Hospital Responsibilities for Medically Unnecessary and Subquality Care: Is the 800-Pound Gorilla Out of the Closet?

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Disclaimer

The sample scenarios contained in this presentation are hypothetical and do not represent actual events. Nothing in the presentation is intended as nor should be relied upon as legal advice.

The Scenario

A call is received by the Compliance Officer on the organization's hotline from an employee who works in the surgery department. The employee claims that a physician had performed a procedure on a patient which was medically unnecessary. This physician is known throughout the department for performing procedures which are questionable. A fellow physician mentioned informally this isn't the first time this physician has performed this type of procedure inappropriately. The employee who reported this incident meets with you and lays out the details of the case.

Hospital vs. Physician Accountability

- Is the hospital really at risk? After all, we were just following a physician's order, right?
- If the complaint is found to be true, how does it impact the hospital?

Informing Key Individuals

- How do I inform senior management and the Board of this incident and when?
- Should I involve legal counsel? If so, when?

Investigation Phase

- Who should conduct the investigation? The hospital or the medical staff?
- Who should I interview? Staff in the surgery department? Should I interview physicians?
- How can I ensure that confidentiality is maintained so that the physician in question is not unfairly judged before a full investigation is completed?
- How do I communicate the resolution of the issue back to the individual or department who originally reported the concern or who was involved in the investigation?

Medical Staff Considerations

- How should I communicate the results of my investigation to the medical staff?
- If the issue is channeled through peer review, how much information will I be privy to? How will I know that the issue has been appropriately addressed?
- What if I feel that the medical staff has not handled the situation appropriately? What if I feel they are "sweeping it under the carpet"?

Self-Disclosure/Refunding Issues

- Would the hospital have to return monies owed on reimbursement received for procedures found to be medically unnecessary when acting under the order of a physician?
- Assuming we decide that a refund is owed, how do I go about doing that?
- Would I voluntarily disclose these funds to the government?

Hospital Liability for Physician Misconduct

- Liability for Medically Unnecessary or Substandard Care Provided by a Physician
  - Respondeat Superior
    - Hospital liability for medically unnecessary treatment or substandard care provided by a staff physician generally is determined in accordance with the vicarious liability theories of agency or *respondeat superior*.

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- Under those theories, an employer or principal may be held liable for the misconduct of an employee or agent acting within the scope of his or her employment or agency, but generally may not be held liable for the acts of an independent contractor.

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- In corporate practice of medicine states, the issue of a hospital's *respondeat superior* liability for physician services often has arisen in connection with resident physicians. *See, e.g., Hedlund v Sutter Medical Service Co.*, 51 Cal. App. 2d 327 (1942) (hospital liable for allergy test administered by resident physician).

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Ostensible Agency

- A hospital also can be found liable for a physician's misconduct or malpractice when the physician is not employed by the hospital but is determined to be the ostensible agent of the hospital. *See, e.g., Elam v. College Park Hospital*, 132 Cal.App.3d 332, 337 (1982), *Meier v. Ross General Hospital*, 69 Cal.2d 420, 434-435 (1968), *Quintal v. Laurel Grove Hospital*, 62 Cal.2d 154, 166-168 (1964).

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- Under California law, a physician is not an agent of a hospital merely because he or she is on the medical staff of the hospital. *Mayers v. Lirow*, 154 Cal. App 2d 413, 418 (1957). However, a physician "may be an agent of a hospital even where the physician bills separately for his or her services and is a member of the medical staff, if other facts are present which indicate that an agency exists." *Jacoves v. United Merchandising Corp.*, 9 Cal.App.4th 88, 102 (1992).

- The court in *Mejia v. Community Hospital of San Bernardino*, 99 Cal.App.4th 1448 (2002), addressed a patient's claims against a hospital, emergency room physician, radiologist, and the medical groups that employed the physician and radiologist who had misdiagnosed the patient's broken neck. The *Mejia* court held that in essence, ostensible agency requires the following two elements:

- (1) conduct by the hospital that would cause a reasonable person to believe that the physician was an agent of the hospital, and
- (2) reliance on that apparent agency relationship by the plaintiff. The court noted that the first factor generally is satisfied when a hospital "holds itself out" to the public as a provider of care.
- To prove this element, according to the court it is not necessary to show an express representation by the hospital; instead, a hospital is generally deemed to have held itself out as the provider of care, unless it gave the patient contrary notice.

