-affiliated providers could develop individualized wellness plans tailored to each patient's needs and desires. In

addition, SSRH plans on selling this data to reputable buyers (e.g., insurance companies and pharmaceutical researchers), enabling SSRH to fund several badly needed construction projects.

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.

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 ACA 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 ACA's most significant provisions were designed to address long-standing problems with the availability and affordability of health insurance. Most importantly, as discussed later, the ACA imposes important new requirements on insurance plans, particularly individual and small group markets, as well as imposes a tax on certain individuals who fail to purchase some form of health insurance.

The ACA also sets the stage for systemic changes in how health care is delivered by moving away from a fee-for-service payment to a model that rewards healthcare providers who can achieve superior outcomes for their patients. Since the enactment of the ACA, the federal government has signaled its intention to make value-based payment its dominant form of reimbursement. In response to this emphasis on quality, cost-effective care, providers have begun to accept the concept of delivering care via accountable care organizations (ACOs)—networks of providers sharing financial and medical responsibility for select populations of patients. ACO participants are eligible to share in savings realized as a result of delivering cost-effective care. As of early 2016, ACOs covered more than 23 million lives in the United States, a number that is expected to grow to 105 million by 2020.

While the effectiveness of certain ACA reforms remains uncertain, the number of Americans with health insurance has continued to climb, especially in states that expanded Medicaid coverage using ACA incentives. Nationally, the percentage of uninsured persons is the lowest it has been in years. This has been especially true among young adults (ages 19–25) whose uninsured rate fell 52% between the ACA's first open enrollment and the end of the third quarter of 2015. The participation of young adults who generally impose a lesser claims burden on the insurance system is critical to the ACA's overall success.

Despite continued political debate over the ACA, many of its payment reforms have rapidly become permanent fixtures of the American health system. Consequently, those entrusted with the financial management of healthcare organizations (HCOs) must continue to remain attentive to ongoing efforts to implement and refine the provisions of this law.

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.
- 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 a 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 experts in federal billing regulations.
- Development of a 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).

In addition, an organization should routinely assess the areas of compliance risk it can reasonably be expected to encounter. For example, almost every healthcare provider should consider the applicability of laws and regulations pertaining to tax, antitrust, environmental, employment, intellectual property, confidentiality, licensing, and controlled substances.

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.

An HCO is particularly vulnerable to fraudulent activities that are taken on its behalf by employees or agents. Many of these are commonplace but can result in considerable economic and reputational harm to the institution. For example, billing for services provided by inadequately supervised medical residents could result in liability under the False Claims Act. Without a properly enforced compliance plan, relatively minor infractions left unchecked can result in multimillion-dollar penalties to the organization.

Developing a plan can take anywhere from several months for a small medical practice to a year or longer for a large hospital. However, 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.

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 the shoulders of management.

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 programs should function together to ensure that an organization is soundly managed from both a financial and legal perspective.

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.

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

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 55 million people: 46.3 million people aged 65 and older and another 9 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 15% of the federal budget in 2015 and 23% of national personal health spending in 2014, Medicare is a significant part of both federal spending and healthcare spending in the United States. Medicare is administered by the DHHS Centers for Medicare and 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 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 ("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 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 3 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 disproportionate 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.

For several decades, hospitals were reimbursed under Part B for most outpatient hospital services in accordance with the outpatient prospective payment system (OPPS). However, as a result of the enactment of the Balanced Budget Act of 2015 (BBA), most services administered in a hospital outpatient department (HOPD) will be reimbursed under the Medicare physician fee schedule (MPFS) or the ambulatory surgical center fee schedule (ASCFS), both of which are less generous than OPPS. The BBA's HOPD reforms are an important first step in what many expect will be a wave of site-neutral payment reforms, which seek to reimburse providers according to the service provided, rather than the setting in which the service is provided.

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 ambulatory patient classification (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 OPPS. 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 ($100 in 2016), guidance services, and imaging supervision and interpretation services.

Medicare Part B pays for physician services based on the MPFS, 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. Indicative of federal policy supporting value-based payment, the Medicare Access and CHIP Reauthorization Act of 2015 authorized the payment of providers based on two models that factor in the quality of care, the amount of resources consumed, clinical practice improvement activities, and the meaningful use of certified electronic health record (EHR) technology.

Medicare Appeals

Appeal Rights: Medicare Beneficiaries

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.

Original Medicare 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.

Medicare Part C 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.

Medicare Part D 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 7 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 7 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.

Appeal Rights: Medicare Providers, Physicians, and Other Suppliers

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.

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 $150 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.
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 $1,500 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.

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. The Medicaid program is a federal-state partnership in which the federal government provides matching grants to states to finance care for certain "mandatory" groups of people. So long as they cover these "mandatory" groups to the extent required by federal law, states have broad discretion to vary the terms of their Medicaid programs. Since there is no funding cap on the Medicaid dollars a state can receive, federal funds are permitted to flow to states based on actual need.

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.

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."[3] 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

In part due to the ACA, Medicaid has been dramatically expanded. In 2013, nearly 72.5 million people, including one-fourth of all children, received Medicaid coverage for at least some portion of the year. Without Medicaid, most of its beneficiaries would remain uninsured.

Like Medicare, Medicaid is a major source of funding for the U.S. healthcare system. It is the main source of financing for long-term care, paying 40% of the nation's 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 much of the low-income population also depend on Medicaid.

[3]42 U.S.C. § 1396b.

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.

As noted previously, federal law requires each state to cover certain "mandatory" groups to receive the federal match. Traditionally, such mandatory groups included only 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.

