Introduction to Health Law

Jennifer A. Stiller, Esq.
Law Offices of Jennifer A. Stiller
Haverford, Pennsylvania

Jan L. Weinstock, Esq. contributed substantially to the original outline.

Assistance in updating outline for 2008 Pennsylvania Bar Institute's *Health Law Institute*:

Lisa W. Clark, Esq.
Duane Morris, LLP

Harriet Franklin, Esq.
Stevens & Lee, PC

Originally published as a chapter for the course manual for the Pennsylvania Bar Institute's March 2008 *Annual Health Law Institute*.

©2008 Pennsylvania Bar Institute. Used with permission.

TABLE OF CONTENTS

I. WHAT IS HEALTH LAW? 1

II. THE INDUSTRY 2

III. ADMINISTRATIVE LAW - THE BASICS 13

IV. LICENSURE/CREDENTIALS - WHO IS PERMITTED TO PROVIDE SERVICES? IS IT REALLY ABOUT QUALITY CONTROL? 17

V. PATIENT CARE AND TREATMENT 24

VI. PAYMENT FOR HEALTHCARE SERVICES 41

VII. FRAUD & ABUSE 49

VIII. TAX-EXEMPT ORGANIZATIONS AND NONPROFIT STATUS 69

IX. ANTITRUST 72

X. WHERE TO FIND THE LAW 76

WHAT IS HEALTH LAW?

A. Health law is business and regulatory law for healthcare providers, third party payors, and other people and entities working within the healthcare field.

B. The fundamentals are a good working knowledge of contract law, corporate law and governance, tort law, criminal law, and administrative law. (Since the majority of Pennsylvania lawyers don't know much about the legal principles undergirding those intrusive regulations from Washington or Harrisburg that everyone complains about, we provide a short course in administrative law in Section III below). Some knowledge of accounting principles is also helpful.

C. Beyond these basics, health law involves the integration of diverse areas of legal knowledge, including:

1. Regulation of healthcare providers.

   a. Qualification to provide services (licensure, certification, and related topics).

   b. Limitations on business activities affecting:

      (1) Market entry, financial resources; and

      (2) How business operates.

   c. Requirements relating to consumer rights and quality, safety, consent and privacy standards.

   d. Government mandates.

2. Taxation, including federal and state tax laws and tax laws relevant to not-for-profit entities.

3. "Fraud and Abuse" = A full panoply of civil and criminal laws and regulations whose stated purpose is to prevent activities that may increase governmental healthcare expenditures.

   a. Healthcare-specific statutes and regulations.

   b. Application of general criminal laws (e.g., mail fraud) to the healthcare industry.

4. Antitrust.

5. Specialized areas of tort law.

6. "Reimbursement" = Healthcare industry payment mechanisms.

   a. Regulations affecting government payment programs and health insurance plans.

   b. Case law arising out of regulations and contract disputes.

7. Other areas of laws including employment and labor relations, environmental, Canon law, financing and capital markets, insurance, intellectual property, pharmaceuticals and medical devices, biosciences and biotechnology.

II. THE INDUSTRY

A. Overview

1. In 2006 (the latest year data are available), total national health expenditures rose 6.7 percent. Total spending was $2.1 trillion in 2006, or $7,026 per person. Total health care spending represented 16 percent of the gross domestic product (GDP). U.S. health care spending is expected to increase at similar levels for the next decade reaching $4 trillion in 2015, or 20% of GDP.

2. In 2006, employer health insurance premiums increased by 7.7% – two times the rate of inflation. The annual premium for an employer health plan covering a family of four averaged nearly $11,500. The annual premium for single coverage averaged over $4,200.

3. Experts agree that our health care system is riddled with inefficiencies, excessive administrative expenses, inflated prices, poor management, and inappropriate care, waste and fraud. These problems significantly increase the cost of medical care and health insurance for employers and workers and affect the security of families.

   - Statement from National Coalition on Health Care
   - Data from Centers for Medicare and Medicaid Services

4. The industry includes –

   a. Those involved in the development of healthcare products, services, and infrastructure (pharmaceutical companies, medical device companies, biosciences companies, research and development units, academic training institutions, information systems/services);

   b. Those who deliver healthcare services (healthcare practitioners, institutional providers (pre-hospital, acute care, post-acute care, home care), integrated delivery systems and provider networks);

   c. Those who distribute healthcare products (durable medical equipment (DME) suppliers, pharmaceutical companies);

   d. Those who pay for services and products (governmental payors, insurers, HMOs, MCOs, pharmacy benefit managers, employers, other private parties); and

   e. Those who receive services (consumers).

5. There is also substantial governmental involvement in health care – as a major payor, as a provider, as a regulator of those in the industry, and as guardian of the public health.

6. There is increasing concern in many quarters that the system for delivering healthcare goods and services in the United States is "broken" and in danger of collapse.

   a. Inability of American business to compete in a global economy where their competitors benefit from government-sponsored (rather than employer-provided) health insurance.

   b. Ever-increasing number of uninsured and under-insured working Americans.

      (1) Those with no access to health insurance of any kind.

      (2) Those who cannot afford the insurance offered by their employers.

      (3) Those with coverage sufficiently inadequate that cost is a barrier to access to needed services (e.g., high-deductible health plan whose deductible amount is beyond what the consumer can afford).

   c. Healthcare delivery system, stripped of "fat" by managed care and burdened by sky-high malpractice insurance premiums, is increasingly unable to take on additional burdens of uninsured and under-insured patients.

      (1) Crisis in emergency services in some parts of the country.

         (a) Increased difficulty of getting specialty medical coverage without the hospital's paying doctors for being on call.

         (b) Closing of emergency departments, obstetrical services and trauma units.

      (2) Physician-owned specialty hospitals avoiding emergency services and uncompensated services, adding to the stress of traditional community Hospitals.

      (3) Refusal of physicians to take Medicaid or charity-care patients and development of practice models available only to the well-to-do.

d. Harvard study published in February 2005 showed that serious illness was responsible for nearly half of consumer bankruptcies filed in 2004.

B. Industry Trends

1. New attention to the uninsured.

a. The Census Bureau announced last summer that the number of uninsured Americans had topped 46.5 million in 2006.

b. The prestigious and nonpartisan Institute of Medicine (IOM) of the National Academy of Science issued a report January 14, 2004 which concluded, based on five years of study, that:

(1) The number of uninsured individuals under age 65 is large, growing, and has persisted even during periods of strong economic growth.

(2) Uninsured children and adults do not receive the care they need. Consequently, they suffer from poorer health and development, and are more likely to die prematurely than those with coverage; 18,000 unnecessary deaths are attributable to lack of health coverage every year.

(3) Even one uninsured person in a family can put the financial stability and health of the whole family at risk.

(4) A community's high rate of uninsurance can adversely affect the overall health status of the community, the financial stability of its health care institutions and providers, and the access of its residents to certain services, such as emergency departments and trauma centers.

(5) The estimated value of healthy years of life gained by providing health insurance coverage to all is almost certainly greater than the costs that would be incurred by providing those without coverage the same level of services enjoyed by those who have insurance.

c. The problem of the uninsured has become a critical issue for the states.

(1) Pennsylvania's Governor Rendell is trying to establish the Cover All Pennsylvanians program to expand health care to the uninsured and the underinsured. Other states, like Massachusetts, have or are trying to establish similar programs.

(2) The issue of health care for the uninsured is a significant issue in the 2008 federal elections, and federal policy could change under a new administration and Congress.

2. Focus on healthcare information technology.

    a. In a demonstration of the growing importance of health information technology, President Bush signed an executive order in April, 2004, creating a National Health Information Technology Coordinator at the sub-cabinet level. The coordinator is to direct a plan to move the nation towards an interoperable and secure health information system intended to reduce medical errors and administrative inefficiencies, and improve quality.

    b. The development of interoperable electronic health records (EHRs) has become a priority for the federal government. However, the effort has been hampered by lack of funds and privacy/security issues.

        (1) In January, 2007, to advance EHRs, HHS established four work groups:

            (a) Standardization

            (b) Architecture

            (c) Privacy

            (d) Certification.

        (2) The Centers for Medicare and Medicaid Services ("CMS") has adopted uniform standards for electronic prescribing under the Medicare prescription drug program. 70 Fed. Reg. 67568 (Nov. 7, 2005).

        (3) CMS has also issued a new Anti-Kickback Statute safe harbor and a new exception to the Stark Law that would permit hospitals, group medical practices, and certain other organizations to provide to physicians without penalty "items and services in the form of hardware, software, or information technology and training services necessary and used solely to receive and transmit electronic prescription information." 71 Fed. Reg. 54140 (August 8, 2006).

        (4) Security of electronic medical records is seen as an important precursor to the development of fully interoperable EHRs. The HIPAA security regulations, which are focused on maintaining the security of electronic medical records, went into effect April 20, 2005.

3. Electronic health care and the Internet.

    a. Increasingly, industry players are relying on the Internet and other technology to provide services. The Pennsylvania Department of Health now requires Internet reporting by providers.

    b. There are broad legal implications, including those relating to licensure, payments, liability and confidentiality.

4. Old wine in new bottles: Public Health gets noticed.

   a. Public health infrastructure, largely ignored and underfunded for two decades, began getting increased attention after 9/11, as it began to be recognized that the first responders for any biological, chemical, or radiological attack would be healthcare providers, the federal Centers for Disease Control, and state and local public health departments.

   b. On July 21, 2004, President Bush signed into law the BioShield Act of 2004. The law authorizes funding of $5.6 billion over ten years for the government to purchase and stockpile vaccines and drugs to fight anthrax, smallpox and other chemical agents. HHS is given authority to expedite research and development of new medicines to defend against bioterrorism.

   c. Fear of bird flu pandemic, coming on top of the slow response by China to the SARS outbreak, has led to increased attention to the status of infrastructure, both at home and in the world at large, to:

      (1) Ensure that developments in the spread of serious infectious diseases are communicated rapidly to public authorities and disseminated widely as needed; and

      (2) Improve mechanisms to control the spread of the disease.

   d. These have resulted in —

      (1) New attention to the flaws in the system for developing and manufacturing new vaccines; and

      (2) Federal and state authorities' revisiting old methods of disease control, such as quarantine (the relevant Pennsylvania statute dates from the 1950s; *see* 35 P.S. § 521.11).

5. Increased visibility of pharmaceutical industry as key player in health care.

   a. The pharmaceutical revolution.

      (1) Rapid growth in ability of physicians to improve patient well-being with new drugs.

      (2) Increase in prescription drug costs –

         (a) Fastest growing category in health spending in 1999, 2000 and 2001. A 2002 study by the Institute of Health Care Management found that between 1997 and 2001, spending on retail prescription drugs nearly doubled, from $78.9 billion in 1997 to $154.5 billion in 2001, with 50 drugs out of almost 9,500 responsible for 60% of the increase.

(b) Higher generic drug use in 2003 slowed the rising cost per prescription to a 7.9% increase – from $51.76 to $55.86. This rate of increase was significantly less than the 13.1% increase from 2001 to 2002, and the lowest rate in the past four years.

(3) The implementation of Medicare Part D (prescription drugs) in 2006 established a new Medicare payment program for pharmaceuticals, causing a major shift in spending from private sources to Medicare for prescription drugs.

(4) Sections 6001, 6002 and 6003 of the Deficit Reduction Act of 2005 (DRA) made significant changes to the Medicaid prescription drug provisions of the Social Security Act. These changes include revising the definition of average manufacturer price (AMP), establishing a new formula for calculating Federal upper limits (FULs), requiring rebates for certain physician-administered drugs, and clarifying rebate liability for authorized generic drugs.

(5) The DRA prescription drug provisions and the implementation of Medicare Part D. Unevenness in degree to which prescriptions are covered by health insurance, leading to whole new classes of haves and have-nots.

b. Has also led to increased attention by the federal government with regard to –

(1) Marketing practices by pharmaceutical companies (inducements to physicians; representations made to consumers; off-label use).

(2) Practices by pharmacy benefit managers and pharmaceutical manufacturers affecting amounts paid by state Medicaid programs.

(3) Antitrust enforcement related to expiration of patents and switch of drugs from prescription to OTC.

c. Questions of adequate government oversight.

(1) Adverse drug interactions.

(2) Rushing drugs to market with inadequate testing.

(3) Lack of publication of adverse scientific information.

(4) Conflict of interest among scientists at NIH.

(5) Direct-to-consumer marketing.

d. Multi-jurisdictional lawsuits against pharmaceutical companies for off-label promotions, attempts to keep cheaper generic versions of drugs on the market and negligence settling for hundreds of millions of dollars.

6. Intense financial and regulatory pressures on providers.

a. The malpractice insurance crisis continues.

(1) The problem:

(i) Limited number of carriers providing coverage and astronomical cost increases when coverage is available.

(ii) Withdrawal of major carriers from the Pennsylvania market has led to inability of physicians in key specialties – even those with clean records – to purchase health insurance at any cost.

(iii) Inability of specialists to obtain coverage threatens shut-down of hospital trauma units and specialty services.

(iv) Surges in professional liability premiums may jeopardize access to care. Some professionals have ceased performing high-risk and other surgery or have relocated their practices. Specialists in geriatrics working full-time as nursing home medical directors are also often unable to obtain coverage, reducing the quality of medical care available for nursing home patients.

(2) In Pennsylvania, three statutes and numerous Supreme Court-imposed rule changes now make it harder for medical malpractice plaintiffs to bring suit and to prevail in such litigation. In 2007, the state Supreme Court reported that statewide medical malpractice filings were 38% lower in both 2005 and 2006 than in the 2000-2002 base period before the passage of the Medical Care Availability and Reduction of Error (MCARE) Act of March 20, 2002 (P.L.154, No. 13), 40 P.S. § 1303.101 et seq.) Likewise, payments for claims by the MCARE Fund (see item (4) below) in 2007 were 50% lower than the amount of payments made by the MCARE Fund in 2003. For further information, see www.courts.state.pa.us/Index/MedicalMalpractice.

(3) Although physicians' malpractice insurance premiums are not rising as rapidly as they previously were, they still remain high, and problems persist.

(4) Mandatory excess coverage insurance is provided in Pennsylvania under the MCARE Fund. Fees for such excess coverage have been abated by the Commonwealth every year since 2003, as follows:

(a) MCARE premiums have been 100% abated for obstetricians, high-risk surgeons, neurosurgeons, orthopedic surgeons, rural physicians who regularly deliver babies, certified nurse midwives, and certain trauma physicians.

(b) All other physicians receive a 50% abatement. Podiatrists and nursing homes were added to the abatement, effective 2005 and 2006, respectively.

(c) Physicians who have been subject to certain disciplinary actions in the past 10 years, or who have a poor medical liability record, were not eligible to receive the abatement.

(d) To qualify for the abatement, a practitioner must promise to continue practicing in Pennsylvania in the current year and for a full year after the year for which the abatement applies. If he/she fails to keep this commitment, the entire abatement must be paid back to the State. There are a few exceptions to this payback rule (e.g., for physicians who die or become disabled, those called up for active military service, and physicians over 70 years old who retire).

(5) The malpractice crisis is not limited to Pennsylvania consumers and providers, though Pennsylvania is one of the states most severely affected.

b. Ever-decreasing payments from third party payors and consolidation of third party payor market power.

(1) Philadelphia area has become one of the toughest markets for providers in terms of third party payments.

(a) Switch to managed care.

(b) Increased market concentration by Independence Blue Cross.

(c) Independence Blue Cross and Highmark (largest Blue Cross and Blue Shield organization in Pennsylvania) scheduled to merge – too early to predict the effect on providers.

(2) Difficulties in collecting the “patient responsibility” share of payment – deductibles, coinsurance, and co-payments – from patients covered by high-deductible health plans.

(3) Is litigation the answer? Increasing number of providers (hospitals and physicians) are seeking relief in court. *See Pascack Valley Hosp., Inc. v. Local 464A UFCW Welfare Reimbursement Plan*, 388 F.3d 393 (3d Cir. 2004).

c. Increased attention to medical errors.

(1) Initial impetus from Institute of Medicine reports, "To Err is Human" and "Crossing the Quality Chasm," published in 1999 and 2001, respectively.

(2) Focus of IOM reports was on system errors and how to fix them – problems occur not so much because one person was negligent as because system didn't have checks and balances to catch problem before someone was injured (compare to airline industry safety requirements).

(3) Inevitable conflation of medical errors with medical malpractice in public discourse.

(4) Implementation at state and federal level of additional requirements to report incidents that resulted or could have resulted in patient harm.

(5) Introduction of pay for performance (P4P) initiatives, such as Medicare's Premier Hospital Quality Initiative, that increasingly will link payments to quality, and deny payments for care resulting from provider errors. Medicare pays slightly less to hospitals that do not submit quality data requested by Secretary of HHS.

(a) The Patient Safety and Quality Improvement Act of 2005 (Pub.L. 109-41), 119 STAT. 425, enacted July 29, 2005, seeks to encourage providers to work internally and with external organizations to promote patient safety by establishing broad privilege and confidentiality protection to "patient safety work product" developed by providers in the course of internal patient safety activities or reported to new "patient safety organizations" charged with analyzing the information to identify ways to prevent medical errors. However, the full implementation of this Act will not occur until CMS promulgates necessary regulations. CMS has indicated that the regulations may be issued in 2008.

d. Pressure to provide financial assistance and charity care to patients, particularly for hospitals.

(1) In Pennsylvania, hospitals must provide and document charity care under the Tobacco Settlement Act, 35 P.S. § 5701.101 *et seq.*, and other state and federal requirements.

e. Sarbanes-Oxley Act's impact on corporate governance.

