SETON HALL LAW

COMPLIANCE GLOSSARY
Commonly Used Terms

– A –

Accreditation – The process by which a private non-governmental organization recognizes a provider, a program of study, or an institution as meeting predetermined standards. Two organizations that accredit managed care plans are the National Committee for Quality Assurance (NCQA) and the Joint Commission (formerly The Joint Commission on Accreditation of Health Care Organizations (JCAHO)). The Joint Commission (TJC) also accredits hospitals and clinics. The Commission on Accreditation of Rehabilitation Facilities (CARF) accredits rehabilitation providers. *See* **TJC**.

ADR (Authorized Distributors of Record) – An entity that is allowed to engage in wholesale distribution of a prescription drug by written agreement with a manufacturer.

AdvaMed (Advanced Medical Technology Association) – The trade association for medical device manufacturers whose advocacy occurs primarily in the United States, but increasingly includes Europe, Japan, and emerging markets in Asia and Latin America as well. AdvaMed has adopted a Code of Ethics on Interactions with Health Care Professionals which is one of the U.S. medical device industry's primary sources for ethics and compliance guidance on interactions between healthcare professionals and medical device manufacturers. The AdvaMed Code can be found at **www.advamed.org**.

Adverse Event – In pharmacology, any unexpected or dangerous reaction to an FDA- approved drug, biologic, medical device or dietary supplement. While both healthcare providers and consumers may report "serious adverse events" to the FDA, it "strongly encourages" healthcare providers to do so. The study and oversight of adverse events is known as pharmacovigilance. *See* **Pharmacovigilance**.

Advisory Opinion – OIG-issued opinion to a requesting party regarding the legality of specific transactions and business arrangements under the fraud and abuse laws. These opinions are made available to the public through OIG's website.

AMP (Average Manufacturing Price) – The average price paid to a pharmaceutical manufacturer for direct and indirect sales to retail community pharmacies. All pharmaceutical manufacturers who participate in the Medicaid Program must report quarterly to CMS the AMP for each covered outpatient drug. *See* **CMS**.

Anti-Kickback Statute – A far-reaching federal criminal law that prohibits the offering, giving, solicitation or receipt of something of value (a "kickback") in cash or in kind, directly or overtly in return for the referral of federal health care program business. The Anti-Kickback Statute provides for civil and criminal penalties. Violations may also result in temporary or permanent exclusion from participation in state or federal health care programs. The Anti-Kickback Statute must be considered when examining business arrangements to ensure that there is no unlawful intent to refer federal or state healthcare business.

Anti-Retaliation – In the context of a *qui tam* relator, the anti-retaliation provisions of the FCA insulate an employee from retaliation, i.e. firing or demotion, by an employer when an employee brings a *qui tam* action or participates in any way in the prosecution of an employer for the employer's fraudulent activity. This provision was added to the FCA in 1986 to encourage *qui tam* relators to come forward under the FCA. Many states also have anti-retaliation provisions whose scope extends beyond FCA complaints. *See also* **Whistleblower**.

Antitrust – A legal concept embodied at the federal level by the Sherman Antitrust Act of 1890 and the Clayton Act of 1914 which seeks to prevent monopolies, restraints of trade, and other anti- competitive activities that harm consumers. These laws are enforced by the Justice Department Anti- Trust Division and the Federal Trade Commission. Many states have "baby anti-trust" laws. In Europe, this body of law is referred to as Competition Law.

ASC (Accredited Standards Committee) – An organization established to create consistent standard data elements for health care transactions in the following categories: claims, eligibility and claim status inquiries and responses, referrals and prior authorizations, and payments. The use of these standards is mandated by HIPAA and is one of six data standards organizations mentioned in HIPAA. *See* **HIPAA**.

Attorney General – The United States Attorney General heads the Department of Justice and serves as chief law enforcement officer of the Federal Government. The Attorney General represents the United States in legal matters generally and gives advice and opinions to the President and to the heads of the executive departments of the Government when so requested. *See also* **DOJ**.

AWP (Average Wholesale Price) – The AWP is the average price at which wholesalers sell drugs to physicians, pharmacies, and other customers, frequently serving as the benchmark for reimbursement under Medicare Part B. Drug manufacturers commonly publish suggested wholesale prices.

– B –

Best Price – The lowest price paid to a pharmaceutical manufacturer for a drug by any wholesaler, retailer, nonprofit entity, or governmental entity, but not taking into account certain sales transactions involving government programs that are excluded by statute. The "best price" includes cash discounts, free goods, volume discounts, and other rebates. It is determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package and does not take into discounts that are merely nominal.

Biologic – An FDA- regulated medicinal product, like a vaccine, blood, or blood component that is used therapeutically to treat diseases.

Biotechnology – The fusion of biology and technology. Biotechnology is the application of biological techniques to product research and development. In particular, biotechnology involves the use by industry of recombinant DNA, cell fusion, and new bioprocessing techniques.

Bonus Payment – An incentive payment paid by Medicare to physicians who provide professional services in any rural or Health Professional Shortage Areas (areas designated by the Health Resources and Services Administration as having shortages of primary medical care, dental, or mental health providers). This is not to be confused with other payments to hospitals, such as the disproportionate share hospital program or the settlement made to facilities at the end of a cost report year. *See* **HPSA**.

Bundled Payment – A single comprehensive payment for a group of related healthcare services. CMS and other payers investigate the billing of unbundled services closely, as it may represent a technique designed by a provider to obtain a greater reimbursement than would be paid if the services were bundled. Unbundling service charges has been a common form of fraud as defined by CMS. *See also* **Unbundling**.

Business Associate – Defined under the privacy section of HIPAA, a business associate is a person or entity that performs a service on behalf of a health care provider (including a researcher) or the health care entity during which individually identifiable health information is created, used, or disclosed. Under final regulations issued in January, 2013 (the "Omnibus Rule"), business associates include vendors that create, receive, maintain, or transmit protected health information (PHI) on behalf of a covered entity. Vendors that maintain PHI over time are covered, even if they don't gain regular access to PHI or disclaim the right to access it. A member of the entity's workforce is not considered a business associate although under the Omnibus Rule subcontractors of business associates performing business associate functions will be considered business associates. *See also* **HIPAA, PHI**.