With the passage of the ACA, states were required to expand Medicaid to all nonelderly individuals with income up to 138% of the federal poverty level, or risk losing federal Medicaid payments. In *NFIB v. Sebelius*, however, the United States Supreme Court ruled that Congress could not condition all of a state's Medicaid funding on its willingness to expand Medicaid to these poor, childless adults. The result of this ruling is that if a state chooses to cover childless adults in the way the ACA contemplates, it receives additional funding from the federal government.

Accordingly, in the 32 states and territories that have adopted the Medicaid expansion as of April 2016, adults with an income below 138% of the poverty level are guaranteed coverage through Medicaid. The income thresholds adults must meet to qualify for Medicaid vary by state.[4] The ACA's Medicaid expansion provisions are estimated to result in 18.3 million new Medicaid enrollees by 2021.

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

[4]http://kff.org/health-reform/state-indicator/medicaid-income-eligibility-limits-for-adults-as-a-percent-of-the-federal-poverty-level/

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 healthcare 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.

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.

Waivers of Medicaid Requirements

In general, states are required to comply with certain requirements in order to receive federal matching funds under the Medicaid program. However, the Social Security Act gives the Secretary of DHHS authority to waive certain requirements to allow an experimental, pilot, or demonstration project that promotes the objectives of the Medicaid and Children's Health Insurance programs.[5] Projects eligible for such "section 1115 waivers" include those that expand eligibility to individuals who are not otherwise Medicaid or CHIP eligible, provide services not typically covered by Medicaid, or use innovative service delivery systems that improve care, increase efficiency, and reduce costs. Section 1115 waivers must be budget neutral and generally are for an initial 5-year period followed by an additional 3-year period if the state obtains an extension from DHHS. The ACA requires opportunity for public comment and greater transparency of the section 1115 waiver process.

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."[6]

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.

Together with the ACA, the Health Care and Education Reconciliation Act of 2010 (HCERA) alters Medicaid payment methodology for certain physicians. In 2013 and 2014, HCERA required that physicians practicing in pediatrics, family medicine, or general internal medicine receive reimbursement equal to at least 100% of the Medicare Part B physician fee, meaning that these physicians could not be paid a smaller fee for seeing Medicaid patients than they would be for seeing Medicare patients. In light of the shortage of practitioners in these areas, it is likely that Congress and agencies will consider exploring ways to attract and retain providers by devising generous reimbursement models.

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.

Because Congress expected the ACA to expand coverage (reducing uncompensated care), it included a provision in that law that phases out DSH payments over time. These phase-outs have had a significant impact on safety-net hospitals, especially in states where Medicaid has not been expanded. Unless Congress acts to correct this unintended consequence of the ACA, it is likely that hospitals in states

[5] 42 U.S.C. §1315(a).

[6] 42 U.S.C. § 1396(a)(30)(A).

where Medicaid has not been expanded will see their uncompensated care costs continue to increase.

Learning Objective 5

Be aware of the most important aspects of the ACA as it relates to financial management in the post-reform environment.

Effect of Healthcare Reform

Among the ACA's most sweeping reforms are those in the area of payment for healthcare services administered to Medicare beneficiaries. This section discusses several ACA-implemented reforms that share a common theme: financially rewarding providers who participate in the Medicare program in models that promote cost-efficient, quality patient outcomes.

The first ACA-contained payment reform is the Medicare Shared Savings Program (MSSP).[7] The MSSP rewards providers who deliver high-quality care to Medicare beneficiaries via ACOs by allowing them to share in any cost savings realized by the federal government. An ACO is a group of providers or suppliers (or a network of such groups) that is jointly responsible for the cost and quality of health care provided to Medicare beneficiaries.

An ACO must apply and be approved for participation in the MSSP by CMS. In order to participate, the ACA requires that ACOs (among other things) (1) be accountable for the overall care of a defined group of not less than 5,000 Medicare beneficiaries; (2) have sufficient participation of primary care physicians; (3) have processes that promote evidence-based medicine, report on quality and costs, and be capable of coordinating care; and (4) consist of a group of providers and suppliers who have an established mechanism for joint decision making.

ACOs participate in the MSSP in either a one-sided model (in which the ACO receives a lower share of savings enjoyed by the federal government, but is not responsible for any cost increases) or a two-sided model (in which the ACO receives a higher share of savings enjoyed by the federal government, but is also liable for any increased care costs associated with its Medicare beneficiary pool). While the ACA's ACO reforms only have a direct impact on government payers, private payers are increasingly encouraging provider participation in accountable care models, with 2015 estimates indicating that more than 50% of accountable care payment arrangements involve commercial payers. From a compliance perspective, there is an inherent tension between collaborative care models (especially ACOs) and the key thrust of the fraud and abuse laws, namely to target certain cooperative relationships among otherwise unaffiliated healthcare providers. As discussed below, CMS has taken steps to alleviate providers' concerns relating to antitrust compliance by issuing "fraud and abuse waivers" that allow ACO participants to deliver high-quality, cost-effective care in collaborative arrangements without running afoul of the fraud and abuse laws.[8] These waivers are discussed more thoroughly in the fraud and abuse section.

The second ACA-contained payment reform is the National Pilot Program on Payment Bundling.[9] Under bundled payment methodologies, providers (e.g., hospitals and physicians) receive a single payment for all care provided for an episode of illness, rather than a separate fee for each service rendered in the course of treating a patient. For example, if a patient has knee replacement surgery, rather than making one payment to the hospital, a second payment to the surgeon, and a third payment to the anesthesiologist, the payer would combine these payments for the specific episode of care (i.e., knee replacement surgery). By requiring each provider in the continuum of care to share one payment "pool," this payment model seeks to encourage cost-effective, quality care by allowing collaborating providers to share in any savings realized by the payer for treatment delivered through the bundled payment model.

