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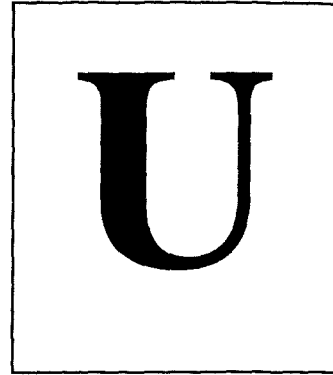
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**Safe Informed Consent (SIC): A Cost Effective Systems
Approach**

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SAFE INFORMED CONSENT (SIC): A Cost Effective Systems Approach

The Centers for Medicare & Medicaid Services (CMS) and the Joint Commission (JCAHO) are requiring health care facilities to do more to improve the healthcare industry, albeit without additional funding. Notwithstanding this challenge, facilities can establish cost conscious policies and procedures to compliment a culture that fosters the number one goal of patient safety and the quality of healthcare. Safe informed consent forms and the systems that support them can be the answer to what many experts have designated "a monumental task" of standardizing a legal document that meets regulatory guidelines and ensures compliance while meeting the patient's rights.¹ No longer shall we tolerate practice in a healthcare industry where "informed consent" is the equivalent of having a patient sign a piece of paper as they are being whisked to the operating room.

Effective communication is the cornerstone of patient safety.² It is also the essence of a bilateral contract; without effective communication there can be "no meeting of the minds" and an opportunity to improve patient safety may be lost. How does the healthcare provider demonstrate its acknowledgement of these widely accepted truths? In this chapter, we will strive to offer some practical guidance to enhance communication, improve patient safety and reduce costs through a well designed safe informed consent (SIC) system.

It is axiomatic that breakdowns in communication between patients and healthcare providers can significantly impair the ability of physicians to diagnose and treat medical problems.³ In fact, communication breakdowns are the primary root cause of nearly 3,000 sentinel events – unexpected deaths and catastrophic injuries reported to

The Joint Commission.⁴ Studies have shown significant positive relationships between various aspects of communication and patients' health outcomes — including recovery of functional and psychological status, symptom recovery and recovery from emotional problems.⁵ Other studies have shown that poor physician-patient communication can lead to increased patient stress levels, decreased patient compliancy, decreased physician satisfaction and increased medical malpractice lawsuits. Not surprisingly, it has been reported that the majority of malpractice suits arise from communication errors not competency errors; and patients' most common complaint is the lack of information provided by the physicians.⁶

In 2004, The Institute of Medicine, through its publication, *Improving Medical Education: Enhancing the Behavioral and Social Science Content of Medical School Curricula*, opined that in order to make measurable improvements in the health of Americans, "physicians must be equipped with the knowledge and skills from the behavioral and social sciences needed to recognize, understand, and effectively respond to patients as individuals, not just to their symptoms."⁷ In the recent past, many of Pennsylvania's medical schools have begun to incorporate innovative programs into their curriculum to foster empathetic encounters between healthcare providers and patients in a variety of situations, such as routine history-taking, handling sensitive information, managing substance abuse, breaking bad news and motivating uncooperative patients.⁸

The behavioral and social science tools can indeed be helpful, but the force working against this heightened level of communication is the "15-minute office visit." It is well known that both time and money work against patient education, as this is seldom a reimbursable physician service.⁹ It is readily apparent that The Center for

Medicare and Medicaid Services (CMS) recognized this quandary in April 2007, when it implemented additional conditions of participation (CoP's) regarding informed consent. These regulations, which will be discussed later in greater detail, guide the healthcare provider and facility as to what is expected of them in connection with the informed consent process, but CMS did not offer remuneration for the time spent for patient education. In this chapter, we will offer suggestions for health care providers to consider in addressing this troubling paradox.

Lest we forget, communication is a two way street and thus far we have been limiting the focus to the healthcare provider. Unfortunately, oftentimes the patient's responsibility for the delivery of his/her healthcare is overlooked. In fact, studies show that many patients do not read the [informed consent] forms they sign before undergoing surgery or medical treatment. More than half of those who do read the forms do not understand them, and only a quarter of [informed consent] forms include all the data the patients need to make an informed decision.¹⁰

In this chapter, we will emphasize that the patient, the patient's family and/or the patient's legal representative (PLR) should be considered a partner in the systematic delivery of health care. Today, the model of patient-provider interaction strongly encourages active involvement of patients in their care management. We see this in a variety of processes such as consumer-directed models that encourage patients to shop around for health insurance, physicians and treatment; health grades, federal and private health insurers pay for performance measurements; and, reporting and quality incentives. The patient-provider model can be further distilled to safe informed consent, especially where the answers to most health care questions are available at the patient's fingertips.

The Evolution of Informed Consent

By way of brief but necessary history, the elements of informed consent can be traced to the 4th century B.C. with the Hippocratic Oath, which provides:

I swear by Apollo, Asclepius, Hygieia, and Panacea, and I take to witness all the gods, all the goddesses, to keep according to my ability and my judgment, the following Oath.

To consider dear to me, as my parents, him who taught me this art; to live in common with him and, if necessary, to share my goods with him; To look upon his children as my own brothers, to teach them this art.

I will prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone.

I will not give a lethal drug to anyone if I am asked, nor will I advise such a plan; and similarly I will not give a woman a pessary to cause an abortion.

But I will preserve the purity of my life and my arts.

I will not cut for stone, even for patients in whom the disease is manifest; I will leave this operation to be performed by practitioners, specialists in this art.

In every house where I come I will enter only for the good of my patients, keeping myself far from all intentional ill-doing and all seduction and especially from the pleasures of love with women or with men, be they free or slaves.

All that may come to my knowledge in the exercise of my profession or in daily commerce with men, which ought not to be spread abroad, I will keep secret and will never reveal.

If I keep this oath faithfully, may I enjoy my life and practice my art, respected by all men and in all times; but if I swerve from it or violate it, may the reverse be my lot.

The "stones" referred to are kidney stones or bladder stones, removal of which was judged too menial for physicians, and therefore was left for barbers (the forerunners of modern surgeons). This oath has been repeated by physicians for thousands of years

and it articulates clearly that the physician knows what is best for his or her patients. For over two thousand years, human culture has put the physician in an almost godlike position in terms of his or her wisdom to practice in the patient's best interest. Many plaintiff lawyers have utilized this culture to espouse the notion that the physician has abused their gifts by failing to secure informed consent to surgery.

Since the early to mid-twentieth century there has been a trend toward patients' rights that has included the right to know what the physician intends to do and why; this is the essence of informed consent. While some state courts addressed concepts of informed consent early in the 20th century, the first formal codification of informed consent occurred in 1947 — The Nuremberg Code. The Code was developed in response to the Nuremberg Trials of Nazi doctors who performed unethical experimentation during World War II, the Code was the first major international document to provide guidelines on research ethics. It made voluntary consent a requirement in clinical research studies, emphasizing that consent can be voluntary only if:

- Participants are able to consent;
- They are free from coercion (i.e., outside pressure); and
- They comprehend the risks and benefits involved.