– C –

CCO (Chief Compliance Officer) – The person or official in charge of overseeing and managing compliance issues within an organization, ensuring, for example, that the organization is complying with legal and regulatory requirements, and that its employees are complying with the organization's internal compliance policies and procedures.

Center for Devices and Radiological Health (CDRH) – The FDA Center responsible for regulating companies that manufacture, repackage, relabel, and/or import medical devices sold in the U.S. Within its purview is also the regulation of radiation-emitting products such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions. CDRH maintains a database that provides information about medical device inspections that are its responsibility beginning in 2008. Warning Letters sent to manufacturers are also posted on this database.

CPI (Center for Program Integrity) – Created in 2010 as a Center within CMS, CPI is the focal point for the prevention and detection of fraud and abuse throughout the Medicare, Medicaid, and CHIP programs. To ensure the most strategic approach to fighting fraud, CPI comprises five groups to target program integrity policies: Data Analytics, Provider Enrollment, Program Integrity Enforcement, and the Medicare and Medicaid Program Integrity Groups.

CIA (Corporate Integrity Agreement) – One of the OIG's primary enforcement tools, a CIA is a multi-year agreement between the Health and Human Services Office of Inspector General (OIG) and a health care provider, drug or device manufacturer, or other entity that arises as a result of a federal health care program investigation whereby the entity agrees to undertake certain ongoing obligations such as strengthening corporate compliance, expanding compliance training, and discontinuing specific conduct such as prohibited promotional practices. In return, the OIG agrees not to seek to exclude the entity from participating in the federal health care program or refer the provider to DOJ for criminal prosecution. One of the goals of a CIA is to improve the quality of health care and ensure that fraudulent behavior does not reoccur. Copies of CIAs can be found on the OIG's website at **oig.hhs.gov/compliance/corporate-integrity-agreements/CIA-documents.asp**.

Civil Monetary Penalties Law (CMPs) – The assessment of significant financial penalties on an entity that has engaged in and profited from illegal activities. In the health care context, CMPs will be imposed for certain instances of fraud and abuse involving a federal health care program.

Class III Medical Devices – A medical device that supports or sustains human life, substantially aids

in health or whose use presents a potential risk of illness or injury. Class III Devices need Premarket Approval (PMA) from the FDA. Examples include power wheelchairs, infusion pumps and surgical drapes. *See* **PMA**.

Clinical Laboratory Improvement Amendments (CLIA) – An act passed by Congress in 1988 that established quality standards for all laboratory testing to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test was performed. CLIA does not cover clinical trials and research. Although funded by user fees, CMS has the primary responsibility for the financial management of CLIA. All clinical laboratories must be properly certified to receive Medicare or Medicaid payments, but CLIA has no direct Medicare or Medicaid program responsibilities.

Clinical Trial – A bio-medical or health-related research study to evaluate the effectiveness and safety of medications, medical devices, or new ways of using known treatments by monitoring their effects on large groups of people. In certain circumstances, clinical trials are required by the FDA, such as in support of a new drug application. Clinical Trials for new substances occur after researchers test the therapeutic agent in the laboratory and/or animal studies and results are favorable. Clinical Trials occur in four phases: Phase I tests a new drug or treatment in a small group to evaluate safety, dosing and side effects; Phase II expands the study to a larger group of people to determine effectiveness and further evaluate safety; Phase III expands the study to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information that will allow the drug or treatment to be used safely. Phase IV takes place after the drug or treatment has been licensed and marketed to determine additional information, including risks, benefits, and optimal use. Clinical trials may be funded and/or conducted by government health agencies such as NIH, researchers affiliated with a hospital or university medical program, independent researchers, or the Sponsor. *See* **Sponsor**.

CMS (Centers for Medicare and Medicaid Services, formerly the Health Care Financing Administration or HCFA) – CMS is a federal agency within the Department of Health and Human Services (DHHS) whose primary responsibilities are to administer programs such as Medicare, Medicaid, and SCHIP and to be responsible for the administrative simplification standards of HIPAA, quality standards of long term care facilities and clinical laboratory quality standards under CLIA.

Corporate Compliance Committee – A group of individuals usually composed primarily of members of a corporate entity's board of directors, responsible for ensuring that the corporation and its employees are acting in accordance with all applicable laws, regulations, ordinances, and rules. The committee monitors and guides all of the organization's compliance activities, including appointment of a corporate compliance officer, approval of compliance program policies and procedures, review of the organization's annual compliance plan, evaluation of internal and external audits to identify potential risks, and implementation of corrective and preventive actions.

Corporate Compliance Program – An organization's self-monitoring system of checks and balances to help ensure that an organization acts ethically and with integrity, and consistently follows applicable laws and regulations relating to its business conduct and activities. *See also* **CPG**.

Covered Entity – A health care provider that transmits any health information in electronic form in connection with a transaction covered under HIPAA. Covered entities include individual health care providers, health plans, such as HMOs and insurance companies, and Health Care Clearinghouses. Under Section 340B of the Public Health Service Act, an entity eligible to receive discounted drug pricing may also be considered a covered entity. *See* **HIPAA**.

CPG (OIG's Compliance Program Guidance for Pharmaceutical Manufacturers) – A set of guidelines published by the OIG that pharmaceutical manufacturers should consider when developing and implementing their own compliance programs. The Guidance for Pharmaceutical Manufacturers was published in 2003 and can be found at https://oig.hhs.gov/compliance/compliance-guidance/index.asp The seven elements found in the CPG are recognized as fundamental to a successful corporate compliance program.

– D –

Debarment – In the context of healthcare fraud, the ultimate penalty of prohibiting an individual or entity from participating in any federal health care program indefinitely, with limited exceptions. In the FDA context, debarment means to penalize a person or a company that has pled guilty to or been convicted of criminal conduct relating to the regulation of any drug product under the Food Drug and Cosmetic Act (FDCA) by temporarily or permanently prohibiting that person from providing services in any capacity to a company that has an approved or pending drug product application with FDA. *See* **FDCA** and **FDA**.