- Additional factors identified by other courts as relevant to an analysis of ostensible agency include (i) whether the physician maintains a practice independent of a hospital and (ii) whether the physician was independently selected or engaged by or on behalf of the injured patient. *Meier v. Ross General Hospital*, 69 Cal.2d 420, 434-435 (1968); *Mayers v. Litow*, 154 Cal. App. 2d 413, 418 (1957). (surgery had been performed by a physician

- The principal inquiry is whether the patient had reason to know that the physician was not an agent of the hospital. *See Contreras v. Childrens Hosp. of Los Angeles*, 2003 WL 21328937 (June 10, 2003) (unreported).

Peer Review and Negligent Credentialing

- California law requires that an organized, self-governing medical staff, through peer review, employ its collective medical expertise in evaluating the care its members provide. 22 CCR §70701(a)(1)(F). A hospital's medical staff is "responsible to the governing body for the adequacy and quality of the medical care rendered to patients in the hospital." 22 CCR §70703(a) (emphasis added).

- California recognizes the tort of negligent credentialing, pursuant to which hospitals can in some circumstances be liable for the negligent conduct of medical staff physicians. *Elam v. College Park Hospital*, 132 Cal.App.3d 332 (1982) (in which a hospital was held liable to patients under the doctrine of corporate negligence for the negligent conduct of independent physicians and surgeons who, as members of the hospital staff, availed themselves of the hospital facilities, but who were neither employees nor agents of the hospital);

- *Oskooi v. Fountain Valley Regional Hospital and Medical Center*, 42 Cal.App.4th 233, 244 (1996); *Santa Rosa Memorial Hospital v. Superior Court*, 174 Cal.App.3d 711, 715 (1985).

The United Memorial Hospital and Redding Medical Center Cases

United Memorial Hospital

- United Memorial Hospital (UMH) in Michigan, on January 8, 2003, entered a guilty plea that, among other requirements, obligated UMH to pay a fine of more than $1,050,000 and to affiliate with another health care entity. *See United States v. United Mem'l Hosp.*, No. 1:01-CR-238 (W.D. Mich. Jan. 8, 2003).

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- The prosecution of UMH arose chiefly out of the unchallenged misconduct of a staff anesthesiologist, Dr. Jeffrey Askanazi, who was separately convicted for submitting false and fraudulent claims for reimbursement of medically unnecessary procedures he performed.

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- Dr. Askanazi's privileges were limited to anesthesiology, and he also performed pain management procedures. Although nurses, staff physicians, and patients raised questions about the frequency of procedures performed and Dr. Askanazi's practices (e.g., performing the same procedures on patients without benefit and frequently without conducting a sufficient examination to make an accurate diagnosis), UMH declined to take any action. Complaining personnel were told that Askanazi generated significant income for UMH and were advised to keep their concerns to themselves or leave the hospital.

- The U.S. Attorney's Office planned to prove at trial that Askanazi repeatedly performed procedures that lacked medical benefit, while UMH did nothing to restrict the number or type of procedures he was performing.

- An outside expert hired by UMH's Professional Activites Committee indicated that he could not render an opinion because of the lack of medical documentation in Askanazi's files. The Professional Activities Committee took no action for eight months, and then counseled Askanazi to improve his paper work.

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- The death of one of Dr. Askanazi's patients led UMH management to obtain a substantive review of Askanazi's practice, and the Professional Activities Committee sent the deceased patient's medical file (along with several others) to the Peer Review Organization of Michigan (the "PROM," now referred to a "QIO").

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- After reviewing 80 charts from Dr. Askanazi's patients, the PROM issued a report stating that the "evaluative process presenters was uniformly inadequate," there was an overutilization of procedures, and the pain management activities appeared to have proceeded "without evidence or [sic] efficacy, quality assurance or outcome evaluation....

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- Despite this opinion and the long history of complaints, Askanazi continued to perform pain management procedures at UMH until he voluntarily resigned, and UMH continued to collect fees for his procedures for several years.

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- As part of its guilty plea, UMH received a term of three years' probation, during which time it would be subject to a compliance plan and the independent auditing of its coding and billing process.