(1) Sarbanes-Oxley Act of 2002 increased obligations by Boards and their committees to provide more comprehensive oversight of management. The Act focuses on –

(a) Reducing the risk of auditors compromising their work and providing an inaccurate financial picture, and on

(b) Improving management practices in preparing and reporting on business conditions

(2) Sarbanes-Oxley applies solely to public corporations, but tremendous pressure exists – financial, legal, and business pressure – for private and nonprofit entities to comply with these mandates.

f. Intense enforcement of Fraud & Abuse laws.

(1) Strict enforcement and tightening up of arcane billing rules, with significant penalties imposed for past acts (when the rules may or may not have been as clear).

(2) Greatly increased governmental resources devoted to such enforcement, particularly at the federal level.

(3) According to the Department of Justice, since 1986, a total of $11.5 billion has been recovered under the False Claims Act for health cases. In some cases, settlement amounts have been sizable. For example, in June 2006, Tenet Healthcare Corporation entered into a $900 million settlement to resolve its liability under the False Claims Act.

(4) Corporate Integrity Agreements. Settlement with the government in a criminal or civil case will likely include an integrity agreement setting forth the terms under which the provider may continue to provide funded services. The OIG monitors corporate integrity agreements in effect and conducts on-site inspections to ensure compliance.

g. Increased payor audit activity by Medicare, Medicaid and private payors, such as Medicare's Recovery Audit Contract (RAC) initiative, and Medicaid's increased audit activity pursuant to the the DRA.

h. Growing workforce shortages resulting from deteriorating finances for all types of institutional providers, employment opportunities outside the health care sector and changing delivery systems. Concerns that these shortages are impacting quality of care, including causing hospitals to go on "divert status."

i. Particularly intense financial pressure affecting long-term care.

(1) Liability crisis: Growth of "nursing home abuse" as a legal specialty, with attendant costs and insurance difficulties.

(2) Increasing regulatory requirements for background checks of employees and barring employment of people with certain personal histories.

j. On the plus side, there have been some new initiatives to fund programs from non-traditional sources.

   (1) Tobacco settlement legislation provides funding for healthcare services, including some coverage for losses from hospital uncompensated care.

   (2) Increased federal funding for community health centers and rural health care.

k. Shakedowns and shakeouts — Financial, legal, and technological pressures have led to continuous transformation of the industry.

   (1) Downsizing, closures, and consolidation among hospitals and other institutional providers.

   (2) Downsizing of hospital staff and attendant growth in management-labor friction. Increasing number of strikes by nurses with key issues being "required overtime" and other staffing concerns.

   (3) Transformation of nonprofits into for-profits.

   (4) Hospital ownership of physician practices: During most of the 90's, hospitals attempted to develop "integrated delivery systems" by acquiring physician practices. When this proved to be economically disastrous, hospitals nationwide have for the most part now divested themselves of these practices. Recently, spurred by the need to subsidize malpractice premiums in order to attract or retain certain specialists, and to avoid Anti-Kickback and Stark liability while doing so, some hospitals have again turned to employing these physicians.

   (5) Movement of care from inpatient to outpatient settings continues, with increased burdens on family members of patients.

   (6) Diversification in services by non-hospital providers and specialty hospitals:

      (a) An exception to the Stark anti-referral law has led to the development of "specialty hospitals" designed to provide only one kind of care (most often cardiac, orthopedic or surgical) and owned by the physicians who practice there.

      (b) Growth in market presence of continuing care retirement communities and long-term care and eldercare networks.

      (c) "Alternative" providers of care seek to fill in the gaps in service (acupuncturists, providers of holistic care, palliative care).

III. ADMINISTRATIVE LAW - THE BASICS

A. Principles

1. An administrative agency derives all of its power from the Legislature, and it has the authority to do only that which the Legislature has delegated to it by statute.

2. Legislative power is the power to make laws. The agency's power to create regulations that have the force of law results from a delegation of a part of the Legislature's powers to the agency.

   a. Promulgation of regulations (rulemaking) is an exercise of delegated legislative power.

   b. The substantive scope of an agency's rulemaking power is limited to that delegated to the agency.

   c. Procedural requirements for rulemaking are spelled out in statutes governing the rulemaking process (described in Section II.B below).

   d. Improper delegation: In order for such delegation to be proper, the legislation must contain adequate standards to guide and restrain the agency's exercise of that power. *Commonwealth v. Sessions*, 532 A.2d 775, 784 (Pa. 1987).

3. "Adjudicatory power" is the power to resolve specific matters through a quasi-judicial review of the facts and law relevant to such matters.

   a. Agency's adjudicatory power is subject to Constitutional due process restrictions (imposed by the courts):

      (1) Reasonable notice;

      (2) Opportunity for hearing; and

      (3) No commingling of prosecutorial and adjudicatory functions.

   b. Subject to statutory requirements as well.

      (1) Federal: Administrative Procedure Act, 5 U.S.C. § 554.

      (2) Pennsylvania:

         (a) Administrative Agency Law, 2 Pa. C.S. §§ 501-754.

         (b) Regulations governing administrative practice and procedure generally: 1 Pa. Code ch. 31, 33, 35. (Individual agencies may have their own regulations that supplement or supersede these.)

c. Appeals from Administrative Proceedings.

(1) Standard of review - Generally appellate in nature.

(2) Agency will be sustained unless the agency's adjudication:

(a) Is not supported by substantial evidence in the record;

(b) Is contrary to law; or

(c) Is arbitrary and capricious.

(3) Forum.

(a) Appeals from Pennsylvania state agencies and Board of Claims - Commonwealth Court.

(b) Appeals from federal agency adjudication - U.S. District Court or as specified in the relevant statute.

B. Regulations

1. There are two types of regulations:

a. Legislative rule:

(1) A rule that creates new law, rights, and duties in what amounts to a legislative act; it imposes distinct obligations on members of the public. *United States v. Yuzary*, 55 F.3d 47 (2d Cir. 1995).

(a) Legislative rules must be promulgated in accordance with the notice-and-comment procedures spelled out in the APA or the equivalent state statute.

(b) Legislative rules are binding on both the agency and the public and have the full force of law.

b. Interpretive rule: A clarification or explanation of an existing statute or rule, designed to apprise the public of the agency's construction of those authorities; it creates no law and has no effect beyond the statute. *La Casa Del Convalenciente v. Sullivan*, 965 F.2d 1175 (1st Cir. 1992).

2. Federal regulations.

a. Substantive authority for rulemaking will be found in the statutes under which the administrative agency operates (e.g., Social Security Act for Medicare and Medicaid, Internal Revenue Code for taxes).

b. Administrative Procedure Act, 5 U.S.C. § 553, spells out procedural requirements for adoption of regulations.

c. Basic types of federal rules usually seen by health lawyers:

(1) Full Federal Register rulemaking.

(2) Interpretive rules.

(a) Manuals

(b) Centers for Medicare & Medicaid Services Rulings

(c) Federal Register preambles

(d) Agency opinions

(3) Negotiated rulemakings – 5 U.S.C. §§ 561-570.

3. Pennsylvania regulations.

a. Statutory authority.

(1) Substantive authority will be found in the general powers of the agency (in title 71 of Purdon's), as well as the statute creating particular powers (e.g., Healthcare Facilities Act, 35 P.S. § 448.803).

(2) Procedural requirements for adoption of regulations:

(a) Commonwealth Documents Law, 45 P.S. § 1101 *et seq*.

(b) Regulatory Review Act, 71 P.S. § 745.1 *et seq*.

C. Important Concepts

1. Deference to the administrative agency.

a. Courts grant substantial deference to an agency's interpretation of the statutes it is charged with administering. However:

(1) No deference is due to agency interpretations at odds with the plain language of the statute itself. *Pub. Employees Retirement Sys. v. Betts*, 492 U.S. 158, 171 (1989).

(2) Agency statements contained in opinion letters, policy statements, agency manuals, and enforcement guidelines lack the force of law and do not warrant the level of deference granted to legislative rules. *Christensen v. Harris County*, 529 U.S. 576, 587 (2000); *Madison v. Res. for Human Dev., Inc.*, 233 F.3d 175, 185 (3d Cir. 2000).

b. Interpretation of agency's own regulations.

(1) Legislative rules.

(a) Generally, the courts will defer to the agency's interpretation of its own regulations: *United States v. Larionoff*, 431 U.S. 864, 872 (1977); *Commonwealth of Pa., Dept. of Public Welfare v. Forbes Health System*, 422 A.2d 480 (Pa. 1980).

(b) An agency's interpretation of its own regulation is not entitled to substantial deference where an alternative reading is compelled by the regulation's plain meaning or by other indications of the agency's intent at the time of the regulation's promulgation. *Mercy Catholic Med. Ctr. v. Thompson*, 380 F.3d 142, 152-53 (3d Cir. 2004).

(2) Courts need not defer to agency interpretation in case of interpretive rule:

(a) An interpretive rule that (i) contradicts the plain language of a legislative rule, (ii) has not been applied consistently, and (iii) is unreasonable, is arbitrary and capricious and subject to no deference. *Mercy Catholic Med. Ctr. v. Thompson*, 380 F.3d 142 (3d Cir. 2004).

(b) Interpretive rules that did not exist when transactions were conducted should be received only "with whatever persuasive force they would enjoy if expressed in a brief filed in the litigation." *Health Insurance Ass'n of America, Inc. v. Shalala*, 23 F.3d 412, 425 (D.C. Cir. 1994).

(c) An interpretive rule that is inconsistent with an existing legislative regulation is invalid. *Nat'l Family Planning and Reproductive Health Ass'n v. Sullivan*, 979 F.2d 227, 235 (D.C. Cir. 1992).

(d) Courts must give deference to the agency but should disregard an interpretive rule if it is "unwise" or violates public policy. *Jay R. Reynolds, Inc. v. Dept. of Labor & Industry, Prevailing Wage Appeals Board*, 661 A.2d 494 (Pa. Cmwlth. 1995).

2. Exhaustion of administrative remedies.

D. Federal vs. State Administrative Law

1. Joint state-federal programs (i.e., Medicaid).

a. In these programs, deference is due to federal agency, but the State's interpretation of federal statute entitled to little if any deference. *Orthopaedic Hospital v. Belshe*, 103 F.2d 1491, 1495 (9th Cir. 1997), cert. denied, 118 S.Ct. 684 (1998).

b. However, when the federal statute requires the State make a determination (e.g., as to what payment rate is reasonable and adequate), deference to the state agency is appropriate. *See Hoodkroft Conv. Ctr., Inc. v. New Hampshire*, 879 F.2d 968, 972 (1st Cir. 1989), *cert. denied*, 110 S.Ct. 720 (1990).

2. Use of federal cases to interpret state law.

a. Principles of administrative law.

b. Cases interpreting similar federal statutes are often useful in interpreting state statutes. *See Commonwealth of Penna. v. Monumental Properties, Inc.*, 329 A.2d 812, 818 (Pa. 1974).

3. *Note that state and federal administrative law are often similar, but not necessarily the same.* For example, the doctrine of improper delegation of legislative power, which is alive and well in Pennsylvania,[1] has no current equivalent in federal administrative law.

IV. LICENSURE/CREDENTIALS - WHO IS PERMITTED TO PROVIDE SERVICES? IS IT REALLY ABOUT QUALITY CONTROL?

Various state administrative agencies are charged with determining who may provide healthcare services. In the case of Medicare and Medicaid and other governmental payors, federal and state administrative agencies also determine who is eligible to get paid for services. "Licensure" refers to who or which entities may provide services as a matter of law. Providing services without a required license is unlawful. Historically, licensure and other standard(s) related to who or which entities could provide services focused on quality of care. As the financing of health care has become as important as the quality of the healthcare services provided, the financial feasibility and viability of the provider have also been scrutinized subjected to scrutiny by the regulating administrative agencies.

"Credentialing" generally refers to a private (rather than governmental) process whereby a practitioner's training, licensure and professional practice patterns and history are evaluated for purposes of determining eligibility for privileges with an institutional entity (such as a hospital or large physician group) or participation in a payor program (such as an HMO).

A. State Approval To Provide Healthcare Services

1. Licensure of individual healthcare practitioners.

a. Individual healthcare practitioners are subject to licensure by their respective state boards. The various boards are responsible for establishing the criteria for initial and ongoing licensure, as well as for disciplining practitioners. *See* Title 63 of Purdon's generally. The various boards are organized within the Department of State, Bureau of Professional and Occupational Affairs.

[1] *See State Board of Medicine v. Lyness*, 605 A.2d 1204 (Pa. 1992).

b. Practitioners who are denied a license or are subjected to disciplinary action are entitled to a due process hearing before the relevant state licensing board.

c. Various state licensing boards impose mandatory reporting requirements on professionals to notify the applicable board of impaired and/or incompetent practitioners. Failure to report may result in the imposition of a fine. Persons or facilities who report in good faith are immune from civil or criminal liability.

d. Hospitals and other healthcare facilities are also required to report adverse actions affecting physicians pursuant to healthcare facility licensure standards. *See* 35 P.S. § 448.806a.

e. Pennsylvania Peer Review Protection Act generally provides immunity from liability for certain peer review activities in addition to providing for confidentiality of certain peer review proceedings and records. *See* 63 P.S. §§ 425.2 *et seq.* However, when a physician challenges the integrity of a hospital's peer review process, records of the peer review proceeding are discoverable. *Hayes v. Mercy Health Corp.*, 739 A.2d 114 (Pa. 1999).

2. Licensure of institutional healthcare providers and facilities.

a. Pursuant to the Health Care Facilities Act, Pennsylvania Department of Health ("DOH") is responsible for licensure of certain healthcare facilities including hospitals, ambulatory surgical facilities, long-term care facilities, hospices, cancer treatment centers using radiation therapy on an outpatient basis, home health agencies, drug and alcohol treatment facilities. *See* 35 P.S. §§ 448.802a *et seq.*; 28 Pa. Code § 101 *et seq.*

(1) DOH has revised its licensure standards for a variety of healthcare facilities to promote uniformity in the licensure and reporting process. Notification of the initiation and or modification of services, a change in ownership and other changes relating to management are required. 28 Pa. Code § 51.1 *et seq.* These include requirements that facilities notify DOH of deaths or serious injuries due to a medication error. 28 Pa. Code § 51.3.

(2) DOH has a variety of sanctions it may seek to institute against a healthcare facility that DOH determines is violating the licensure standards. Healthcare facilities have due process rights and can appeal certain determinations made by DOH. Agencies publicize their investigations and decisions, and the resulting public reaction may be more severe than the penalty imposed.

b. The Pennsylvania Department of Public Welfare ("DPW") is responsible for licensure of mental health, mental retardation and residential facilities, including private psychiatric hospitals, daycare centers, community residential rehabilitation centers for the mentally ill, psychiatric outpatient clinics, and personal care homes. *See* 62 P.S. § 902 *et seq.*

(1) Assisted living facilities have been licensed as personal care homes.

(2) On July 25, 2007, the Pennsylvania legislature enacted Act 2007-56, establishing standards for the licensure of assisted living facilities ("ALFs"). Once fully implemented, the new law will prohibit an entity from using the term "assisted living" unless it is licensed as an ALF. Existing ALFs will continue to be licensed as personal care homes under 55 Pa. Code Chapter 2600 until DPW adopts final regulations under the new law.

(3) Like DOH, DPW has a variety of sanctions it may seek to institute against a facility or program that is not in compliance with applicable standards, facilities and programs have various due process rights.

(4) DPW is also responsible for determinations regarding participation as a provider in the Medicaid program.

3. Other state approvals to operate facilities, programs or payors.

   a. Continuing care retirement communities ("CCRCs") are regulated by the Department of Insurance ("DOI"). A provider must obtain a "certificate of authority" to operate a CCRC. Standards emphasize financial viability of provider and residents' rights. 40 P.S. § 3201 *et seq.*; 31 Pa. Code § 151 *et seq.*

   b. Health maintenance organizations are regulated by the Departments of Insurance and Health. A certificate of authority is issued jointly. 40 P.S. § 1551 *et seq.* Both DOI and DOH have published regulations to implement the Pennsylvania Quality Health Care Accountability and Protection Act, addressing quality standards, patient protection standards, and timeliness of payment. On June 9, 2001, DOH published final regulations implementing the provisions of the Act and revising the state's HMO regulations. *See* 31 Pa.B. 3043 (June 9, 2001).

   c. Preferred provider organizations (both risk assuming and non-risk assuming) are regulated by the Department of Insurance with input from the Department of Health. 40 P.S. § 764a.

   d. DOH and DOI Policy Statements on Integrated Delivery Systems. *See* 31 Pa. Code § 301.301 *et seq.*, 29 Pa. Code Ch. 9, Subch. D.

4. Pennsylvania Healthcare Cost Containment Act establishes the "PHC4" and provides for the collection and publication of patient and provider data, such as the annual Cardiac Surgery Report. PHC4 was reauthorized in 2003 for an additional 5 year term which sunsets June 30, 2008. 35 P.S. § 449.1 *et seq.* In June, 2003, PHC4 moved into the patient safety arena by adopting regulations requiring hospitals to report nosocomial (hospital-acquired) infections.

B. Credentialing by Hospitals, HMOs, Physician Groups and Other Providers and Networks

1. Hospitals, HMOs, etc. have formal procedures whereby they determine whether to permit a physician or other practitioner to participate professionally in their organization. This process may or may not involve due process protections for the practitioner, although providing such protections may give the organization substantial benefits under the Health Care Quality Improvement Act (discussed in Section C below).

2. Board Certification/Eligibility. The various physician specialty associations provide for national specialty boards which impose extensive requirements regarding the eligibility and training of physicians who seek the specialty certification. Increasingly, board eligibility or certification is becoming an element of credentialing by private parties.