The Code also states that researchers should minimize risk and harm, make sure that risks do not significantly outweigh potential benefits, use appropriate study designs, and guarantee participants' freedom to withdraw at any time. The Nuremberg Code was adopted by the United Nations General Assembly in 1948.¹¹

Civil litigation emerged over informed consent to include injury to one's person or property that is intentionally or negligently inflicted by a physician's failure to disclose

the injury, measured in terms of monetary damages. With the medical advances that emerged in the beginning of the twentieth century, such as improved anesthesia and surgical interventions, physicians began to disclose basic information without necessarily outlining all potential risks. The first important introduction of the notion of informed consent is in the case of Mohr v. Williams, 104 N.W. 12 (Minn. 1905). In this case, a physician obtained Mohr's consent to an operation on her right ear. While operating, the surgeon determined that the left ear needed surgery instead, and proceeded to operate on it. A court found that the physician should have obtained the patient's consent to the surgery on the left ear. The court decided that a physician needs to advise a patient of all the information related to a particular procedure and must review all the risks and benefits. Only after this exchange does the patient enter into a contract, a contract that authorizes the physician to operate *only* to the extent of the consent given.¹²

In the late 1950s a series of legal cases in California and the District of Columbia forever changed society's vision of the doctor-patient relationship. In California, radiation therapy went awry for a young woman, leaving her in much worse condition than prior to the treatment. After the therapy she was acutely fatigued and suffering from radiation burns. These side effects far exceeded the side effects described by the physician. She sued the physician, saying he never adequately explained the risks of her radiation procedure. The court found that unless such consent was based on full information, and that the patient fully understood all of the risks of the procedure, the doctor was not protected for liability. In several jurisdictions, beginning in 1972 in the District of Columbia, Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972) informed consent

emerged as a legal right with full legal redress equivalent to battery if informed consent was not provided.¹³

Today, informed consent can generally be defined as an autonomous authorization by an individual regarding a medical intervention or involvement in biomedical research. Typically, an individual must do more than express agreement or comply with a proposal for this to be considered informed consent. Informed consent is a process between physician and patient that must contain an information component and a consent component. The information component refers to the disclosure of information and comprehension of what is disclosed. The consent component refers to a voluntary decision and agreement to undergo a recommended procedure. Legal, regulatory, philosophical, medical, and psychological literature tends to favor the following elements as the necessary components of informed consent: (1) competence; (2) disclosure; (3) understanding; (4) voluntariness; and (5) consent.¹⁴

Pennsylvania's Informed Consent Laws

In Pennsylvania, a claim of a lack of informed consent sounds in the intentional tort of battery because an operation performed without the patient's consent is deemed to be the equivalent to a technical assault. Smith v. Yohe, 194 A.2d 167, 174 (Pa. 1963). To obtain a patient's informed consent, doctors must provide patients with "material information necessary to determine whether to proceed with the surgical or operative procedure or to remain in the present condition." Duttry v. Patterson, 771 A.2d 1255, 1258 (Pa. 2001) (quoting Sinclair by Sinclair v. Block, 633 A.2d 1137, 1140 (Pa. 1993)). This information must give the patient "a true understanding of the nature of the

operation to be performed¹⁵, the seriousness of it, the organs of the body involved, the disease or incapacity sought to be cured, and the possible results." Id. (quoting Gray v. Grunnagle, 223 A.2d 663, 674 (Pa. 1966)). While doctors are not required to disclose "all known information," **they are required to "advise the patient of those material facts, risks, complications and alternatives to surgery that a reasonable person in the patient's situation would consider significant in deciding whether to have the operation."** Gouse v. Cassel, 615 A.2d 331, 334 (Pa. 1992) (Emphasis supplied).¹⁶ The doctrine of informed consent was expanded by The Medical Cost and Reduction of Error (MCARE) Act. The MCARE Act's informed consent provision legislatively overruled the Duttry decision and now a physician can be liable on an informed consent theory for knowingly misrepresenting his or her professional credentials, training or experience¹⁷.

In Pennsylvania, civil liability for securing informed consent essentially rests with the physician. Valles v. Albert Einstein Medical Center, 569 Pa. 542 (2002) The claim against AEMC was premised, inter alia, upon a theory of vicarious liability for the battery committed by Co-defendant, Dr. Allen, due to his failure to obtain informed consent prior to performing a aortogram. The lower court determined that nothing in the record indicated that AEMC exercised control over the manner in which Dr. Allen was to perform radiology work. The lower court relied on Kelly v. Methodist Hospital, 664 A.2d 148 (Pa. Super. 1995), wherein the Superior Court determined that a hospital could not be held liable under a theory of corporate negligence based on its failure to promulgate policies and procedures relating to informed consent. The court in Kelly reasoned that the surgeon was in the best position to advise each patient of such risks, and **it would be**

unworkable to have the hospital draft the forms imparting the substantive information relative to each procedure. Id. at 151. (Emphasis supplied.)¹⁸

The Supreme Court of Pennsylvania in Valles held that a battery which results from a lack of informed consent is not the type of action that occurs within the scope of employment. In the Supreme Court's view, a medical facility cannot maintain control over this aspect of the physician-patient relationship, and therefore, the Supreme Court declined to interject an element of a hospital's control into this highly individualized and dynamic relationship; "to do so would be both improvident and unworkable." Citing to the Restatement (Second) of Agency, §212 ("A person is subject to liability for the consequences of another's conduct which results from his directions as he would be for his own personal conduct if, with knowledge of the conditions, he intends the conduct...."), the Supreme Court held that as a matter of law, a medical facility lacks the control over the manner in which the physician performs his duty to obtain informed consent so as to render the facility vicariously liable.

Healthcare System Overhaul

Coincidentally, at or about the time the Valles case was on appeal, in 1999, the Institute of Medicine released its groundbreaking report, "To Err is Human."¹⁹ This report supplied statistical data on preventable medical errors and the cost on our nation's healthcare system. In 2003, Stanton Smullens, Chief Medical Officer of Jefferson Health System in Philadelphia and vice-chair of the Board of the Patient Safety Authority (PSA) testified before the Senate Banking and Insurance Committee and referred to the report as a "wake up call for America."²⁰ Similarly, on March 16, 2005, the Pennsylvania Bar

Association issued a Research Document of the Legislative Department of the Pennsylvania Bar Association (PBA) titled, "Patient Safety in Pennsylvania: An Indication of Quality and Cost." This document focused on the debate on the etiology of the medical malpractice crisis. The PBA acknowledged that much of the debate centered on non-economic damage tort awards as the key-underlying factor.²¹ The PBA referred to the data compiled by the Pennsylvania Supreme Court, which strongly indicated that these awards were not a significant factor in the cost and availability of health care in Pennsylvania. Giving credence to the reports of the Institute of Medicine, the PBA claimed, "It was clear that inadequate patient safety is the real cost driver of medical malpractice and its impact on health care expenditure and physician income...When the number of medical errors is decreased, the cost of the medical errors will be reduced; when the cost of medical errors is reduced, a significant cost driver in both the medical malpractice insurance and healthcare delivery will be eliminated – productivity and profitability will increase."²²

Clearly, the report "To Err is Human" spawned The Patient Safety and Quality Improvement Act of 2005 and other patient safety laws across the country, including, but not limited to Pennsylvania's MCARE's patient safety provisions. In furtherance of the goal to improve patient safety in April 2007 CMS mandated that hospitals develop and implement systems to ensure proper informed consent.²³ CMS expects each hospital to have in place a well-designed informed consent process, which should include, but not be necessarily limited to, a description of the procedure, the patient's diagnosis, the procedure's risk, the potential benefits, treatment alternatives, the patient's prognosis if

he or she declines treatment, whether other practitioners will be involved, and a discussion of the role(s) of residents (if present).