- Additionally, as noted above, UMH agreed to pay a fine of $1,050,908, to make full restitution for all amounts billed for medically unnecessary procedures, and to reimburse the U.S. Attorney's office for cost of prosecution. As part of the agreement, the individuals involved in the fraudulent activity were also barred from positions of authority at the hospital.

Redding Medical Center

- In the Redding Medical Center case, an investigation was triggered by a 2002 whistleblower complaint under the False Claims Act alleging numerous unnecessary invasive cardiac procedures by two cardiovascular surgeons.

- The case was settled with payments of $54 million to state and federal governments and the creation of a special monitoring component for cardiac procedures performed at the facility

- Additionally, the OIG notified the hospital of its intent to exclude it from participation in Medicare and other governmental programs, which ultimately was resolved through a divestiture agreement

Potential Government Enforcement Actions

- <u>The Concept of Medical Necessity</u>
- The Medicare and Medicaid programs employ the concept of "medical necessity" to delineate the scope of covered benefits. However, the definitional and procedural parameters of "medical necessity" are ill-defined.

- For example, the Medicare statute provides coverage for an extensive list of specific categories of items and services, as well as identifying certain items and services that are always excluded from coverage. *See* 42 U.S.C. § 1395y(a)(1).

- Within the covered categories, Medicare limits program coverage to items and services that are "reasonable and necessary for the diagnosis or treatment of illness or injury." *See* 42 U.S.C. § 1395y(a)(1)(A).

- However, the statute fails to specify any means of determining what services are reasonable and necessary -- or, in fact, who should make that determination.

- Similarly, the Medicaid program is structured to permit each state to design its own program within certain statutorily specified parameters, including covered categories of services. *See* 42 U.S.C. § 1396a. The Medicaid regulations specifically permit each state Medicaid program to place "appropriate limits on a service based on such criteria as medical necessity." 42 C.F.R. § 440.230(d). However, no definition of medical necessity is included in the Medicaid statute or regulations.

Practitioner Determinations

- Given the lack of statutory guidance, determinations of medical necessity historically have been left to individuals' treating physicians, subject to the potential review of carriers, fiscal intermediaries and QIOs.

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- In recent years, however, Congress has sought to narrow the concept of medical necessity to limit the deference accorded to treating physicians and to incorporate an element of cost-effectiveness into the federal health programs.

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- Accordingly, a provision of the Social Security Act, applicable to both Medicare and Medicaid programs, imposes an obligation on healthcare practitioners and providers to assure that health services ordered for government patients are "provided economically and only when, and to the extent, medically necessary." 42 U.S.C. § 1320c-5(a)(1); 42 C.F.R. § 1004.10(a). Again, however, the term "medically necessary" is undefined.

Medicare Contractor Determinations

- In addition to practitioners, Medicare carriers and intermediaries are responsible for medical necessity determinations on a day-to-day basis in the processing of Medicare claims. *See* 42 U.S.C. §§ 1395h(a)(2)(B), 1395u(a)(1)(A), 1395u(a)(1)(C) (2004); 42 C.F.R. §§ 421.100; 42 C.F.R. pts. 400, 405., 1989)

- As noted by CMS, "[i]n the absence of a national coverage decision, local Medicare Contractors have the discretion to determine whether a particular service meets all other requirements for coverage, appears to be reasonable and necessary, and therefore is covered by Medicare." 54 Fed. Reg. 4302-03, 4311 (January 30

- Additionally, carriers and intermediaries make medical necessity determinations when developing Local Coverage Determinations ("LCDs") and Local Medical Review Policies ("LMRPs") and conducting medical review. *See generally* CMS Manual System, Pub. 83, Transmittal No. 27, Change Request 2141 (July 2, 2002).

CMS Guidance

- Further guidance is issued in the form of National Coverage Determinations, published by CMS in the Federal Register. A National Coverage Determination, or "NCD," is a national policy statement describing Medicare coverage (or lack thereof) of a specific service or item. NCDs do not include determinations regarding assignment of codes to or the amount of payment for particular items or services.

Hospital Requirements

- The Medicare conditions of participation for hospitals require certain utilization review activities regarding services to Medicare and Medicaid patients with respect to at least three considerations: admissions, length of stays, and professional services (including drugs and biologicals). *See* 42 C.F.R. § 48230(c)(1); *see also* 42 U.S.C. §§ 1395x(e)(6)(A), 1395x(k).