To promote the use of bundled payments, the ACA created the Center for Medicare and Medicaid Innovation (Innovation Center). The Innovation Center was charged with testing innovative payment and service delivery models that have the potential to reduce Medicare, Medicaid, or CHIP expenditures while preserving or enhancing the quality of care for beneficiaries. In exercising this duty, the Innovation Center created the Bundled Payments for Care Improvement (BPCI) initiative,[10] which consists of four broadly defined models of care that link payments for the multiple services that beneficiaries receive during an episode of care. While the ACA has ensured that public payers will remain active promotors of bundled care payment models, private payers—including large employers such as Lowe's[11]—have likewise been eager to engage providers in bundled payment arrangements.

[7] ACA § 3022; 42 U.S.C. 1395jjj.

[8] https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html

[9] ACA § 3023; 42 U.S.C. 1395cc-4.

[10] https://innovation.cms.gov/initiatives/bundled-payments/

[11] http://www.npr.org/sections/health-shots/2016/04/20/474413496/some-firms-save-money-by-offering-employees-free-surgery

A third ACA-contained payment reform is the payment adjustment for conditions acquired in hospitals.[12] Specifically, the ACA penalizes hospitals whose patients are plagued by a high number of hospital-acquired conditions (HACs) by reducing their Medicare payments. Since fiscal year 2015, hospitals have been ranked based on their number of HACs, with the 25% of "worst-offender" hospitals in the top quarter experiencing overall inpatient payment reductions of 1% (in addition to current payment penalties for HACs).

A fourth ACA-contained payment reform is the Hospital Readmissions Reduction Program (HRRP).[13] The HRRP requires CMS to reduce payments to hospitals paid under the inpatient prospective payment systems (IPPS) for excess readmissions. More information on the HRRP program can be found on CMS's website.[14]

A fifth and final ACA-contained payment reform involves the treatment of Patient-Centered Medical Homes (PCMHs). Similar to the ACO model, the PCMH model is based on a vision of primary care practice in which a "team" of health professionals provides comprehensive and timely care to patients who are more actively involved in receiving care. The PCMH model finds support in several ACA provisions,[15] and generally seeks to promote a cooperative, ongoing relationship between primary care physician and patient, including by incentivizing the early discovery and management of chronic conditions.

As these and other ACA payment reforms become increasingly widespread, 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.

Learning Objective 6

Identify the most common federal regulatory issues, such as fraud and abuse, Stark Law, HIPAA, EMTALA, and IRS requirements for tax-exempt organizations, as well as less common concerns that arise under the antitrust laws and federal and state laws regulating third-party payers.

[12]ACA § 3008; 42 U.S.C. § 1395ww(p).

[13]ACA, §§ 3025, 10309; 42 U.S.C. § 1395ww(p).

[14]https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html

[15]ACA, §§ 3021, 3502, 5301, 5405.

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 overutilization. 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 55 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. In addition, these 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. The Racketeer Influenced and Corrupt Organizations Act (RICO 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. Furthermore, 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).

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, 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. 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 next.

Self-Referrals and Kickbacks

The Anti-Kickback Statute (AKS) and the Stark Physician Self-Referral Law (Stark Law) are two important fraud and abuse authorities. They are among 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 False Claims Act, discussed later. Under current law, submitting a claim to Medicare when the provider has violated AKS or the Stark Law may be 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, there are significant regulations adding safe harbors and exceptions, and specifying details are 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 the 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.

For example, AKS and the Stark Law often frustrate parties' efforts to enter into collaborative arrangements (especially ACOs) that are both encouraged by the ACA and widely viewed as integral to decreasing the cost of health care while simultaneously improving outcomes. This is so because AKS and Stark, broadly speaking, are primarily concerned with discouraging certain collaborative relationships among healthcare providers, based on the theory that such relationships frequently result in "sweetheart" deals that are at odds with the government's interest in cost-efficient care and patients' interest in neutral medical advice that is not shaded by a provider's financial bias. Unfortunately, this silo-based conception of healthcare delivery is at odds with the growing recognition—especially among government and private payers—that provider integration and cooperation leads to increasingly efficient care and better outcomes.

In response to provider concerns over the intersection between the fraud and abuse laws and MSSP ACOs, CMS issued an October 2015 final rule[16] aimed at "adequately protecting beneficiaries and federal healthcare programs while promoting innovative structures within the [MSSP]." While legal counsel must be engaged to determine whether an arrangement satisfies one or more of the final rule's five waivers, a brief description of each follows:

- *The ACO Pre-Participation Waiver* waives the requirements of the Stark Law and AKS with respect to start-up arrangements that predate an ACO's agreement to participate in the MSSP.
- *The ACO Participation Waiver* waives the requirements of the Stark Law and AKS with respect to any arrangement of (1) an ACO, (2) one or more of its ACO participants or its ACO providers/suppliers, or (3) a combination thereof, provided that ACO's governing body has determined that the arrangement is reasonably related to the purposes of the MSSP.
- *The Shared Savings Distribution Waiver* waives the requirements of the Stark Law and AKS with respect to shared savings paid by CMS to the ACO and then distributed either (1) to ACO participants, providers, and suppliers during the year shared savings were earned or (2) outside the ACO for activities necessary for (or directly related to) the ACO's participation in and operations under the MSSP.
- *The Compliance with the Stark Law Waiver* provides that with respect to any financial relationship between or among the ACO, its participants, or its provider/suppliers that implicates the Stark Law but falls within an exception, AKS's requirements are

[16] 80 Fed. Reg. 66,726 (Oct. 29, 2015).

waived. This waiver obviates the need for duplicate legal review under the AKS where an arrangement qualifies for an exception under the Stark Law.

- *The Patient Incentives Waiver* waives the requirements of AKS (and the Beneficiary Inducements CMP[17]) with respect to items or services provided to beneficiaries for free or below market value by an ACO, its participants, or its providers/suppliers.