3. Credentialing in some cases includes a query to the National Practitioner Data Bank (discussed below).

4. Is credentialing about quality? Credentialing decisions include quality assessments, utilization review, and intangibles as well. Satisfaction of credentialing requirements does not guarantee "participation" in a program.

C. Federal Oversight of Professional Credentialing and Disciplinary Activity

1. Congress assumed a more active role in monitoring the competence of healthcare professionals through enactment of the Health Care Quality Improvement Act of 1986 ("HCQIA"), 42 U.S.C. §§ 11101 - 11152. The purpose of the HCQIA is to encourage peer review in an effort to improve quality. This law established the National Practitioner Data Bank. (*Note:* Pay close attention to the definitions included in the Act and implementing regulations.)

2. Reporting requirements -

   a. The HCQIA requires hospitals and other healthcare facilities to report any professional review action that adversely affects the clinical privileges of a physician or dentist for longer than 30 days, the surrender by a physician or dentist of clinical privileges while an investigation relating to possible incompetence or improper professional conduct is underway, and revisions to such actions. Hospitals and healthcare entities may report on other healthcare practitioners.

   b. Others required to report include state medical and dental boards, professional societies, and medical malpractice payors. Individual healthcare practitioners do not report on their own behalf.

c. Consequences of failure to report may include: a civil monetary penalty (for medical malpractice payors), loss of immunity with respect to professional review activities for a period of 3 years (for hospitals or professional societies).

3. Duty to investigate physician status.

   a. The HCQIA requires hospitals to request information from the Data Bank (i) when a physician, dentist or other practitioner applies for a medical staff position or clinical privileges, and (ii) on a biannual basis for all physicians, dentists or other healthcare practitioners to whom the hospital has already granted a medical staff position or privileges.

   b. If a hospital fails to investigate, knowledge of the information available is presumed.

   c. Hospitals, state licensing boards, other healthcare entities, professional societies, plaintiff's attorneys (under limited circumstances) may query the Data Bank for information in accordance with the regulatory standards.

   d. Individual healthcare practitioners may query the Data Bank regarding their own files.

   e. Persons not specifically permitted by statute or regulation to query the Data Bank (including malpractice carriers), are not permitted to do so.

4. Peer review. The HCQIA provides broad immunity under both state and federal laws for professional review bodies of hospitals and other healthcare entities, and persons serving on or otherwise assisting such bodies as long as all of the requirements of the HCQIA are satisfied.

   a. For persons who provide information concerning the competence or professional conduct of a physician, unless the information provided is knowingly false.

   b. For "peer review bodies" and persons assisting them in the professional review activities. In order to receive immunity, the peer review action must be taken in accordance with the standards of the HCQIA which includes compliance with various due process rights.

5. The Health Insurance Portability and Accountability Act of 1997 required the establishment of a national healthcare fraud and abuse data collection program and a data bank for reporting certain final adverse actions taken against healthcare providers, suppliers and practitioners. The "Healthcare Integrity and Protection Data Bank ("HIPDB") is designed to supplement the National Practitioner Data Bank.

a. Regulations at 45 C.F.R. Part 61 require reports by state and federal agencies and "health plans" (i.e., third party payors).

(1) State and federal agencies must report final adverse licensing or certification actions and exclusions from state or federal healthcare programs.

(2) State and federal prosecutors must report criminal convictions of providers, suppliers and practitioners related to delivery of a healthcare item or service.

(3) State and federal attorneys and health plans must report civil judgments related to delivery of a healthcare item or service, as well as other adjudicated actions or decisions (broadly defined; *see* §61.3).

b. Only state and federal agencies and health plans can access the specific information (as opposed to aggregate statistical data) in the HIPDB; healthcare providers, suppliers and practitioners can obtain only information pertaining to themselves.

6. New Pennsylvania legislation designed to improve patient safety was enacted in 2002, which among other things imposed a variety of reporting requirements on healthcare facilities and practitioners and required physicians to have 100 hours of continuing medical education every two years. See V.B.1(c) below.

7. Emergency Medical Treatment and Labor Act ("EMTALA") requires hospitals that participate in Medicare to provide emergency services to presenting patients regardless of the patients' ability to pay. 42 U.S.C. §§ 1395dd, 1393cc(a)(1)(I) and 1395cc(a)(1)(N)(iii); 42 CFR §§ 489.20 and 489.24.

a. Expanded interpretations by CMS provide that EMTALA's reach is beyond the emergency room and may include individuals presenting on hospital property/campus or in a building operating under the same CMS number.

b. EMTALA also applies to specialty hospitals (e.g., cardiac or orthopedic hospitals). Per special guidance issued by CMS on April 27, 2007, specialty hospitals must be able to appraise and initiate treatment in emergency situations as well as arrange for a referral or transfer to another facility when appropriate.

c. Each hospital must furnish an appropriate medical screening to emergency room patients and those in active labor to determine whether the patient has an emergency medical condition, and, if so, must stabilize the patient before transfer or release.

d. Supreme Court held in *Roberts v. Galen of Virginia, Inc.*, 525 U.S. 249 (1999), that it is not necessary to show that a hospital acted with improper motive to have a violation of EMTALA.

e. See 64 Fed. Reg. 61353 (Nov. 10, 1999) for a CMS Special Advisory Bulletin outlining hospitals' obligations to provide emergency services to managed care enrollees.

D. Accreditation

"Accreditation" is credentialing by private organizations. However, increasingly accreditation is relied upon by state and federal agencies in evaluating quality and compliance by healthcare providers.

1. Hospitals accredited by the Joint Commission are deemed to meet most requirements for Medicare certification. Pennsylvania licensure law also allows the Department of Health to rely on Joint Commission to the extent it determines the standards are similar to DOH regulations, in certain instances, on the reports of the federal government or accrediting agencies in licensure determination.

2. Range of accrediting organizations include:

   a. Joint Commission;

   b. National Committee for Quality Assurance (NCQA);

   c. Utilization Review Accreditation Commission (URAC); and

   d. Accreditation Association for Ambulatory Health Care (AAAHC).

E. Certification

Refers to conditions for participation in federal and state payment programs.

1. Certification standards typically require licensure as a condition of certification, among other standards.

   a. Medicare conditions of participation.

   b. Medicaid conditions of participation.

2. Certification standards are not limited to quality standards.

3. Following the sunset of the Pennsylvania certificate of need program, DPW issued a Policy Statement stating its intention to deny any provider agreement for replacement or new nursing home beds, ICF/MR beds, inpatient psychiatric beds or rehabilitation beds, absent the applicant's satisfaction of certain "exceptions" criteria. The criteria include qualitative

standards, as well as criteria relating to the "best interests" of DPW for the beds. *See* 55 Pa. Code § 1101.42b, 1101.77a, and 1187.21a *et seq*.

4. Certification determinations are likely to impact the financial viability of an entity or provider. Some due process rights are associated with such determinations.

F. Whose job is it really?

1. Scope of practice issues. May a physician supervise an unlicensed individual in the provision of service or must a physician, physical therapist or other licensed individual provide the service? This may present a payment issue if insurers refuse payment without a licensed professional directly providing the service.

2. The snowball effect. One adverse credentialing action may have a snowball effect and result in adverse action by other private or public bodies. Must a practitioner appeal every determination? A state licensing board may revoke the license of a practitioner based upon disciplinary action by another state. *Girgis v. Board of Physical Therapy*, 859 A.2d 852 (Pa. Commw. Ct. 2004).

3. Isn't a license enough? In an effort to measure and promote quality, many networks may require specialty certification. Who should be "grandfathered" and is mere "board eligibility" enough? Will "board" status be included in facility licensure standards?

V. PATIENT CARE AND TREATMENT

A. Negligence

1. Medical malpractice means medical negligence.

2. In order to prove negligence, the plaintiff must prove:

   a. Duty - The plaintiff must show that the physician owed the patient a particular duty or obligation. This duty, created by the physician-patient relationship, requires the physician to act in accordance with applicable standards of care.

   b. Breach of Duty - The plaintiff must demonstrate that the physician failed to act in accordance with the standard (act or omission).

   c. Causation - The plaintiff must show that the negligent conduct of the physician was the proximate cause of injury.

   d. Damages - The plaintiff must establish that, because of the physician's acts, actual loss or damage has occurred.

3. Referrals to specialists: A physician must utilize the scientific means and facilities available to the physician for the diagnosis and treatment of patients. Failure to exercise reasonable care in consulting or referring a patient to a specialist may result in liability (i.e., providers must know when to refer and to whom they are referring).

4. Whose negligence is it anyway?

   a. Captain of the Ship Doctrine – Liability imposed on the surgeon in charge of an operation for negligence of assistants during the period they were under surgeon's supervision and control, even though employees of hospital.

   b. Respondeat Superior – Employer is responsible for the negligence of its employees; principal is responsible for the negligence of its agent.

   c. Ostensible Agency – The MCARE Act establishes a standard for ostensible agency in cases involving hospitals. 40 P.S. § 1303.516.

      (1) A hospital can only be held vicariously liable to the acts of another health care provider through principles of ostensible agency if:

         (a) A reasonably prudent person in the patient's position would be justified in the belief that the care in question was being rendered by the hospital or its agents; or

         (b) The care in question was advertised or otherwise represented to the patient as care being rendered by the hospital or its agents.

      (2) Evidence that a physician holds staff privileges at a hospital is insufficient to establish vicarious liability through principles of ostensible agency unless the claimant establishes either (a) or (b) above.

   d. Corporate Negligence –

      (1) A corporate entity can be negligent in its own right for negligent selection of a particular physician or other provider. *See Thompson v. Nason Hospital*, 591 A.2d 703, 708 (Pa. 1991) (theory of corporate negligence as it relates to hospitals); *Shannon v. McNulty*, 718 A.2d 828 (Pa. Super. 1998) (application of corporate liability to HMOs). However, the doctrine of corporate negligence has not been extended to physicians' professional corporations or to non-hospital health care clinics. *See, e.g.*, *Sutherland v. Mononghela Valley Hospital*, 856 A.2d 55 (Pa. Super. 2004); *Milan v. American Vision Ctr.*, 34 F. Supp.2d 279 (E.D. Pa. 1998); *Dibble v. Penn State Geisinger Clinic, Inc.*, 42 Pa. D. & C.4th 225, 233 (Lackawanna C.C.P. 1999).

      (2) A hospital is *directly liable to the patient* under the doctrine of corporate negligence if it fails to uphold any one of four duties: (i) a duty to use

reasonable care in the maintenance of safe and adequate facilities and equipment; (ii) a duty to select and retain only competent physicians; (iii) a duty to oversee all persons who practice medicine within its walls as to patient care; and (iv) a duty to formulate, adopt and enforce adequate rules and policies to ensure quality care for the patients. *Thompson*, 591 A.2d at 707.

(3) A *prima facie* case of corporate negligence is established if the plaintiff proves (i) the hospital acted in deviation from the standard of care; (ii) the hospital had actual or constructive notice of the defects or procedures which created the harm; and (iii) that the conduct was a substantial factor in bringing about the harm. *Rauch v. Mike-Mayer*, 783 A.2d 815, 827 (Pa. Super. 2001).

(4) Constructive notice of cause of harm:

(a) Because hospital staff members and employees have a duty to recognize and report abnormalities in the treatment and condition of patients, if an attending physician fails to act in accordance with standard medical practice, it is incumbent upon the hospital staff to so advise hospital authorities in order that appropriate action might be taken. A hospital is properly charged with constructive notice when it should have known of the patient's condition. *Rauch*, 783 A.2d at 828.

(b) Court will impose constructive notice when the failure to receive actual notice is caused by the absence of supervision. *Id.*

e. In *Sharpe v. St. Luke's Hosp.*, 821 A.2d 1215 (Pa. 2003), the state Supreme Court held that where a hospital collected urine samples and performed drug tests under a contract with an employer that required mandatory drug tests for its employees, the hospital owed a reasonable duty of care to the employee with regard to the collection and handling of her urine specimen.

5. Failure to comply with statutory standards may serve as evidence of negligence.

   a. In denying a motion to dismiss, court held that violation of state and federal statutes and regulations governing nursing homes, while not providing a private cause of action, could be used to establish negligence *per se*. *McCain v. Beverly Health & Rehab. Services, Inc.*, 2002 U.S. Dist. LEXIS 12984 (E.D. Pa. July 15, 2002).

6. Pennsylvania Supreme Court has narrowed the application of the doctrine of res ipsa loquitur in medical malpractice cases. In *Toogood v. Rogal*, 824 A.2d 1140 (Pa. 2003), the Court stated that expert testimony is required to prove the standard of care and a breach of the standard of care, unless a layperson is able to determine as a matter of common knowledge that the

result which has occurred does not ordinarily occur in the absence of negligence (e.g., surgical sponge left in patient's body). However, the Pennsylvania Supreme Court has declined to apply the *Toogood* limitations to a "non complex medical scenario" in which a quadriplegic patient fell from an examining room table. *See Quinby v. Plumsteadville Family Practice*, 907 A.2d 961 (Pa. 2006).

7. Negligence claims against HMOs.

    a. The Pennsylvania State Supreme Court ruled in *Pappas v. Asbel*, 724 A.2d 889 (Pa. 1998), that the federal Employee Retirement Income Security Act of 1974 ("ERISA") does not preempt state negligence claims against an HMO.

    b. When the U.S. Supreme Court determined two years later that the financial incentives HMOs give physicians to hold down healthcare costs do not make HMOs liable under ERISA for violating a duty to put their patients first, *Pegram v. Herdrich*, 530 U.S. 211 (2000), it vacated the Pennsylvania Court's decision and remanded it for further consideration. *U.S. Healthcare Systems of Pennsylvania, Inc. v. Pennsylvania Hosp. Ins. Co.*, 530 U.S. 1241 (2000).

    c. In April, 2001, the Pennsylvania Supreme Court affirmed its original decision in *Pappas*. 768 A.2d 1089 (Pa. 2001). The state Supreme Court read *Pegram* and the U.S. Supreme Court's earlier decision in *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645 (1995), together, and found that when an HMO makes a mixed treatment and coverage decision, there may be no claim of breach of fiduciary duty under ERISA, but there may be a state law claim under a theory of medical malpractice. The U.S. Supreme Court denied certiorari on June 24, 2002.

    d. Then, in *Aetna Health, Inc. v. Davila*, 542 U.S. 200 (2004), the U.S. Supreme Court held the plaintiffs' claims under the Texas Healthcare Liability Act, which imposed a duty of ordinary care in the handling of coverage decisions, were completely preempted by ERISA. In a sweeping unanimous decision, the Court held that:

        (1) "If an individual, at some point in time, could have brought his claim under ERISA §502(a)(1)(B), and where no other independent legal duty is implicated by defendant's actions, then the individual's cause of action is completely pre-empted by ERISA;" and

        (2) Any "state-law cause of action that duplicates, supplements, or supplants the ERISA civil enforcement remedy conflicts with the clear congressional intent to make the ERISA remedy exclusive and is therefore pre-empted."

    The Court distinguished *Pegram*, stating that that case's "mixed treatment and coverage determination" rule applies only when, as in that case, the "plaintiff's treating physician was also the person charged with administering

plaintiff's benefits" and that physician was the person "who decided whether certain treatments were covered." In most cases, the Court said, an HMO acts purely as a fiduciary when determining whether or not a particular medical treatment is covered under an ERISA health benefit plan.

e. Third Circuit decisions.

(1) As of the end of 2007, there were no district or appellate cases within the Third Circuit that dealt with HMO negligence in the context of ERISA pre-emption post-*Aetna Health*. However, the Court of Appeals did use the reasoning of the *Aetna* case to hold that ERISA pre-empts Pennsylvania's bad faith statute for insurance claims, 42 Pa. C.S. § 8371. *Barber v. UNUM Life Ins. Co. of Am.*, 383 F.3d 134 (3d Cir. 2004).

(2) Two earlier cases reached different results:

(a) In *U.S. Healthcare v. Bauman*, 120 S.Ct. 2687 (2000), the U.S. Supreme Court let stand a Third Circuit decision to allow for a state court suit against an HMO (and avoid ERISA preemption) where the Court of Appeals reasoned that the situation involved the adequacy of the care the HMO provided, not the benefits it failed to provide. *In re U.S. Healthcare, Inc.*, 193 F.3d 151 (3d Cir. 1999).

(b) In a decision subsequent to *Pegram*, the Third Circuit ruled that an HMO's delay in approving surgery was "conduct falling squarely within administrative function" and upheld dismissal of the patient's claim against the HMO. *Pryzbowksi v. U.S. Healthcare, Inc.*, 245 F.3d 266 (3d Cir. 2001).

B. Recent Pennsylvania Malpractice Reform Legislation

1. The Medical Care Availability and Reduction of Error (MCARE) Act (Act of March 20, 2002 (P.L.154, No.13), 40 P.S. § 1303.101 *et seq.*) instituted changes to three areas:

a. Tort reform:

(1) Reduction in statute of limitations.

(2) Modification of collateral source rule; damages will be reduced if the medical care was paid for by health insurance or if the plaintiff received disability insurance payments.

(3) Damages in excess of $100,000 must be in the form of periodic payments.

(4) Damages for lost earnings or earnings capacity to be reduced to present value.

(5) Medical expert must be a physician who is engaged in active clinical practice or teaching and who is experienced in the care at issue. Experts on the standard of care must be of the same or similar specialty of the defendant, and must be board certified in the same or similar specialty if the defendant is board certified (unless the defendant was practicing outside his/her specialty).

(6) Defendants may seek, and courts may order, reduction of verdict based on impact to health care in the community and/or limitations on appeal bonds.

b. Mandatory insurance coverage changes:

(1) Physicians, podiatrists, and hospitals are still required to have malpractice insurance (or self-insurance) and state-sponsored excess coverage, but the amounts have been changed.