- Additionally, hospitals are required to maintain an organized medical staff that is responsible for reviewing the credentials of the physicians who provide or order services in the facility and for recommending the clinical privileges to be granted to each member of the medical staff. 42 CFR §§ 48122(a)(2), (c)(6).

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- Therefore, while institutional medical providers are not licensed to practice medicine and do not exercise professional medical judgment regarding patient treatment, they nevertheless have an obligation to carefully credential physicians practicing within the organization and to limit clinical privileges to services that the physician is competent to provide.

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- Hospitals have been investigated and sanctioned by law enforcement agencies for allegedly failing to conduct these activities or to take appropriate action to prevent the provision of, and billing for, services in the facility that were not reasonable and necessary.

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OIG Compliance Program Guidance

- The OIG's Compliance Program Guidance for Hospitals, issued on February 23, 1998, identifies determinations of medical necessity as an area of "special concern." *See* OIG Compliance Program Guidance for Hospitals, 63 FR 8992 (February 23, 1998).

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- The OIG indicated that a hospital's compliance program "should provide that claims should only be submitted for services that the hospital has reason to believe are medically necessary and that were ordered by a physician or other appropriately licensed individual." *Id.*

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- To ensure compliance with this general standard, the OIG has stated that hospitals are expected to monitor the quality of care delivered at their facilities, including by physicians.

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- In its Supplemental Program Guidance for Hospitals, issued on January 31, 2005, the OIG referenced its authority to exclude hospitals that provide "unnecessary items or services (*i.e.*, items or services in excess of the needs of a patient) or substandard items or services (*i.e.*, items or services of a quality which fails to meet professionally recognized standards of health care)." *See* OIG Supplemental Compliance Program Guidance for Hospitals, 70 FR 4858, 4870 (January 31, 2005).

- Specifically, the OIG indicated that
  - [t]o achieve their quality-related goals, hospitals should continually measure their performance against comprehensive standards. Medicare participating hospitals MUST meet all of the Medicare hospital conditions of participation (COPs), including without limitation, the COP pertaining to a quality assessment and performance improvement program at 42 CFR 482.21 and the hospital COP pertaining to the medical staff at 42 CFR 482.22.

- In addition, according to the OIG, in reviewing the quality of care provided, hospitals must not limit their review to the quality of their nursing and other ancillary services. Hospitals must monitor the quality of medical services provided at the hospital by appropriately overseeing the credentialing and peer review of their medical staffs. *Id.* at 4870-4871 (emphasis added).

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Civil False Claims Act, 31 U.S.C. §§3729 et seq.

- The Civil False Claims Act, 31 U.S.C. § 3729 et seq. (the "False Claims Act" or "FCA"), prohibits any person from knowingly presenting (or causing to be presented) to the Federal Government a false or fraudulent claim for payment or approval. *See* 31 U.S.C. § 3729(a)(1).

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- Additionally, the False Claims Act prohibits knowingly making or using (or causing to be made or used) a false record or statement to get a false or fraudulent claim paid or approved by the Federal Government or its agents, such as carriers, other claims processors or Medicaid. 31 U.S.C. § 3729(a)(2).

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- Accordingly, the False Claims Act can reach medical necessity issues based on certifications in claims submission regarding medical necessity.

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- *False Claim*. A "false claim" is a claim for payment for services or supplies that were not provided specifically as presented or for which the provider is otherwise not entitled to payment. Examples of false claims for services or supplies that were not provided specifically as presented include the possibility of the following:

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- (i) a claim for a service or supply that was never provided;
- (ii) a claim indicating the service was provided for some diagnosis code other than the true diagnosis code in order to obtain reimbursement for the service (which would not be covered if the true diagnosis code were submitted);

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- (iii) a claim indicating a higher level of service than was actually provided;
- (iv) a claim for a service that the provider knows is not reasonable and necessary; or
- (v) a claim for services provided by an unlicensed individual.

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- *"Knowingly."* To "knowingly" present a false or fraudulent claim means that the provider: (1) has actual knowledge that the information on the claim is false; (2) acts in deliberate ignorance of the truth or falsity of the information on the claim; or (3) acts in reckless disregard of the truth or falsity of the information on the claim.

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- Notably, the government does not have to demonstrate a specific intent to defraud: a provider may be found liable under the FCA even where it did not deliberately intend to defraud the federal government. 31 U.S.C. §3729(b).