While the Waivers have alleviated some fraud and abuse concerns, their detailed requirements and the steep penalties associated with noncompliance have discouraged many providers from organizing into models that have the potential to deliver the quality, cost-efficient outcomes that stakeholders universally agree are sorely needed.

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

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."[18] In addition, a provider may not bill Medicare for a claim based on a prohibited referral. Unlike AKS, the Stark Law is a strict liability statute and may be violated irrespective of intent. 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 when 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.

"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 may also be implicated, as discussed previously.

Although the Stark Law prohibition is broad, there are a number of statutory and regulatory exceptions.[19] Some of these exceptions apply to ownership arrangements only, compensation arrangements only, or both ownership and compensation arrangements.

For physicians practicing as part of a group practice, there are "in-office ancillary services" and "physician services" exceptions that allow 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 space meeting the exception's location requirements, and the services must be billed by the performing or

[17] 42 U.S.C. § 1320a–7a(a)(5).

[18] 42 U.S.C. § 1395nn.

[19] 42 C.F.R. §§ 411.350 *et seq.*

supervising physician, his/her group, an entity wholly owned by any of the above, or a third-party billing company as agent for any of the above.

Compensation-related exceptions generally focus on ensuring relationships are consistent with fair market value and commercially reasonable and require that compensation does not vary with or take into account the volume or value of referrals. For example, in *United States ex rel. Drakeford v. Toumey*,[20] the court concluded that the Stark Law was violated by a hospital's part-time employment of 19 physicians for outpatient surgeries. Specifically, the court noted that the physicians—who were paid a base salary based on past production with a substantial productivity bonus equal to nearly 80% of compensation—had a compensation package on which Toumey stood to lose $1.5 to 2 million per year on the physician's compensation when compared to their collections. In addition, the physicians' compensation was deemed to vary based on the volume or value of referrals because every case involved compensation via technical and facility fees, which were earned from professional procedures that had to be delivered at the hospital's outpatient facilities. Accordingly, the physicians did not qualify for a Stark Law exception for bona fide employment arrangements, and the agreement was otherwise noncompliant with Stark. As a result of submitting claims for payment in violation of the Stark Law, Toumey was found to be in violation of the False Claims Act, and ordered to pay damages and civil penalties totaling $237,454,000 (which was reduced to $72.4 million in a final settlement agreement reached with regulators). There are also exceptions to Stark liability for renting office space and renting equipment, each with a number of specific requirements. Importantly, both the equipment and space rental exceptions forbid "perclick" and percentage-based 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.

Other major Stark exceptions include those 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 commercially reasonable, 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.

[20]792 F.3d 364 (4th Cir. 2015).

Like AKS, Stark has a process by which providers may self-disclose actual or potential violations in an effort to reduce penalties, avoid exclusion, and provide protection from *qui tam* suits. Known as the self-referral disclosure protocol, this process—though by no means effortless—can help providers avoid the ruinous liability that sometimes accompanies violations of the Stark Law.

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).[21] 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."[22] 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 also 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.[23] AKS is violated if *one purpose* of

[21]42 U.S.C. § 1320a-7b(b).

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

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

the payment is to induce referrals.[24] 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."[25] Therefore, any intent to induce referrals would fulfill the requirements under AKS.[26]

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 later).

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.

There are 25 safe harbors identified by the OIG. Some commonly used safe harbors are 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 earlier, 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, for certain discounts for products, and for waiver of coinsurance or deductibles, among others. These safe harbors each contain a number of requirements that must be met 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 to 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.

False Claims Act

The False Claims Act (FCA) is the federal government's primary civil remedy for improper or fraudulent claims.[27] 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.

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

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

[26] 42 C.F.R. § 1001.952.

[27] 31 U.S.C. §§ 3729 *et seq.*

Specific intent to defraud the government is not required to violate the FCA; 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 knowingly submitted a false claim, 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.

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.[28]

The American Recovery and Reinvestment Act of 2009 contains the Health Information Technology for Economic and Clinical Health Act (HITECH Act), which amends HIPAA.[29] The 2013 Omnibus Rule was issued to implement certain provisions of the HITECH Act.

By law, DHHS is required to issue HIPAA regulations regarding standards for privacy of individually identifiable health information (the "Privacy Standards"); security standards for the protection of electronic protected health information (PHI; the "Security Standards"); standards for notification in case of a breach of unsecured PHI (the "Breach Notification Standards"); and rules for compliance and investigations, impositions of civil monetary penalties, and procedures for hearings (the "Enforcement Rule"). After a brief overview of HIPAA's structure, this section examines the four HIPAA rules and standards in detail.

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

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

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

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 who performs functions or activities on behalf of, or certain services for, a covered entity or another business associate that involve the use or disclosure of protected health information." 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 Omnibus Rule specified that the following types of service providers are considered business associates: providers of certain data transmission services, a person that offers a personal health record, and a subcontractor who handles PHI on behalf of the business associate.

While a covered entity is generally liable for compliance with all HIPAA rules and standards, business associate liability is narrower. Specifically, in addition to liability for impermissible uses and disclosures of PHI, a business associate is directly liable under the HIPAA rules for a failure to (1) provide breach notification to the covered entity; (2) provide access to a copy of electronic PHI to either the covered entity, the individual, or the individual's designee, as specified in the parties' contract; (3) disclose PHI where required by DHHS to investigate or determine the business associate's compliance with HIPAA; (4) provide an accounting of disclosures; and (5) comply with the requirements of the Security Standards.

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 any time 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 authorization, as required by law; or, under certain circumstances, if the PHI is stripped of information that may identify the patient. Furthermore, 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.

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.

Security Standards Covered entities must comply with the Security Standards with respect to electronic PHI (e-PHI). Compliance requires the covered entity to meet the following standards:

- 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 the policies and procedures regarding the 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 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.

