The Hospital + Healthsystem Association of Pennsylvania
Leading for Better Health

HAP BULLETIN

DATE: June 30, 2017

TO: Chief Executive Officers, Chief Medical Officers, Chief Nursing Officers, Compliance Officers, and Governmental Relations Officers of HAP Member Hospitals and Health Systems

FROM: Jennifer Jordan, Vice President, Regulatory Advocacy

SUBJECT: Pennsylvania Supreme Court Decision on *Shinal v. Toms*

Issue: In its June 20 ruling in *Shinal v. Toms*, the Pennsylvania Supreme Court held that a physician may *not* delegate to others his or her obligation to provide sufficient information in order to obtain a patient's informed consent. The Court asserted that informed consent requires direct communication between the physician and patient and contemplates a back-and-forth, face-to-face exchange, which might include questions that the patient feels the physician must answer personally before the patient feels informed and becomes willing to consent.

This Bulletin will recommend member action, provide background on the *Shinal v. Toms* decision and the Medical Care Availability and Reduction of Error Act (MCARE Act), and outline proposed next steps (including investigating legislative options).

Member Action: The Supreme Court's June 20 ruling overturns the trial and Superior Court decisions in *Shinal v. Toms* and sets new legal precedent related to obtaining informed consent. To the extent that previous court decisions permitted a physician to fulfill the duty to provide sufficient information to obtain a patient's informed consent through delegation to a qualified staff, this decision now invalidates that legal precedent. Effective June 20, Pennsylvania physicians can no longer rely upon the aid of their qualified staff in obtaining informed consent. This decision will likely impact the regulatory interpretation of the MCARE Act requirements—meaning that Pennsylvania Department of Health (DOH) and Professional Licensing Boards could adopt a similar interpretation in their respective enforcement approaches—and likely invalidates any previous sub-regulatory guidance on the use of "qualified staff" in obtaining informed consent (i.e., DOH's message board posting regarding the role of Physician Assistants in obtaining informed consent for blood transfusion).

HAP recognizes that this decision will have significant implications for Pennsylvania's hospital community as well as the broader health care delivery system. HAP recommends that members take immediate action to absorb this decision and align their operations with this new legal precedent. We recommend that members take the following actions:

- Carefully review the Pennsylvania Supreme Court's decision in *Shinal v. Toms*
- Review the MCARE requirements—paying specific attention to subsection 1303.504(a) Duty of physician and subsection and 1303.504(b) Description of procedure
- Review your current policies, procedures, medical staff bylaws and privileges related to obtaining informed consent
- Consult your legal counsel to evaluate compliance and ensure that your practices support the conditions and requirements outlined in the majority opinion
- Alert HAP if DOH surveyors or accreditation organizations surveying to DOH standards flag or cite "informed consent" issues during the course of a licensure survey or complaint investigation

***Shinal v. Toms*:** On June 20, the Pennsylvania Supreme Court issued a splintered (4-3) ruling in *Shinal v. Toms*, a medical malpractice suit premised upon lack of informed consent. One of the primary questions driving the plaintiff's appeal was whether or not the trial court misapplied the common law and the MCARE Act when it instructed the jury that it could consider information provided to the patient by the physician's "qualified staff" in deciding whether the physician obtained informed consent for the procedure. The defendant argued that a physician is not required to supply all of the information personally in fulfilling his or her duty to obtain informed consent and that it is the information conveyed rather than the person conveying the information that determines informed consent. However, the Supreme Court rejected the defendant's argument and found that only a physician—not a member of the physician's staff—can obtain informed consent from a patient prior to a medical procedure. The court stated that a physician "cannot rely upon a subordinate to disclose the information required to obtain informed consent."

Justice David N. Wecht writing for the majority (Justices Christine L. Donohue and Kevin M. Dougherty, Debra Todd) found that the duty to obtain the patient's informed consent belongs solely to the physician and that the physician's duty to provide information to a patient sufficient to obtain her informed consent is non-delegable: "Informed consent requires direct communication between physician and patient, and contemplates a back-and-forth, face-to-face exchange, which might include questions that the patient feels the physician must answer personally before the patient feels informed and becomes willing to consent." The court stated that direct dialogue and a two-way exchange between the physician and patient is required for the physician to be confident that the patient comprehends the risks, benefits, likelihood of success, and alternatives.