Indeed, healthcare experts have determined that informed consent systems are necessary in the era of the "15 minute" office visit, particularly in view of the advent of pay-for-performance healthcare. Moreover, plaintiff medical malpractice lawyers are taking advantage of the culture created by the "15 minute office visit." Today, it is not uncommon for plaintiff attorneys to argue, and for reasonable people to consider, that patients are not being adequately informed about their health and reasonably available treatment options. Taxpayers, government officials, health care executives, insurance executives, doctors and patients all have a stake in the future of healthcare. We can improve patient safety and establish a cost effective SIC system to strengthen communication checks and balances to ensure:

1. Patient competency;
2. Voluntariness;
3. Active participation;
4. Full disclosure;
5. Education;
6. Understanding;
7. Consent;
8. Provider competency; and,
9. The provision of quality healthcare.

Federal Regulations

CMS CoP's for hospitals related to informed consent can be found at: (A) the Patients' Rights CoP at 42 CFR 482.13(b)(1)(2); (B.) the Medical Records CoP at 482.24(c)(2)(v); and, (C.) the Surgical Services CoP at 482.51(b)(2). (Appendix "A.")

A. Title 42 CFR 482.13(b)(1)(2) (Tag A-0049) sets forth the following:

(b) Standard: Exercise of rights.

(1) The patient has the right to participate in the development and implementation of his or her plan of care.

(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in the care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

The interpretive guidelines to §482.13(b)(1)(2) provide:

The right to make informed decisions means that the patient or patient's representative is given the information needed in order to make "informed" decisions regarding his/her care. A patient may wish to delegate his/her right to make informed decisions to another person. To the degree permitted by State law, and to the maximum extent practicable, the hospital must respect the patient's wishes and follow that process. In some cases, the patient may be unconscious or otherwise incapacitated. If the patient is unable to make a decision, the hospital must consult the patient's advance directives, medical power of attorney or patient representative, if any of these are available. In the advance directive or the medical power of attorney, the patient may provide guidance as to his/her wishes in certain situations, or may delegate decision-making to another individual as permitted by State law. If such an individual has been selected by the patient, or if a person willing and able under applicable State law is available to make treatment decisions, relevant information should be provided to the representative so that informed health care decisions can be made for the patient. However, as soon as the patient is able to be informed of his/her rights, the hospital should provide that information to the patient.

The right to make informed decisions regarding care presumes that the patient has been provided information about his/her health status, diagnosis

and prognosis. Furthermore, it includes the patient's participation in the development of the plan of care, including providing consent to, or refusal of, medical or surgical interventions, and in planning for care after discharge from the hospital. The patient or the patient's representative should receive adequate information, provided in a manner that the patient or the patient's representative can understand, to assure that the patient can effectively exercise the right to make informed decisions.

Hospitals must establish processes to assure that each patient or the patient's representative is given information on the patient's health status, diagnosis and prognosis. Giving informed consent to a treatment or a surgical procedure is one type of informed decision that a patient or patient's representative may need to make regarding the patient's plan of care.

Hospitals must utilize an informed consent process that assures patients or their representatives are given the information and disclosures needed to make an informed decision about whether to consent to a procedure, intervention, or type of care that requires consent. See the guidelines for 482.51(b) (2) pertaining to surgical services informed consent and the guidelines for 482.24(c)(2)(v) pertaining to medical records for further detail.

Informed decisions related to care planning also extend to discharge planning for the patient's post-acute care. See the guidelines for 482.43(c) pertaining to discharge planning for discussion of pertinent requirements.

Hospitals must also establish policies and procedures that assure a patient's right to request or refuse treatment. Such policies should indicate how the patient's request will be addressed. However, hospitals are under no obligation to fulfill a patient's request for a treatment or service that the responsible practitioner has deemed medically unnecessary or even inappropriate.

CMS investigators have been provided with a list of procedures in order to determine whether a participating facility is compliant with §482.13(b)(2). For instance, the surveyors may ask:

(1) Is there a hospital policy addressing:

- The patient's right to make informed decisions; the ability of the patient to delegate this right; and, how the hospital assures patients' ability to exercise this right;
- The patient's right to have information on his/her medical status, diagnosis, prognosis; how the patient will be involved in care planning and treatment; and how the hospital assures patients have this information and exercise this right;

- The patient's right to refuse treatment and how patient refusal of treatment will be handled;
- The patient's right to request treatment; how patient requests for treatment will be handled; and, in particular, the circumstances under which a patient request for treatment can be denied; and,
- State laws or regulations governing patients' rights and whether the hospital's policies comply with them?

(2) Is there evidence that the hospital routinely complies with its policies?

(Such evidence could be obtained through review of medical records, interviewing current patients and/or interviewing hospital personnel to determine their understanding of the hospital's informed decision-making policies and how they are implemented. Review of evidence would be designed to determine whether patients/patient representatives are provided adequate information about the patient's medical status, diagnosis, and prognosis and then allowed to make informed decisions about their care planning and treatment.)

B. Title 42 CFR 482.51(b)(2) (Tag A-0392) sets forth the following:

(b) Standard: Delivery of service. Surgical services must be consistent with needs and resources. Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.

(1) There must be a complete history and physical work-up in the chart of every patient prior to surgery, except in emergencies. If this has been dictated, but not yet recorded in the patient's chart, there must be a statement to that effect and an admission note in the chart by the practitioner who admitted the patient.

(2) A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.

The interpretive guidelines to §482.51(b)(2) provide:

The primary purpose of the informed consent process for surgical services is to ensure that the patient, or the patient's representative, is provided information necessary to enable him/her to evaluate a proposed surgery before agreeing to the surgery. **Typically, this information would include potential short- and longer-term risks and benefits to the patient of the proposed intervention, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's professional judgment.** Informed consent must be obtained, and the informed consent form must be placed in the patient's medical record, prior to surgery, except in the case of emergency surgery.

“Surgery” includes any procedure that is listed as a surgical procedure in any of the various billing coding systems used by CMS or the hospital, regardless of whether Medicare pays for that surgical procedure.²⁴

Hospitals must assure that the practitioner(s) responsible for the surgery obtain informed consent from patients in a manner consistent with the hospital’s policies governing the informed consent process.

It should be noted that there is no specific requirement for informed consent within the regulation at §482.52 governing anesthesia services. However, given that surgical procedures generally entail use of anesthesia, hospitals may wish to consider specifically extending their informed consent policies to include obtaining informed consent for the anesthesia component of the surgical procedure.

For facilities to be compliant with 42 CFR 482.51(b)(2), CMS surveyors will determine whether the hospital’s surgical informed consent policy describes the following:

- Who may obtain the patient’s informed consent;
- Which procedures require informed consent;
- The circumstances under which surgery is considered an emergency, and may be undertaken without an informed consent;²⁵
- The circumstances when a patient’s representative, rather than the patient, may give informed consent for a surgery;
- The content of the informed consent form and instructions for completing it;
- The process used to obtain informed consent, including how informed consent is to be documented in the medical record;
- Mechanisms that ensure that the informed consent form is properly executed and is in the patient’s medical record prior to the surgery (except in the case of emergency surgery); and,
- If the informed consent process and informed consent form are obtained outside the hospital, how the properly executed informed consent form is incorporated into the patient’s medical record prior to the surgery.