Breach Notification Standards The Breach Notification Rule was issued as part of the 2013 Omnibus Rule and sheds significant light on when a breach involving patient information occurs, what entities can be held liable for such a breach, and what obligations are triggered in the event of a breach.

A "breach" is the "acquisition, access, use, or disclosure" of PHI "in a manner not permitted" under the Privacy Rule, which "compromises the security or privacy" of the PHI. Breaches do not include instances in which (1) a workforce member—acting in good faith, unintentionally, and within the scope of employment—acquires or accesses PHI in a way that does not result in further use or disclosure, (2) a person authorized to access PHI inadvertently discloses PHI to another authorized person within the same organization, so long as the PHI is not further used or disclosed, or (3) the covered entity makes a disclosure to a person the entity reasonably believes would not have been able to retain the PHI.

Unless a covered entity or business associate can satisfy one of these three exceptions, any activity meeting the definition is presumptively a breach unless a party can show "low probability" that the PHI has been compromised. Based on agency commentary, it seems unlikely that a low probability of compromise will be found in most situations.

Once a covered entity or business associate discovers (or, if it had exercised reasonable diligence, would have discovered) a breach, certain notification

requirements are implicated. First, when a business associate discovers it has committed a breach, it is required to notify the covered entity "without unreasonable delay" (which in no case can exceed 60 days).

Second, and more importantly, both covered entities and providers are required to notify each individual whose PHI has been compromised by a breach. This notification must be made "without unreasonable delay," and in no case later than 60 days after discovery of the breach, unless a law enforcement exception applies. The required notification must be written in plain language and include, to the extent possible: (1) a brief description of what happened, including the date of the breach and the date of the discovery of the breach, if known; (2) a description of the types of unsecured PHI that were involved in the breach; (3) any steps individuals should take to protect themselves from potential harm resulting from the breach; (4) a brief description of what the covered entity or business associate is doing to investigate the breach, to mitigate harm to individuals, and to protect against any further breaches; and (5) contact procedures for individuals to ask questions or learn additional information.

Third, if the breach involves more than 500 residents of a state, the covered entity must—within the time frame described earlier—notify prominent media outlets serving the state. Fourth, a covered entity must also notify DHHS following the discovery of a breach of unsecured PHI. For breaches involving 500 or more individuals, a covered entity must provide notification to DHHS contemporaneously with the notice to the individual. For breaches involving less than 500 individuals, a covered entity must maintain a log or other documentation of such breaches and, not later than 60 days after the end of each calendar year, provide notification to the DHHS for such breaches in the manner specified on the DHHS website.

Enforcement Rule The HIPAA Enforcement Rule contains several important provisions relating to compliance and investigations, the imposition of civil money penalties for violations of HIPAA, and procedures for related hearings. The HITECH Act revised the HIPAA Enforcement Rule in the following ways:

- Establishing four categories of violations with increasing levels of liability
- Establishing four corresponding tiers of civil money penalties that significantly increase the minimum penalty amount for each violation
- Establishing a maximum civil money penalty amount of $1.5 million for all violations of an identical provision in a calendar year
- Eliminating the previous bar on the imposition of civil money penalties where there was no knowledge of the violation
- Prohibiting imposition of penalties for any violation that is not due to willful neglect and is corrected within a 30-day time period

Subject to a number of affirmative defenses, a civil money penalty may be imposed on a covered entity (or business associate) if DHHS determines that the covered entity (or business associate) has violated a provision of HIPAA. It is important to note that if the Secretary determines that more than one covered entity or business associate was responsible for a violation, the Secretary will impose a civil money penalty against each such covered entity or business associate. Additionally, a covered entity is liable for certain acts of an agent, including a workforce member or business associate, acting within the scope of the agency.

Civil money penalties range from $100 to $50,000 per violation, up to a maximum of $1.5 million per calendar year for violating the same requirement of the HIPAA rules. Criminal penalties are $50,000 and/or 1 year in prison for wrongful disclosure and up to $250,000 and/or 10 years in prison for an offense committed with intent to sell, transfer, or use PHI for commercial advantage. These penalties apply to both covered entities and business associates. Furthermore, the attorney general of any state may bring civil action for damages and may recover court costs and attorney fees.

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 whether the patient requires such care.[30] 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),

[30] 42 U.S.C. § 1395dd.

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 does 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.

Tax Exemption Issues for Healthcare Organizations

Nonprofit HCOs are a significant part of the healthcare industry. At the state level, the traditional rule has historically been that state exemption usually follows from federal tax exemption. While that still remains mostly true, a noteworthy trend seems to indicate that states will no longer uniformly follow federal determinations with respect to tax-exempt status.[31]

The most common way for an HCO to achieve tax-exempt status is via § 501(c)(3) of the Internal Revenue Code. The Internal Revenue Service (IRS) not only enforces the code, but also 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.[32] Therefore, most § 501(c)(3) HCOs 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. Furthermore, 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

[31]http://www.modernhealthcare.com/article/20151111/NEWS/151119974

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

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."[33] A § 501(c)(3) organization may meet public charity requirements as a result of its status if the 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, 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.[34]

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.

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.

The ACA imposes new requirements on nonprofit hospitals related to charity care requirements. 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

[33]26 U.S.C. § 509.

[34]Treas. Reg. § 1.170A-9(c)(1).

patients for emergency or other medically necessary care, and (4) make reasonable efforts to determine whether a patient is eligible for the previously mentioned 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.[35] 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.

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, officers 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 HCO'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 later. 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 HCOs commonly participate. For example, the IRS has found that both pharmacy sales and laboratory tests performed by a tax-exempt HCO are substantially related to exempt purposes and therefore income is exempt from taxes, where sales are to, or tests are 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) HCOs are required to file an annual disclosure form with the IRS called 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.[36]

[35] 26 U.S.C. §§ 511–14.

