Health Law From 30,000 Feet

By Gregory J. Naclerio[*]

Introduction:

Let me be clear: There is no such thing as "Health Law." Rather, health law is the practice of civil and criminal litigation, administrative, corporate, contract, employment and any other field of law that impacts the delivery of health care. As it is the goal of this paper to provide the fundamentals of a health law practice to newly admitted attorneys, the topic will be discussed at a macro level with cites and other guidance to help you get down to the micro level you need to be at in order to practice any area of the law.

The health law bar is relatively small and most practitioners are available to help new attorneys learn the craft – after all, that's how we did it. The Health Law Section is the youngest and fastest growing section of the Bar Association and provides various services including a "ListServe" where members share issues confronting their practice and our health law blog, S*upraspinatus* (Attachment 1).

The practice of health law is heavily sprinkled with acronyms. You need to learn these shortcuts to understand the conversation and convince the client you are a health law attorney. It's only by speaking to other health law practitioners and attending CLE's devoted to health law that you will be able "to speak the language." While none of us intended to be physicians, you will need to know about the basics of the practice of medicine and of the particular subspecialty your client practices. While you can get a rough medical education via the Internet, you can learn on the job by having your client explain the procedure in question to you…but get the

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explanation confirmed by another practitioner as well. Be eager to learn, as doctors like to teach and soon you will know your "EEG" from an "NCV."

Health Care Entities/Reimbursement.

Hospitals, Skilled Nursing Facilities, Diagnostic and Treatment Centers and Ambulatory Surgery Centers are the large providers of health care. Not just anyone can open one of these facilities. To do so requires a Certificate of Need (CON) application to the Department of Health ("DOH"). The CON procedure is a review process pursuant to Public Health Law Article 28, which governs the "establishment, ownership, construction and renovation of health are facilities…" (http: www.health.state.ny.us/facilities/cons/). A CON application is required "before new health care facilities are built or existing facilities are renovated; before facilities acquire major medical equipment, add or delete services and when ownership of a facility is changed or transferred" (supra).

The CON application generally addresses:

(a) "Need" for the new hospital/nursing home or diagnostic;

(b) The "character and competency" of the proposed owner to operate such a facility;

(c) The financial "feasibility" of the project;

(d) Compliance with architectural and engineering regulations; and

(e) A legal review of the application.

Starting December 1, 2010, the CON application will go to the newly formed Public Health and Health Planning Council (PHHPC) for final approval (See, NYLJ, July 27, 2010, State's *New Council on Public Health and Planning*). Once "established" by the PHHPC an Operating Certificate, listing what services the entity can perform, is issued. Only services so listed can legally be engaged in by the newly established health care facility.

Hospitals are reimbursed for the services they render Medicare patients by the use of Diagnostic Related Groups (DRG's). As Medicare is the largest payor of health services most other commercial carriers also use DRG's. The concept of a DRG is to classify hospital cases into one of approximately 500 groups for which the hospital receives a flat prospective payment.

Skilled Nursing Facilities, commonly called nursing homes (SNF), are reimbursed using the Resource Utilization Groups (RUG's) system. RUG's is a prospective payment system based upon the patient's medical needs or patient acuity. A Patient Review Instrument (PRI) is used to assess a patient's physical, medical and cognitive characteristics. Depending on how many services a nursing home resident is deemed to require, a RUG is assigned and a prospective payment is made to the SNF. Most SNF patients are Medicaid recipients… thanks to attorneys who practice elder law.

Diagnostic Treatment Centers (DTC's) or "Clinic's," as well as Ambulatory Surgery Centers (ACS's) are reimbursed by the Ambulatory Patient Groups (APG) methodology. The APG system provides greater reimbursement for high intensity services and relatively less reimbursement for low intensity services. APG's takes into account the patient's condition/severity and packages the cost of certain ancillary labs and radiology into one overall payment.

Physician offices, be they solo practices or large multi-specialty group practices, all bill services based upon CPT Codes. A listing of "Current Procedural Terminology" covers just about any service a physician can render and with the use of "Modifiers" describe the specific service rendered by the physician. CPT Codes are used to bill all payors. One basic set of codes you need to know about are the Evaluation and Management (E/M) Codes that physicians use to detail a patient examination. A physical examination will range from a Level 1 code (99201) for

an exam lasting approximately 10 minutes to a Level 5 Code, (99205) for an exam with a comprehensive history and physical and medical decision-making of high complexity. This Level 5 exam usually last approximately 60 minutes.