DHHS (U.S. Department of Health and Human Services) – The federal agency responsible for protecting the health of the American people, comprises several divisions, including the Centers for Medicare and Medicaid Services (CMS), Centers for Disease Control (CDC), Food and Drug Administration (FDA), National Institutes of Health (NIH) and the Office of Inspector General. The Secretary of DHHS is a member of the President's Cabinet. DHHS' website is **www.hhs.gov**. *See also* **Fraud** and **OIG**.

Disclosure – The release of identifiable health information regarding a patient or patient(s). Disclosure involves the release of such information to any person or any entity outside of the covered entity. *See also* **HIPAA Privacy Rule** and **Protected Health Information**.

DOJ (U.S. Department of Justice) – The DOJ is the primary agency for enforcement of U.S. federal laws. The DOJ investigates and prosecutes individuals and entities accused of engaging in "fraudulent" activity. The DOJ is led by the Attorney General who is nominated by the President and confirmed by the Senate. The DOJ encompasses numerous divisions, including Antitrust, Criminal, and Civil Rights. The regional representatives of the DOJ are the U.S. Attorney's Offices, of which there are currently 94 throughout the country. The DOJ's website is **www.justice.gov**. *See also* **Attorney General**, **FBI, Fraud**, **OIG**, and **U.S. Attorney**.

DPA (Deferred Prosecution Agreement) – A voluntary and often multi-year agreement between the government and a defendant. A DPA defers the criminal prosecution of a person or entity in exchange for the defendant fulfilling certain requirements. Upon the government's satisfaction that the defendant has met all of the DPA requirements, all criminal charges will be dismissed. *See* **NPA**.

DRG (Diagnosis-Related Group) – System that classifies inpatient stays into groups according to diagnoses for Medicaid reimbursement and other payment purposes. Providers are then paid a fixed rate according to the DRG group to which a patient is assigned.

Drug Categories – Groupings that reflect therapeutic uses of drugs based on the International Classification of Diseases diagnostic codes. In 2004, the United States Pharmacopeia (USP), a non-profit non-governmental organization, as a result of a directive from the Medicare Modernization Act, published guidelines of drug categories and classes. These guidelines are used by prescription drug plans (PDPs) in developing their formularies for the Medicare population. The USP defined 41 therapeutic categories, 32 of which are further divided into pharmacologic classes. Currently using ICD-9, all U.S. healthcare entities covered by HIPAA must transition to ICD-10 codes for its electronic billing and reimbursement. A compliance date of October 1, 2014 has been set by DHHS. *See also* **Medicare Part D** and **Prescription Drug Plan**.

Drug Classes – Subcomponents of drug categories based either on the chemical structure of the drug or on its "mechanism of action," i.e., how it works to achieve its results. Certain classes are subdivided into an additional level of specificity. In 2004, the United States Pharmacopeia (USP), a non-profit non-governmental organization, received a directive from the Medicare Modernization Act to publish guidelines on drug categories and classes. *See also* **Medicare Part D** and **Drug Categories**.

Drug Formulary – A listing of FDA-approved brand name and generic drugs approved by a health plan for reimbursement based upon efficacy, safety and cost-effectiveness. Formularies are either "closed," including only certain drugs, or "open," including all drugs. Both types of formularies typically impose a cost scale requiring consumers to pay more for certain brands or types of drugs.

Drug Risk Sharing Arrangements – An agreement between a third-party payer and a manufacturer where both parties share the costs of a new drug to accelerate the timing of the release of a new drug, resulting in access to drugs that may not have been available otherwise. This type of arrangement has been questioned due to high administration costs, lack of transparency, and conflicts of interests.

DUR (Drug Utilization Review) – Review of an insured population's drug use with the goal of determining how to reduce the cost of utilization. Reviews often result in recommendations to prescribers and pharmacies, including generic substitutions, use of formularies and copayments, and education. DUR may be connected to a financial incentive program that rewards or penalizes practitioners depending upon their drug prescription-related costs and utilization.

– E –

EAC (Estimated Acquisition Cost) – A state Medicaid agency's best estimate of the price generally paid by pharmacies for a particular drug, historically derived from the AWP minus a discount percentage. *See also* **Average Wholesale Price (AWP)**.

EHR (Electronic Health Record) – An electronic record of patient information including patient demographics, progress notes, medications, past medical history, vital signs, immunizations, laboratory data, and radiology reports that is theoretically capable of being shared across different health care settings. Under HITECH, providers are incentivized to adopt the use of EHRs and, beginning in 2015, Medicaid providers will be penalized if they have not converted to EHRs. *See* **HITECH**.

Exclusion Authorities – OIG's delegated authority to exclude an owner, officer, or managing employee of an entity from participation in any federal health care program. While an owner may be excluded if he/she knew or should have known of the conduct that led to the sanction, officers and managing employees may be excluded based solely on their position within the entity.

– F –

FBI (Federal Bureau of Investigation) – An agency under the DOJ, the FBI investigates violations of federal criminal law and provides law enforcement assistance to federal, state, local, and international agencies. *See also* **DOJ** and **OIG**.

FCA (False Claims Act) – A federal civil law that imposes liability on both individuals and entities who defraud government programs by submitting or causing another to submit a bill that contains false information for payment under a government program. FCA claims typically involve health care,

military, or other government spending programs. The FCA has become the government's most important weapon against fraud because it has an intent requirement that is easier for the government to prove than criminal alternatives and because of the provision that allows for treble damages. As a result, many FCA cases are settled. Finally, the law permits private individuals, called *Qui tam* Relators or whistleblowers, to bring an action under the FCA and, if ultimately successful, to share in the recovery. Several states have their own false claims acts. Federal Law financially incentivizes states to enact state false claims acts that meet certain requirements. *See also* **FERA**, ***Qui tam***, and **Whistleblower**.