- Examples include the possibilities of the submission of claims where the services were not provided as claimed or claims that are outright false or fraudulent.

- *"Deliberate Ignorance."* To act in "deliberate ignorance" suggests that a provider has deliberately chosen to ignore the truth or falsity of the information on a claim submitted for payment, even though the provider knows, or has notice, that information may be false.

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- This standard arguably could be violated where a provider fails to maintain current knowledge of carrier's billing guidance, for example. When claims for non-reimbursable services are submitted as a result, it is possible that the False Claims Act could be violated.

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- The recent decision of *In Re: Cardiac Devices Qui Tam Litigation*, No. 3:03MD1505 (D. Conn. May 12, 2004), is illustrative here. That case addressed claims against providers that had misinterpreted payment regulations and billed the government for non-FDA approved cardiac devices (the FDA had approved the clinical trials involving the devices, but not the devices themselves; accordingly, the devices were not covered by Medicare).

- In allowing the qui tam case to proceed, the court ruled that health care providers have a duty to familiarize themselves with requirements for reimbursement. Further, the court noted that the Medicare program's definition of "medical necessity" is an express condition of payment, explicitly linking each Medicare payment to the requirement that the particular item or service be reasonable and necessary.

- As such, when a provider submits a claim form to Medicare, the provider implicitly certifies
  - (i) compliance with the medical necessity definition, and
  - (ii) that such provider is seeking payment only for services that are reasonable and necessary.

- Therefore, the court held, when a claim form includes requests for payment for services that are not reasonable and necessary, and the provider knew or should have known the claims were not medically necessary, the claims are legally false under an "implied certification" theory.

- *"Reckless Disregard."* To act in "reckless disregard" means that the provider pays no regard to whether the information on a claim submitted for payment is true or false.

- This standard has been described as "an aggravated form of gross negligence," "simply a linear extension of gross negligence, a palpable failure to meet the appropriate standard of care," or "gross negligence-plus," requiring no evidence of willful misconduct. *See United States v. Krizek*, 111 F.3d 934, 939-40 (D.C. Cir. 1997).

- As the court noted in that case, a sponsor of the 1986 amendments to the FCA stated:
  - Subsection 3 of Section 3729(c) uses the term "reckless disregard of the truth or falsity of the information" which is no different than and has the same meaning as a gross negligence standard that has been applied in other cases.

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- While the Act was not intended to apply to mere negligence, it is intended to apply in situations that could be considered gross negligence where the submitted claims to the government are prepared in such a sloppy or unsupervised fashion that resulted in overcharges to the government.

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- The Act is also intended not to permit artful defense counsel to require some form of intent as an essential ingredient of proof. This section is intended to reach the "ostrich-with-his-head-in-the-sand" problem where government contractors hide behind the fact they were not personally aware that such overcharges may have occurred.

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- *Penalties*. The penalty for violating the False Claims Act is a minimum of $5,500 up to a maximum of $11,000 for *each* false claim submitted. In addition to the penalty, a provider could be found liable for damages of up to three times the amount unlawfully claimed.

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- Moreover, a health care provider found to have violated the False Claims Act is obligated to repay all of the mistakenly obtained reimbursement. Exclusion from Medicare and Medicaid programs may also be imposed. In addition, the government may attempt to impose a corporate integrity agreement.

- *Defenses to False Claims Actions Based on Medical Necessity*. To establish a False Claims Act violation, the government must demonstrate that the defendant "knowingly" made a false claim or statement in support of a claim.

- In *U.S. ex rel. Hagood v. Sonoma County Water Agency*, 81 F.3d 1465 (9th Cir. 1996), the Ninth Circuit examined the scope of the term "knowingly" and the intent required before a False Claims Act violation may be found, and affirmed its earlier ruling that an "innocent mistake is a defense to the criminal charge or civil complaint. So is mere negligence." *Id.* at 1478.

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- As such, the Ninth Circuit held that where the evidence "innocent mistake or mere negligence," there is no showing of knowing fraud and thus no False Claims Act violation:

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- The False Claims Act, to repeat, requires a showing of knowing fraud. The requisite intent is the knowing presentation of what is known to be false, as opposed to innocent mistake or mere negligence. ... The statutory phrase 'known to be false' does not mean scientifically untrue; it means 'a lie.'

