Message from the Chair

Hi, everyone,

My name is Susan Saba Roinick, and I am the new chair of the Health Care Law Committee. For our new members, I would like to introduce you to the work of the committee. Currently we meet biannually on PBA Committee/Section Days and discuss proposed legislation affecting health care in the commonwealth.

We also have several sub-committees: Health Information, Health Innovation, Mental Health, Newsletter, Payment Reform, Bioethics, Legal Action, and Health Professional Networking. Please email me at sroinick@seegerweiss.com if you are interested in joining a committee or would like me to help organize a meeting of a subcommittee.

Our membership runs the gamut of the healthcare space, from plaintiffs’ attorneys, such as myself, to defense attorneys, health care transaction attorneys and attorneys who work for health plans, hospital networks, behavioral health organizations, nonprofits and the government. Law students have joined our committee, which shows the interest in this area of the law. We can help them find their place in the practice of health care law.

Please let me know what the committee can do for you. All ideas, suggestions and questions are welcome.

Sincerely,
Susan Saba Roinick
2022-2023 Chair

PBA Health Care Law Committee Listserv

The PBA Health Care Law Section Listserv allows members to pose questions and offer answers to other members practicing within their areas of interest. The Listserv allows members to distribute emails to its list of other committee Listserv subscribers.

To join a Listserv, a PBA member must be member of the committee or section offering the Listserv.

Sign up for the committee Listserv.

Sub-committees:
- Health Information
- Health Innovation
- Mental Health
- Newsletter
- Payment Reform
- Bioethics
- Legal Action
- Health Professional Networking

Email Chair Susan Saba Roinick at sroinick@seegerweiss.com.

Save the date:
Thursday, Nov. 17
PBA Committee/Section Day
Health Care Law Committee Meeting
Pennsylvania Medical Consent Law Updated

By Janet M. Lis

The Pennsylvania medical consent law as it existed in 2017 at 40 P.S. Section 1303.504 is copied below.

(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 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.

(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 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.

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Shinal v. Toms

On June 20, 2017, in the case of Shinal v. Toms, 162 A3d 429 (Pa. 2017), the Pennsylvania Supreme Court held that a physician could not delegate his or her obligation to obtain a patient’s informed consent for the above-enumerated procedures. Shinal involved brain surgery, where the surgery could have been done as a total or as a subtotal resection of a tumor. The patient’s complaint stated that Dr. Toms failed to explain the risks of surgery to her or to offer her the lower risk surgical alternative of subtotal resection of the benign tumor, followed by radiation. Dr. Toms testified that he reviewed the alternatives, risks and benefits of total versus subtotal resection of the tumor during a pre-operative visit, but no clear choice of surgical approach was decided upon. After this, Ms. Shinal had a telephone discussion with Dr. Toms’ physician assistant regarding scarring, post-operative radiation, the date of surgery and the incision. The physician assistant then met with Ms. Shinal in person and obtained her medical history, performed a physical examination, provided information about the surgery, and had the consent form signed. The consent form itself solely referred to a “resection” and did not address specific risks related to total or subtotal resection. The more aggressive total resection approach was used; surgery resulted in significant residual injuries following carotid perforation.

The lower courts in their jury instructions allowed information provided by Dr. Toms’ physician assistant to be presented to the jury along with testimony of Dr. Toms. The trial court jury found for Dr. Toms and the Superior Court affirmed, relying on two prior cases to opine that information communicated to a patient for the purpose of obtaining informed consent may be conveyed by a qualified professional acting under the attending physician’s supervision. The Pennsylvania Supreme Court, however, held that the duty to obtain the patient’s informed consent belongs solely with the physician, the physician may not delegate to others his or her obligation to provide sufficient information to obtain a such consent. The court opined that “[i]nformed 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 fully informed and becomes willing to consent.” Cases that hold otherwise were overruled.1 One dissent to the decision does note the use of passive voice in section (b) of the law as a basis to allow for input by other “qualified staff.”