FCPA (**Foreign Corrupt Practices Act of 1977)** – A federal law that prohibits U.S. companies and their subsidiaries, as well as their officers, directors, employees, and agents, from making or causing to be made "corrupt" payments, i.e. bribes, to "foreign officials" for the purpose of obtaining or retaining business. The FCPA requires U.S. companies that issue debt or equity, i.e. publicly-traded companies, to maintain internal accounting controls and to keep books and records that accurately reflect all transactions. Both the anti-bribery and the recordkeeping and internal accounting controls provisions apply to worldwide operations of any U.S. company. The FCPA is enforced jointly by the SEC and the DOJ. *See also* **DOJ** and **SEC**.

FDA (U.S. Food and Drug Administration) – A federal agency within DHHS consisting of nine centers and offices that is responsible for ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, food, cosmetics, products that emit radiation, and the manufacture, marketing, and distribution of tobacco products. The website is: **www.fda.gov**. *See also* **Debarment**, **FDAMA**, and **FDCA**.

FDAAA Amendments Act of 2007 – The federal law that updated the FDCA to reauthorize the Prescription Drug User Fee Act (PDUFA), which provides resources to FDA to help it review potential new drugs more effectively, and the Medical Device User Fee and Modernization Act (MDUFMA), which allows FDA to improve the medical device approval process. The legislation also included the reauthorizations of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, which enable more pediatric research by broadening the definition of pediatric studies while narrowing the timeframe for sponsors to qualify for pediatric designation. FDAAA also requires registration and reporting of clinical trial results of drugs and devices subject to FDA regulation. *See also* **FDCA**.

FDAMA (Food and Drug Administration Modernization Act of 1997) – A federal law that amended the FDCA by: streamlining the drug approval process and eliminating many outdated components of the drug license application, increasing patient access to experimental drugs and medical devices, and requiring a manufacturer to notify patients when it intends to discontinue a drug that is life-sustaining or treats a serious and/or debilitating disease. *See also* **FDA** and **FDCA**.

FDCA (Food, Drug and Cosmetic Act of 1938) – A federal law that established the legal framework within which the FDA operates. The FDCA originally authorized the FDA to oversee the safety of food, drugs, and cosmetics. The FDCA has been amended several times to address, for example, drug efficacy, development and approval of orphan drugs, medical devices and dietary supplements. The misdemeanor provision of the FDCA contains a strict liability standard that has been relied upon to find corporate officers "strictly liable" for company actions, absent direct knowledge on the officer's part. *See also* **FDA**, **FDAAA**, **FDAMA**, **MDUFMA**, and **Responsible Corporate Officer Doctrine**.

Federal Health Care Program – Defined by federal statute, any plan or program that provides health benefits, directly or indirectly, through an insurance program which is funded directly, whether fully or partially, by the U.S. Government or any state insurance program, including, but not limited to Medicare and Medicaid.

FERA (Fraud and Enforcement Recovery Act of 2009) – A federal law designed to combat fraud which, among other things, revised the FCA's liability provisions to make recovery under the statute easier. *See also* **FCA**.

Fiduciary – A legal term that describes a trusted or confidential relationship that arises out of superior knowledge or training by one party and therefore carries special obligations. For example, a physician has a fiduciary relationship with her patient, and an attorney has a fiduciary relationship with his client. A fiduciary relationship requires the fiduciary, such as the physician or attorney, to act solely on behalf of the other person's or organization's interests in matters which affect that other person or organization.

FOIA (Freedom of Information Act) – A federal law that requires the U.S. Government to disclose certain information to the public when it receives a written request for records of the Executive Branch of the U.S. Government. FOIA does not apply to records of Congress or Federal Courts, nor to state governments, local governments, or private groups. All 50 states, including the District of Columbia, have their own state freedom of information legislation that governs the discovery of state and local documents.

Fraud – The intentional deception or misrepresentation that an individual knows, or should know, to be false, or does not believe to be true, and makes, knowing the deception could result in unauthorized payment or benefit to himself or some other person or entity.

Fraud and Abuse – In the context of healthcare, a legal term describing activities by an individual or entity which result in defrauding a federal health care program through false or fraudulent pretense. Intent may or may not be relevant, depending on the applicable law. For example, under the Stark Law, the mere existence of financial relationship with an entity to which a referral is made will give rise to liability while the Federal Anti-Kickback Law has been widely interpreted to include an intent element. While "fraud" is defined as a knowing or willful execution of a scheme, "abuse" includes conduct that is inconsistent with sound medical or business practices and, resulting in overpayments to a health care provider by a federal health care program. Common examples of fraud and abuse include: billing for services not rendered, altering claim forms to obtain higher reimbursement rates, falsifying information in medical records, or providing medical services that are unnecessary given the condition of the patient. *See also* **Federal Health Care Program**.

– G –

GDP (Good Distribution Practices) – Part of a system of quality assurance which ensures that the quality of human medicinal products is maintained throughout the distribution process. *See also* **GMP**.

GMP (Good Manufacturing Practices) – Part of a system of quality assurance which ensures the proper design, monitoring, and control of manufacturing processes and facilities for human medicinal products. GMP may include storage, distribution, transportation, packaging, labeling, documentation, and record-keeping practices. GMP helps to reduce the risks of contamination, cross-contamination, mix-ups, and other errors. In the U.S., GMP inspections are performed by the FDA. Within the EU, GMP inspections are performed by the National Regulatory Agencies. *See also* **GDP**.

GLB Act (Gramm-Leach-Bliley Act) – Also known as the Financial Services Modernization Act of 1999, a federal law that requires financial institutions (such as banks, mortgage lenders, and insurance companies) to disclose their information-sharing practices to their customers and to safeguard their customers' sensitive data, for example financial information and health information. GLB also established detailed guidelines for the collection, storage, protection, and disclosure of customer financial information which guidelines apply not only to financial services institutions, but also to any entity that provides or receives this information. In addition, GLB requires companies that provide insurance services to protect their customers' health information, similar to the privacy requirements of HIPAA

Good Reprint Practices (Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices) – A guidance document explaining FDA's current thinking with regard to the distribution of a medical journal article and/or scientific or medical reference publication by a drug or medical device manufacturer that discusses an unapproved use of an FDA-approved drug or medical device marketed in the U.S. to healthcare professionals and entities. The guidance is available on the FDA website at **www.fda.gov/oc/op/goodreprint.html**.