Lastly, in addition to Medicare and Medicaid, a host of third party payors is involved in the provision of medical care. They include commercial carriers (Aetna, Oxford), no-fault auto insurance, worker's compensation and finally self-payors. All are billed by CPT Codes. Generally, a CPT Code is selected after the physician performs the exam and/or procedure and notes the services provided on a "Super Bill." This is the document the patient is given after the physician service and is told to bring it to the front desk.

The Regulators: Medicare.

Medicare was signed into law in 1965 as part of President Johnson's "Great Society" program. Medicare provides health insurance coverage to people aged 65 and over or who meet other special criteria. Medicare is administered by the Center for Medicare and Medicaid Services (CMS) which is part of the Department of Health and Human Services (HHS). In Fiscal Year (FY) 2008, Medicare paid out approximately 469.2 Billion dollars in claims or about 20% of the total national health care budget. (Estimates are Medicare expenditures will continue to grow at approximately 6% through 2019).

The Government estimated that between 3% to 10% of the Medicare expenditure is siphoned off by fraud.[1] This has caused Attorney General Eric Holder to declare health care fraud as "…one of our most urgent, destructive and widespread national challenges."[2]

It is the task of the HHS, Office of Inspector General (OIG) to investigate Medicare frauds. In conjunction with agents of the FBI, OIG agents conduct audits and investigations which lead to arrests of those suspected of Medicare fraud. These cases are prosecuted by the

local United States Attorney's Office. The U.S. Attorney's Offices for both the Eastern and Southern Districts have dedicated Assistant United States Attorneys (AUSA) assigned solely to prosecute Medicare/Medicaid fraud. Recently, the Department of Justice (DOJ) joined with HHS/OIG to establish the Medicare Fraud Strike Force as part of its Health Care Fraud Prevention and Enforcement Action Team (HEAT). The Strike Force uses real time billing data to detect potential and investigate fraudulent conduct. HEAT strike forces are currently working in Brooklyn and other cities across the nation believed to be hot beds of Medicare fraud. In FY 2009, the Federal government opened 1,014 new criminal fraud investigations concerning 1,786 potential defendants. Also, during this time, DOJ secured convictions (by plea or trial) of 583 individuals. On the civil side, DOJ attorneys commenced 886 healthcare fraud investigations and recovered (by verdict or negotiation) $1.63 billion. With new monies being provided by Congress to fight fraud, these numbers will likely increase every year.

HHS has also commenced additional audit projects using Recovery Audit Contractors (RAC's) and Zone Program Integrity Contractors (ZPIC's) to conduct audits. These auditors are paid a percentage of the overpayment they find. There are a number of appeal steps a provider can take from an RAC or ZPIC audit finding and these procedures should be utilized by providers.

Federal Statutes: Criminal.

In addition to the traditional statutes used to prosecute fraud (§371 Conspiracy[3] §1001 False Statements; §1351 Mail fraud), Congress passed statutes designed specifically at health care fraud. Section 1347 makes it a felony to defraud a health benefit program (public or private) or to falsely obtain property owned by such a benefit program. A violation subjects a

person to not more than 10 years. However, if the violation results in serious bodily injury or death the maximum sentence is 20 years and life respectively.

Other health care fraud statutes of note are:

Section 669 Theft embezzlement in connection with health care

Section 1035 False statements relating to health care matters

Section 1518 Obstruction of criminal investigation of health care offenses.

The Antikickback Statute: Criminal, Civil, Administrative.

In addition to Title 18 offenses, another statute of significance in the practice of health law is the Medicare/Medicaid Antikickback statute located at 42 USC 1320a-7b (b). The Antikickback Statute (AKS) makes it a felony, punishable by a fine of $25,000 or five years in jail or both, to solicit, offer, receive or pay any remuneration (including any kickback, bribe or rebate) directly or indirectly, in cash or in kind in return for the referring of an individual to a person for the furnishing or arranging of any items or serviced paid for in part or in whole by a federal health care program.

The AKS is unique because it not only has criminal consequences but civil and administrative consequences as well. The Civil Monetary Penalty Law (CMPL) 42 USC 1320a-7a provides a civil penalty of $50,000 for each kickback act. In addition a penalty of three times the remuneration paid/received can be imposed. The statute also provides that a violator can be excluded from the Medicare or Medicaid Program.