(2) Nursing homes, ambulatory surgical centers, primary healthcare centers, birth centers, and certified nurse midwives are now required to have malpractice insurance (or self-insurance) and state-sponsored excess coverage.

(3) State-sponsored Medical Professional Liability Catastrophe Loss Fund ("CAT Fund") is replaced by the Medical Care Availability and Reduction of Error (MCARE) Fund, with subsidies to reduce the amount of annual surcharge physicians and hospitals have to pay to the Fund, and additional discounts for physicians in their first four years of practice after residency.

(4) Coverage obligations and MCARE Fund participation vary with percentage of practice/business done within Pennsylvania.

c. Patient safety:

(1) "Medical facilities" hospitals, birth centers and ambulatory surgical facilities must develop and submit to the Department of Health a patient safety plan.

(2) There are requirements for medical facilities to report events which result in death, compromise patient safety and result in unanticipated injury requiring additional medical care, or involve disruption of the facility's infrastructure or patient care, as well as incidents that might have resulted in patient injury but did not, to the Department of Health and/or a new Patient Safety Authority. A medical facility required to report under the new statewide reporting system (PA-PSRS) ceases to report under sections 1.3 (f) and (g) of 28 Pa. Code. There are also new requirements for hospitals and nursing homes facilities to report health-care acquired infections (HAIs) effective February 14, 2008. 40 PS § 1303.401 *et seq*.

(3) Medical facilities are required to notify the affected patient or an adult family member within seven days of an event which results in death or "compromises patient safety and results in an unanticipated injury requiring delivery of additional health services to the patient."

(4) Physicians are required to self-report to their state licensure board any medical professional liability complaints filed against them, any disciplinary action taken against them by another jurisdiction, any controlled substance abuse convictions, and any arrests for certain offenses.

(5) Starting in 2003, physicians must meet a continuing medical education requirement of 100 hours every two years.

(6) A physician's misrepresentation of his/her professional credentials, training, or experience defined as a breach of the requirement that a surgeon obtain informed consent.

(7) Entries in medical records are required to be made contemporaneously or as soon as practicable. Healthcare providers (including employees of healthcare providers) are required to report improper alteration and destruction of medical records to the appropriate licensing board.

2. Apportionment of liability:

a. Act 57 of 2002 (June 19, 2002), known as the "Fair Share Act," amended 42 Pa. C.S. § 7102 to eliminate joint and several liability where a defendant is found to be negligent but responsible for less than 60% of the total liability apportioned to all parties. Under Act 57, joint and several liability still applies in cases involving intentional torts and intentional misrepresentations. The statutory history of Act 57 also indicated that it would be applicable only to cases where the cause of action arose after the effective date. *See e.g.*, *Slayton v. Gold Pumps*, Court of Common Pleas of Allegheny County, GD 03-010873, Opinion by Strassburger, J. (10/25/04) (identifying date of diagnosis as relevant date for determining application of the Act).

b. In July, 2005, the Commonwealth Court declared Act 57 unconstitutional on grounds that it violated the single subject requirement of Article III, Section 3 of the Pennsylvania Constitution. Act 57 amended the DNA Detection of Sexual and Violent Offenders Act and also included a provision relating to joint and several liability for acts of negligence. The Commonwealth Court overturned the Act on the grounds that the elimination of joint and several liability did not "bear a proper legislative relation" to amendments to the DNA Act. *DeWeese v. Weaver*, 880 A.2d 54 (Pa. Commw. Ct. 2005). On September 28, 2006, the Pennsylvania Supreme Court, in a Per Curiam Order, affirmed the Commonwealth Court's holding. *DeWeese v. Cortez*, 906 A.2d 1193 (Pa. 2006).

No further opinion was issued by the Supreme Court, leaving the ruling by the Commonwealth Court to stand as the last word.

c. On February 3, 2006, the Pennsylvania Bar Association reported that the state House of Representatives would likely be voting soon on legislation, Senate Bill 435, that would re-enact joint and several liability reform and minimize hospitals and businesses as "deep-pockets" in liability lawsuits. The Fair Share Act was, in fact, redrafted by the Pennsylvania Legislature in 2006 to comply with the specifications of Pennsylvania's Single Subject Rule, however this legislation was vetoed by Governor Edward G. Rendell.

3. Venue: Act 127 of 2002 (effective December 16, 2002) amended 42 Pa. C.S. to add a new section 5101.1 to limit venue for medical professional liability actions to the county in which the cause of action arose. The Pennsylvania Supreme Court has amended the venue rules to conform to this requirement, applicable to cases filed on or after January 1, 2002.

C. Informed Consent of Patient

1. Doctrine in Pennsylvania based upon theory of battery and requirement of informed consent is limited to physically intrusive procedures such as surgery.

2. Doctrine requires disclosure of the nature of the operation, the risk, side effects and alternate treatment. Failure to obtain informed consent may result in liability even if no "negligence" was involved.

3. Exceptions - Where these apply, consent should be obtained from a legally authorized person (guardian, power of attorney) or next of kin.

   a. Patient is unconscious or otherwise incapable of consenting and the harm from failure to provide care is imminent.

   b. Disclosure poses a significant and serious threat to the patient's health so as to outweigh the benefits of disclosure ("therapeutic privilege").

4. Statutory definition under the Pennsylvania Health Care Services Malpractice Act provides that a physician owes a duty, except in emergencies, to obtain the informed consent of a patient or a patient's authorized representative before performing, surgery; administering anesthesia, radiation, chemotherapy, or a blood transfusion; insertion of a surgical device or appliance; administration of an experimental medication or device; or performance of a procedure in an experimental manner. 40 P.S. § 1301.811-A.

5. The informed consent doctrine requires physicians to provide patients with "material information necessary to determine whether to proceed with the

surgical or operative procedure or to remain in the present condition." *Sinclair by Sinclair v. Block*, 633 A.2d 1137, 1149 (Pa. 1993).

6. The responsibility of advising the patient of his or her condition and obtaining the consent rests with the physician (*see, e.g., Foflygen v. R. Zemel, M.D.*, 615 A.2d 1345 (Pa. Super. 1992), *app. den'd* 629 A.2d 1380 (Pa. 1993)), who must give the patient "a true understanding of the nature of the operation to be performed, the seriousness of it, the organs of the body involved, the disease or incapacity sought to be cured, and the possible results." *Gray v. Grunnagle*, 223 A.2d 663, 674 (Pa. 1966). Thus, a physician must "advise the patient of those material facts, risks, complications and alternatives to surgery that a reasonable person in the patient's situation would consider significant in deciding whether to have the operation." *Gouse v. Cassel*, 615 A.2d 331, 334 (Pa. 1992).

7. Effective for causes of action arising on or after March 20, 2002, a physician may be found liable "for failure to seek a patient's informed consent if the physician knowingly misrepresents to the patient his or her professional credentials, training or experience." 40 P.S. § 1303.504(d)(2). This legislative expansion of the doctrine of informed consent was enacted in response to the Pennsylvania Supreme Court's decision in *Duttry v. Patterson*, 771 A.2d 1255 (Pa. 2001), where the court held that information personal to the physician, such as his/her experience in performing the procedure in question, was irrelevant to the doctrine of informed consent, whether the patient had specifically sought such information or not.

8. A patient's informed consent claim against a physician arising out of an allegedly defective medical device may not be based on the physician's failure to inform the patient of the device's FDA status. *Southard v. Temple University Hospital*, 781 A.2d 101 (Pa. 2001).

9. Pennsylvania statutes identify special consent situations where prior written consent in accordance with the statutory provisions must be obtained. These include abortion, breast surgery, organ donation, HIV testing, and autopsies. *See, e.g.*, 35 P.S. § 7605 (consent requirements for HIV testing).

D. Who Exercises the Right to Make Decisions Regarding Treatment?

   1. Who can make decisions?

      a. Adults. Adults generally have the right to make treatment decisions on their own behalf, unless they are "incapacitated." Pennsylvania's Act 169 on advanced directives and other health care decision-making also uses the term "incompetent" to describe when a person is unable to make treatment decisions. See discussion on Act 169 further below.

b. Minors. Generally, care may be rendered to a minor with the consent of the minor's parent or legal guardian. Pennsylvania law generally defines a minor as an individual under the age of 18. 20 Pa. C.S. § 102.

(1) Any minor may consent to care

(a) To determine the presence of or treat pregnancy and venereal disease (not including abortion).

(b) Relating to the use of a controlled or harmful substance. 71 P.S. § 1690-112.

(2) For mental health care for minors 14 and older, Act 147 of 2004, effective January 22, 2005, provides that:

(a) Either the minor him/herself, or the minor's parent or legal guardian, may give consent for the minor's outpatient mental health examination and treatment;

(b) Without the need for the other to consent as well; and

(c) The minor cannot abrogate the parent/guardian's consent, nor can the parent/guardian abrogate the minor's consent.

(3) With regard to inpatient mental health treatment -

(a) A minor's parent or legal guardian can consent to voluntary inpatient treatment on behalf of a minor on the recommendation of a physician who has examined the minor; the minor's consent is not necessary.

(b) A minor 14 years of age or older may also consent to his/her own voluntary inpatient mental health treatment.

(c) A minor 14 years of age or older who has been confined for inpatient treatment under consent of his/her parents and who objects to that treatment has a right to petition the court of common pleas requesting withdrawal from or modification of treatment.

(d) Act 147 also contains provisions regarding such court proceedings, continued court supervision in situations when court intervention has been sought, disputes regarding the minor's inpatient treatment between custodial and non-custodial parents, and handling of minors' mental health treatment records.

2. Persons who are incapacitated.

a. The term "incapacitated person" is defined to mean "an adult whose ability to receive and evaluate information effectively and communicate decisions in any

way is impaired to such a significant extent that he is partially or totally unable to manage his financial resources or to meet essential requirements for his physical health and safety." 20 Pa. C.S. § 5501.

b. Guardianships. A guardian may make treatment decisions on behalf of an incapacitated person.

    (1) The guardian has a fiduciary duty to the patient and must act in that person's best interests.

    (2) There are plenary (i.e., full), limited, and emergency guardianships under Pennsylvania law.

    (3) In connection with healthcare decisions the emergency guardianship is most frequently utilized. The emergency guardian has only those powers and duties as directed by the court in its order, and serves only for such time as the court directs in its order. 20 Pa. C.S. § 5513. Generally, an emergency guardian does not serve for more than 20 days.

c. Persons holding a power of attorney. The power of attorney is a legal device pursuant to which the principal may empower his attorney in fact or agent to perform certain acts such as "authorize medical and surgical procedures." The law does not expressly provide that an agent may refuse treatment. 20 Pa. C.S. § 5601 *et seq.*

d. Execution of an advance directive (living will and/or power of attorney) pursuant to Act 169.

3. Persons with diminished capacity. Often, the most difficult cases are those when the patient probably would not meet the legal standard of incapacity, but does appear disoriented.

E. When Can Treatment Be Refused?

1. Implicit within the right to consent to treatment is the right to refuse treatment. This is not an absolute right.

2. The state or other persons may have rights which outweigh the patient's. The state's interests may include:

    a. Preservation of life: A balancing test which weighs the state's interest in prolonging a life against the interests of an individual in rejecting burdensome emotional and financial costs of prolongation.

    b. Protecting innocent third parties: Generally, the impact of refusal of treatment in any minor children.

    c. Preventing suicide (versus death by natural causes).

d. Preserving the ethical integrity of the medical profession: Historically, this rationale was cited as in support of refusing to discontinue treatment. However, prevailing medical and ethical concerns no longer dictate that all efforts toward life prolongation be made on behalf of certain patients.

3. Can treatment be refused?

   a. A competent adult has the right to refuse medical treatment. This is a qualified right.

   b. In *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990), the U.S. Supreme Court:

      (1) Acknowledged the right of a competent adult to refuse treatment; and

      (2) Upheld Missouri's right to require "clear and convincing evidence" of the now-incompetent patient's intent before allowing withdrawal of life-sustaining treatment.

   c. The Pennsylvania Supreme Court has also affirmed the right of an adult to refuse treatment, and has set forth guidelines as to who may serve as surrogate decision maker where the patient never expressed his wishes while competent. *In re Fiori*, 438 Pa. Super. 610, aff'd 543 Pa. 592 (1996).

   d. In a case involving a Jehovah's Witness who had executed a clear advance directive refusing blood transfusion therapy of any kind, the Superior Court held that the patient's right of self-determination must be respected, despite the fact that without a transfusion her death was inevitable. *In re Duran*, 769 A.2d 497 (Pa.Super. 2001).

   e. In January, 2006, the U.S. Supreme Court held that federal Controlled Substances Act (CSA), 21 U.S.C. § 829(a), did not criminalize physicians' prescribing drugs intended to painlessly end the life of dying persons under Oregon's Death With Dignity Act, which legalizes physician-assisted suicide under certain limited circumstances. In doing so, the Court held that Congress had not intended, in enacting the CSA, to "[delegate] to a single Executive officer the power to effect a radical shift of authority from the States to the Federal Government to define general standards of medical practice in every locality." *Gonzales v. Oregon*, 126 S. Ct. 904 (2006).

4. Advance Directives and Healthcare Decision-making Under Act 169.

   a. Act 169 of 2006, which became effective January 29, 2007, amends existing statute governing living wills and health care powers of attorney, known as "advanced directives." It also clarifies the responsibilities of providers with respect to advanced directives and other end-of-life issues.

b. Act 169 addresses who has authority for health care decisions for an individual who is deemed to be "incompetent." A "competent" individual is defined as one who:

   (1) understands the potential material benefits, risks and alternatives concerning a specific, proposed health care decision;

   (2) is able to make that health care decision on his own behalf; and

   (3) is able to communicate that health care decision to another person.

c. Persons with authority to make health care decisions on behalf of an incompetent individual include:

   (1) health care agents, who are specifically appointed to make health care decisions for the individuals in a living will or a health care power of attorney;

   (2) health care representatives, who are empowered to make health care decisions in the absence of a living will or health care power of attorney, according to a priority list established by Act 169 (spouses, children, etc.); and

   (3) legal guardians pursuant to existing state law on general guardianship (see discussion above).

      (a) If the patient already has a general power of attorney, and is determined to be incapacitated, the health care agent is accountable to the guardian as well as to the patient.

d. An "advanced health care directive" can be a:

   (1) Living will, which is a document that communicates an individual's specific wishes about life sustaining treatment and other end-of-life care. Living wills become "operable" when an individual is determined to be incompetent and have either an end-stage medical condition or is permanently unconscious; or

   (2) Health care power of attorney, which is a document in which an individual names a power of attorney to make choices for the individual, and under what circumstances. A health care power of attorney also may include instructions for specific circumstances, such as which hospital at which the patient wishes to seek treatment.

   (3) A combined living will/power of attorney. Act 169 includes a sample, combined living will/health care power of attorney form. Other forms may be used, as long as they meet the statutory requirements.

e. In order for an advanced health care directive to be valid, the individual making the directive must be an adult (18 years or older) of sound mind, or a minor of sound mind who has graduated from high school, has married, or is emancipated.

f. The directive must be written, signed and dated, and witnessed by two adults.

g. In order for a living will to become operable, it must be presented to the attending physician, and the individual must:

   (1) Be determined to be incompetent, as determined by the individual's physician, or in some instances a team of practitioners; and

   (2) Have an end-stage medical condition or be permanently unconsciousness. An end-stage medical condition is one which is incurable and irreversible, in an advanced state, and will result in death, despite medical treatment.

h. Act 169 clarifies that the provider must assume that the individual would want artificial hydration and nutrition unless specifically stated otherwise in writing, or it is clear based on the individual's preferences and values that the individual would not want life-sustaining treatment.

i. Physicians and providers who act in good faith pursuant to the law have broad immunity protections.

j. Judicial intervention may be necessary in the event of a dispute between family members and/or others, where the living will or power of attorney does not provide clear guidance or there are multiple health care representatives with equal authority.

k. A provider may refuse to comply with directions to withhold or withdraw life-sustaining treatment if he/she/it informs the individual or his/her patient's agent or representative, and assists in the transfer of the individual to another provider who will comply.

l. Act 169 codifies the requirements governing out-of-hospital do-not-resuscitate (DNR) orders to be followed by emergency medical services (EMS) personnel in the event of cardiac or respiratory arrest. A competent person with an end-stage medical condition or his/her agent, or the parent of a minor with an end-stage medical condition, may request a DNR order from his/her physician.

m. An individual may have a health care advanced directive and a mental health care advanced directive, or the health care advanced directive may address mental health issues.

5. Advance Directives for Mental Health Care. Effective January 30, 2005, Act 194 of 2004 (20 Pa. C.S. §§ 5308-5808) provides a statutory means whereby adults can make their wishes for mental health care known through

either of two new legal instruments: a mental health declaration or a mental health power of attorney.

a. Adults are presumed capable of making mental health decisions, including the execution of a mental health declaration or power of attorney, unless they are adjudicated incapacitated, involuntarily committed, or found to be incapable of making mental health decisions after examination by at least two specified health professionals, one of whom must be a psychiatrist.

b. Directives for mental health care.

   (1) Mental health declaration becomes effective once the declarant ("principal') is incapacitated, and provides instructions as to his/her treatment preferences (e.g., as to facility, medication preferences, court-appointed guardian, and whether or not the declarant consents to electroconvulsive therapy and/or participation in experimental studies or drug trials).

   (2) Mental health power of attorney appoints another person ("agent") to make decisions on behalf of the person who executes it ("principal").

   (3) The two instruments may be combined in a single document, whereby the mental health agent is only empowered to act with regard to issues left unresolved by the mental health declaration.

   (4) Mental health declarations and mental health powers of attorney expire after two years; however, if the principal is incapable of making mental healthcare decisions at the time the document would expire, it remains in effect until the principal regains capacity.