Civil Monetary Penalties, 42 U.S.C. §1320a-7a

- The CMP statute prohibits health care providers from presenting, or causing to be presented, claims for services that the provider "knows or should know" were not medically necessary. *See* 42 USC §13204-7a(a)(1)(E).

- The CMP statute also prohibits any person from knowingly presenting or causing to be presented to the federal government a claim for a medical or other item or service and the person knows or should know the claim is false or fraudulent. 42 USC §1320a-7a(a)(1)(B).

- The reach of the CMP statute was extended with the enactment of HIPAA which, among other enumerated prohibitions, added a provision to the CMP law that directly addresses unnecessary medical services. 42 USC §1320a-7a(a)(1)(E).

- For purposes of the CMP statute, the term "should know" means that the provider (i) acted in deliberate ignorance of the truth or falsity of the information; or (ii) acted in reckless disregard of the truth or falsity of the information. 42 USC § 1320a-7a (i)(7).

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- Like the False Claims Act, to establish liability under the CMP statute, the federal government does not have to show that a provider specifically intended to defraud a federal health care program. *Id*.

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- Violation of the CMP law may result in a penalty of up to $10,000 per item or service and up to three times the amount unlawfully claimed. 42 USC §1320a-7a(a). In addition, the provider may be excluded from participation in federal health care programs. Sanctions under the CMP statute are "in addition to any other penalties that may be prescribed by law." 42 USC § 1320a-7a(a); 42 CFR §1003.108.

- After the HIPAA amendments were enacted, the OIG relied on the medical necessity provision to successfully litigate a CMP claim, obtaining a $126,000 penalty and seven-year program exclusion against a physician. *See Inspector General v. O'Connor*, No. CR1206 (Aug 27, 2004).

Potential Exclusion from Federal Health Care Programs

- Federal regulations provide that the OIG may exclude an individual or entity that has "[f]urnished, or caused to be furnished, to patients (whether or not covered by Medicare or any of the State health care programs) any items or services substantially in excess of the patient's needs, or of a quality that fails to meet professionally recognized standards of health care." 42 CFR §1001.701(a) (implemented under section 1128(b)(6)(B) of the Social Security Act and 42 USC §1320a-7(b)(6)(8)).

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- According to the OIG, neither knowledge nor intent is required for exclusion under this provision. *See* OIG Supplemental Compliance Program Guidance for Hospitals, 70 FR 4858, 4870 (January 31, 2005).

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- Moreover, the exclusion can be based upon unnecessary or substandard items or services provided to any patient, even if that patient is not a Medicare or Medicaid beneficiary. *Id*.

- The OIG has endeavored to rely on this provision to exclude facilities at which allegedly unnecessary procedures were performed, irrespective of the fact that the services were not ordered by the facilities themselves

- Under one regulatory exception, a provider "will not be excluded . . . for furnishing . . . items or services in excess of the needs of patients, when the items or services were ordered by a physician . . . and the . . . entity furnishing the items or services was not in a position to determine medical necessity or to refuse to comply with the order of the physician . . . . 42 C.F.R. §1001.701(c)(2). Under this provision, the need for a medical procedure originally must be determined by a physician.

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Medicare Overpayment Disclosure and Repayment Obligations

- Medicare will not make payment for any items or services, even if statutorily covered, where the item or service is not medically necessary. 42 U.S.C. 1395y(a)(1). In this way, medically unnecessary and/or substandard care could form the basis for allegations of Medicare overpayment.

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- Under proposed rule, an "overpayment" is defined as "Medicare funds a provider, supplier, an individual, or other entity . . . contracting with CMS has received in excess of amounts payable under the Medicare statute and regulations." *Id*. at 3665.

- Providers may be subject to allegations of Medicare overpayments under a number of statutes and regulatory enforcement mechanisms, including the following (many of which are discussed in greater detail above):

- *Social Security Act § 1128B; 42 U.S.C. §1320a-7b(a)(1)-(3).* With respect to overpayments, a longstanding section of the Social Security Act provides as follows:

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- Whoever, having knowledge of an occurrence of any event affecting (A) a party's initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual on whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized.

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- Violation of this provision is a felony that could subject the provider to up to five years in prison and/or monetary penalties of up to $25,000 for individuals or $500,000 for corporations

- The OIG has indicated its position that the provision requires disclosure of all known overpayments, regardless of whether the overpayment was initially obtained innocently or through fraud. *See* OIG Compliance Program Guidance for Hospitals, 63 FR 8987, 8992 (February 23, 1998).