For facilities to be compliant with 42 CFR 482.51(b)(2), CMS surveyors will determine whether the hospital’s surgical informed consent policy verifies the following:

- The hospital has assured that the medical staff has specified which procedures are considered surgery and, thus, are those that require a properly executed informed consent form; and,

- The hospital's informed consent policies address the circumstances when a surgery would be considered an emergency and thus not require an informed consent form be placed in the medical record prior to surgery.

Surveyors will investigate whether there are additional requirements under State law for informed consent and whether the hospital is in compliance with those requirements. The surveyors are directed to review a minimum of six medical records of surgical patients to verify that they did not involve emergency surgery and that they contain informed consent forms that were executed prior to the surgery. Surveyors are also instructed that when possible, they are to review medical records of patients who are about to undergo surgery, or who are located in a surgical recovery area; and, interview two or three post-surgical patients, as appropriate based on their ability to provide a cogent response, or the patients' representatives to see how satisfied they are with the informed consent discussion prior to their surgery.

According to CMS, a well-designed informed consent process would include discussion of the following elements:

- A description of the proposed surgery, including the anesthesia to be used;
- The indications for the proposed surgery;
- Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity;
- Treatment alternatives, including the attendant material risks and benefits;
- The probable consequences of declining recommended or alternative therapies;
- Who will conduct the surgical intervention and administer the anesthesia;
- Whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies. Important surgical tasks include: opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, administering anesthesia, implanting devices and placing invasive lines;
- For surgeries in which residents will perform important parts of the surgery, discussion is encouraged to include the following:

- That it is anticipated that physicians who are in approved post graduate residency training programs will perform portions of the surgery, based on their availability and level of competence;
- That it will be decided at the time of the surgery which residents will participate and their manner or participation, and that this will depend on the availability of residents with the necessary competence; the knowledge the operating practitioner/teaching surgeon has of the resident's skill set; and the patient's condition; and,
- Those residents performing surgical tasks will be under the supervision of the operating practitioner/teaching surgeon.
- Whether, based on the resident's level of competence, the operating practitioner/teaching surgeon will not be physically present in the same operating room for some or all of the surgical tasks performed by residents;
- Note: a "moonlighting" resident or fellow is a postgraduate medical trainee who is practicing independently, outside the scope of his/her residency training program and would be treated as a physician within the scope of the privileges granted by the hospital; and,
- Whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the hospital.

(C) Title 42 CFR 482.24(c)(2) (Tag A-0238) sets forth the following:

- (2) All records must document the following, as appropriate:
- (i) Evidence of a physical examination, including a health history, performed no more than 7 days prior to admission or within 48 hours after admission;
 - (ii) Admitting diagnosis;
 - (iii) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient;
 - (iv) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia; and,
 - (v) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.

The interpretive guidelines to §482.24(c)(2)(v) provide:

The medical record must contain a document recording the patient's informed consent for those procedures and treatments that have been specified as requiring informed consent. Medical staff by-laws should address which procedures and treatments require written informed consent. There may also be applicable Federal or State law requiring informed consent. The informed consent form

contained in the medical record should provide evidence that it was properly executed.

Informed Consent Forms

A properly executed informed consent form should reflect the patient consent process. Except as specified for emergency situations in the hospital's informed consent policies, all inpatient and outpatient medical records must contain a properly executed informed consent form prior to conducting any procedure or other type of treatment that requires informed consent. An informed consent form, in order to be properly executed, must be consistent with hospital policies as well as applicable State and Federal law or regulation.

A properly executed informed consent form contains the following minimum elements:

- Name of the hospital where the procedure or other type of medical treatment is to take place;
- Name of the specific procedure, or other type of medical treatment for which consent is being given;
- Name of the responsible practitioner who is performing the procedure or administering the medical treatment;
- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative; (Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by the practitioner's professional judgment, the determination of which material risks, benefits and alternatives will be discussed with the patient.)
- Signature of the patient or the patient's legal representative;
- Date and time the informed consent form is signed by the patient or the patient's legal representative; and,
- If there is applicable State law governing the content of the informed consent form, then the hospital's form must comply with those requirements.²⁶

According to CMS, a well-designed informed consent form might also include the following additional information:

- Name of the practitioner who conducted the informed consent discussion with the patient or the patient's representative;
- Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form;

- Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative;
- Explain to the patient what to expect during the recovery period and hospitalization;
- Explain any other residual effects from the procedure;
- Encourage and welcome the patient to ask questions;
- Document these discussions²⁷;
- Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner; and,
- Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.

For facilities to be compliant with 42 CFR 482.51(b)(2), CMS surveyors will determine whether the hospital's surgical informed consent policy:

- Verifies that the hospital has assured that the medical staff has specified which procedures and treatments require written patient consent; and,
- Verifies that the hospital's standard informed consent form contains the elements listed above as the minimum elements of a properly executed informed consent.

Surveyors will compare the hospital's standard informed consent form to the hospital's policies on informed consent, to verify that the form is consistent with the policies. They will also determine if there is applicable State law, verify that the form is consistent with the requirements of that law. Surveyors are expected to review a minimum of six random medical records of patients who have, are undergoing, or are about to under a procedure or treatment that requires informed consent. They are expected to verify that each medical record contains informed consent forms; and, that each completed informed consent form contains the information for each of the elements

listed above as the minimum elements of a properly executed informed consent, as well as any additional elements required by State law and/or the hospital's policy.

Impression

In the past, informed consent forms were merely a compliance tool and they did not do much to increase the knowledge of those who were committing to allow the performance of treatments and procedures that may be associated with significant risks. The forms and the absence of correlating systems limited opportunities for health care providers to prove that they have invested significant time and effort to impress upon patients and their families the importance of educating themselves with respect to the patient's health, procedures and alternative care plans. Moreover, in the event of an untoward event, the forms of the past and the absence of systems left the health care provider and the facility vulnerable to lawsuits.

Today, we may be able to improve patient safety and limit the patient's ability to credibly plead ignorance with a well established SIC system complimented by the World-Wide-Web and alternative communication modalities. With these advances, it naturally follows that the patient should also shoulder some of the responsibility of securing all of the information he/she deems necessary to be adequately informed and should be deprived of the opportunity to credibly state that he/she was not informed or provided with the opportunity to know and participate in the delivery of their healthcare. The healthcare provider should continue to be the primary facilitator of this knowledge and the system should add a secondary tier of checks and balances to prove that the provider/facility took reasonable steps to ensure that the patient was: competent, educated, informed, encouraged to participate, understanding of his/her health condition,

accepting of the alternative plans of care, including each alternatives risks, benefits and percentage chances of optimal outcomes and voluntarily availing themselves to surgery.

Per CMS a well-designed SIC system should compliment the SIC contract, which can otherwise be defined as a bilateral agreement that demonstrates that the patient (Patient's Legal Representative "PLR") has been advised and understands those material facts, risks, complications and alternatives to surgery that the patient/PLR or any reasonable person in the patient's situation would consider significant in deciding whether to have the operation.