[36] 26 U.S.C. §§ 6033 & 6104.

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 HCOs, requires more detail regarding how the organization is satisfying the community benefit standard, discussed previously.

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 a 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.[37]

Antitrust in Health Care

The purpose of the antitrust laws is to promote a competitive, free marketplace; these laws are intended to protect the public from the adverse effects of monopoly power and business practices that unreasonably restrain trade. The federal government and 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. Section 2 of the Sherman Act prohibits monopolization. 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. Section 5 of the Federal Trade Commission Act prohibits unfair methods of competition.

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. Some types of conduct, 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 more lenient "rule of reason."

The Sherman Act penalizes conduct that is likely to result in higher prices or lower quality of services to the ultimate consumer. Many business practices that are penalized under the Sherman Act may have a business justification but are deemed illegal because they "unreasonably" restrain trade (i.e., the anticompetitive effect of the business practices outweigh their pro-business 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 might be justified on business grounds to protect the value of the business acquired by the buyer, the clause's provision could nevertheless unreasonably restrain trade if it is not geographically and temporally reasonable. Some practices, however, are penalized 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. These are discussed further later in this chapter.

Enforcement of antitrust laws is jointly shared by the Department of Justice (DOJ) and the Federal Trade Commission (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.

[37] 26 U.S.C. § 6652.

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 a group of competing providers forms the network, 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 provider networks can minimize the antitrust risks associated with joint conduct is by sharing "substantial" financial risk, referred to as "financial integration." Financial integration can be achieved, for example, if the compensation each provider 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 health maintenance organizations 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 post-delivery 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 regarding exactly what 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 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.

As previously explained, healthcare reform has encouraged a variety of collaborative relationships between payers and providers in the interest of reducing cost and improving quality. One such initiative is the MSSP, which establishes provider-controlled contracting networks known as ACOs. If the ACOs' participants include otherwise independent providers who join together to provide an array of services and contract with payers, the Sherman Act's prohibition on agreements that restrain trade is logically implicated.

Accordingly, in response to concerns by providers interested in forming ACOs, the FTC and DOJ released the 2011 *Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program* (the "Policy Statement"). Despite the Policy Statement's reference to the MSSP only, the Agencies have made clear that it is intended to ensure that "health care providers have the antitrust clarity and guidance needed to form procompetitive ACOs that participate in both Medicare and commercial markets." Consistent with earlier pronouncements in similar contexts, the Policy

Statement indicates that the permissibility of an ACO arrangement will turn, in large measure, on whether its participants are either financially or clinically integrated. Financial integration is analyzed using the approach outlined above, while clinical integration exists where the ACO meets CMS's eligibility conditions for participation in the MSSP program (which concern establishing a formal legal structure, a leadership and management structure that includes clinical and administrative processes, and other factors). In other words, so long as an ACO meets CMS's eligibility requirements, it will be subject to antitrust review under a deferential "rule-of-reason" approach.

In order to further insulate itself from antitrust scrutiny, an ACO may attempt to operate in a way that would bring it within an antitrust "safety zone." The Policy Statement explains that an ACO is within the "safety zone" where—among other requirements—its participants neither (1) demonstrate an impermissible control of a given market for services, as measured by the ACO's percentage of the market share, nor (2) require participants to exclusively contract with payers via the ACO. The Policy Statement explains that even if an ACO does not fall within the "safety zone," its conduct "may be pro-competitive and legal," but its participants should take care to ensure that certain safeguards are implemented (such as prohibitions on sharing competitively sensitive information and tying arrangements).

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."[38] 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.

Under the Clayton Act either the DOJ or FTC may investigate a merger or joint venture between two or more hospitals, although the FTC has tended to handle most hospital merger investigations. 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 DOJ. Private parties and state attorneys general may also sue to block mergers or joint ventures under either the Sherman or Clayton Act.

The Hart-Scott-Rodino Antitrust Improvements Act of 1976 requires that parties notify both the FTC and DOJ of certain mergers, acquisitions, joint ventures, or tender offers before consummation of the agreements.[39] Parties satisfying the HSR filing thresholds (currently, transactions where assets or voting securities valued in excess of $78.2 million are being acquired) are required to file HSR forms with the agencies and then wait 30 days before consummating the transaction. Based on information provided in the HSR forms, the DOJ and FTC decide whether to allow the proposed merger to proceed or, if the transaction raises potential competition concerns, to extend the HSR waiting period and investigate the transaction more thoroughly. The investigation may involve issuance of a "Second Request" for additional information, after which the agencies will decide whether to challenge the proposed merger or collaboration as a potential violation of antitrust laws.

Reviews of potentially problematic mergers often include interviews of customers and competitors, as well as an in-depth analysis of the marketplace. The views of customers are particularly important to the merger analysis and have proven to be a source of valuable evidence in cases where the agencies have sought to challenge a transaction.

The DOJ/FTC *Horizontal Merger Guidelines*, issued in 1992 and subsequently revised in 2010, outline the general analytical methodology used by the agencies in deciding if they will challenge a merger. In most cases, the agencies will first determine the relevant market(s) impacted by the transaction and whether the merger will result in market concentration levels that indicate a likelihood of anticompetitive effects. If not, then the analysis generally will typically not proceed any further. However, if so, then the agencies will assess the significance of the anticompetitive concerns, taking into account whether another competitor can make a timely market entry to deter or counteract the competitive concern. Then, the agencies will assess any merger-specific efficiencies resulting from the transaction, and may also consider ancillary issues, such as whether either party to the merger would fail absent the merger, resulting in the failing party's assets exiting the market.

