

Patient Informed Consent Process

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Overview

- Review the informed consent doctrine
- Twelve states protect the ability of patients to receive appropriate care prescribed by the physician with override provisions
- Evaluate various state statutes of the step therapy override exception laws
- Review proposed provisions to augment the standard model

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American Medical Association

- Code of Medical Ethics Opinion 2.1.1
- The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention.
- Basic Elements of Informed Consent
- The physician should include information about: the diagnosis (when known), the nature and purpose of recommended interventions, the burdens, risks, and expected benefits of all options, including forgoing treatment.

<https://www.ama-assn.org/delivering-care/ethics/informed-consent>

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Current Regulatory Patient Informed Consent Process

- Pennsylvania Informed Consent Statute 40 P.S. 1303.504a(i)
- Medical Care Availability and Reduction of Error (MCARE) Act
- Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient ... prior to.. performing surgery.

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Pennsylvania Supreme Court Opinion

- Shinal v Toms, 640 Pa. 295 (2017)
- Common law doctrine of informed consent
 - Informed consent is a product of the physician-patient relationship
 - The duty to obtain a patient's informed consent is a non-delegable duty owed by the physician conducting the surgery or treatment
 - The physician cannot rely upon a subordinate to disclose the information required to obtain informed consent

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Pennsylvania Supreme Court Opinion (cont.)

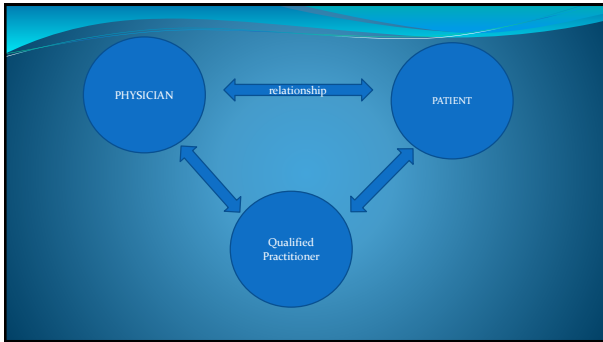
- Shinal v Toms, 640 Pa. 295 (2017)
- MCARE codification of informed consent
 - Under the plain language of the statute, the duty to obtain a patient's informed consent for the several enumerated procedures, including surgery, belongs to the physician
 - Section 504 does not merely require that the patient's consent be informed: it specifically imposes the duty upon physicians to provide to the patient the requisite information and to obtain informed consent

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Pennsylvania Supreme Court Ruling

- Shinal v Toms, 640 Pa. 295 (2017)
- The physician may not delegate to others his or her obligation to provide sufficient information in order to obtain a patient's informed consent
- Informed consent requires direct communication between physician and patient, and contemplates a back-and-forth, face-to-face exchange
- The duty to obtain the patient's informed consent belongs solely to the physician
- The court overruled prior decisions that permitted the physician to fulfill through an intermediary the duty to provide sufficient information to obtain a patient's informed consent

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Centers for Medicare & Medicaid Services (CMMS)

- Patients' Rights Condition of Participation
- 42 CFR 482.13b(4)
 - The patient ... has the right to make informed decisions regarding his or her care.
- 42 CFR 482.51b(2)
 - A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies.
- 42 CFR 482.24c(2)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.
 - Interpretive Guideline- A well-designed informed consent form might also include ... Name of the practitioner who conducted the informed consent discussion with the patient.

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Conventional Reform Proposals

- State level (PA HB 1580)
 - The physician's duty may be fulfilled by the physician or the physician's qualified practitioner
 - Qualified practitioner as defined in the Health Care Facilities, and has specific knowledge of the patient's condition and the procedure, and is acting under the supervision of, at the direction of or in collaboration with a physician.
 - "Health care practitioner" An individual who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Commonwealth licensing agency or board.
 - Nothing in the proposal requires the physician to delegate the authority
- State level (PA SB 761)
 - Similar provisions
 - Qualified practitioner means a physician assistant, certified registered nurse practitioner, midwife or nurse-midwife, and a registered nurse who is authorized under the registered nurse's scope of practice to perform the procedure as delegated by the physician or a registered nurse authorized to administer anesthesia

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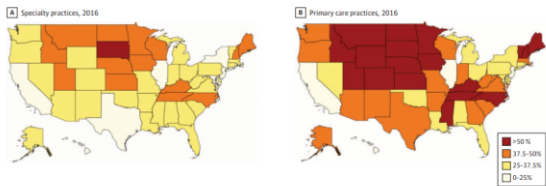
Discussion

- Balanced Approach
- Build Patient- Physician Relationship
- Preserve freedom to select
- Develop and adopt protocols
- Patient Right of Self-Determination Doctrine
- Principle of Autonomy
- Access any increased risk
- Consider Patient Understanding
- Interventions to improve communication
- Evidence-based strategies
- Create "Patient-centered Team-based care" delivery model
- Teach Back approach
- Continuously Test Criteria/ Maintain Clinical Rigor

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Trends

Figure. Percent of Physician Practices With Advanced Practice Clinicians by State



Marnoff G.R., Barnes, H., Richards, M.R., Ray, K.N., Bloom, H.M., McHugh, M.D. (2018). Employment of Advanced Practice Clinicians in Physician Practices. JAMA Internal Medicine. *enb_488-epi*.

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Future Considerations & Conclusion

- Future medical research
- Examine the merits of delegation
- Physician work environment
- Enhance physician productivity
- Decrease in performance
- Referrals and consultations
- Insurer considerations
- Impact on the quality of patient care
- Measurers of performance
- Define the appropriate standard of care
- Right to autonomous decisions
- Right to self- determination
- Maintain physician-patient relationship

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Questions



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