- "Failure to repay overpayments within a reasonable period of time could be interpreted as an intentional attempt to conceal the overpayment from the Government, thereby establishing an independent basis for a criminal violation with respect to the hospital, as well as any individuals that may have been involved." *Id*.

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- *Civil False Claims Act, 31 U.S.C. §§ 3729 et seq*. The Civil False Claims Act prohibits a person from knowingly submitting claims or making a false record or statement to ensure that a false or fraudulent claim is paid by the government.

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- In this context, "knowing" and "knowingly" are defined to include actual knowledge, deliberate ignorance of the truth, or reckless disregard for the truth or falsity of the information. As such, a knowing receipt and/or retention of an overpayment may be a violation of the False Claims Act.

- For example, in February 2002, St. Joseph's Hospital in Houston, Texas, agreed to pay $1,569,000 to settle a *qui tam* case alleging false claims act violations in connection with the hospital's failure to disclose a known overpayment of $798,000 from Medicare. The theory presented in the lawsuit was that health care providers are obligated to disclose known overpayments from the Medicare program arising out of past reimbursement errors

- In addition, an enforcement trend has emerged in connection with Medicare overpayment actions, based on so-called "reverse false claims." Reverse false claims are premised on allegations that an entity has fraudulently attempted to reduce the amount it owes to the government, generally by making a material misrepresentation to avoid paying money owed to the government (such as failing to disclose an overpayment).

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- For example, in the case of *In re Cardiac Devices Qui Tam Litigation*, 221 F.R.D 318 (Dist. Ct. 2004) (discussed above), the government's claims against a hospital were based on its failure to disclose and reimburse the government for overpayments for false claims submitted for investigational cardiac devices.

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- *Civil Monetary Penalties, 42 US C § 1320a-7a(a); Section 1128A(a)(1) of the Social Security Act*. Civil monetary penalties may be assessed for improperly filed claims. This includes claims that are for
  - (a) medical or other items or services that the person knows or should know was not provided as claimed;
  - (b) medical or other items or services where the person knows or should know the claim is false or fraudulent; or
  - (c) 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)-(3).

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- Accordingly, knowing receipt and/or retention of an overpayment could subject a provider to sanction under the CMP law. *See, e.g. Office of Inspector General v. Vo, M.D. et al.*, Docket No. C-45 (August 15, 1989).

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- *Exclusion under Section 1128(b)(6)(B) of the Social Security Act*. A provider may be excluded from participation in any Federal health care program if it has furnished or caused to be furnished items or services to patients (whether or not eligible for benefits under Medicare or Medicaid) substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of care.

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- *Section 1862(1) of the Social Security Act*. Similar to § 1128(b)(6)(B), under § 1262(1), no payment may be made under Medicare Part A or Part B for any expense incurred for items or services which are not reasonable and necessary.

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Obligation to Disclose and Refund Overpayments

- In October 1998, the OIG issued guidance on voluntary disclosures of health care fraud. *See* 63 FR 58399 (October 30, 1998). Generally, the self-disclosure protocol states that if an initial assessment by a provider uncovers suspected fraud or other problems, the provider is encouraged to report the discovery to the OIG.

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- In March 2000, HHS Inspector General June Gibbs Brown issued an "Open Letter" to health care providers, stating that the OIG would show greater leniency on providers that voluntarily disclose wrongdoing and that have effective compliance programs.

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- Different statutes and regulations address recoupment when Medicare discovers the overpayment, including (i) 42 C.F.R. §§ 405.371, *et seq*. (suspension, offset, and recoupment of Medicare payments to providers and suppliers of services); (ii) 42 C.F.R. § 405.376(b) (suspension and termination of collection action and compromise of claims for overpayment); and (iii) 31 U S.C. § 3711 (collection and compromise).

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- However, neither the voluntary disclosure guidance nor the Inspector General's open letter have the weight of legal authority, and neither provides any protection to providers making disclosures in accordance therewith.

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- For example, the OIG's self-disclosure protocol recognizes that "[b]ecause a provider's disclosure can involve anything from a simple error to outright fraud, the OIG cannot reasonably make firm commitments as to how a particular disclosure will be resolved or the specific benefit that will enure [sic] to the disclosing entity."