GPO (Group Purchasing Organization) – An entity that combines the collective purchasing power of multiple organizations or facilities in order to obtain lower prices for equipment and supplies. An agreement between a provider and a GPO must fit within a regulatory safe harbor to avoid liability under the Federal Anti-Kickback law.

– H –

Health Care Clearinghouse – An entity that assists health care providers to submit and process claims for payment to insurers and health plans. A health care clearinghouse is considered a "Business Associate" under HIPAA. *See also* **Business Associate** and **HIPAA**.

HEAT (Health Care Fraud Prevention and Enforcement Action Team) – A joint task force initiative among OIG, DOJ, and other DHHS agencies whose purpose is to target areas of health care fraud and identify and arrest health care fraud perpetrators. As part of this initiative, HEAT has conducted provider compliance training focusing on Medicare and Medicaid fraud and the importance of implementing an effective compliance program. Information about HEAT can be found at http://oig.hhs.gov/compliance/provider-compliance-training/index.asp.

HIPAA (Health Insurance Portability and Accountability Act of 1996) – HIPAA is comprised of two sections. Title I addresses protecting health insurance coverage for people who lose or change jobs; Title II addresses the privacy and security of protected health information and the standardization of healthcare related information systems. *See also ASC*, Business **Associate**, **Covered Entity**, **Health Care Clearinghouse**, **PHI**, and **HITECH Act**.

HITECH Act (Health Information Technology for Economic and Clinical Health Act) – A federal law that defines the compatibility requirements of HIPAA's security and privacy regulations. The HITECH Act also expands the standards that aid in electronic exchange of health information nationally and provides incentives for covered entities that adopt Electronic Health Records (EHR). Under the HITECH Act, those who are non-compliant with HIPAA are more vulnerable to civil

penalties. The HITECH Act includes mandatory penalties for "willful neglect," i.e., no compliance program. *See also* **HIPAA**.

HUD (Humanitarian Use Devices) – A medical device intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4,000 individuals in the United States per year. To obtain FDA approval for an HUD, an HDE (Humanitarian Device Exemption) must be submitted to FDA. While similar to obtaining PMA, an HDE application is exempt from the effectiveness requirements of a PMA; although, it still must provide an assurance that the probable health benefits outweigh the risks of injury or illness from its use. In addition, no comparable device must be available to treat the disease or condition and no alternative path to bring such device to the market may exist. Any clinical trial result information must be submitted to the ClinicalTrials.gov data bank.

– I –

IFPMA (International Federation of Pharmaceutical Manufacturers & Associations) – A non-governmental organization founded in 1968, the IFPMA is a trade organization representing the international pharmaceutical industry, including the biotech and vaccine sector. Based in Switzerland, IFPMA's mission is to advocate for policies that enable the discovery of and access to life saving and life-enhancing new medications to improve patients' health. IFPMA publishes a Code of Pharmaceutical Marketing Practices, advocating that self-regulation is the most effective approach to ensure ethical marketing practices and drug promotion by manufacturers. The website is **www.ifpma.org**.

IND (Investigational New Drug) – A new drug that is used in a clinical research trial. It also includes a biological product used in vitro for diagnostic purposes.

Informed Consent – A process required by legal and ethical norms by which a patient or research participant receives key information to facilitate consent prior to the commencement of treatment or a clinical trial. Federal law dictates the content of the consent process for clinical trials, and the actual consent form must be approved by an Institutional Review Board (IRB). The process enables a person to learn key facts about the proposed clinical trial, including the fact that it is not intended as treatment, but is part of research, and the potential risks and benefits, before deciding whether or not to participate in a study. Informed consent may be withdrawn at any point during the clinical trial.

Intermediary Carriers – Non-government organizations or agencies that process Medicare claims for providers. They serve as fiscal agents between providers and the federal government, applying the

Medicare coverage rules to determine the appropriateness of claims. Intermediary Carriers are in the process of being replaced by CMS with Medicare Administrative Contractors (MACs).

IPO (Initial Public Offering) – The sale of a company's shares to the public in an effort to raise funding for the company's business expansion and to increase investment. Also referred to as "going public." In this process, the company's equity is sold through an investment banking firm. It is the first time that the company's owners give up a part of their ownership to stockholders.

IRB (Institutional Review Board) – A committee of physicians, statisticians, researchers, community advocates, and others that reviews proposed research involving human participants to ensure that it is ethical and that the rights of study participants are protected. All clinical trials in the U.S. must be approved by an IRB before they begin. Every institution that conducts or supports biomedical or behavioral research involving human participants must, by federal regulation, have or contract with an IRB that initially approves and periodically reviews the research in order to protect the rights of human participants.

– M –

MDUFMA (**Medical Device User Fee and Modernization Act of 1997/2002)** – A federal law that amended the FDCA to provide user fees to fund the FDA's pre-market reviews of medical devices, new provisions allowing establishment inspections to be conducted by accredited persons (third parties), and new regulatory requirements for reprocessed single-use devices. *See* **FDCA**.

MedSun (Medical Product Safety Network) – Launched in 2002, MedSun is an FDA program designed to identify problems with medical devices used in clinical settings. MedSun representatives located in 350 hospitals, nursing homes, and other health care institutions collect and submit information about problems (or potential problems) with medical devices that may require action by the FDA or the manufacturer(s).

Medicare Fraud Strike Force – A joint HHS-DOJ team effort designed to combat Medicare fraud through the use of Medicare data analysis/mining and increased focus on community policing. In addition to making arrests, strike force agents also execute search warrants in connection with ongoing strike force investigations.

Medicare Trust Fund – The funding to provide Medicare benefits that is derived from two sources. Part A, which covers in-patient hospital costs, is financed by a trust fund called the Hospital Insurance Fund, and comes out of employee paychecks. Employers also pay into this fund. This payroll tax provides the majority of the money that is used to cover Part A expenses for Medicare beneficiaries.

Part B, which covers outpatient care, is funded by the Supplemental Medical Insurance Trust Fund (SMI Fund). Enrollee premiums and funds from the general federal government budget finance the SMI Fund.