   (5) A mental health declaration or power of attorney may be revoked by the principal at any time, unless he or she has been found to be incapable of making mental health decisions or has been involuntarily committed. Special rules apply if the principal has been involuntarily committed.

6. Anatomical donation*:* The Uniform Anatomical Gift Act provides that any competent individual 18 years of age or older may execute a document gifting all or any part of the person's body. The gift becomes effective upon the donor's death. 20 Pa. C.S. § 8601 *et seq*.

7. The Federal Patient Self Determination Act requires that at the time of admission to a hospital or nursing home, an adult patient must be advised of his or her rights to refuse treatment under state law and questioned whether they have an advance directive. Any advance directive should be made a part of the medical record.

F. Privacy and confidentiality

1. Pennsylvania courts recognize a tort for breach of physician-patient confidentiality in circumstances where judicial proceedings are not involved. *Haddad v. Gopal*, 317, 787 A.2d 975 (Pa. Super. 2001), appeal denied, 813 A.2d 842 (Pa. 2002). The *Haddad* court noted that the case concerned the disclosure of information on a patient's sexually transmitted disease, which other Pennsylvania courts have deemed to be highly sensitive information.

   a. Physicians have a duty to obtain either express or implied consent prior to releasing confidential information to third parties. Failure to do so will result in civil liability. *Id.* at 981.

   b. In limited circumstances, based on an objective review of the totality of the circumstances, a patient's conduct may result in implied consent to disclose confidential information. Such consent also serves as an affirmative defense to an action for breach of physician-patient confidentiality. *Id.* (Although the Pennsylvania courts have not addressed the issue, implied consent could be based on the patient's execution of a HIPAA notice. See HIPAA discussion below.)

   c. *Haddad*, by its own terms, applies only to disclosures by physicians. Disclosures by others would presumably be governed by earlier case law, where Pennsylvania courts recognized that improper disclosure of health information might constitute the tort of invasion of privacy. *See Chicarella v. Passant*, 494 A.2d 1109, 1114 (Pa. Super. 1985).

2. Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191), 110 Stats. 1936 (Aug. 21, 1996) ("HIPAA").

   a. Under the Administrative Simplification provisions of HIPAA, HHS was mandated to promulgate a set of interlocking standards and protections for healthcare information. The three areas of focus include:

      (1) Transaction and Code Set Standards: Federal regulations provide a national standard electronic format to be used in certain healthcare transactions, including electronic transactions with payors. 68 Fed. Reg. 8381 (Feb. 20, 2003).

      (2) Security Standards: Regulations include a number of required elements for the secure storage, maintenance and transmission of protected health information become effective April 20, 2005. 68 Fed. Reg. 8333 (Feb. 20, 2003).

      (3) Privacy Standards: regulations apply to healthcare providers and health insurance plans. 67 Fed. Reg. 53182 (Aug. 14, 2002). The HIPAA privacy regulations survived a comprehensive court challenge in *Citizens for Health v. Leavitt*, 428 F.3d 167 (3d Cir. 2005).

3. The HIPAA privacy regulations.

   a. The regulations provide that covered entities (health care plans, health care clearinghouses and covered health care providers) generally must provide an individual with written notice of the individual's privacy rights and its privacy practices with regard to Protected Health Information ("PHI"), and to make a good faith effort to obtain a written acknowledgement of the individual's receipt of the notice.

      (1) The regulations prescribe the amount of information which may be disclosed and the rights of patients regarding access to and information regarding release of their confidential patient information.

      (2) Certain permitted disclosures without consent or authorization are provided for in the regulations (e.g. judicial proceedings, coroner, funeral directors, organ and tissue procurement organizations, etc.).

      (3) Entities that are not covered healthcare entities are regulated indirectly through the imposition of standards on covered healthcare entities' relationships with Business Associates.

      (4) Regulations require a HIPAA Compliance Plan.

   b. State privacy laws that are more protective of patient privacy or that give patients greater access to their personal health information preempt HIPAA; otherwise HIPAA preempts state law. More stringent Pennsylvania laws include:

      (1) Confidentiality of HIV-Related Information Act, 35 P.S. §§ 7601 - 7612.

      (2) Certain records protected by the Mental Health Procedures Act, 50 P.S. § 7101 *et seq*.

   c. Certain small physician practices and other providers that do not use electronic billing or electronic verification of patient eligibility for health insurance coverage are not considered to be "covered entities" and so are not subject to the HIPAA privacy regulations – but the rules are tricky and an experienced HIPAA lawyer should be consulted as to whether this exception applies to any particular practitioner.

   d. Enforcement/Penalties: Statutory criminal and civil penalties and fines. Fines of up to $250,000 and imprisonment for "knowing" violations. The highest penalties apply when the violation is committed under false pretenses and when the privacy breach is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm. There is no general good faith exception.

e. On June 1, 2005, the Office of Legal Counsel of the Department of Justice issued a formal ruling to the effect that only "covered entities" (i.e., health care providers, insurers, and clearinghouses) – but not necessarily their employees or outsiders who steal patient data – may be held liable under this criminal provision.

(1) The ruling is binding upon the executive branch of the federal government, but not on judges.

(2) As of the time of the ruling, there had already been former employee sentenced to jail for improper use of patient information, based on an interpretation of the law inconsistent with the DOJ's ruling.

VI. PAYMENT FOR HEALTHCARE SERVICES

A. The Importance of Third Party Payors

1. Health care is unique in the American economy in that most people do not pay for most of it themselves. Instead, their health care is paid for by their employers, insurance companies paid by their employers, and/or a government program. These paying entities are known as "third party payors."

2. As a result:

a. Many believe that because the customer (patient) is generally divorced from the cost of the service he receives, the usual market checks on excess consumption do not apply.

b. Thus, concerns about the volume of services utilized, and their cost, manifest themselves not in dealings between doctor and patient, but:

(1) Between employers and health insurance companies[2] (including HMOs);

(2) Between employers and labor unions, if the workforce is unionized; and

(3) For governmental programs, in the political arena.

c. Concerns are beginning to arise over the degree to which payors' economic interests are affecting actual patient care with regard to:

(1) Setting and nature of care.

(a) Inpatient vs. outpatient

---

[2] In Pennsylvania, HMOs, Blue Cross, and Blue Shield are technically not "insurance companies," since they are licensed under different statutes. We use the term in this outline in the conversational sense, to mean all non-governmental entities that operate as third party payors.

(b) Length of stay

(c) Access to medical specialists

(2) Access to specialized services such as:

(a) Expensive diagnostic equipment such as MRIs;

(b) Rehabilitation;

(c) Mental health treatment; and

(d) Cutting-edge technologies and therapies.

d. Pay for Performance Initiatives.

(1) Recently both private payors and Government payors have created incentives to improve quality through its payment systems.

(2) CMS, along with accreditation and provider organizations, has played a critical role in building the infrastructure to move to pay for performance. The agency has identified and developed quality measures, collected standard data on quality, and published information on the performance of some providers. The agency also has developed demonstration programs to test various aspects of pay for performance.

B. Types of Third-Party Payment Arrangements

1. Indemnity-type insurance*:* Patient chooses service, incurs cost, and is reimbursed for all or part of her out-of-pocket expenses by the insurer.

a. Historically, two kinds:

(1) Blue Cross/Blue Shield plans.

(a) Blue Cross covers institutional health services such as hospital stays; Blue Shield covers the services of physicians and other practitioners.

(b) The Blues are typically not-for-profit under state law, however are taxable under federal law.

(c) Often (as in Pennsylvania), they are licensed under special statutes.

(d) They are often required to do "community rating" (i.e., health risk data such as age, habits, etc. are drawn from a community profile, rather than from a smaller group of insureds).

(e) Historically, the Blues have contracted directly with hospitals and physicians; payment goes directly to the provider rather than as reimbursement to the patient.

(2) Commercial insurance.

(a) Licensed as insurance companies and taxed.

(b) Historically did not contract directly with providers but indemnified the patient for his expenses.

b. Pure traditional indemnity health insurance now exists more in theory than in practice, as such products have taken on more and more of the attributes of managed care, and traditional indemnity insurers have developed managed care products and subsidiaries.

2. Managed care.

a. Managed care is a model of healthcare delivery that involves some type of coordinated and often prevention-oriented healthcare plan entailing some degree of restriction on a beneficiary's choice of provider.

b. Managed care may be used by any payor, public or private.

c. Managed care payor arrangements include health maintenance organizations (HMOs) and preferred provider organizations (PPOs).

3. Health maintenance organizations (HMOs).

a. A health maintenance organization is a healthcare delivery system which, in exchange for the subscriber's monthly payments, undertakes to provide all healthcare services, from the most routine (e.g., well baby care) to the most sophisticated.

b. HMOs generally function by using a primary care physician ("PCP") (i.e., family practitioner, internist, pediatrician or, in some cases, OB-GYN or other specialist) as a "gatekeeper" who:

(1) Serves as the patient's sole source of entry into the healthcare system (except in those limited circumstances recognized by the HMO as emergencies); and

(2) Must approve the patient's use of other healthcare services such as:

(a) Use of medical specialists;

(b) Diagnostic tests not performed at the PCP level (e.g., CT scan, upper GI series);

(c) Hospitalization or other institutional treatment; and

(d) Surgery.

c. HMOs are a hybrid of healthcare delivery (i.e., provision of services) and insurance (i.e., shifting of the risk of loss); thus they are regulated by both the Department of Health and the Insurance Department. *See* 40 P.S. § 1551 *et seq.*; 31 Pa. Code § 301.1 *et seq.*

4. Point-of-service ("POS") products are a hybrid between managed care and indemnity plans.

   a. Under POS plans, an HMO patient may choose an out-of-network provider, and the HMO will act like an indemnity insurer, paying what would typically be a portion of the provider's charges after the patient has met her annual deductible and subject to patient coinsurance. If the amount the HMO will pay is less than the provider's full charges, the provider may balance-bill the patient for the rest. (The POS patient has little or no additional financial exposure of this kind if she chooses to receive healthcare services through the HMO's network and in accordance with its referral requirements.)

   b. Regulations governing POS products are at 31 Pa. Code § 301.201 - 301.204.

5. Preferred provider organizations (PPOs) are delivery systems where the plan administrator assembles a provider network for the delivery of health care.

   a. Typically, a PPO plan allows the beneficiary to use any physician and any hospital. However, the beneficiary will be assessed much higher out-of-pocket costs if he or she uses a "non-preferred" provider (i.e., one that is not a member of the PPO's network).

   b. Like HMOs, PPOs are subject to regulatory oversight by both the Insurance Department and the Department of Health. *See* 40 P.S. § 764a; 31 Pa. Code § 152.1 *et seq.*

6. High deductible health plans and Health Savings Accounts.

   a. This new approach (known to businesses and health insurers as "consumer-directed health care") first became available as part of the Medicare Modernization Act of 2003. The President in his 2006 State of the Union Address proposed expanding it.

   b. Health Savings Accounts (HSAs) are an IRA-like mechanism that permits individuals to save, tax-sheltered, for future healthcare needs. They are available *only* to persons covered by a high deductible health plan who are not also covered by another health plan or by Medicare.

c. A high deductible health plan (HDHP) has a deductible of at least $1,050 for an individual and $2,100 for family coverage. Annual out-of-pocket expenses for deductible, copayments, and coinsurance may not exceed $5,000 for an individual or $10,000 for a family. (IRS rules provide that some expenses a consumer might consider legitimate need not count toward these limits.)

d. The high deductible means that expenses for the first $2,100 worth of healthcare services a family needs in a year are paid out-of-pocket by the family. Theoretically, they will be paid out of the HSA.

e. The theory behind these arrangements is that they will force consumers to be more cost-conscious in their use of healthcare services.

f. In their consumer-friendliest form, an employer would offer an HDHP and put the amount of the deductible into the employee's HSA. Even though HDHPs cost the employer less than more generous health coverage, this kind of subsidy is probably not economically feasible given the cost of HDHPs. More often, the employer may contribute an amount less than the deductible to employees' HSAs, or may contribute nothing at all to them.

g. The consumer may also make tax-deductible contributions to his or her HSA.

h. Money may be taken out of HSAs only for healthcare items and services that would be deductible (for a qualifying taxpayer) under IRS rules. If money is left in an HSA when the owner reaches Medicare age, the owner may use that money for any purpose.

C. Governmental Programs

1. Medicare.

a. Medicare is an exclusively federal program providing two types of health insurance for eligible elderly and other individuals, under which physicians, hospitals, and other providers are paid for the covered services they provide to Medicare beneficiaries.

(1) Part A, "Hospital Insurance," provides payment for inpatient hospital, skilled nursing, home health, and related care.

(2) Part B, "Supplementary Medical Insurance," pays for physicians' services and other medical services.

(3) Actual payment methodologies vary depending on type of provider.

(4) It should be noted that Medicare, because of its national scope and controlling published regulations, often becomes the standard for other payors.

b. Medicare is administered at the national level by the Centers for Medicare & Medicaid Services ("CMS") within HHS.[3]

c. Medicare payment arrangements:

(1) Regular Medicare is modeled after Blue Cross/Blue Shield as an indemnity-type arrangement. Providers are paid fee-for-service based on payment rates set by the program.

(2) HMOs may contract with Medicare to provide the full range of covered services to those Medicare beneficiaries who signed up for HMO coverage. The primary means by which HMOs have been paid under such contracts was the "risk method," whereby the HMO agreed to provide such services for a flat per-member per-month ("PMPM") fee.

(3) As part of the Balanced Budget Act of 1997, Congress enacted Medicare Part C (42 U.S.C. § 1395w-21 *et seq*.), which consolidated and expanded provisions whereby private entities may contract with Medicare to take over management and payment for covered services by:

(a) Expanding risk contracting eligibility to various kinds of "Medicare+CHOICE organizations," including:

(i) HMOs;

(ii) Indemnity insurers; and

(iii) "Provider sponsored organizations" ("PSOs").

(b) Reducing the PMPM fees Medicare paid to such organizations; and

(c) Adding a number of regulatory requirements applicable to Medicare+CHOICE organizations.

(4) In the 2003 Medicare Prescription Drug, Improvement and Modernization Act, Congress changed the name of "Medicare+CHOICE" to "Medicare Advantage" ("MA"). In addition, the new statute:

(a) Immediately increased payments to MA plans to 100% of the what Medicare would spend under regular, fee-for-service Medicare.

(b) Allowed Medicare managed care plans to cover broader, potentially multi-state regions rather than just local (county or equivalent) areas, and encouraged plans to provide national coverage.

---

[3] CMS was formerly known as the Health Care Financing Administration ("HCFA").

(c) Authorized MA plans to offer PPO-type services, by permitting them to charge beneficiaries higher cost-sharing amounts if they seek care from non-contracted providers.

(d) Will provide financial subsidies to encourage regional MA plans to enter and remain in the Medicare market.

(e) Allows regional MA plans serving more than one state to choose to operate under the licensure laws of any state in their service region, with other states' laws not applicable.

(f) Scaled back the degree of oversight the federal government can exercise over the managed care plans' offering of incentives to physicians to control plan beneficiaries' access to healthcare services.

(g) Preempts state laws and regulations (other than licensing laws or laws relating to plan solvency), and prohibits states from taxing the plans' premiums.

(h) Starting in 2010, there will be a six-year demonstration project in six metropolitan statistical areas, whereby traditional fee-for-service Medicare will compete on a cost basis with Medicare managed care plans.

d. Sources of law (Medicare):

(1) Statute - 42 U.S.C. § 1395 *et seq.* (Title XVIII of the Social Security Act).

(2) Regulations - 42 C.F.R. § 405.465 *et seq.*; *see also* 42 C.F.R. § 400.200.

(3) Interpretive rules: Manuals, regulatory preambles, CMS rulings.

(4) Other sources of guidance:

(a) Carriers and intermediaries; and

(b) Administrative hearing decisions (PRRB, CMS Administrator, MGCRB, DAB).

2. Medicaid.

a. Medicaid (also known as "Medical Assistance" or "M.A.") is a program of medical assistance, funded jointly by federal and state government, for impoverished individuals who are aged, blind or disabled, or members of indigent families with dependent children that meet income and resource standards set by the state. State Medicaid programs are governed by state rules and criteria that vary widely within a broad framework of federal guidelines.

b. Sources of law (Medicaid):

(1) "State Plan" - General scheme of reimbursement developed by each state which is approved by federal officials.

(2) Federal statute - 42 U.S.C. § 1396 *et seq.* (Title XIX of the Social Security Act).

(3) Pennsylvania statute - 62 P.S. § 441.1 *et seq.*

(4) Federal regulations - 42 C.F.R. Part 430. *See also* 42 C.F.R. § 400.203.

(5) Pennsylvania regulations – 55 Pa. Code § 1101.11 *et seq.*

3. Other governmental programs.

a. State Children's Health Insurance Program - Provides federal matching funds to states who provide expanded insurance coverage to low-income children.

b. Pharmaceutical Assistance Contract for the Elderly (PACE) - Subsidized prescriptions for low-income elderly Pennsylvanians.

D. Importance of all this to health lawyers

1. Because third party payors are effectively the only significant source of payment for healthcare providers, knowledge of their requirements is essential for structuring business arrangements in the healthcare field. Such requirements are found in:

a. Regulations (including interpretive rules); and

b. Contract requirements (in multiple contracts with different payors).

2. Governmental programs are the mechanism whereby many, many regulations not directly related to payment are imposed on healthcare providers. Examples:

a. Limitations on physician referrals (Stark law).

b. Emergency Medical Treatment and Active Labor Act (EMTALA) = requirements for intake in hospital emergency rooms.

c. Requirements for advance directives (living wills).