In addition to the minimum criteria identified above, the contract should demonstrate to third parties the efforts the provider/facility is making to impress upon the patient and/or the patient's family or PLR why the contract is necessary and why the patient's participation is an indispensable part of patient safety and the delivery of quality healthcare. For example, the contract's introductory paragraph could offer the following:

This is a healthcare delivery contract between the patient/Patient's Legal Representative ("PLR") and the physician. The primary purpose of this contract is to enhance and ensure appropriate communication between the provider and the patient to optimize patient safety and the provision of quality healthcare. Serious bodily injury and/or death can result if information is not properly disclosed and understood by the parties to this contract. Accordingly, it is important that the patient, the patient's family or PLR:

- (1) Fully participates in the gathering and disclosure of information concerning the patient's health condition and that they understand that their failure to do so can increase the opportunity for a less than optimal outcome;
- (2) Understands the patient's diagnosis, prognosis and recommended course of treatment;
- (3) Understands the nature of the procedure(s), what it is designed to accomplish; the anatomy involved, its risks and benefits, the reasonably available treatment alternatives, the risks and benefits of pursuing reasonably available treatment options and the reasonably anticipated outcomes of all reasonably available treatment options;
- (4) Is satisfied with the education, training and experience of the physician(s) and his/her assistants, fellows, residents, students or designees involved in the

performance of the procedure and what duties and/or responsibilities, if any, each will have in the performance of the procedure;

(5) Understands that medicine is not an exact science and although not desirable, there are known risks to the procedure, otherwise known as reasonably anticipated complications and that these complications can occur in the absence of error or mistake;

(6) Understands that any complication, foreseen or unforeseen, encountered during and/or arising from the procedure can lead to additional surgical procedures not contemplated prior to the procedure, serious bodily injury and/or death; and,

(7) Understands that the patient/PLR shall NOT sign this contract unless the patient/PLR feels reasonably certain that they know and understand the information set forth above.

Patient Participation

Just recently, JCAHO released its 2009 patient safety goals and goal 13 states, "Encourage patient's active involvement in their own care as a patient safety strategy."²⁸ In order to prove that the system encourages patients/PLRs to be active participants in the delivery of healthcare one can consider constructing the contract in a fashion that provides for patient participation. Of course, some patients/PLRs may choose not to be active participants in the delivery of healthcare, and these differences need to be honored. Unfortunately, it is not uncommon that the individuals who elect not to fully participate in the delivery of their healthcare are the first to cry foul in the event of an untoward outcome. With a well designed SIC contract, the non-compliant and/or non-participating patient may be limited in their capacity to credibly plead ignorance after the fact if a known complication arises. This is true since the contract exploits the patient's indifference, thereby limiting, and perhaps in some circumstances, extinguishing an opportunity for a patient to credibly claim that they were not properly informed. In other words, irrespective of the patient's efforts, a well designed SIC system can aid in

demonstrating to the public that the healthcare provider has complied with the federal and state laws and did everything reasonably expected of them and within their control to improve patient safety and provide quality healthcare.

Particular to Patient

Secondly, a well designed informed consent system should demonstrate that the informed consent discussion is particular to the patient. As stated above, physicians are required to "advise the patient of those material facts, risks, complications and alternatives to surgery that a reasonable person in the patient's situation would consider significant in deciding whether to have the operation." Occasionally, plaintiffs who have experienced an untoward event following surgery have complained that the physician did not explain to them what impact, if any, one or more of their co-morbid conditions may impact the outcome of surgery. For instance, a plaintiff complained that while he knew that a perforation and subsequent infection were known complications of the surgical procedure, he argued that had he known that his diabetes placed him at greater risk for the development of infection and greater risk for succumbing to infection, he would not have had the procedure.

Mechanism to prove patient particularity and fostering of patient participation

The U.S. Department of Health and Human Services, Office for Civil Rights (OCR) set for principles regarding electronic health information of change. The first four are identified as follows:

- (1) Individual Access Principle: Individuals should be provided with a simple and timely means to access and obtain their individually identifiable health information in a readable form and format;
- (2) Correction Principle: Individuals should have a way to timely question the accuracy or integrity of their individually identifiable health information, and to have erroneous information corrected or to have a dispute documented if their requests are denied;
- (3) Openness and Transparency Principle: There should be openness and transparency about policies, procedures, and technologies that directly affect individuals and/or their individually identifiable health information; and,
- (4) Individual Choice Principle: Individuals should be provided a reasonable opportunity and capability to make informed decisions about the collection, use and disclosure of their individually identifiable health information.²⁹

Considering these principles, the SIC system should underscore the importance patient compliance and participation, including but not limited to the disclosure of a complete and accurate history and what impact anything less might have on the future of their health and wellbeing. If possible, the healthcare facility and/or physician might consider creating a policy and procedure whereby, in non-emergent matters, the patient has the opportunity to review, discuss, question, revise and/or supplement the H&P in advance of surgery; this document can then be updated throughout the patient's care. This process would also afford the patient an opportunity to conduct research on his/ her

particular condition, the contemplated procedure, its risks and the reasonably available treatment alternatives. This process could facilitate discussion between the physician and the patient concerning the patient's particular circumstances and the contemplated procedure and may lead to better patient outcomes. Ultimately, this process provides for another check and balance without much added cost and it may limit a patient's ability to credibly claim that the physician failed to individualize the informed consent. By requiring review and discussion of the H & P, the system provides an objective standard to show that the facility and the physician are committed to the patient's safety and the delivery of quality health care. For instance, the SIC contract might state:

Please respond truthfully and in detail to the following:

The patient/PLR understands the importance of patient compliance and participation, including, but not limited to, full disclosure of a complete and accurate patient history.

Yes No

If no, please explain: _____

The patient/PLR has read and agrees that the information contained within the History & Physical, attached hereto, is accurate and complete to the best of their knowledge.

Yes No

If no, please explain: _____

The patient/PLR agrees that the patient has been afforded the opportunity to review the H & P and the informed consent contract at least twice prior to the performance of the procedure and finds both complete and accurate in all material respects.

Yes No

If no, please explain: _____

Encouraging self-education

The contract should stress the importance of self education, particularly when the information is readily available. This by no means should be construed as "dumping" the responsibility of securing the necessary information to be "informed" onto the patient, but merely a supplemental check and balance. Patients should understand and accept the notion that as they become more knowledgeable about their health they increase the opportunity for better patient outcomes. To that end, the system should provide direct access to medical staff, written materials and/or medical web-sites for additional information. Non traditional methods of contact, such as e-mail, may be considered. Recent studies have shown that providing a surgeon's e-mail address nearly triples the likelihood that a patient will contact the doctor about the surgery.³⁰ The contract may contain the following provisions:

The patient/PLR has been provided with access to medical staff, literature and medical websites to facilitate patient education about their health condition and the reasonably available treatment options.

Yes No

If no, please explain: _____

The patient/PLR has been encouraged repeatedly to ask questions and/or seek second opinions relative to their health condition and the reasonably available treatment options.

Yes No

If no, please explain: _____

Another issue that arises in the course of litigation is the scope of the operative permit. Occasionally, the physician does not fully appreciate the circumstances of the patient's medical condition and the medically reasonable and necessary treatment until he/she has had an opportunity to explore the patient intra-operatively. Plaintiffs sometimes complain that while they consented to a part of the surgery, they did not consent to the performance of all of it. Therefore, the following statement can be considered:

The patient/legal representative understands that during the course of the procedure, unforeseen conditions may be revealed, which may necessitate an extension of the original procedure or different procedure than those discussed.