MMA (Medicare Modernization Act) – Signed into law in 2003, the MMA reformed the Medicare program to, most significantly, include a prescription drug benefit, otherwise known as Medicare Part D, through tax breaks and subsidies. It also closed some of the loopholes in the Hatch-Waxman Act that delayed access to affordable generic medicines.

– N –

NCPDP (National Council for Prescription Drug Programs) – An ANSI-accredited group that maintains a number of standard formats for use by the retail pharmacy industry, some of which have been adopted as HIPAA standards. Some ANSI standards that are required for HIPAA compliance are: the telecommunications standard, developed to provide a standard format for the electronic submission of third-party claims, the batch format standard, providing a file submission standard for use between pharmacies and processors, and a Medicaid subrogation standard which allows a Medicaid agency to communicate to a third-party processor for reimbursement. The NCPDP also created profile standards for EHRs to support the sharing of EHRs between providers.

NDA (New Drug Application) – The process through which pharmaceutical manufacturers seek FDA approval to sell and market a new drug in the United States. This process often takes from 1-2 years to complete, from the time the NDA is filed with the FDA.

NDC (National Drug Code) – The NDC is a classification system for drug identification, similar to a UPC code for commercial goods. It is a unique, 10 digit, 3 segment numeric identifier that lists the labeler (manufacturer or distributor), the product (strength and dosage), and the package (form and size) codes.

NIH (National Institutes of Health) – NIH is a medical research agency within DHHS consisting of 27 Institutes and Centers (e.g., National Cancer Institute, National Eye Institute, Center for Scientific Review), each with a specific research agenda. NIH is the largest source of funding for medical research in the world.

NPA (Non Prosecution Agreement) – An informal agreement between the government, usually the U.S. Attorney's Office, and a provider or manufacturer whereby the manufacturer agrees to certain terms in exchange for the prosecutor not filing charges. NPAs are usually more informal than a DPA and do not require an admission of guilt because no criminal charges are filed. The government will

maintain the right to file criminal charges against the manufacturer in the event it does not comply with the terms of the NPA. *See* **DPA**.

– O –

OECD (Organisation for Economic Co-operation and Development) – An organization of 34 member countries, including most of Europe, the United States, Japan, Korea, Mexico, Chile, Australia and New Zealand, whose mission is to promote policies that will improve the economic and social well-being of people around the world. The OECD focuses on helping governments in four main areas: (i) the restoration of confidence in the financial markets and the companies that make them function, (ii) the re-establishment of public finances to sustain future growth, (iii) growth through innovation, environmentally friendly strategies, and emerging economies, and (iv) ensuring that people of all ages can develop the skills to be productive members of the workforce. http://www.oecd.org/

OECD Anti-Bribery Convention – Also known as the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions (adopted in 1997), the Convention establishes legally binding standards which criminalize bribery of foreign public officials in international business transactions and applies to member countries that have signed on to the Convention. The Convention requires each member country to enact legislation that criminalizes the bribing of public officials in that country, for example, the FCPA and UK Bribery Act. As of 2014, 34 countries are members.

Off-Label Use – The practice of prescribing a drug for an unapproved indication, age group, dose or form of administration. While pharmaceutical manufacturers many not promote the off-label use of a drug, FDA does not have the authority to regulate the practice of medicine, and, therefore, may not prohibit a provider from prescribing an off-label use.

OIG (Office of Inspector General of the U.S. Dept. of Health & Human Services) – The office responsible for fighting waste, fraud and abuse, and improving the efficiency of Medicare, Medicaid and other HHS programs through a system of audits, evaluations, criminal and civil investigations of fraud and misconduct, and enforcement actions when necessary. OIG also issues regulatory guidance and, upon written request, Advisory Opinions to parties seeking guidance as to the legality of a particular arrangement. The OIG Advisory Opinion website is **http://oig.hhs.gov/compliance/advisory-opinions/.** *See also* **DHHS, DOJ, FBI**, and **Fraud**.

Office of Prescription Drug Promotion (OPDP) – Formerly known as the Division of Drug Marketing, Advertising and Communications (DDMAC), OPDP is an office within FDA with the responsibility of reviewing all prescription drug advertising and promotion materials to ensure they are accurate, balanced, and not false or misleading. OPDP's website is **http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/uc**

m090142.htm.

OTC (over-the-counter) – Medicines and health care products for which no prescription is required and therefore may be sold directly (or "over-the-counter") to the consumer.

– P –

PAP (Patient Assistance Program) – A private, non-governmental program that provides medicines free of charge or at a reduced rate to eligible individuals, primarily the uninsured who, without assistance, could not afford needed medicines. PAPs are commonly sponsored by pharmaceutical companies but can also be sponsored by independent charities. PAPs must be structured so as to avoid Anti-Kickback liability, particularly with respect to pharmaceutical manufacturer's provision of free or reduced outpatient prescription drugs. OIG has issued several Advisory Opinions regarding such strategies.

PBM (**Pharmacy Benefit Management)** – A third-party administrator of prescription drugs under contract with managed care organizations, self-insured companies, and government programs. PBM companies are responsible for processing and paying drug claims, developing and maintaining the formulary, contracting with pharmacies, and negotiating discounts and rebates with drug manufacturers.

PDUFA (Prescription Drug User Fee Act of 1992) – A federal law that allows FDA to collect fees from drug manufacturers to fund the new drug approval process. PDUFA has been amended several times since its enactment in 1992.

Pharmacovigilance – The science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients regarding the adverse effects of medications, herbs and biologicals with the goal of identifying new information about the dangers associated with certain drugs and preventing harm to patients. *See* **Adverse Event**.

PhRMA (Pharmaceutical Research and Manufacturers of America) – A trade association founded in 1958 that represents leading pharmaceutical research and biotech companies and is dedicated to effective advocacy for public policies encouraging the discovery of important new medications by the pharmaceutical and biotech industries. The PhRMA Code on Interactions with Healthcare Professionals sets forth industry guidelines governing interactions between healthcare professionals and pharmaceutical companies and the marketing of such products. The PhRMA Code can be found at www.phrma.org.