3. Specific regulations relating to government payment.

a. Billing rules.

b. Record-keeping requirements (including medical records).

c. Whether and to whom accounts receivable may be assigned.

VII. FRAUD & ABUSE

A. Health lawyers use the term "fraud and abuse" as shorthand for the laws and regulations that have been adopted to further the government's goal of ensuring that publicly funded healthcare programs - primarily Medicare and Medicaid - are not improperly exploited for financial gain by fraud or overuse.

B. The principal "fraud and abuse" laws are:

1. Those sections of the Social Security Act originally enacted as the "Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977," and amended many times since (the principal substantive portions of which are now codified at 42 U.S.C. §§ 1320a-7, 1320a-7a, 1320a-7b, and 1320a-5), collectively referred to in this outline as the "F&A Act;"

2. The physician anti-referral law, known as the "Stark Law" or "Stark II" (42 U.S.C. § 1395nn); and

3. The False Claims Act (31 U.S.C. §§ 3729-3731).

C. Principal areas of concern:

1. **The single most important thing to learn about health law is that in the healthcare industry it is illegal to offer or give (or receive) *anything* of value to encourage the referral of business.** (The anti-referral laws are discussed in detail in sections VII.G through J below).

2. False billing laws, which form the basis of most enforcement activity, are discussed in section VII.K below.

D. Most important prohibitions in the F&A Act (i.e., those for which for which the law provides both criminal and civil penalties):

1. Knowing and willful making of a false statement or misrepresentation of a material fact in connection with application for or determination of rights to benefits or payment. 42 U.S.C. § 1320a-7b(a).

2. Knowing and willful solicitation or receipt of any remuneration in return for referring persons or arranging for acquisition of goods or services. 42 U.S.C. § 1320a-7b(b).

3. Knowing and willful making or inducement of any false statement or representation of a material fact with respect to the conditions or operation of any institution or facility in order that such institution or facility may qualify to participate in the Medicare or Medicaid program. 42 U.S.C. § 1320a-7b(c).

4. Knowing and willful charging or acceptance of excess payments under Medicaid. 42 U.S.C. § 1320a-7b(d).

E. Due process

1. Criminal prosecutions involves the full range of constitutional protections.

2. Civil penalties are imposed via administrative proceedings with very limited appeal rights; see 42 U.S.C. § 1320a(c)-(f); 42 C.F.R. § 1001.100 *et seq*.

F. Penalties

1. Criminal: The acts listed above (in their various permutations) are felonies, punishable by fines of up to $25,000 and imprisonment of up to 5 years, per violation. (The F&A Act also creates two misdemeanors not detailed here.)

2. Civil:

a. Exclusion.

(1) Mandatory exclusion.

(a) HHS Secretary *must* exclude from participation in Medicare, Medicaid, and state health programs funded through Title V, XX, or XXI of the Social Security Act (the "Programs"), any individual or entity that has been convicted under federal or state law:

(i) Of a criminal offense related to the delivery of an item or service under the Programs. 42 U.S.C. § 1320a-7(a)(1).

(ii) Of a criminal offense relating to neglect or abuse of patients. 42 U.S.C. § 1320a-7(a)(2).

(iii) After August 21, 1996, of a felony relating to fraud, theft, embezzlement, breach of fiduciary duty, or other financial misconduct.

a) In connection with the delivery of a healthcare item or service; or

b) With respect to any act or omission in a healthcare program (other than the Programs) financed in whole or part by a governmental agency.

42 U.S.C. § 1320a-7(a)(3).

(iv) After August 21, 1996, of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance. 42 U.S.C. § 1320a-7(a)(4).

(b) *Note:* The statute defines "conviction" to include a plea of guilty or *nolo contendere*. See 42 U.S.C. § 1320a-7(i).

(2) Permissive exclusion: 42 U.S.C. § 1320a-7(b).

(a) HHS Secretary *may* exclude a person or entity from the Programs for approximately 15 different reasons listed in the statute.

(b) Criteria for permissive exclusion: *see* 42 C.F.R. § 1001.201 *et seq.*

(3) Consequences of exclusion.

(a) Medicare and Medicaid will not pay for any items or services supplied by the excluded person during the exclusion period. *See* 42 U.S.C. § 1395y(e) [Medicare]; 42 U.S.C. § 1396b(i)(2) [Medicaid] and OIG's Special Advisory Bulletin published at 64 Fed. Reg. 52791 (Sept. 30, 1999) and available online at: http://oig.hhs./fraud/advisory opinions/opinions/html.

(b) Exclusion under any one of the Programs means exclusion, for the same period of time, under all of them. 42 U.S.C. § 1320a-7(d).

(c) If an excluded person owns or controls an entity that provides healthcare goods or services under any of the Programs, that entity may be excluded as well. 42 U.S.C. § 1320a-7(b)(8). If the excluded person transfers ownership or control of the entity to a relative or a member of her household, the entity can still be excluded. 42 U.S.C. § 1320a-7(b)(8)(iii).

(d) Following enactment of the Balanced Budget Act of 1997, it is highly unlikely that an excluded person will be able to find work in the healthcare industry, since anyone who employs or contracts with such a person to provide services under any of the Programs is now subject to a substantial civil monetary penalty. 42 U.S.C. § 1320a-7a(a)(6).

b. Civil monetary penalties (42 U.S.C. § 1320a-7a).

(1) The Secretary of Health and Human Services, through the Office of the Inspector General ("OIG") may initiate proceedings to assess civil monetary penalties against any person or entity for various acts and omissions spelled out in the statute, including:

(a) False or fraudulent billing;

(b) Billing for goods or services provided by a person who has been excluded from the program;

(c) Giving false or misleading coverage information to influence a decision to discharge a patient from a hospital;

(d) Contracting with or employing a person who has been excluded from any of the Programs;

(e) Violation of the anti-kickback statute;

(f) Offering remuneration to a Medicare or Medicaid beneficiary in order to influence his/her choice of healthcare provider or supplier; and

(g) Various other acts and omissions too numerous to summarize here.

(2) Such penalty, which is supplemental to any other penalties prescribed by law, is generally up to $10,000 per item or service, plus an assessment of three times the amount claimed for each such item or service. 42 U.S.C. § 1320a-7a. Exceptions:

(a) Violation of anti-kickback statute - $50,000 per offer or transfer of remuneration, plus assessment of up to three times the amount of remuneration.

(b) Misleading information that might cause hospital discharge - $15,000 for each individual as to whom such information was given.

(3) OIG has taken the position that each false item on a bill represents a separate false claim.

(4) Civil monetary penalties can be imposed for a variety of other offenses, including (for example) negligent or intentional violation of EMTALA, which requires that emergency room patients be screened, treated for emergency conditions, and stabilized before transfer. 42 U.S.C. § 1395dd. Note that during 1999 OIG's attention to this area intensified significantly.

c. Civil liability under the False Claims Act.

(1) U.S. Attorney General ("AG") or a private person may bring a civil action in the name of the United States against any person who has obtained or attempted to obtain money from the U.S. Government by making a false statement or otherwise filing a false claim. *See* 31 U.S.C. §§ 3729-3731.

(a) Civil penalty is $5,000-$11,000, plus three times the amount of damages sustained by the government. 28 CFR 85.3 (a)(9).

(b) "Qui tam" actions may be initiated by a private party ("complainant") who prepares a Complaint to initiate litigation in the name of the United States government, and submits it to the AG for review and possible prosecution.

(i) If the AG decides to prosecute the action:

a) The complainant may continue to participate in it as a party; and

b) If the government succeeds in recovering a civil penalty, the court must award the complainant 15-25% of the proceeds.

(ii) If the AG chooses not to take the case, the complainant may prosecute it himself; if he prevails, the court must award him 25-30% of the proceeds, plus reasonable attorney's fees and costs.

(c) False Claims Act used to prosecute providers who billed for services not rendered and more recently to prosecute who failed to comply with quality of care regulations.

G. The Anti-Referral Laws, Part One: The Anti-Kickback Statute

1. Basic prohibition: Knowing and willful solicitation or receipt of any remuneration in return for referring persons or arranging for acquisition of goods or services. 42 U.S.C. § 1320a-7b(b).

a. "Remuneration" is broadly defined; the actual statutory language prohibits the solicitation or receipt of "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1320a-7b(b)(1).

b. The prohibition extends to payments in connection with both the referral of "an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part" under Medicare or Medicaid to payment "in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part" under either program. 42 U.S.C. § 1320a-7b(b)(1)(A), (B).

c. It is also prohibited to knowingly and willfully offer or pay any remuneration for any of the above activities. 42 U.S.C. § 1320a-7b(b)(2).

d. Statutory exceptions:

(1) Discounts obtained by a provider "if the reduction in price is properly disclosed and appropriately reflected in the costs, claims or charges made" by the provider.

(2) Payments by an employer to a bona fide employee.

(3) Certain group purchasing arrangements.

(4) Provider risk-sharing arrangements.

2. Judicial interpretations.

a. If *one purpose* of the payment is to induce referrals, the law is violated. *United States v. Greber*, 760 F.2d 68, (3d Cir. 1985), *cert. denied*, 474 U.S. 988 (1985). *See also*, *United States v. LaHue*, Nos. 99-3344, 99-3347, 99-3352, 2001 WL 708749 (10th Cir. June 18, 2001) (10th Circuit affirmed conviction of Baptist Medical Center CEO and two physicians under the Anti-Kickback statute and rejected arguments that the one purpose application is unconstitutional).

b. Whether the payment increases the government's costs is irrelevant. *United States v. Ruttenberg*, 625 F.2d 173, 177 (7th Cir. 1980).

c. Government is not required to prove that Medicare funds were in fact used to make the referral payment. *United States v. Bay State Ambulance*, 874 F.2d 20, 33-34 (1st Cir. 1989).

d. If the payment is intended to induce referrals, the fact that services were actually rendered by the referring doctors will not foreclose prosecution. *Greber*.

e. A defense of reliance on counsel will not be sustained when the evidence shows that the defendant told the lawyers what to put in the contract with the referring physicians, and not vice versa. *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000).

f. There need not be an actual agreement to refer program-related business. *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995). Nor is it necessary that money actually change hands; the offering or suggestion of an illegal scheme is enough to sustain a conviction. *United States v. Universal Trade and Industry Medical Laboratories*, 695 F.2d 1151 (9th Cir. 1983).

g. However, in the one civil anti-kickback case to reach a federal appellate court, the Ninth Circuit overturned exclusions, in the context of clinical laboratory joint ventures with physicians, holding that:

(1) The law's "knowing and willful" requirement required proof that the joint venturers to "engage in prohibited conduct with the specific intent to disobey the law;"

(2) The fact that a large number of physician-investor referrals to the joint venture resulted in a potential high return on investment, or that the practical effect of low referral rates would be failure of the venture, was insufficient to prove that those involved offered or paid remuneration to induce referrals; and

(3) Even though the joint venture labs were themselves liable (through respondeat superior) under the statute, the physicians who were partners in the joint venture labs were not. *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995). Whether this decision will be followed as to any of these holdings by other circuits remains to be seen.

3. Penalties for violating the anti-kickback law:

   a. Criminal: Any violation provable beyond a reasonable doubt is a felony subject to a $25,000 fine and/or five years imprisonment.

   b. Civil:

      (1) Violation of the anti-kickback law is one basis for permissive exclusion from the Programs.

      (2) Civil monetary penalties: Effective August 5, 1997, the anti-kickback law may be enforced by civil money penalties of $50,000 per act of paying, receiving, offering, or soliciting remuneration, plus three times the amount of remuneration paid, received, offered, or solicited, regardless of whether a portion of such remuneration was for a lawful purpose.

      (3) A number of courts have accepted the premise that a violation of the anti-kickback law can give rise to False Claims Act liability. *Compare United States ex rel. Pogue v. Diabetes Treatment Ctrs. of America., Inc.*, 238 F. Supp. 2d 258, 269 (D.D.C. 2002), *United States ex rel. Pogue v. American Healthcorp, Inc.*, 914 F. Supp. 1507 (M.D.Tenn. 1996) *with U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899 (5th Cir. 1997), *Perales v. St. Margaret's Hosp.*, 243 F.Supp.2d 843 (C.D. Ill. 2003). *See also US ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004); *US ex rel. McNutt v. Haleyville Medical Supplies, Inc.*, 423 F.3d 1256 (11th Cir. 2005).

4. The "Safe Harbor" regulations (42 C.F.R. § 1001.952).

   a. The Secretary of HHS, in consultation with the Attorney General, is required to publish regulations specifying payment practices that would not be treated as a criminal offense under the anti-kickback provisions. Pub. L. 100-93, § 14(a). The statute provides that, once these rules are promulgated, any payment practice specified in such regulations will be considered not to be illegal.

   b. The safe harbor regulations spell out specific conditions under which various types of business arrangements are considered non-abusive.

   c. Common themes in the safe harbors: Fair market value, written contracts of at least a year's duration, full disclosure.

d. Types of arrangements covered in the existing safe harbor regulations (if they meet the conditions spelled out in those regulations):

(1) Investment interests in:

(a) Large, publicly traded companies;

(b) Smaller ventures;

(c) Ambulatory surgical centers; or

(d) Group practices.

(2) Lease of space.

(3) Equipment rental.

(4) Personal services and management contracts.

(5) Sale of practitioner practice.

(6) Referral services.

(7) Warranties.

(8) Discounts.

(9) Bona fide employees.

(10) Group purchasing organizations.

(11) Cooperative hospital service organizations.

(12) Waiver of certain beneficiary coinsurance and deductible amounts.

(13) Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans.

(14) Practitioner recruitment in medically underserved areas.

(15) Subsidies for obstetrical malpractice insurance in medically underserved areas.

(16) Specialty referral arrangements between providers.

(17) Shared risk arrangements:

(a) Between capitated managed care organization and downstream providers and sub-providers.

(b) Between qualified managed care providers and contractors with whom they share "substantial risk."

(18) Ambulance restocking by hospitals/receiving facilities that replenish supplies used by first responders when transporting to the hospitals/receiving facilities.

e. Effect of Safe Harbor rules.

(1) The safe harbor rules did not expand the scope of activities prohibited by the statute. An arrangement that does not fall within any of the safe harbors:

(a) Might not violate the statute at all (i.e., the arrangement is not intended to induce the referral of business reimbursable under the Programs);

(b) Might be a clear violation of the statute with prosecution likely; or

(c) Might constitute a less serious violation of the statute where the degree of risk of investigation and possible prosecution depends on the evaluation of many factors. OIG stated in the preamble to the original safe harbor regulations:

"Certainly, in many (but not necessarily all) instances, prosecutorial discretion would be exercised not to pursue cases where the participants appear to have acted in a genuine good-faith attempt to comply with the terms of a safe harbor, but for reasons beyond their control are not in compliance with the terms of that safe harbor."

"In other instances, there may not even be an applicable safe harbor, but the arrangement may appear innocuous. But in other instances, we will want to take appropriate action."

(2) If multi-purpose payment arrangements involve remuneration from more than one safe harbor area, the conditions of each safe harbor must be met in order to be exempt from liability.

5. Fraud Alerts.

OIG periodically publishes "Special Fraud Alerts" to give continuing guidance to healthcare providers with respect to practices the OIG regards as unlawful. They are published in the Federal Register and are available online at: http://oig.hhs.gov/fraud/fraudalerts.html#1.

6. Advisory opinions.

   a. Since 1996, HHS has been required to provide formal guidance regarding application of the anti-kickback law and the safe harbor regulations, as well as other aspects of the F&A Act, in the form of advisory opinions to particular parties that request them.

   b. The failure to seek an advisory opinion may not be introduced into evidence to prove that a person intended to violate the provisions of the F&A Act.

   c. Advisory opinions are valid only as to the party or parties requesting them. An advisory opinion not issued to a person may not be introduced into evidence to prove that such person did not intend to violate the F&A Act.

   d. Regulations governing advisory opinions: 42 C.F.R. §§ 1008.1 - 1008.59.

   e. Advisory opinions are available online at: http://oig.hhs.gov/fraud/advisoryopinions/opinions.html.

H. The Anti-Referral Laws, Part Two: Stark

1. The Stark Law, 42 U.S.C. § 1395nn, provides that if a physician (or his family member) has a financial relationship with an entity:

   a. The physician may not "make a referral to the entity for the furnishing of *"designated health services"* for which payment may be made under Medicare or Medicaid; and

   b. The entity may not bill for designated health services furnished pursuant to such referral.

2. Key concept: Financial relationship.

Subject to exceptions spelled out in the statute, either of the following is a "financial relationship" that will give rise to the referral ban:

   a. An ownership or investment interest in the entity:

      (1) Such interest "may be through equity, debt, or other means."

      (2) An indirect ownership interest is still an ownership interest.

   b. A compensation arrangement between the physician (or family member) and the entity:

      (1) "Compensation arrangement" is defined as any arrangement involving any remuneration between the physician (or family member) and the entity, other than the following:

(a) Forgiveness of amounts owed for inaccurate tests or procedures, or the correction of minor billing errors;

(b) The provision of items, devices or supplies used solely to collect, transport, process or store specimens for the entity providing the items, etc., or solely to order or communicate the results of tests or procedures for such entity; or

(c) Certain payments made by an insurer or self-insured plan to a physician in satisfaction of a fee-for-service claim.

(2) "Remuneration" is defined as "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind."

3. Key concept: Designated health services*:* A physician who has a financial relationship with an entity may not refer a Medicare or Medicaid patient to that entity for the furnishing of any of the following:

   a. Clinical laboratory services;

   b. Physical therapy, occupational therapy and speech-language pathology services;

   c. Radiology, including MRI, CT scans, and ultrasound services;

   d. Radiation therapy services and supplies;

   e. Durable medical equipment and supplies;

   f. Parenteral and enteral nutrients, equipment, and supplies;

   g. Prosthetics, orthotics, and prosthetic devices;

   h. Home health services and supplies;

   i. Outpatient prescription drugs; or

   j. Inpatient and outpatient hospital services.