Yes No

If no, please explain: _____

OR

The patient/legal representative understands that circumstances not known to the physician may present themselves during the performance of the procedure, and therefore, the performance of other procedures not originally contemplated amongst the parties to this agreement, may be necessary for the patient's safety.

Yes No

If no, please explain: _____

Most importantly, it is incumbent upon the physician to advise the patient/PLR of those material facts, risks, complications and alternatives to surgery that the patient/PLR or any reasonable person in the patient's situation would consider significant in deciding

to have the operation. As stated above, the informed consent discussion must be specifically tailored to the patient. The following series of statements will help to show that the physician has fulfilled this legal requirement:

The patient/PLR understands and accepts the significance of the following: the patient's complaints, the patient's past medical history, the clinical examination findings, the diagnostic studies, the differential diagnosis, the prognosis, the reasonably available treatment options and their attendant reasonably anticipated outcomes.

Yes No

If no, please explain: _____

The patient/PLR understands the indications for and nature of the procedure, including the anesthesia to be administered, the parts of the body that may be affected, the disease or incapacity sought to be cured, the means by which the physician will attempt to achieve the intended outcome and the reasonably anticipated outcomes.

Yes No

If no, please explain: _____

The patient/PLR understands that there are risks to the procedure, otherwise known as reasonably anticipated complications of the procedure that can occur in the absence of error, mistake and/or carelessness. These complications can occur under the best circumstances and they can lead to serious injury and/or death. The patient/PLR understands that the material risks could include a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity.

Yes No

If no, please explain: _____

The patient/PLR understands that the following risks and/or complications may develop during the course of or subsequent to the procedure: _____

The patient understands that the physician has taken into consideration his/her individual

condition and available clinical evidence in explaining the likelihood of the
aforementioned risks and their relative severity.

Yes No

If no, please explain: _____

The patient/PLR agrees that the physician has discussed the reasonably available
treatment alternatives to the procedure, including the attendant material risks and
benefits, the reasonably anticipated outcomes of all reasonably available treatment
options and the reasonably anticipated consequences of declining recommended and
alternative treatment.

Yes No

If no, please explain: _____

The patient/legal representative understands while it is the intention and the goal
of the physician to achieve an optimal outcome, there are no guarantees that an optimal
outcome will be achieved.

Yes No

If no, please explain: _____

As stated earlier, the MCARE Act has an informed consent provision that now
makes it possible for a physician to be liable on an informed consent theory for
knowingly misrepresenting his or her professional credentials, training or experience. In
fact there are a plethora of plaintiff medical malpractice law firms that inform patients of
this conduct. For example the following excerpt was taken from a plaintiff's malpractice
firm's website:

A physician should always be competent and proficient in performing the
recommended procedure and the hospital or medical facility where the procedure

is going to be done has a legal obligation to make sure that the physician is qualified and experienced in doing the procedure. Make sure to ask your physician questions about his or her experience in performing the procedure and obtain information regarding the physician's education, training and experience. Ask if the physician is board certified, which would demonstrate he or she has passed an examination in their particular area of medicine. Also, determine the specifics of the procedure and limit your consent to just the procedure discussed. At times, a physician will do a procedure outside the scope of their hospital privileges. What this means is that despite the fact that a hospital specifically approves a physician for certain types of surgeries or procedures, the physician does something outside of these approved procedures. Another situation that can arise is when a physician fills out the consent form for one surgical procedure but actually does another. In these circumstances, you as a patient may have the right to file a claim against the physician and hospital for lack of informed consent.

You as a patient have the right to make educated and informed decisions about your health. If you or a loved one believes you were misinformed or misled about a surgery or some type of medical treatment, you may have a claim.³¹

Accordingly, the contract may include the following statement:

The patient/legal representative understands and is satisfied with the education, training and experience of the physician(s) and his/her assistants, fellows, residents, students or designees involved in the performance of the procedure and what duties and/or responsibilities, if any, each will have in the performance of the procedure.

Yes No

If no, please explain: _____

The physician and healthcare facility want to demonstrate that the patient is competent and has voluntarily consented to the performance of the procedure, and therefore, the following statement might be considered.

The patient/PLR agrees that the patient/PLR has entered into this contract knowingly, voluntarily and of his/her own free will and that the physician has afforded me several opportunities to ask questions and/or seek a second opinion.

Yes No

If no, please explain: _____

Lastly, one might consider offering a final attestation which may include the following:

If you have answered "No" to any of these questions and have NOT had the opportunity to discuss your questions or concerns to your satisfaction, do NOT sign this document! By signing this document you are assuring the physician that you have been supplied with all of the information that you wanted and needed to know before consenting to the procedure.

I, _____ (patient/PLR), hereby acknowledge and accept as true the following: The physician has reviewed this ____ (# of pages) document and the History & Physical with me to my satisfaction. The information contained in the History & Physical is accurate and complete to my knowledge and the physician has explained to me to my satisfaction the significance of all of the information contained therein. I understand the indications for and the nature of the procedure, what it is designed to accomplish, the seriousness of it, the anatomy involved, the disease or incapacity sought to be cured, the alternatives to the procedure and the possible outcomes of all available treatment options. I am satisfied with the education, training and experience of the physician(s) and his/her assistants, fellows, residents, students or designees involved in the performance of the procedure and what duties and/or responsibilities, if any, each will have in the performance of the procedure. I understand that medicine is not an exact science. The physician has not supplied me with any guarantees in connection with the performance of or the outcome of the procedure. I understand that there are known risks of the procedure, otherwise known as reasonably anticipated complications of the procedure. I understand that complications can occur in the absence of error, mistake and/or carelessness and that they can arise under the best circumstances. I understand the likelihood and relative severity of the risk/complications as they fit with my particular health circumstances. I understand that complications, foreseen and/or unforeseen, can lead to serious bodily injury and/or death. I understand that circumstances not known to the physician prior to the procedure may present themselves during the performance of the procedure, and therefore, the performance of other procedures not originally contemplated amongst the parties to this agreement, may be necessary for the patient's safety. The physician has encouraged me to seek further information concerning the patient's medical condition, the procedure and the availability of reasonably alternative treatment options. I have been given an opportunity to seek a second opinion and have been encouraged to ask questions. By signing this document, I agree that all of my questions have been answered to my satisfaction and that the physician has supplied me with all of the required and

requested information necessary to allow me to voluntarily make an informed consent to this procedure.

I, therefore, authorize the performance of: _____

_____ (identity of procedure) and other procedures as are necessary in the exercise of professional judgment. (The authority granted shall extend to treating all conditions that require treatment and are not known to the physicians at the time the procedure is commenced.) to be performed by: _____

(Identity of physician(s), his/her assistants, fellows, residents, students or designees).

Conclusion

The development, implementation and enforcement of a well designed informed consent system may improve patient safety and the quality of healthcare by reducing: medical error, health care costs and litigation costs, which in turn should decrease the cost of health and malpractice insurance. If nothing else, it may limit the patient's ability to credibly argue that they were not properly informed.