Since the ACA's enactment in 2010, the agencies have shown an increased willingness to challenge mergers and acquisitions by both hospitals and physician practices. In the hospital context, the FTC

[38] 15 U.S.C. § 18.

[39] 15 U.S.C. § 18a.

challenged a merger agreement between ProMedica and St. Luke's, the largest and fourth largest hospital providers in the Toledo, Ohio area. After a 5-year legal battle with the FTC, ProMedica was forced to divest St. Luke's. Other FTC challenges to hospital mergers include the 2015 merger of two large Chicago-area health systems (Advocate Health Care and North-Shore University Health System), as well as the 2015 merger of a large medical center and health system in Pennsylvania (Penn State Hershey Medical Center and Pinnacle Health System).

In the physician acquisition context, the FTC has been similarly eager to challenge what it views as anti-competitive conduct by hospitals and health systems. In 2012, the FTC challenged Renown Health's successive acquisitions of 15 and 16 physician cardiology practices in Reno, Nevada, claiming that the acquisition would result in Renown controlling 88% of the market for adult cardiology services. To resolve the allegations, Renown entered into a consent decree requiring a rare "structural" remedy: divestiture. Specifically, Renown agreed to release 10 cardiologists from their contractual noncompete provisions, allowing them to work at competing practices without penalty.

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 were discussed earlier. 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 four 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.

Self-Insured Plans

Self-insured plans are health plans sponsored by an employer or organization and 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 primarily 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 those services are provided out of network under a closed-network policy. Another important state insurance regulation concerns a practice known as "balance billing." Balance billing occurs when a provider bills a patient for all charges not paid for by the patient's insurance plan (e.g., where an out-of-network emergency room seeks to bill a patient for nonemergency services that the insurer refuses to pay). While most states allow some measure of balance billing, many regulate the types of services and patients that can be balance billed. Especially in states with restrictive balance billing laws (e.g., New York's "Surprise Bill" Law), a provider's uncompensated care costs can be affected by balance billing restrictions.

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).[40] 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.

With the enactment of the ACA in 2010, the federal government now heavily regulates many aspects of insurance in a way that traditionally was the province of state government. While an in-depth exploration of the ACA's impact on insurers is beyond the scope of this chapter, a few of the most important ACA provisions are detailed here. It should be noted that several ACA reforms apply only to individual and small group insurance plans, while others also apply to large group insurance plans.

[40] 29 U.S.C. § 1001 *et seq.*

First, insurers are required to spend a certain portion of premiums received (between 80 and 85%, depending on the type of insurer) on care and quality improvement. If an insurer fails to meet these requirements, it must issue a rebate to either the group policyholder or to individual participants.

Second, insurers are responsible for paying several annual fees, which are used in part to fund research to improve healthcare delivery and outcomes. These fees vary depending on number of covered lives, type of insurer, rate of premium growth, and other factors.

Third, insurers are required to sell plans containing coverage for "essential health benefits," a category that includes ambulatory patient services, emergency services, hospitalization, maternity and newborn care, mental health and substance use disorder services, prescription drugs, rehabilitative and habilitative services and devices, laboratory services, preventive and wellness services and chronic disease management, and pediatric services, including oral and vision care.

Fourth, insurers must provide coverage for preexisting conditions (i.e., medical conditions that existed when benefits under a plan commenced).

Fifth, when determining premium rates for certain plans, insurers may consider only whether the plan is for individual or family coverage, geographic rating area, age, and tobacco use. This requirement effectively disallows consideration of many factors that were once central to premium rate determinations (e.g., health status, gender, industry, and use of an intermediary to obtain health coverage).

Sixth, the ACA imposes a 40% excise tax on any "excess benefit" provided through certain types of employer-sponsored, high cost health coverage. Commonly referred to as the "Cadillac Tax," this controversial measure has been delayed until 2020, but will likely be the target of repeal efforts before then. Should it go into effect, the Cadillac Tax seeks to lower healthcare expenditures by limiting overutilization of care, which proponents argue frequently accompanies plans that allow covered individuals to seek care with little regard for out-of-pocket expenses.

Seventh, the ACA created the reinsurance, risk corridor, and risk adjustment programs (3Rs), which will likely have a profound impact on how risk is redistributed among carriers in certain markets.

Clinical Integration

Since the 1980s, the American healthcare system has experienced an increase in clinical integration (CI). CI occurs where a network of otherwise independent physicians collectively commit to deliver high-quality, cost-effective care to patients by working closely with one another. While participants in a clinically integrated network (CIN) often remain organized in separate legal structures, their combined bargaining power gives them leverage in negotiations with—and the ability to extract more favorable reimbursement rates from—commercial payers. While they have enjoyed a resurgence, CI models are not new. Previous decades have seen competing physicians organizing in both independent practice associations (IPAs) and physician hospital organizations (PHOs) to negotiate jointly with payers.

Generally speaking, CINs are multispecialty in nature and involve some or all of the following attributes:

- A set of clinical and administrative metrics defining the CIN's performance improvement goals
- Membership limited to those physicians able to advance those goals
- A system to monitor physician attainment of these goals
- A physician-led governance structure—supported by administrative staff—to oversee program operations
- A health information technology (HIT) infrastructure to identify improvement opportunities and facilitate the exchange of patient information among participants
- Performance-based payment incentives to incentivize physician productivity
- Joint contracting with commercial payers for physician services

While CINs and ACOs both seek to encourage collaborative relationships among HCOs in the interest of quality, cost-efficient care, there are two distinctions worth emphasizing. First, while CI efforts are focused on improving care by physician practices across specialty types, ACOs focus on care improvement for an entire patient population across the entire care continuum (including, in addition to physicians, hospitals, post-acute care providers, and others). Second, while a CIN can serve as the basis for an ACO, not every CIN takes the additional steps required to become an ACO. For example, a CIN might choose to focus primarily on basic quality and efficiency improvement metrics without taking on the full spectrum of care coordination and population health management functions needed to succeed in the reimbursement risk–heavy ACO model.