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CMS Focus on Error Rate Reduction

- In recent years, CMS has focused on reducing improper fee-for-service Medicare claims payments, using increasingly aggressive oversight and improved processing efforts.

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- According to CMS, the Medicare fee-for-service error rate has declined from 14.2 percent in 1996, when the Medicare improper payment rate was first reported, to a current level of 52 percent. *See* CMS Statement, "Medicare Reduces Improper Claims Payments By Half."

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- According to CMS Administrator Mark McClellan, the unprecedented, $9.5 billion reduction in improper Medicare payments reflects our commitment to careful measurement and targeted oversight, and we intend to keep building on these efforts. . . .

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- We are measuring the accuracy of payments more closely, and that enables us to target our efforts more effectively with Medicare contractors and providers." *Id.*

- Among the factors identified by CMS as impacting and/or elevating the number of improper payments is claims submitted for medically unnecessary services. For example, CMS reviewed approximately 160,000 fee-for-service Medicare claims in 2005 as part of its Medicare error rate testing program.

- Errors found in those claims included the following: (i) non-responses to request for medical records (0.7 percent); (ii) insufficient documentation (1.1 percent); (iii) medically unnecessary services (1.6 percent); (iv) incorrect coding (1.5 percent); and (v) other errors (0.2 percent).

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- Given the significant financial impact of its error reduction efforts, providers can expect that CMS will continue to focus on reducing the error rate as a high priority, including continued scrutiny on medical necessity determinations.

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Accreditation Issues: Patient Disclosure

- Adverse event disclosure became a risk management focus in 2001, when new JCAHO safety standards made patient notification of unanticipated medical outcomes an industry standard.

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- Under JCAHO standard RI.2.90, patients are entitled to be informed of unanticipated outcomes of care.

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- Specifically, RI.2.90 provides as follows: "[p]atients and, when appropriate, their families are informed about the outcomes of care, treatment, and services that have been provided, including unanticipated outcomes."

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- The elements of performance (also referred to as the "intent statements") for standard RI.2.90 require, at a minimum, disclosure of two types of outcomes.

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- a. "[o]utcomes of care, treatment and services that have been provided that the patient (or family) must be knowledgeable about to participate in current and future decisions affecting the patient's care, treatment and services;" and

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- b. unanticipated outcomes of care, treatment and services related to sentinel events, when the patient is not already aware of the occurrence, or further discussion is needed."

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- Therefore, patients must be notified where the outcome of care either (i) will affect current and future patient care decisions, or (ii) was unanticipated and relates to a reviewable sentinel event.

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- Unfortunately, there is no bright line method of determining whether and when disclosure is necessary, particularly for incidents that may not be sentinel events.

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- *Who should make the disclosure?* With respect to unanticipated outcomes that are reviewable sentinel events, the intent statement provides that the "responsible licensed independent practitioner or his or her designee" must inform the patient or family.

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- The intent statement further indicates that " in settings where there is no licensed independent practitioner, the staff member responsible for the care of the patient is responsible for sharing information about such outcomes."

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- *Patient Notification In Various Other States*. Perhaps because the JCAHO rule is both vague and fraught with potential legal landmines, a number of state legislatures have supplemented the accreditation standards by establishing a statutory duty of notification directly applicable to hospital facilities.

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- These statutes and regulations generally protect notifications of adverse or unanticipated outcomes from use in later legal proceedings, removing the uncertainty that otherwise surrounds the issue.

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- For example, Pennsylvania's Medical Care Availability and Reduction in Error (MCARE) Act, enacted in 2002, provides that within seven days of occurrence or discovery, a "medical facility through an appropriate designee shall provide written notification to a patient affected by a serious event... Notification under this subsection shall not constitute an acknowledgement or admission of liability." 40 P.S. §1303 308(b), *see also* New Jersey Patient Safety Act, N.J.S.A. 26:2H-12:25(d) (enacted in 2004).

- Likewise, Florida's patient safety statute, enacted in 2003, requires that an "appropriately trained person designated by each licensed facility shall inform each patient... in person about adverse incidents that result in serious harm to the patient. Notification of outcomes of care that result in harm to the patient under this section shall not constitute an acknowledgment or admission of liability, nor can it be introduced as evidence." West's F.S.A. § 395.1051.