4. Reports.

   a. Medicare: Each entity providing items and services under Medicare must report financial relationships with physicians (and their immediate relatives) to the Secretary of HHS.

      (1) Information is to be provided in the "form, manner, and at such times as the Secretary shall specify."

(2) Interim final regulations effective July 26, 2004 require all Medicare-participating entities to retain documentation that would enable them to respond to a specific CMS or OIG request for:

(a) The name and unique Medicare physician identification number ("UPIN") of each physician with a reportable financial relationship with the entity;

(b) The name and UPIN of each physician that has an immediate family member who has such a reportable financial relationship;

(c) The covered services furnished by the entity; and

(d) The nature of the financial relationship between each of the physicians described above with the entity, including the extent and/or value of the ownership or investment interest or compensation relationship. (69 Fed. Reg. 16053 (Mar. 26, 2004); *see* 69 Fed. Reg. 17933-34 (Apr. 6, 2004)).

(3) Such documentation must be provided to CMS or the OIG upon request, and may be subject to public disclosure by the government agency.

(4) There is no requirement that such information must be reported to the government agencies absent such a request.

b. Medicaid: The OIG has proposed a regulation that would require physicians and entities to submit information to the state Medicaid agency in such form, manner, and at such times as the agency specifies. 63 Fed. Reg. 1705, 1727-28 (proposed § 455.109) (Jan. 9, 1998). This requirement has still not been finalized. *See* 69 Fed. Reg. 16055 (Mar. 26, 2004).

5. Penalties.

a. Most penalties for violations are imposed upon the entity that bills for services provided pursuant to the prohibited referral.

(1) Denial of payment by Medicare.

(2) Required refunds of payments made by individuals.

(3) Civil money penalties and possible exclusion from Medicare and Medicaid.

b. Penalties applicable to both physicians and entities:

(1) Substantial civil money penalty and possible exclusion by Medicare and Medicaid for entering into an arrangement or scheme to circumvent the statute (such as a cross-referral arrangement).

(2) Civil money penalties and possible exclusion from Medicare and Medicaid for failure to make required reports.

(3) Possible exposure to suits by government or private parties under the False Claims Act.

6. Exceptions.

a. The heart of Stark II, from the business lawyer's perspective, is the exceptions.

b. The statute and regulations provide detailed descriptions of each of the following exceptions:

(1) Group practices;

(2) Services furnished by HMOs and other prepaid group health plans;

(3) Investment interests in certain companies with assets or equity in excess of $75 million;

(4) Services provided by a hospital located in Puerto Rico;

(5) Rental of office space;

(6) Equipment leases;

(7) Bona fide employment relationships;

(8) Personal service arrangements;

(9) Certain physician incentive plans (but not others);

(10) Remuneration not related to the provision of designated health services;

(11) Physician recruitment;

(12) Isolated financial transactions;

(13) Certain group practice arrangements with a hospital;

(14) Payments by a physician for items and services; and

(15) Ownership or investment interest in a rural provider (other than a "specialty hospital").

c. Whole-hospital exception - the Stark Law also includes an exception for ownership or investment interest in an entire hospital (but not a subdivision of a hospital). This exception applies only to ownership or investment interests, and not to compensation arrangements.

7. Regulations.

a. The Stark Law was enacted in two phases. Regulations covering Stark I (which did not apply to any of the "designated health services" except clinical laboratory services) were adopted at 60 Fed. Reg. 41914 (Aug. 14, 1995). The Stark II regulations were adopted in three phases; the Phase I regulations were published at 66 Fed. Reg. 856 (Jan. 4, 2001), the Phase II regulations were published at 69 Fed. Reg. 16053 (Mar. 26, 2004), and the Phase III regulations were published at 72 Fed. Reg. 51012 (September 5, 2007). The combined Stark I/Stark II-regulations have been codified at 42 C.F.R. §§ 411.350 – 411.361.

b. In addition to the statutory exceptions listed in 6.b and 6.c above, the regulations create some significant additional exceptions, including:

(1) Fair market value compensation;

(2) Situations where the entity providing the designated health service is unaware of the identity of the referring physician;

(3) Non-monetary compensation up to $300;

(4) Incidental benefits provided to a hospital's medical staff;

(5) Risk-sharing arrangements;

(6) Provision of IT support to enable community physicians to participate in community-wide health information system;

(7) Temporary lapse in Stark compliance;

(8) Retention payments in underserved areas;

(9) Application of AKS safe harbors for referral services and obstetrical malpractice insurance subsidies to Stark; and

(10) Certain "professional courtesy" arrangements.

8. Advisory Opinions.

a. The Balanced Budget Act of 1997 required the HHS Secretary to issue advisory opinions with regard to whether or not a referral was prohibited under the Stark

Law. Advisory opinions are binding on the Secretary and on the parties requesting them.

b. Regulations concerning such advisory opinions, codified at 42 C.F.R. §§ 411.370 - 411.386, were retroactively reinstated by CMS in order for CMS to use the advisory opinion process for rulings as to whether particular specialty hospitals met the requirements of MMA § 507 as having been in existence or under development as of Nov. 18, 2003. *See* 69 Fed. Reg. 57226-57230 (Sept. 24, 2004).

9. Alleged Stark violation may serve as basis of a federal enforcement action under the civil False Claims Act. (Massachusetts group B.J. Carlen f/k/a Pastor Medical agreed to pay $230,000 to settle federal civil false claims charges related to alleged laboratory billing violations under Stark).

I. Distinctions between the Anti-Kickback Law and Stark II:

1. Stark II:

a. Does not generally require proof of intent (there is a limited good-faith exception in the regulations).

b. Applies only to referrals by physicians.

c. Provides that an activity is improper unless it fits one of the exceptions.

d. Applies only to Medicare and Medicaid programs.

e. Penalizes only the billing entity for simple violation (e.g., having an arrangement that does not comply and sending a bill).

f. Contains reporting obligation.

2. The Anti-Kickback Law:

a. Turns on unlawful intent.

b. Applies to any person or entity.

c. Can result in a technical violation that is not penalized because good faith effort to comply was made, unlawful intent is not apparent, and there are no adverse consequences to government programs (i.e., failure to fall within a safe harbor may not be fatal).

d. Applies to federally funded state healthcare programs in addition to Medicare and Medicaid.

e. Penalizes any participant for an improper arrangement.

f. Contains no reporting obligation.

J. The Anti-Referral Laws, Part Three: Related Pennsylvania Laws

1. Health insurance: It is a first degree misdemeanor (punishable with up to five years imprisonment) for a healthcare provider to compensate or give anything of value to a person to recommend or secure the provider's service to a patient. 18 Pa. C.S. § 4117(b)(2). In addition, an insurer who brings a civil action for compensatory damages may recover such damages (including reasonable investigation expenses, costs of suit, and attorney fees) if the court determines that the defendant "has engaged in a pattern of violating this section." 18 Pa. C.S. § 4117(g).

2. Workers Compensation: It is unlawful for a provider to refer a person for laboratory, physical therapy, rehabilitation, chiropractic, radiation oncology, psychometric, home infusion therapy, or diagnostic imaging goods or services if the provider has a financial interest with the person or entity that receives the referral. 77 P.S. § 531(3)(iii).

   a. Penalty is non-payment of receiving entity's bills under workers compensation insurance.

   b. By regulation, arrangements that meet any current or future safe harbor or exception to Stark are permissible. 34 Pa. Code § 127.301.

3. Medicaid: Any anti-kickback violation involving goods or services for which payment may be made under Medicaid is a third degree felony, punishable by seven years imprisonment and a $15,000 fine (ten years and $25,000 for a second or subsequent offense), plus mandatory exclusion from Medicaid for five years after the date of conviction. 62 P.S. § 1407(a)(2).

4. Medicaid: Interrelationships of providers – 55 Pa. Code § 1101.51 (c) includes various prohibitions on providers with respect to referrals.

5. Under 35 P.S. § 449.22, healthcare practitioners are required to:

   a. Inform patients that they have the freedom to choose a facility or entity to which they are referred; and

   b. Disclose to patients any financial interest the practitioner has in an entity to which the practitioner makes a referral.

      The penalty for violation is $1,000.

K. False billing involving Medicare or Medicaid

1. Criminal prohibitions: It is unlawful for a person:

   a. To knowingly and willfully make or cause to be made any false statement or representation of material fact —

      (1) in any application for benefit or payment under any of the Programs; or

      (2) for use in determining rights to such benefit or payment. 42 U.S.C. § 1320a-7b(a)(1), (2).

   b. Having knowledge —

      (1) Of any event affecting his initial or continued right to program benefits or payments; or

      (2) Of such rights on behalf of another individual on whose behalf the actor has applied for or is receiving such benefit or payment, to conceal or fail to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized. 42 U.S.C. § 1320a-7b(a)(3).

   c. Having applied for benefits or billed the program for payment on behalf of another, to convert such benefit or payment to his own use. 42 U.S.C. § 1320a-7b(a)(4).

   d. To present or cause to be presented a claim for payment for a physician's service under any of the Programs, if the person doing so knows that the individual who furnished the service is not licensed as a physician. 42 U.S.C. § 1320a-7b(a)(5).

2. Penalties for the acts described in paragraph 1 above:

   a. False statement, misrepresentation, conversion, etc. by the person furnishing the covered items or services is a felony punishable by five years imprisonment and/or a $25,000 fine.

   b. Such acts by the person who did not furnish the items or services is a misdemeanor, punishable by one year and/or $10,000.

   c. These acts may also provide the basis for exclusion which is mandatory, if there is a criminal conviction; permissive, without such a conviction. 42 U.S.C. § 1320a-7(a)(1), (b)(7).

3. Civil monetary penalties relating to false billing may be imposed on any person who:

   a. Knowingly presents or causes to be presented a claim that the HHS Secretary determines:

      (1) Is for an item or service that the person knows or should know was not provided as claimed (including a person who engages in a pattern or practice of coding services in such a way as to improperly increase the amount of payment);

      (2) Is for an item or service and the person knows or should know that the claim is false or fraudulent;

      (3) Is presented as a physician's service (or "incident to" a physician's service), and the person knows or should know that the physician (or purported physician) in question --

         (a) Was not licensed as a physician;

         (b) Was licensed, but had obtained that license through a misrepresentation of material fact (including cheating on an examination required for licensing); or

         (c) Represented to the patient at the time of service that the physician was certified by a medical specialty board when the physician was not so certified;

      (4) Is for an item or service provided during which the person was excluded from the program under which the claim was made; or

      (5) Is for a pattern of medical or other items or services that a person knows or should know are not medically necessary. 42 U.S.C. § 1320a-7a(a)(1).

   b. Knowingly presents or causes to be presented a request for payment which is in violation of various agreements affecting the amount a provider can bill. 42 U.S.C. § 1320a-7a(a)(2).

4. Materiality of the misrepresented fact is a question of law. *United States v. Brown*, 763 F.2d 984, 993-994 (8th Cir. 1984). *Accord, Greber.*

   a. A statement is material if it is necessary "to put the claimant in a position to receive government benefits, whether rightfully or wrongfully." *United States v. Adler*, 623 F.2d 1287, 1291 (8th Cir. 1980).

   b. Materiality does not require actual reliance by the government. *Brown* at 993.

5. Kinds of false statements that have led to convictions include:

    a. Filing a claim for payment with Medicare for services that have already been paid for by another party. *United States v. Lipkis*, 770 F.2d 1447, 1452, (9th Cir. 1985) (conviction under predecessor to 42 U.S.C. § 1320a-7b(a)(1)).

    b. Billing for services not provided. N.B.: Patient testimony is not necessary for a conviction and poor medical record-keeping may help convict the provider. *See United States v. Varoz*, 740 F.2d 772 (10th Cir. 1984) (conviction under predecessor to 42 U.S.C. § 1320a-7b(a)(1)(i)).

    c. Billing for brand-name drugs when generic drugs were dispensed. *Brown* at 993-994 (conviction under predecessor to 42 U.S.C. § 1320a-7b(a)(1)(i)).

    d. Completing and submitting to state Medicaid program forms that misrepresented nursing home patients' actual conditions and the level of care provided, where the program paid lower per diems for class C (minimum care) and class B (intermediate care) than it did for class A (skilled care). *United States v. Huckaby*, 698 F.2d 915 (8th Cir. 1982) (conviction under predecessor to 42 U.S.C. § 1320a-7b(a)(3)).

    e. Cases involving the making of false statements can also be (and frequently are) brought under statutes prohibiting making false statements to a federal agency, 18 U.S.C. § 1001, and mail fraud, 18 U.S.C. § 1341. *Greber; United States v. Simon*, 510 F. Supp. 232 (E.D. Pa. 1981).

6. False claims under Pennsylvania Medicaid program.

    a. 62 P.S. § 1407(a)(1), (3)-(9) prohibits false claims under Medicaid.

    b. This is a criminal statute, violations of which are punishable by seven years imprisonment and/or a $15,000 fine (10 years/$25,000 for a second or subsequent offense). 62 P.S. § 1407(b)(1).

    c. In addition, the sentencing judge is required to order the convicted person to repay "the amount of excess benefits or payments plus interest on that amount at the maximum legal rate," plus to pay an amount of up to three times that amount. 62 P.S. § 1407(b)(2).

    d. Finally, the convicted person is ineligible to participate in Medicaid for a period of five years from the date of conviction. 62 P.S. § 1407(b)(3).

    e. Even though only subsection (1) of 62 P.S. § 1407(a) contains specific requirements that the submission of the improper claims be "knowing" or "intentional," the Pennsylvania Supreme Court has held that an essential element of any violation of 62 P.S. § 1407(a)(4), (7), and (9) is knowing or intentional conduct as set forth in § 1407(a)(1). *Commonwealth v. Lurie*, 569 A.2d 329 (Pa.

1990). Presumably, the same rationale would apply to the rest of § 1407(a) as well.

L. Insurance fraud statutes applicable to all third party payors

1. It is a federal crime to:

    a. Willfully execute (or attempt to execute) a scheme or artifice – (1) to defraud any health care benefit program; or (2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any health care benefit program, in connection with the delivery of or payment for health care benefits, items, or services. 18 U.S.C. § 1347.

    b. In any matter involving a health care benefit program, knowingly and willfully – (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or (2) makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for health care benefits, items, or services. 18 U.S.C. §1035.

2. For purposes of these federal statutes, "health care benefit program" is defined as "means any public or private plan or contract, affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract." 18 U.S.C. § 24(b).

3. It is a Pennsylvania crime to:

    a. Knowingly and with the intent to defraud any insurer or self-insured, present or cause to be presented to any insurer or self-insured any statement forming a part of, or in support of, a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim. 18 Pa. C.S. § 4117(a)(2).

    b. Knowingly and with the intent to defraud any insurer or self-insured, assist, abet, solicit or conspire with another to prepare or make any statement that is intended to be presented to any insurer or self-insured in connection with, or in support of, a claim that contains any false, incomplete or misleading information concerning any fact or thing material to the claim, including information which documents or supports an amount claimed in excess of the actual loss sustained by the claimant. 18 Pa. C.S. § 4117(a)(3).

    c. Knowingly benefit, directly or indirectly, from the proceeds derived from a violation of this section due to the assistance, conspiracy or urging of any person. 18 Pa. C.S. § 4117(a)(5).

d. Being the owner, administrator or employee of any health care facility, and knowingly allowing the use of such facility by any person in furtherance of a scheme or conspiracy to violate any of the provisions of this section. 18 Pa. C.S. § 4117(a)(6).

4. For purposes of this Pennsylvania statute, "insurer" is defined to mean a "company, association or exchange defined by section 101 of the act of May 17, 1921 (P.L. 682, No. 284), known as The Insurance Company Law of 1921; an unincorporated association of underwriting members; a hospital plan corporation [i.e., Blue Cross]; a professional health services plan corporation [i.e., Blue Shield]; a health maintenance organization; a fraternal benefit society; and a self-insured health care entity." 18 Pa. C.S. § 4117(l).

VIII. TAX-EXEMPT ORGANIZATIONS AND NONPROFIT STATUS

A. Tax-exempt and nonprofit organizations are subject to specific rules on how their activities are conducted.

B. Federal Tax Exemption

1. Sections 501(a) and (c)(3) of the Internal Revenue Code of 1986, as amended ("IRC") provide for the exemption from federal income tax of organizations that, among other requirements, are organized and operated "exclusively" for charitable purposes, no part of the net earnings of which inures to the benefit of any private shareholder or individual.

a. Organized and operated "exclusively" for charitable purposes: The regulations define "exclusively" to mean "primarily." An organization will not be regarded as organized and operating exclusively for charitable purposes if more than an insubstantial portion of its activities is not in furtherance of an exempt purpose. Reg. § 1.501(c)(3)-1(c)(2).

b. Private Inurement Standard: An organization is not operated exclusively for exempt purposes, if its net earnings inure in whole or in part to the benefit of private shareholders or individuals. Reg. § 1.501(c)(3)-1(c)(2) (the "insiders" test).

c. Private Benefit Standard: An organization is not operated exclusively for exempt purposes if it serves a private rather than public interest. Reg. § 1.501(c)(3)-1(d) (1)(ii). Any private benefit must be incidental.

d. Participation by an exempt entity in a joint venture or partnership with a taxable entity may jeopardize the exempt entity's status. *See St. David's Health Care System, Inc. v. United States*, 349 F.3d 232 (5th. Cir. 2003) for a discussion of the factors to be evaluated in determining whether the exempt organization is operated exclusively for one or more exempt purposes.