Payer–Provider Convergence

Payer–provider convergence is defined as the joining of disparate subsectors within the healthcare industry that previously operated separately.

Payers have been acquiring provider groups, allowing them to realize several benefits, including (1) market share gains, as patients change plans to maintain their current providers, (2) increased customer satisfaction through expanded provider networks, and (3) improved coordination between the financial and clinical aspects of the care continuum.

While payers are increasingly performing many of the functions traditionally associated with providers, the same can also be said of providers who have taken steps to form health plans of their own. According to 2015 data, roughly 13% of health systems currently offer a health plan. Collectively, these 107 systems operate health plans covering 18 million members, approximately 8% of all insured lives. Benefits to a health system of offering a health plan include the potential for increased volume, the opportunity to leverage economies of scale and skill, the creation of strategic option value for the future (e.g., through revamped utilization management efforts), lower barriers to entry in many markets, and preserving market competition in areas dominated by a few payers.

While the distinction between traditional payer and provider functions is unlikely to collapse entirely, ACA-driven payment reforms will eventually require most providers and payers to achieve a level of clinical integration that promotes the delivery of quality, cost-efficient care. While the appropriate level of clinical integration for a given organization must be determined on a case-by-case basis, an ability to appreciate the challenges and opportunities presented by post-reform payment models is essential for successful navigation of this ever-changing landscape.

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. An HCO is exposed to many areas of risk where legal audits and investigations, as part of a robust and comprehensive 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 by or under the direction of 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 the 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. Furthermore, 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 seeks 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 organization. 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.

Hospital Employment of Physicians

Physician Employment Models

In the post-reform environment, hospitals and physicians are increasingly seeking to affiliate via employer–employee relationships, which better reflect the continued emergence of shared-risk models. Although physicians historically have resisted efforts to sacrifice a measure of autonomy by becoming hospital employees, this trend has begun to reverse itself, with approximately 43% of physicians working as employees in 2014. Given the expected increase in hospital employment of physicians, the remainder of this section focuses on two issues, compensation and billing, that frequently concern hospitals with physician employees.

Physician Compensation

When determining the method by which to compensate its employed physicians, a hospital should begin by asking what behavior it seeks to incentivize. For example, under the (increasingly outdated) fee-for-service model a hospital would be reimbursed for the volume of services delivered by an employed physician, which incentivized hospitals to increase a physician's compensation in a way that would reward high-volume producers.

In the post-reform environment, however, reimbursement for physician services is increasingly tied not to the quantity of procedures performed, but to the quality of outcomes experienced by patients. For example, DHHS has announced an initiative designed to tie 90% of traditional payments for healthcare services to quality or value by the year 2018. Additionally, in 2015 Congress passed the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which repealed the so-called "Doc Fix" in favor of a system that reimburses Medicare-participating physicians under one of two models, both of which are designed to expand pay-for-performance incentives.

Physician Billing Issues

When a hospital bills for services rendered by employed physicians, it should be mindful of several issues, including billing/coding and cash management. For a thorough exploration of the billing issues that confront HCOs, refer to Chapters 2 and 22 of this text.

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 these types of legal issues and should plan to address them on a regular basis. The ACA has ushered in a period of even greater regulatory oversight as access to health care has been expanded and payment methods have been 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 HCO's culture and the foundation of its financial security.

ACKNOWLEDGMENTS

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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 has the ACA reshaped financial arrangements among 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 payer 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 the hospital's emergency department could not receive heart failure patients 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 federal law would be most implicated by CIO Tiffany Technophile's proposal? Are there safeguards available to ensure that one or both of the proposals remain compliant with this federal law?
9. Describe how new payment models are blurring the distinction between payers and providers.
10. Compare and contrast Medicare and Medicaid.
11. Discuss the various types of third-party payers.
12. What are the four operational requirements for a § 501(c)(3) tax-exempt organization?

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 ACA continues to be implemented, hospitals and outpatient providers will merge not only 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 health care program is paying for healthcare services or items, such a plan is difficult and risky in practice. If CCI is truly 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.

   However, there is always a risk that patients may have Medicare as a secondary payer and the hospital would mistakenly bill Medicare or other government payer for services provided under the CCI arrangement. In addition, if the relationship with CCI includes HMO, Inc. as a third-party payer, it is very likely that HMO, Inc. includes a Medicare Advantage plan and/or a Medicaid managed care plan, both of which would implicate the Stark Law and the Anti-Kickback Statute. Therefore, limiting a service line to private payers 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. HIPAA is the federal law most implicated by Technophile's proposal. In order to remain HIPAA compliant, the proposal—depending on its precise details once implemented—may benefit from one or more of the following safeguards: (1) obtain individual authorization that meets the requirements of the Privacy Standard, (2) de-identify data using an expert in statistical analysis, and/or (3) obtain approval from a Privacy Board or IRB in accordance with 45 C.F.R. § 164.512(i).
9. New payment models are blurring the distinction between payers and providers in several ways. First, a growing number of provider organizations (e.g., physician practices) are owned by health plans, which may seek to tie physician reimbursement to the quality and value of outcomes they produce. Second, sophisticated risk-sharing arrangements such as ACOs are encouraging providers to shoulder some of the risks previously borne (and realize some of the rewards previously limited to) payers. Third, providers who are especially well-positioned to deliver high-quality, cost-efficient care are forming their own health plans, eliminating the need to involve a separate payer in the care continuum.
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.
11. Generally, third-party payers are either public or private. Public payers 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 payers are nongovernmental 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.