As the scope of the AKS was interpreted very broadly by the courts (*US v. Katz*, 871 F.2d 105 (9th Cir 1989), *US v. Gerber*, 760 F.2d 68 (3rd Cir, 1985)), Congress was urged by the provider industry to reign in the AKS's expanse. As a result, HHS promulgated certain Safe Harbors (42 CFR 1001.952), which in essence states that if a provider meets each and every

element of a required safe harbor, he can be assured he will not be deemed in violation of the AKS. Notwithstanding the safe harbor protection, one must "knowingly and willfully" violate the AKS. Therefore, not being in a safe harbor does not mean you violate the AKS, rather being in a safe harbor assures you are not violating the AKS.

The AKS has taken on additional significance as the Patient Protection and Affordable Care Act (PPACA) makes it clear that a violation of the AKS can also constitute a violation of the Federal False Claims Act (FCA) 31 USC 3729-3733. Pursuant to the FCA, anyone who submits a false claim to the government (such as Medicare or Medicaid claim form) can be subject to treble damages plus a penalty of $5,500 to $11,000 *PER CLAIM*. The potential for significant damage awards has encouraged citizens under the Qui Tam provision of the FCA to sue providers on behalf of themselves and the United States and share in part of the recovery after trial or by settlement (ex. Pfizer paid 1 million to satisfy an FCA claim due to kickbacks and off-label marketing; Tenet Health Care paid 900,000 for kickbacks and other claims). Qui Tam plaintiffs stand to receive 15-25% of the recovery based on certain criteria set forth in the FCA.

Stark Law: Civil.

The Stark Law (named for Rep. Pete Stark who sponsored the legislation) is located at 42 1395nn. In short, the Stark law prohibits a physician to refer a Medicare or Medicaid patient for the provision of certain Designated Health Services (DHS) to an entity the physician, or a family member, have a financial interest. Key DHS's include but are not limited to clinical lab services, physical therapy, imaging services (MRI, CT, PET) prosthetic and orthotic devices. Moreover, Medicare defines a "physician" to include an MD, DO, dentist, podiatrist, optometrist, or chiropractor, (42 USC 1395x (r).)

Notwithstanding the statutes prohibition on referrals to entities a physician has a "financial interest," there are 20 "exceptions" which permit such referrals. Additionally, HHS has promulgated hundreds of pages of regulations addressing the Stark Law "exceptions" which must be read and understood. The Stark Law is a strict liability statute and if a prohibited referral is made the provider must refund the amount of the claim submitted to Medicare/Medicaid and each improper claim is punishable by a $15,000 civil money penalty. Any attempt to "circumvent" the law (such as Dr. A agrees to send all his MRI's to an entity owned by Dr. B and vice versa) can be punished by an additional $100,000 penalty and possible exclusion.

While the Stark law itself is relatively straightforward, the regulations promulgated thereunder can be difficult, at best, to understand and apply. Fortunately, the Patient Protection and Affordable Care Act of 2010 (PPACA) has authorized CMS to render Advisory Opinion to providers who would like an official position as to the legality of a certain transaction. Currently, HHS/OIG provides Advisory Opinions concerning potential kickback scenarios and publishes them on its website (http://oig.hhs.gov). The OIG website also provides information on Provider Self-Disclosure. The OIG's Self-Disclosure Protocol (SPD) allows a provider to voluntarily disclose evidence of wrong doing to the OIG. While no promises are made by the OIG, generally if a provider uses the SPD, the multiplier of damages is reduced (recall under the FCA treble damages are possible) and penalties are likewise reduced. Also, the odds of staying in the Medicare Program are enhanced by a self-disclosure coupled with a Corporate Integrity Agreement (CIA). A CIA can be imposed by the OIG as part of a settlement with a provider. In essence, to avoid exclusion from Medicare, a provider enters into an agreement to establish a Compliance Program which generally includes:

- the hiring of a Compliance Officer
- a written "Code of Conduct" and "Compliance Procedures"
- employee training
- establishment of a company disclosure program for employees to notify management of breeches of the code of conduct; and
- annual reports to the OIG

The OIG also provides guidance to the provider community by means of "Alerts and Bulletins" which are published on its website. Additionally, the OIG provides sample voluntary compliance programs to be used by hospitals, home health agencies, clinical labs, third party billing companies, durable medical equipment (DME) providers, hospice, small group physicians etc. A review of the published "Compliance Guidance" provides an excellent tool to identify potential areas for fraudulent conduct.