PHI (Protected Health Information) – Under HIPAA, any individually identifiable health information that is transmitted by or maintained in electronic media or any other form or medium. PHI includes names, dates, phone numbers, email addresses, Social Security numbers, medical record numbers, health plan beneficiary numbers, account numbers, and more. *See also* **HIPAA**.

PMA (Premarket Approval) – The FDA review process for evaluating the safety and effectiveness of Class III medical devices. If approved, the PMA is, in effect, a private license granted to the applicant for marketing a particular medical device. PMA is the most stringent type of device marketing application required by the FDA and an applicant must receive approval of its PMA application prior to marketing the device. The PMA process is comparable to the NDA process required for new drugs.

PPACA (Patient Protection and Affordable Care Act) – A 2010 federal law frequently referred to as PPACA, the Affordable Care Act, or the ACA. PPACA reforms the delivery of health care in the United States, affecting aspects of the private health insurance industry and public health insurance programs by: expanding access to insurance for over 30 million Americans; increasing coverage for individuals with pre-existing conditions; increasing projected national medical spending; and lowering Medicare spending. Other notable aspects of PPACA include authorizing the FDA to approve generic versions of drugs 12 years after patent approval of the innovator drug thus making it faster for generics to hit the market. PPACA also mandates that certain insurance plans allow children to remain on their parents' insurance plan until the age of 26, with limited requirements, and allows DHHS to review planned rate increases of health insurance companies. PPACA also sought to expand Medicaid coverage by mandating that states expand Medicaid eligibility to cover more individuals. Health insurance policies issued before the law's passage are grandfathered from PPACA's requirements, with limited exceptions. In June, 2012, after a constitutional challenge by 28 states, the United States Supreme Court upheld most of PPACA's provisions. Most notable, while the individual mandate was upheld, requiring all individuals to purchase health insurance with limited exceptions, the Court ruled that states may choose to increase Medicaid eligibility to cover more individuals, but are not required under PPACA to do so.

– Q –

QA (Quality Assurance) – Similar to QI (Quality Improvement), the aim of QA is to ensure the quality of care of a specific product or service by demonstrating that such product or service meets a set of defined requirements or criteria. *See* **Quality Improvement**.

QARI (Quality Assurance Reform Initiative) – A health care quality improvement system for Medicaid managed care plans originally developed by the Health Care Financing Administration (now

CMS). QARI was unveiled in 1993 to assist the states in the development of continuous quality improvement systems, external quality assurance programs, internal quality assurance programs, and focused clinical studies.

Qui tam – A Latin phrase meaning "he who brings a case on behalf of our lord the King, as well as for himself."The FCA includes a *qui tam* provision that allows a private person (a "relator") with knowledge of a fraud committed against the federal, or, if applicable, state government, to bring a lawsuit on behalf of the government when he or she has information that the defendant has knowingly submitted or caused the submission of a false or fraudulent claim for payment to the government. The federal government provides a 10% increase in a state's recovery if, among other requirements, the state FCA has provisions that are as effective in rewarding and facilitating qui tam actions as the federal FCA. Filing a *qui tam* lawsuit is referred to as "whistleblowing." *See also* **FCA** and **Whistleblower**.

QI (Quality Improvement) – QI is a management technique to assess and improve internal operations that focuses on organizational systems rather than individual performance and seeks to continuously improve quality of an organization's products and services. QI refers to the betterment of a practice or service that the organization provides. Although similar to QA, QI has a slightly different meaning, and specifically attempts to avoid the assignment of blame, instead creating systems to prevent future errors from occurring. This is the more commonly used term in healthcare today. *See* **QA**.

– R –

Recovery Audit Program – Identifies and corrects improper Medicare payments. Originally started as a demonstration program, the program was made permanent by Congress following a return to the Medicare Trust Fund of over $900 million and almost $38 million in underpayments being issued to healthcare providers.

Referral – The process of sending a patient from one health care provider to another for health care services, typically for specialty services, but also for products. Health plans may require that primary care providers authorize a referral for coverage of specialty services before the patient may receive health care services from anyone except the primary care provider. Without a referral, a health plan may not pay for the care. In the context of the Anti-Kickback Statute this term refers to the provision of a financial incentive or inducement to cause a provider to recommend federal health care business to another provider.

Responsible Corporate Officer Doctrine (also called the Park doctrine**)** – In the 1975 Supreme Court decision *United States v. Park*, the Court ruled that individuals who assume positions of authority in businesses that affect the public health are held to a strict and rigorous standard of accountability under the Food, Drug, and Cosmetics Act and broadly defines a responsible corporate officer as someone

who has the authority to exercise control over the corporation's activities that is causing the violation, not actually exercise authority over the activity. *See* **FDCA.**

Restitution – The recovery of a victim's loss attributable to a defendant's or accused's fraudulent actions or schemes.

– S –

Safe Harbor Regulations – A subset of regulations that, although potentially implicating the Anti-Kickback statute, are determined to not be violations under the law.

Sarbanes-Oxley Act (SOX) – A federal law enacted in 2002 to protect investors by improving the accuracy and reliability of corporate disclosures made pursuant to the securities laws and to ensure the independence of securities analyst advice and recommendations. The Act applies to any issuer that has securities registered or is required to file reports under the Securities Exchange Act of 1934.

SEC (U.S. Securities and Exchange Commission) – A government agency with primary responsibility for regulating the U.S. securities industry and its stock and options exchanges, and for enforcing the federal securities laws. The SEC is charged with the responsibility of promoting stability in the financial markets and protecting U.S. investors. The SEC website is **http://www.sec.gov**.

SFO (United Kingdom's Serious Fraud Office) – An independent UK Government department that investigates and prosecutes serious or complex fraud and corruption including violations of the U.K. Bribery Act. The SFO's stated goal is to protect society from pervasive, deliberate deception which could threaten public confidence in the financial system. The website is **www.sfo.gov.uk**.

SOPs (Standard Operating Procedures) – A written document or instruction detailing all of the steps of an organization's process or procedure in order to achieve uniformity in carrying out certain tasks. Commonly used to implement the company's corporate compliance program, SOPs are designed to minimize any ambiguity with respect to certain company policies and procedures.