¹ For the Record Magazine, available at www.fortherecordmag.com/archives/fr_07092007p18.shtml

² The Joint Commission's White Paper, "What Did the Doctor Say?" Improving Health Literacy to Protect Patient Safety (2007)

³ The Joint Commission, Low Health Literacy Puts Patients at Risk The Joint Commission's Solutions to National Problems

⁴ Joint Commission Sentinel Event Data, available at www.jcaho.org

⁵ http://www.phac-aspc.gc.ca/ccdpc-cpcmc/bc-cds/pdf/tt1_e.pdf

⁶ http://www.phac-aspc.gc.ca/ccdpc-cpcmc/bc-cds/pdf/tt1_e.pdf

⁷ <http://www.physiciansnews.com/cover/706.html>

⁸ <http://www.physiciansnews.com/cover/706.html>

⁹ The Wall Street Journal (February 6, 2008), available at www.online.wsj.com/article/the_uninformed_patient.html

¹⁰ Id

¹¹ <http://www.cancer.gov/clinicaltrials/conducting/informed-consent-guide/page4>

¹² <http://www.deathreference.com/Ho-Ka/Informed-Consent.html>

¹³ Id

¹⁴ Id

¹⁵ In Valles v. Albert Einstein Medical Center, 569 Pa 542 (2002), The Supreme Court of Pennsylvania held that the manner or method in which the surgeon performs the proposed procedure is not encompassed within the purview of the informed consent doctrine

¹⁶ In Southard v. Temple University Hospital, 781 A 2d 101 (Pa 2001), The Supreme Court of Pennsylvania held that the doctrine of informed consent does not require physicians to advise their patients of the federal Food and Drug Administration (FDA) regulatory status of a medical device

¹⁷ 40 Pa Stat Â§1303 504(d)(2)

¹⁸ Many of the informed consent forms used by physicians are standardized forms created by the hospital's in which they practice

¹⁹ *To Err is Human Building a Safer Health System* Linda T Kohn, Janet M Corrigan, and Molla S Donaldson, eds, Institute of Medicine, Washington DC National Academy Press, 2001

²⁰ Testimony Before the Senate Banking and Insurance Committee, Commonwealth of Pennsylvania Patient Safety Authority, March 11, 2003

²¹ Pennsylvania Bar Association, "Patient Safety in Pennsylvania An Indication of Quality and Cost

²² *Id* Citing, *To Err is Human, supra*, and *Crossing the Quality Chasm A New Health System for the 21st Century*, Committee on Quality Health Care in America, Institute of Medicine, Washington, DC National Academy Press, 2001

²³ Centers for Medicare & Medicaid Services, Memorandum "Revisions to the Hospital Interpretative Guidelines for Informed Consent" April 13, 2007

²⁴ Almost universally, a physician must obtain informed consent in the following five circumstances (1) Performance of surgery, including the related administration of anesthesia, (2) Administration of radiation or chemotherapy, (3) Administration of a blood transfusion, (4) Inserting devices and/or appliances under the skin, and, (5) Administering experimental devices or medication
<http://www.physiciansnews.com/law/404roediger.html>

²⁵ Less than one-third of the reports [to the Pennsylvania Patient Safety Authority] indicated emergency situations or other circumstances where obtaining consent might be particularly difficult After excluding these emergency or otherwise problematic cases, the most commonly reported problem involved cases where patients received several procedures during the same episode of care and consented to some procedures but not others For example, a patient who had consented to cystoscopy, possible transurethral resection of the prostate and possible biopsy also underwent placement of bilateral ureteral catheters to which he had not consented A second type of problem occurs during a procedure when a need for additional, unconsented procedures becomes apparent and consent cannot be readily obtained—such as during surgery when a patient is already anesthetized In one case reported to PA-PSRS, a patient who had consented only to a total vaginal hysterectomy also had a fallopian tube and ovary removed that were adhered to the uterus Another report concerned a patient who had consented to a ventral hernia repair but also had a loose tooth removed due to risk of aspiration while under anesthesia The surgery team obtained a dental consult before deciding to remove the tooth, but there was no consent for the tooth extraction Several reports address cases in which patients received a procedure different from that to which they consented In one case, a patient underwent insertion of a different brand of catheter for hemodialysis access than that to which he had consented In another case, a patient consented to placement of a left-side catheter but received bilateral catheters In limited circumstances, a physician may be justified in carrying out a different procedure from that which the patient authorized However, these usually are medical emergencies and unanticipated events (such as during surgery) that necessitate immediate action to avoid endangering the life or health of the patient
http://www.psa.state.pa.us/psa/lib/psa/advisories/v1n2june2004/june2004vol1_article_c_informed_consent.pdf

²⁶ The Supreme Court of Pennsylvania held that the doctrine of informed consent does not require physicians to advise their patients of the federal Food and Drug Administration (FDA) regulatory status of a medical device Southard v. Temple University Hospital, et al, 781 A 2d 101 (Pa 2001)

²⁷ One might consider creating a hand-written progress note regarding the consent. To ensure that this note is as supportive as possible, it is suggested that this note be made contemporaneously to the obtaining of the consent.

²⁸ http://www.jointcommission.org/NR/rdonlyres/D619D05C-A682-47CB-874A-8DE16D21CE24/0/HAP_NPSG_Outline.pdf

²⁹ <http://www.hhs.gov/ocr/hipaa/hit/>

³⁰ Archives of Surgery, *Arch Surg* 2008,143(2) 164-168, available at <http://archsurg.ama-assn.org/cgi/content/abstract/143/2/164>

³¹ <http://www.r-klaw.com/PracticeAreas/InformedConsent.asp>



Safe Informed Consent: A Cost Effective Systems Approach

By Tyler J. Smith Esquire

Safe Informed Consent (SIC)

- New Culture
 - Patient Safety
 - Quality Care
 - Brand Recognition
- Reduced Health Care Costs
- Reduced Litigation
- Mitigate Damages

Communication

- Communication breakdowns are the primary root cause of nearly 3,000 sentinel events – unexpected deaths and catastrophic injuries – that have been reported to The Joint Commission
- Studies show
 - Positive relationships between various aspects of communication and patients' health outcomes, and,
 - Poor physician-patient communication can lead to increased patient stress levels, decreased patient complacency, decreased physician satisfaction and increased medical malpractice lawsuits

Paradox

- Institute of Medicine
 - "Physicians must be equipped with the knowledge and skills from the behavioral and social sciences needed to recognize, understand, and effectively respond to patients as individuals, not just to their symptoms "
- "15-minute office visit"
 - Time and money work against patient education, as this is seldom a reimbursable physician service
- Patient participation is often overlooked

Informed Consent Evolution

- Hippocratic Oath
- The Nuremberg Code
- Mohr v Williams, 104 N W 12 (Minn 1905)

Informed Consent Components

- Competence
- Disclosure
- Understanding
- Voluntariness
- Consent

Pennsylvania Law

- Smith v. Yohe, 194 A 2d 167, 174 (Pa 1963)
- Gray v. Grunnagle, 223 A 2d 663, 674 (Pa 1966)
- Gouse v. Cassel, 615 A 2d 331, 334 (Pa 1992)
- Kelly v. Methodist Hospital, 664 A 2d 148 (Pa Super 1995)
- Duttry v. Patterson, 771 A 2d 1255, 1258 (Pa 2001)
- Southard v. Temple University Hospital, 781 A 2d 101 (Pa 2001)
- Valles v. Albert Einstein Medical Center, 569 Pa 542 (2002)
- MCARE — the "Medical Care Availability and Reduction of Error" Act, 40 Pa Stat. Â§1303.504(d)(2)

Valles v. Albert Einstein Medical Center

- Restatement (Second) of Agency, §212
 - "A person is subject to liability for the consequences of another's conduct which results from his directions as he would be for his own personal conduct if, with knowledge of the conditions, he intends the conduct."
- The Supreme Court of Pennsylvania held that as a matter of law, a medical facility lacks the control over the manner in which the physician performs his duty to obtain informed consent so as to render the facility vicariously liable.