This opinion generated much discussion regarding consent procedures. The lack of congruence between much existing practice and the stringent application of the medical consent law in the Shinal case, where only the physician performing the procedure can obtain consent and evidence of information provided in other discussions cannot be presented to the court, led to a need to review and revise medical informed consent procedures. In an era where health care providers, such as resident physicians or fellows, nurse practitioners and physician assistants provide many of the patient interactions and may perform duties that are enumerated in the consent law, and where

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1 The Shinal court relied on Valles v Albert Einstein Medical Center, 805 A2d 1232 (Pa. 2002), which held that the medical center cannot be held vicariously liable for physician’s failure to obtain informed consent. The Shinal court interpreted this to mean that the physician had a non-delegable duty to obtain informed consent. The Shinal court did not address that consent in Valles was obtained by resident physicians, not the physicians performing the procedures; or the secondary Valles holding that informed consent does not need to cover the manner or method to be used in performing a surgical procedure.
multiple physicians may be involved in the care of surgical and related anesthesia care, the inflexible nature of the holding presented issues.

Shinal’s mandate that informed consent is a non-delegable physician duty brought many activities into question and created the need for multiple consents in certain circumstances. For instance, a person being interviewed pre-operatively for surgery/anesthesia may meet with one physician but the surgery/anesthesia may then be performed by another group member. A nurse practitioner may be performing a procedure which he/she is licensed to perform, but because it is covered by the consent law a physician must obtain consent.

**Act 61 of 2021**

The ensuing discussions led to passage of a law amending this statutory section with Act 61 of 2021, approved June 30, 2021, and immediately effective. This amendment also applied to pending litigation, any action in which a final order was not entered prior to the effective date of the amendment.

This amendment allows for fulfillment of the physician consent obligations by delegation of this task to a “qualified practitioner,” for procedures performed by the delegating physician or by the “qualified practitioner.” Physicians and “qualified practitioners” performing a procedure may rely on information provided by another “qualified practitioner” and no new consent need be obtained. Where there are claims related to failure to obtain informed consent, evidence of information provided by the physician or by a “qualified practitioner” may be presented as competent evidence.

“Qualified practitioners” are defined in the law as certified registered nurse practitioners, physician assistants, midwives and nurse-midwives, registered nurses practicing within their scope of practice, registered nurses authorized to administer anesthesia, and other physicians, including residents and fellows, when such persons are knowledgeable regarding the patient’s condition and the procedure to be performed and are acting under the supervision of, at the direction of, or in collaboration or cooperation with, the delegating physician.

Delegation of authority to obtain consent is not required. A patient or a patient’s “authorized representative” retains the ability to request that the physician with the duty to obtain consent respond to questions regarding the procedure or the risks or alternatives to the procedure, or to obtain informed consent. In such a case that physician must obtain informed consent.

The law also specifies that consent obtained in a human subjects research study as approved by an institutional review board or similar entity in accordance with federal regulations found at 45 CFR Part 46 (HHS) and 21 CFR Part 50 (FDA) and any other applicable federal laws and regulations is deemed to comply with the law.

Liability sections of the law were expanded to cover “qualified practitioners.” Most references to the necessary party for the informed consent discussion and documentation now include both the patient and the patient’s “authorized representative,” although references to the patient’s “authorized representative” were not added in the liability section.

This law does not change the listing of procedures for which informed consent is required, the content of information to be provided in the informed consent discussion, or the need for expert testimony or liability criteria. It does clarify and update the statute to specifically allow delegation of the responsibility for obtaining informed consent, identifying to whom that responsibility may be delegated, and stating that in litigation challenging sufficiency of informed consent information provided by the physician or by the “qualified practitioner” is competent evidence.