2. What is the effect of tax-exempt status?

   a. The entity does not have to pay federal income tax, except on income that is unrelated to its tax-exempt purposes.

   b. State income tax determinations may require a separate and distinct analysis.

3. Why worry about the status of the tax-exempt organization?

   a. Possible loss of tax-exempt status and assessment of back taxes.

   b. Imposition of Intermediate Sanctions.

      (1) The law allows for the imposition of penalty excise taxes on certain "excess benefit transactions" involving certain tax-exempt organizations and "disqualified persons."

      (2) Sanctions may be imposed for non-fair market value transactions, unreasonable compensation transactions, and private inurement transactions between the exempt organization and certain insiders.

      (3) A penalty excise tax will be imposed on both the disqualified person and the organization's manager who participated in the transaction knowing it to be an excess benefit transaction. IRC § 4958.

      (4) Department of Treasury has issued final regulations relating to penalty excise taxes. 67 Fed. Reg. 3076 (Jan. 23, 2002), codified primarily at 26 C.F.R. §§ 53.4958-0 – 53.4958-8. Among other clarifications, the regulations provide an expanded safe harbor available to organizational managers who rely on the advice of counsel with regard to a transaction.

      (5) In proposed regulations, the Treasury Department listed factors it would consider in determining whether excess benefit transactions in violation of the intermediate sanctions rules are sufficiently severe, relative to the nonprofit organization's activities in furtherance of its exempt purpose, as to warrant revocation of tax-exempt status. 70 Fed. Reg. 53599 (Sept. 9, 2005).

4. Special Concerns – The IRS view on Fraud and Abuse

   a. IRS has stated in GCM398622 (Dec. 4, 1991) that engaging in conduct or arrangements that violate the anti-kickback statute is inconsistent with continued exemption as a charitable hospital. No matter how economically rewarding, such activities cannot be viewed as furthering exempt purposes.

5. Questions to ask:

   a. Is there an exempt organization involved?

b. Does the proposed activity promote the exempt purpose?

c. Who are the other participants in the transaction and what is their relationship to the exempt organization?

d. Is the deal fair or reasonable? How do you know? What documentation exists?

C. Pennsylvania Law on Nonprofit Organizations

1. Under the Pennsylvania Nonprofit Corporation Law (15 Pa. C.S. § 5101 *et seq.*) —

   a. A nonprofit corporation may be incorporated for any lawful purpose or purposes.

   b. Income and associated profits received from the activities of a nonprofit corporation are to be applied to the maintenance and operation of the lawful activities of the corporation and are not to be divided or distributed among the members, directors or officers of the corporation.

2. The Pennsylvania Tax Reform Code of 1971, as amended in 1997 (effective Jan. 1, 1998), specifically excludes from state corporate net income and capital stock taxes, Pennsylvania nonprofits that are qualified under Section 501(c) of the Federal IRC.

3. The Pennsylvania Institutions of Purely Public Charities Act (Act 55 of 1997) codified standards announced by the Pennsylvania Supreme Court in 1985 defining what is a "purely public charity" for purposes of exemption from local real estate taxes and Pennsylvania sales taxes. 10 P.S. § 371 *et seq.*

4. The Pennsylvania Supreme Court has held a hospital's use of surplus revenue to capitalize a for-profit parent and sister corporation for the purposes of increasing the efficiencies of its own operations did not preclude it from operating as a purely public charity. *Wilson Area School District v. Easton Hospital*, 747 A.2d 877 (Pa. 2000).

5. Property exempt from real estate related taxes may not be used in such a manner as to compete with commercial enterprise. 72 P.S. § 5453.202(a)(3). Thus, in *Jameson Care Center, Inc. v. County of Lawrence et. al.*, 753 A.2d 902 (Pa. Commw. Ct. 2000), *allocatur denied*, 764 A.2d 1073 (2000), the Commonwealth Court held that a nonprofit corporation was not entitled to tax exemption because it was in direct competition with similar for-profits.

6. Conversions and Asset Transfers.

   a. Property committed to charitable purposes may not be diverted from the objects to which it was donated, granted or devised, without Orphan's Court approval. 15 Pa. C.S. § 5547(b).

b. The Charitable Trusts and Organizations Section of the Attorney General's Office has released its internal procedural guide for reviewing fundamental change transactions involving control or ownership of nonprofits. The guide is used by the Attorney General's Office in reviewing nonprofit conversions, as well as the acquisition by a nonprofit of another nonprofit. *See* http://www.attorneygeneral.gov/consumers.aspx?id=229.

c. In October 2002, following a controversy involving the potential sale of the controlling interest in Hershey Foods Corporation owned by the Milton Hershey School Trust, the General Assembly amended the "prudent investor rule" applicable to fiduciaries of charitable trusts, to consider, in making investment and management decisions, "the special relationship of the asset and its economic impact as a principal business enterprise on the community in which the beneficiary of the trust is located and the special value of the integration of the beneficiary's activities with the community in which the asset is located." 20 Pa. C.S. § 7203, as amended by Act 2002-133. The new law also establishes special procedures to be followed before a charitable trust holding a controlling interest in a publicly traded business corporation received as an asset from the settlor may consummate a decision effecting a change in the trust's control of the corporation.

IX. ANTITRUST

A. The basic objective of the antitrust laws is to eliminate practices that interfere with free competition. The laws are designed to promote a competitive economy in which each business enterprise has a full opportunity to compete on the basis of price, quality and service.

B. The principal federal antitrust statutes are the Sherman Act, the Federal Trade Commission Act, the Clayton Act and the Robinson-Patman Act.

1. The Sherman Act prohibits:

    a. Contracts, combinations and conspiracies in restraint of interstate trade or commerce. Sherman Act, Section 1 (15 U.S.C. § 1).

    b. Monopolization, attempts to monopolize and conspiracies to monopolize any part of interstate trade or commerce. Sherman Act, Section 2 (15 U.S.C. § 2).

2. The Clayton Act prohibits:

    a. Discrimination in prices between different purchasers in the sale of a commodity, where the discrimination may lessen competition. 15 U.S.C. § 13 (Robinson-Patman Amendments.)

    b. Exclusive dealing arrangements, tying arrangements and requirements contracts involving the sale of a commodity, where the effect may be to substantially lessen competition. 15 U.S.C. § 14.

c. Merger and acquisitions the effect of which may be substantially to lessen competition, or tend to create a monopoly. 15 U.S.C. § 18.

3. Section 5 of the Federal Trade Commission Act (15 U.S.C. § 45) prohibits:

a. "Unfair methods of competition." Has been held to include not only Sherman and Clayton Act violations, but also restraints of trade contrary to the policy or spirit of those laws.

b. "Unfair deceptive acts or practices." Has been held to include false or misleading advertisements or representations.

C. Enforcement and Penalties

1. Federal antitrust laws are enforced by the Antitrust Division of the Department of Justice, the Federal Trade Commission and private parties.

2. Despite the absence of any Pennsylvania antitrust statute, the state Attorney General also has an interest in the maintenance of competition in the marketplace and enforces federal laws within the Commonwealth.

3. Criminal and/or civil penalties are available. Private parties may bring suit to recover treble damages.

D. Application of the Antitrust Laws to the Healthcare Industry

1. Antitrust laws focus on restraints on trade or commerce. Healthcare professionals are not exempt from trade or commerce for purposes of application of antitrust laws.

2. Because almost all business has some connection with interstate commerce, it is unlikely that a defense to a Sherman Act or Federal Trade Commission Act violation on the basis of lack of interstate commerce will prevail.

3. However, a nonprofit corporation that controlled the management and operation of three hospitals and two physician groups in Lycoming County (and whose formation had been approved pursuant to an antitrust Consent Decree with the Pennsylvania Attorney General), was found to be a single entity for purposes of antitrust analysis, resulting in the holding that combined actions by the corporation's component parts would not violate Sherman Act §1 or Clayton Act §8. *HealthAmerica Pennsylvania v. Susquehanna Health System*, 278 F.Supp.2d 423 (M.D. Pa. 2003).

E. Standards of Review

1. Per Se Rule. The Supreme Court has held that certain types of restraints of trade are so inimical to competition that they will be conclusively presumed

illegal. These include price fixing (direct and indirect), division of markets, group boycotts and tying arrangements.

2. Rule of Reason. For situations involving restraints of trade other than the per se violations, the legal analysis utilized is the "rule of reason" approach. This allows for consideration of the underlying facts, the conditions before and after the restraint is applied, and the objectives in imposing the restraint.

F. Large Transactions: The Hart-Scott-Rodino provisions of the Clayton Act require pre-acquisition, merger and tender offer notification to the Department of Justice and the Federal Trade Commission to allow those agencies the opportunity to investigate the proposed action. 15 U.S.C. § 18a.

1. Trigger points include:

    a. One or both of the parties is engaged in commerce or in any activity affecting commerce;

    b. One party has total assets or annual net sales of $100 million or more and the other party has total assets or annual net sales of $10 million; and

    c. As a result of the acquisition, the acquiring party will hold: (i) at least 15% of the voting securities or assets of the acquired party; or (ii) an aggregate total amount of voting securities and assets of the acquired party in excess of $15 million.

2. The transaction cannot be closed until waiting period is over (generally at least 30 days).

G. Exemptions

1. State action: Antitrust laws apply to private organizations, not to governments. Actions taken directly by states are immune from antitrust laws. Private behavior regulated by the state may also be exempt under the state action doctrine if the behavior is a clearly articulated and affirmatively expressed state policy and actively supervised by the state itself.

2. Noerr - Pennington Doctrine: Petitioning the government, or concerted attempts to influence units or instrumentalities of state or federal government in order to obtain legislation, redress or other favorable action is exempt from antitrust scrutiny.

3. Business of Insurance: The McCarran-Ferguson Act establishes an exemption from federal antitrust laws for actions that constitute the "business of insurance." The primary purpose of this act is to allow the states to regulate insurance company activities.

H. Agency Pronouncements

1. 1994 and 1996 Statements of Antitrust Enforcement Policy in Health Care issued by the U.S. Department of Justice and the Federal Trade Commission.

   a. In 1994, and later modified in 1996, the Department of Justice and the Federal Trade Commission generally described those agencies' enforcement policies regarding analysis of mergers and various joint activities in the healthcare area. The nine statements give healthcare providers guidance in the form of "antitrust safety zones," which described conduct the agencies will not challenge under the antitrust laws, absent extraordinary circumstances.

   b. The statements address:

      (1) Mergers among hospitals (also refers to the DOJ and FTC's 1992 Horizontal Merger Guidelines, as amended in 1997);

      (2) Hospital joint ventures involving high technology or other expensive healthcare equipment;

      (3) Hospital joint ventures involving specialized clinical or other expensive healthcare services;

      (4) Providers' collective provision of non-fee-related information to purchasers of healthcare services;

      (5) Providers' collective provision of fee-related information to purchasers of healthcare services;

      (6) Provider participation in exchanges of price and cost information;

      (7) Joint purchasing arrangements among healthcare providers;

      (8) Physician network joint ventures; and

      (9) Multi-provider networks.

   c. Networks involving physicians frequently fall short on the requirement of sharing substantial financial risk included in the safety zones. The DOJ and the FTC have stated that such-risk sharing can be through an agreement by the venture to provide services at a "capitated rate," for a predetermined percentage of premium or revenue from a health plan, use of the venture of significant financial incentives for its physician participants as a group to achieve specified cost containment goals, or an agreement by the venture to provide services for an "all inclusive case rate."

2. Determinations regarding specific proposals. The 1996 Statements also set forth the DOJ's business review procedure and the FTC's advisory opinion

procedure under which the healthcare community can obtain the agencies' enforcement intentions regarding specific proposed conduct on an expedited basis (no later than 90 days or 120 days after all of the necessary information has been submitted).

3. Guidelines for collaborations among competitors were issued by FTC and DOJ in April, 2000. These are a statement of general enforcement policy, consistent with the Guidelines discussed above, which "remain in effect to address issues in their specific [context]."

4. While announcing no new principles, a July 2004 joint FTC/DOJ report entitled "Improving Health Care: A Dose of Competition" provides a summary of current enforcement priorities. It is available online at: http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf.

X. WHERE TO FIND THE LAW

A. Government Sources

1. Key federal statutes:

   a. Medicare (includes program participation requirements, coverage description, payment rules, extra requirements on providers (e.g., EMTALA, Stark law, etc.): 42 U.S.C. § 1395 *et seq*.

   b. Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173 is available online at: http://waysandmeans.house.gov/media/pdf/hr1/hr1 conflegtext.pdf.

   c. Medicaid: 42 U.S.C. § 1396 *et seq*.

   d. Health Care Quality Improvement Act: 42 U.S.C. § 11101 *et seq.*

   e. Fraud & Abuse Act: 42 U.S.C. § 1320a-7 (exclusions), § 1320a-7a (civil monetary penalties), § 1320a-7b (criminal), and § 1320a-5 (reporting of ownership and control interests).

   f. Stark physician anti-referral law: 42 U.S.C. § 1395nn.

   g. False Claims Act: 31 U.S.C. §§ 3729-3731.

2. Key Pennsylvania statutes:

   a. Medical Care Availability and Reduction of Error (MCARE) Act: 40 P.S. § 1303.101 *et seq*.

b. Licensure:

(1) Health care facilities (hospitals, nursing homes, ambulatory surgery centers, etc.): 35 P.S. § 448.801a *et seq*.

(2) Other institutions (especially mental health): 62 P.S. articles IX and X.

(3) Continuing care retirement communities: 40 P.S. § 3201 *et seq.*

(4) Personal care homes: 62 P.S. §§ 1057.1-1057.3.

(5) Assisted living facilities: 62 P.S. § 1021.

(6) Practitioners: Professional licensing statutes are collected in title 63 of Purdon's.

(7) Blue Cross and Blue Shield plans: 40 Pa. C.S. § 6101 *et seq*. (Cross) and § 6302 *et seq*. (Shield).

(8) HMOs: 40 P.S. § 1551 *et seq*.

(9) PPOs: 40 P.S. § 764a.

c. Medicaid fraud: 62 P.S. §§ 1401-1412.

d. Mental Health Procedures Act: 50 P.S. §§ 7101 *et seq*.

e. Most other health-related Pennsylvania statutes can be found in title 35 of Purdon's.

3. Regulations.

a. Standard regulation sources: Federal Register, Code of Federal Regulations (title 42), Pennsylvania Bulletin, Pennsylvania Code.

b. Pennsylvania Code titles of interest:

(1) Health - title 28.

(2) Medicaid, Mental Health - title 55.

(3) Insurance - title 31 (last volume).

(4) Practitioner licensure - title 49.

(5) Rules of Administrative Procedure - title 1.

B. General Reference Works

1. American Health Lawyers Association. *Fundamentals of Health Law* program binder, published annually.

2. Gosfield, Alice G. (Ed.). *The Health Law Handbook* (West Group), published annually.

3. Furrow, Greaney, Johnson, Jost and Schwartz. *Hornbook on Health Law*, 2d Ed. (West Group 2000).

C. Specialized Books in Looseleaf Format

1. *Hospital Law Manual* (Aspen Publishers).*

2. *Medicare & Medicaid Guide* (CCH).*

3. *Nursing Home Regulations* (Thompson Publishing).

4. *BNA's Health Law and Business* (BNA).*

5. Miles, John J. *Health Care and Antitrust Law* (West Group).

* Also available on CD-ROM and/or online.

D. Other CD-ROMs and/or on-line subscription services

1. AHLA Health Law Archive (searchable online access to past AHLA program papers, most non-book-length publications, and more).

2. American Health Lawyers Association HEALTH LAW ON CD-ROM™ (West Group).

3. BNA Health Law Library.

4. MediRegs.com – Online compliance and federal regulatory materials database.

E. Newsletters: A wide variety of newsletters and similar services are available -- for a price. Most are available as an on-line subscription; many also offer a print version. Without attempting an exhaustive list, here are some we find useful:

1. Health Lawyers Weekly (Weekly updates of news, major cases, and federal and state legislative and regulatory updates, plus analysis. Provided as a member benefit by AHLA or available by paid subscription).

2. BNA Health Law Reporter (Weekly print or online newsletter with content similar that of Health Lawyers Weekl.). BNA also publishes a daily newsletter, Health Care Daily Report.

3. AHLA Health Law Digest (comprehensive monthly case report (for members only), with full text service).

4. BNA Health Care Fraud Report (Fraud & Abuse ("F&A")).

5. Report on Medicare Compliance (Healthcare Financial Management Association and Atlantic Information Services, Inc.) (F&A).

F. Websites

1. American Health Lawyers Association - http://www.healthlawyers.org.

Excellent site with useful "Ask Health Lawyers" and "Current Briefs" features with hypertext links to recently released government documents and on-line ordering of documents not available on the web. Other features include links to other sites, information on AHLA publications, services, and seminars, a job bank, and access to e-mail discussion groups on various health law topics. Searchable. Additional features and content are available to AHLA members only.

2. Center for Health Law Studies, St. Louis University School of Law – http://law.slu.edu/healthlaw/.

Searchable site with handy "What's Hot in Health Law" page, with links to new cases. However, a great many of the links are to commercial sites (e.g., LEXIS), for which you will have to pay for access.

3. Institute of Medicine reports are available on its website at: http://www.iom.edu.

G. Sources for Other Specialized Publications

1. AHLA (Fax info, 1-888-833-6452; request document #1000 for current index): Books, loose-leaf guides, Practice Guide series, monographs, course materials.

2. ABA Health Law Section (312/988-5548; website http://www.abanet.org/health/home.html): Bi-monthly newsletter, monographs, course materials.

3. Joint Commission (Joint Commission): accreditation manuals.

4. Other trade associations.