The Regulators in New York State:
Medicaid Fraud Control Unit/Office of Medicaid Inspector General

The Medicaid Program in New York is overseen by the Medicaid Fraud Control Unit (MFCU) in the State Attorney General's Office and the Office of the Medicaid Inspector General (OMIG), which reports directly to the Governor.

OMIG's (www.omig.ny.gov) mission is "to improve and preserve the integrity of the Medicaid program by conducting and coordinating fraud, waste and abuse control activities" for State services funded by Medicaid. The OMIG conducts provider audits and issues a "Draft Audit Report" of their findings. The provider can challenge the Draft Report and submit additional material to OMIG. Once the OMIG issues a Final Audit Report the provider can still challenge any findings before a Department of Health Administrative Law Judge (ALJ) and

ultimately via an Article 78 Proceeding to the State Supreme Court. The OMIG also has the power to exclude or not enroll providers in the Medicaid Program.

One unique procedure adopted by OMIG is the use of "extrapolations" to calculate overpayments. In this method, OMIG selects at random 200 provider charts out of all the providers charts and performs a billing audit matching what was billed vs. what is documented in the patient chart. The results of the audit are then applied against the provider's entire billing for the period rendering an extrapolating finding. For example, a random "sample finding" of $500 can be statistically extrapolated to an overpayment demand of several hundreds of thousands of dollars to a 95% statistical confidence level.

While OMIG only has civil and administrative authority, the Medicaid Fraud Control Unit (MFCU) has both criminal and civil prosecutorial power. As part of the Attorney General's Office, the MFCU through its auditors and investigators can conduct audits aided by subpoena, if necessary. Investigative tactics used by most prosecutor's offices are also used by the MFCU (wiretaps, undercover operations, etc.) The Special Assistant Attorney Generals assigned to the Unit appear before grand juries and prosecute criminal or civil claims in Court. While the underlying goal of OMIG is to collect dollars, the MFCU's goal is to secure criminal convictions.

State Statutes.

The MFCU prosecutes its fraud cases by charging all or some of the following Penal law provisions:

Larceny – Section 155.00

Health Care Fraud – Section 177.00

Offering a False Instrument for Filing – Section 175.30

Falsifying Business Records – Section 175.05

The MFCU also prosecutes cases of patient abuse in nursing homes including assault (§120.00); and endangering the welfare of a vulnerable elderly person (§260.34).

Office of Professional Medical Conduct/Office of professional Discipline: Licensure.

The Office of Professional Medical Conduct (OPMC) (www.health.state.ny.us/professionals/doctors/conduct) investigates every complaint made concerning physicians, physician assistants (PA's) and specialist assistants (SA's). Complaints concerning a physician committing an act or acts of professional medical misconduct (as defined Education Law 6530) are mandatory for physicians, hospital administrators and medical societies (PHL §230(11). As an OPMC investigation concludes the subject physician is offered an opportunity to meet, with an OPMC investigator and a medical coordinator to discuss the facts of the case from the physician's perspective. The physician can, and should, have counsel present. At the conclusion of the investigation the case is either closed or presented to an investigative committee for the filing of charges. If charges are filed, the physician is entitled to a hearing before a three-member panel consisting of two physicians and a public representative. An ALJ presides over the hearing but does not vote. If the physician is found guilty of professional misconduct the sanctions that can be imposed range from censure and reprimand to revocation of license (See PHL §230).

The Office of Professional Discipline (OPD) supervises 48 professions ranging from acupuncture to veterinary medicine. (See www.op.nysed.gov). If a licensee is accused of violating the rules of the Board of Regents as set forth in the Education Department Regulations, (8 NYCRR 29) an investigation similar to that by OPMC is conducted and the licensee has an opportunity to state his position in an interview with the OPD investigator. Should changes be

voted a hearing is conducted. Should the licensee be found guilty of violating the Board's rules he can be punished by a censure and reprimand up to license revocation.

With both OPMC and OPD any adverse decision can be challenged in an Article 78 proceeding.

Attachment A

End Notes:

[1] Acting Deputy Attorney General Gary Grinder Speech www.justice.gov/dag/speeches/2010/dag-speech-100614.html.

[2] Attorney General Holder Speech, www.justice.gov.ag/speeches/2010/ag-speech-100128.html.

[3] Unless noted all citations are to Title 18 United States Code.