The majority reasoned in its conclusion that a physician may not delegate to others his or her obligation to provide sufficient information in order to obtain a patient's informed consent is consistent with the plain language of the MCARE Act, which states that "a physician owes a

duty to a patient to obtain informed consent." The Court reasoned that the plain language of the MCARE Act "specifically imposes the duty upon physicians to provide the patient the requisite information. . ." The Court went on to determine that the language of the Act does not allow conversations between the patient and others to control the informed consent analysis or satisfy the physician's legal burden.

Despite a fervent dissent written by Justice Baer, the Court majority ultimately concluded that the trial court had in fact erred when it instructed the jury to consider information provided by the defendant's qualified staff in deciding the merits of the informed consent claim. The Supreme Court reversed the Superior Court's order affirming the judgment entered in favor of the defendant and granted a new trial to the plaintiff.

Also of note, in its decision, the Pennsylvania Supreme Court also referenced its 2002 decision in *Valles v. Albert Einstein Medical Center*, which addressed the requirements of informed consent and held that hospitals could not be held liable for physicians' failures to obtain informed consent. The Court in *Valles* held:

- "[A] battery which results from a lack of informed consent is not the type of action that occurs within the scope of employment. In our view, a medical facility cannot maintain control over this aspect of the physician-patient relationship. Our lower courts have recognized that the duty to obtain informed consent belongs solely to the physician. Informed consent flows from the discussions each patient has with his physician, based on the facts and circumstances each case presents. We decline to inject an element of a hospital's control into this highly individualized and dynamic relationship. We agree with the lower court that to do so would be both improvident and unworkable. Thus, we hold 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."

Medical Care Availability and Reduction of Error Act: As noted above in issuing its ruling, the majority opinion interpreted the language of Subsection 1303.504 the MCARE Act, which states as follows:

(a) Duty of physicians. Except in emergencies, a physician owes a duty to a patient to obtain the informed consent of the patient or the patient's authorized representative prior to conducting the following procedures:

1. Performing surgery, including the related administration of anesthesia
2. Administering radiation or chemotherapy
3. Administering a blood transfusion
4. Inserting a surgical device or appliance
5. Administering an experimental medication, using an experimental device or using an approved medication or device in an experimental manner

(b) Description of procedure. Consent is informed if the patient has been given a description of a procedure set forth in subsection (a) and the risks and alternatives that a reasonably prudent patient would require to make an informed decision as to that procedure. The physician shall be entitled to present evidence of the description of that procedure and those risks and

alternatives that a physician acting in accordance with accepted medical standards of medical practice would provide as in 40 P.S. § 1303.504.

(c) Expert testimony. Expert testimony is required to determine whether the procedure constituted the type of procedure set forth in subsection (a) and to identify the risks of that procedure, the alternatives to that procedure and the risks of these alternatives.

(d) Liability.

1. A physician is liable for failure to obtain the informed consent only if the patient proves that receiving such information would have been a substantial factor in the patient's decision whether to undergo a procedure set forth in subsection (a).
2. A physician may be held liable for failure to seek a patient's informed consent if the physician knowingly misrepresents to the patient his or her professional credentials, training or experience.

HAP Next Steps: HAP will continue to monitor this issue and advocate on behalf of our members.

- HAP is monitoring the situation to alert members on any potential regulatory impact. We meet regularly with DOH's Division of Acute and Ambulatory Care (DAAC) leadership and will keep you informed as to how DAAC plans to adjust their enforcement approach.
- HAP is actively investigating legislative options to remedy the resulting operational burden. We will engage members in shaping our legislative advocacy strategy. We will convene a member call in July to discuss the operational impacts of the decision and solicit input on potential legislative language. Please note that given the legislative calendar, legislative advocacy will be focused on securing a legislative solution during the Fall legislative session.
- HAP is engaging other provider stakeholders including the Pennsylvania Medical Society, Pennsylvania Society of Physician Assistants, and Pennsylvania Coalition of Nurse Practitioners to identify ways that we can coordinate our efforts to resolve this issue.

For More Information: HAP will continue to keep our members updated as to any future developments. Please contact me at (215) 575-3741 with questions or concerns.