Healthcare System Overhaul

- To Err is Human
- MCARE
- Pennsylvania Bar Association — "Patient Safety in Pennsylvania: An Indication of Quality and Cost"
- The Patient Safety and Quality Improvement Act of 2005
- "Never Events", a.k.a. Serious Preventable Adverse Events
- Pay-for-performance
- CMS Informed Consent CoPs

Federal Regulations

- Patients' Rights – 42 CFR 482.13(b)(2)
- Medical Records – 42 CFR 482.24(c)(2)(v)
- Surgical Services – 42 CFR 482.51(b)(2)

Patient Rights : 42 CFR 482.13(b)(1)(2)

- Right to participate in the development and implementation of plan of care
- Right to make informed decisions regarding care
- Right to request or refuse treatment

Guidelines to Patient Rights

- Right to make informed decisions means
 - Patient is "Informed" – presumes that the patient has been provided information about his/her health status, diagnosis and prognosis, and,
 - Patient participates in the development of the entire plan of care

Guidelines to Patient Rights

- Process to assure that each patient or the patient's representative is given information on the patient's health status, diagnosis and prognosis
- Process that assures patients or their representatives are given the information and disclosures needed to make an informed decision about care planning
- Process to assure a patient's right to request or refuse treatment

Surveys

- Establishment and Compliancy
 - Medical records review,
 - Current patient interviews, and,
 - Staff interviews

Surgical Services: 42 CFR 482.51(b)(2)

- History and physical work-up in the chart of every patient prior to surgery, except in emergencies
 - At least a statement to that effect and an admission note in the chart by the practitioner who admitted the patient
- A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies

System Guidelines

- "Surgery" includes any procedure that is listed as a surgical procedure in any of the various billing coding systems used by CMS or the hospital, regardless of whether Medicare pays for that surgical procedure
- Five circumstances (1) Performance of surgery, including the related administration of anesthesia, (2) Administration of radiation or chemotherapy, (3) Administration of a blood transfusion, (4) Inserting devices and/or appliances under the skin, and, (5) Administering experimental devices or medication

Policy Must Describe:

- Who may obtain
- Which procedures require
- Emergency situations
- Patient v Patient Representative
- Content

Policy Must Describe:

- Instructions for completion
- Process used
- How to document
- Safeguards to ensure in chart prior to surgery
- Outside hospital process

Policy must verify:

- Measures to assure that the medical staff has specified which procedures are considered surgery, and,
- Emergency surgery

Surveys

- State requirements
- Minimum – 6 Charts
- Surgical/Recovery room patient charts
- 2 – 3 Post surgical patient interviews

System Should Assure Communication Of:

- A description of the proposed surgery and anesthesia,
- The indications for the proposed surgery,
- Material risks and benefits for surgery and anesthesia
 - Likelihood
 - Severity
- Material risks and benefits of treatment alternatives,
- Probable consequences of declining recommended or alternative therapies,

**System Should Assure Communication
Of:**

■ **Surgeon's Professional Credentials**

- Education
- Training
- Experience
 - Generally
 - Specifically

**System Should Assure Communication
Of:**

■ **Residents/Qualified medical practioners**

- Anticipate assistance
- Direct or Indirect supervision circumstances
- Game time decision
 - Who
 - What
- Based upon
 - Availability and level of competence
 - Surgeon's comfort level
 - Patient's condition

**System Should Assure Communication
Of:**

■ **Who will perform important surgical tasks**

- Opening and closing,
- Dissecting tissue,
- Removing tissue,
- Harvesting grafts,
- Transplanting tissue,
- Administering anesthesia,
- Implanting devices, and,
- Placing invasive lines

FYI

- "Moonlighting" resident or fellow
 - Outside the scope of his/her residency training program
 - Within the scope of the privileges granted by the hospital
 - Treated as a physician within the scope of the privileges

Medical Records: 42 CFR 482.24(c)(2)

- (2) All records must document
 - History & Physical examination – no more than 7 days prior to admission or within 48 hours after admission,
 - Admitting diagnosis,
 - Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient,
 - Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia, and,
 - Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent

Form Guidelines

- Informed consent form should reflect the patient consent process
 - Emergency Exceptions
- Chart must contain a properly executed informed consent form prior to procedure
- "Properly executed" – must be consistent Federal, State laws and hospital policies

Guidelines – Minimum Elements

- Name of the hospital,
- Name of the specific procedure,
- Name of the responsible practitioner,

Guidelines – Minimum Elements

- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative,
- Signature of the patient or the patient's legal representative, and,
- Date and time the informed consent form is signed by the patient or the patient's legal representative

Guidelines – Recommended Elements

- Indication or listing of the material risks discussed,
- Anticipated recovery period and hospitalization,
- Anticipated residual effects from the procedure,

Guidelines – Recommended Elements

- Other physicians/qualified medical personnel will be performing important tasks related to the surgery/anesthesia within their scope of practice, in accordance with hospital policies and state and federal law and under the supervision of the responsible practitioner

Guidelines – Recommended Elements

- Name and signature of the practitioner who conducted the informed consent discussion with the patient or the patient's representative,
- Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form
- Encourage questions
- Discourage signing if not satisfied with explanation

Surveys

- Whether the hospital's surgical informed consent policy verifies
 - Hospital has assured that the medical staff has specified which procedures and treatments require written patient consent,
 - Hospital's standard informed consent form contains the elements listed above as the minimum elements of a properly executed informed consent, and,
 - Hospital's standard informed consent form is consistent with the hospital's policies and state law

Impression

- More than compliancy
- Patient/Family responsibility to participate
- Increased opportunity for better communication and better outcomes
- Decrease vulnerability for attack

SIC Contract

- Must impress upon third parties that provider/facility is working hard to educate the patient/family/PLR of the importance of participation

Patient Participation

- Contract should provide opportunity for patient participation
- Bilateral contract
- Contract confirms patient's understanding and acceptance or exploits patient's indifference in optimizing outcome

Particular to Patient

- Check and balance for provider to consider patient's co-morbidities and what impact, if any, they have on the procedure

- Limit opportunity for patient to state that co-morbidities were not considered

Mechanism for Particularity and Participation

- History & Physical
 - Provide patient opportunity to
 - Review
 - Correct inaccuracies
 - Supplement
 - Ask questions
 - Educate selves

Encourage Education and Questions

- Direct access to medical staff, written materials and/or medical web-sites for additional information

- Non traditional methods of contact, such as e-mail, should be considered as a supplement

Remaining issues

- Scope of operative permit
- Risks, benefits, alternatives, and reasonably anticipated outcomes of each
- Provider credentials
- Voluntariness
- Final attestation