SPAPs (State Pharmaceutical Assistance Programs) – State subsidy programs designed to assist residents who lack insurance coverage for medicines or who do not qualify for other government assistance programs.

Sponsor – The entity funding a Clinical Trial. A sponsor can be an individual provider, medical institution, pharmaceutical company, or federal agency. *See* **Clinical Trial**.

Stark Law – The federal physician "self-referral" law that prohibits federal or state health care

payments when a physician refers patients for certain designated health services to an entity with which the physician has a financial relationship, defined by statute. If certain, legitimate arrangements fall within a statutory exception, the Stark Law will not be violated. The intent of the parties is irrelevant under Stark and if there is a financial relationship, an exception must be met for a self-referral to be permissible.

Startup Company – A company that is in its first stages of operation. This type of company is oftentimes bankrolled by its founders in an attempt to capitalize on a developing product. Therefore, the company's founders are often in full control of the enterprise.

Sunshine Act (Physician Payment Sunshine Act) – The Sunshine Act is included as Section 6602 of PPACA and requires all pharmaceutical, medical device, biological and medical supply manufacturers to report to DHHS any payment or "transfer of value" made to either physicians or teaching hospitals, subject to certain exclusions. Failure to comply with the Act can result in significant civil monetary penalties: $1,000 to $10,000 for each payment or transfer of value that is not reported (maximum of $150,000); and $10,000 to $100,000 for each knowing failure to report (maximum of $1 million). Some of the exclusions include: transfers of value of less than $10, product samples given to patients for their own use but not intended to be sold, and educational materials that directly benefit or are intended for patients. The Sunshine Act is intended to preempt state law to the extent that a state law requires a manufacturer to disclose the same kind or similar information as the Sunshine Act. In February 2013, long-awaited final regulations were released and data collection began August, 2013. The first reporting date is March 31, 2014. *See also* **PPACA.**

– T –

TJC (The Joint Commission, formerly the Joint Commission on Accreditation of Healthcare Organizations(JCAHO)) – A U.S., not-for-profit organization that accredits over 19,000 health care organizations and programs in the U.S., its mission is to improve health care for the public by evaluating health care organizations and encouraging them to provide safe and effective care. Many state governments have come to recognize this accreditation as a condition of licensure and receipt of Medicaid reimbursement.

– U –

UK Bribery Act of 2010 – An act that modernizes the UK criminal legal framework to combat bribery both in the UK and abroad. At the urging of the OECD, effective in 2011, the Act repeals common law bribery provisions and replaces them with the crimes of (1) active bribery, (2) passive bribery, (3) bribery of foreign public officials, and (4) the failure of commercial organizations to prevent bribery on their behalf. The Act applies to UK citizens and residents, companies established under UK law,

and non-UK companies doing business in the UK.

Unbundling – Unlawful practice of submitting bills for services in a piecemeal manner so as to maximize reimbursement, when the services should be billed together for reimbursement at a lower rate.

Upcoding – Unlawful practice of using a billing code that provides a higher reimbursement rate as opposed to a more appropriate billing code that provides a lower reimbursement rate.

Untitled Letter – Correspondence issued by the FDA to an individual or entity advising such entity or individual about FDA violations which do not meet the regulatory significance threshold of a Warning Letter. An Untitled Letter does not include a warning statement regarding enforcement action, nor provide for any enforcement action for failure to take corrective action. All FDA Untitled Letters are posted on the FDA website at **www.fda.gov/drugs/guidancecomplianceregulatoryinformation**. These are also known as Notice of Violation Letters, or NOVs. *See* **Warning Letter**.

U.S. Sentencing Commission – Independent agency within government's judicial branch, which establishes the U.S. Sentencing Guidelines. The Commission establishes sentencing policies and practices for federal courts, advises and assists Congress and the executive branch to develop crime policies, and collects and analyzes data regarding federal crime and sentencing issues.

U.S. Sentencing Guidelines – In effect since 1987, the guidelines provide certainty and fairness in sentencing federal crimes. These guidelines are advisory, not mandatory. However, the Supreme Court did state that "district courts, while not bound to apply the Guidelines, must consult those Guidelines and take them into account when sentencing." *U.S. v. Booker*, 543 U.S. 220, 224 (2005).

-- V--

Voluntary Self-Disclosure Protocol – The OIG's Provider Self-Disclosure Protocol enables health care providers and drug and device manufacturers who wish to voluntarily self-disclose evidence of potential fraud without the costs and disruptions of a government-directed investigation. The Protocol describes the type of information that must be included in a self-disclosure submission to OIG. When resolving self-disclosed matters, OIG will consult with the DOJ and other relevant Agencies. http://oig.hhs.gov/compliance/self-disclosure-info/index.asp.

Venture Capital – A type of private equity; consists of money that investors provide to a company which, for reasons such as size, assets, or stage in development, among others, cannot obtain capital from traditional funding sources, such as banks or public markets.

– W –

WAC (Wholesale Acquisition Cost) – A published price created by the manufacturer and excluding rebates or discounts. It is the price a wholesaler pays to a manufacturer for a drug.

Warning Letter – Correspondence issued by the FDA to a manufacturer communicating violations of the FDCA, its implementing regulations, or other federal statutes, that it has documented during an FDA inspection and/or investigation. Warning Letters are issued for violations of regulatory significance in that failure to adequately and promptly take corrective action could result in enforcement action should the violation(s) continue. This type of letter is the most serious communication before the FDA takes enforcement action against a company, and it is the FDA's principal means of achieving prompt voluntary compliance with the law. All FDA Warning Letters are posted on the FDA website at **www.fda.gov/drugs/guidancecomplianceregulatoryinformation**. *See also* **Untitled Letter**.

Whistleblower – An individual who reports alleged misconduct occurring within a government department or a public or private company. A whistleblower in a successful federal False Claims Act case will receive 15-30% of the government's recovery. A person may become a whistleblower for a number of reasons, including ethical and moral considerations, quality of care issues, concerns about personal liability, and money. Many state and federal laws, including the FCA, provide certain whistleblower protections to employees. *See also* **Anti-Retaliation**, **FCA**, and ***Qui tam***.