Janet M. Lis is a co-vice chair of the PBA Health Care Law Committee and chair of its Bioethics Subcommittee. Her law practice has focused on health-care-related matters, including guardianship, advance directives and human subjects research. She received a B.A. degree from Bucknell University and B.S.N. and J.D. degrees from Georgetown University. Janet practiced nursing prior to practicing law. She is a member of the Delaware County Bar Association Elder Law Committee.
Pennsylvania State Senators Maria Collett and Nikil Saval sent a memorandum to their fellow Senate members asking them to support a bill that would require entities that receive state funds to operate nursing homes and long-term-care facilities to target a minimum of 75% of those funds to direct resident care, provide annual financial reports and full transparency into the ownership structure of the facility. Collett and Saval’s bill has not been assigned an SB# yet but read Collett’s answers below, which include information on SB 38, which would provide a Pennsylvania a False Claims Act.

Sen. Collett answered the following questions regarding her bill:

**Nursing Home Resident Protections**

*If passed, how will the requirements of the Nursing Home Resident Protections bill be enforced?*

**COLLETT:** This bill package contains four separate but complementary components: consolidated financial reporting, minimum bedside care funding, ownership transparency and licensure reform. Together, these bills will hold nursing home operators to higher and more transparent standards for care, quality and effectiveness than ever before. To ensure robust enforcement, the Department of Health will need dedicated staff and systems in place to review the comprehensive financial and ownership data made available through the legislation. Reform will require collaboration and buy-in among all the stakeholders: the administration, the General Assembly, the nursing home industry, its residents and the public-at-large. I am committed to making this happen.

*Currently, outside of the tort system, is there any private right of action against entities who fail to meet the current needs of their residents?*

**COLLETT:** Unfortunately, outside of the tort system, I am not aware of any private legal remedies for addressing inadequate care, but this doesn’t leave Pennsylvanians without options. The Department of Health has the duty and authority to enforce safety regulations across the industry, including the ability to revoke a provider’s license for noncompliance, and if need be place a facility in receivership – effectively taking over a facility while a new operator is identified. Concerned residents, family members and staff can always file a complaint with the Department of Health, who can investigate the complaint and impose a penalty if necessary, or with the Attorney General, who has been known to investigate nursing homes for criminal neglect. These reforms in our legislation will allow us to be proactive. We can and should identify and head off...
Nursing Home Protections
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nursing homes that place profits above patients before they become a bigger problem.

Who has standing to bring a claim?

COLLETT: While we are still developing this legislation, we have not drafted any new expansion of private rights of action. However, if SB 38, introduced by Senators Lindsey Williams and Kristin Phillips-Hill to establish the Commonwealth Fraud Prevention Act were to pass, individuals could seek remedy for false claims utilizing taxpayer funds. This could include fraudulent use of taxpayer funds while not providing the type of care reported to the Commonwealth observed by employees, residents or visitors of a nursing facility.

How will you convince lawmakers, who take exception to any infringement upon corporate ability to accept tax dollars, to support the bill?

COLLETT: There is nothing wrong with a corporation using taxpayer money to provide services on behalf of the Commonwealth, and the proof is the number of public-private partnerships the state works through all the time. But we know the keys to a successful public-private endeavor are trust, transparency and accountability for the taxpayer’s investment. Providers have long called for additional funding, and the Commonwealth already funds at least 60% of this industry's bottom line. We can't have an honest conversation in the legislature about the amount of funding providers need to ensure high quality care if we don’t have a fully transparent reporting process in place. That means knowing to whom and where any profits from public funds are going – especially as private equity investments in health care, and nursing homes in particular, continue to rise. The general assembly has a responsibility to make sure there is no waste, fraud or abuse among recipients of taxpayer funds – and this includes at the corporate level.

Committee Chair Susan Saba Roinick is a staff attorney at Seeger Weiss LLP. As an attorney and registered nurse, Susan concentrates her practice in drug and medical device litigation. Prior to joining Seeger Weiss, she was a public defender at the Lycoming County Court of Common Pleas and served as law clerk to President Judge Nancy L. Butts of the same and Judge Robert C. Daniels of the Superior Court of Pennsylvania.

PA Lawmakers Push for Increased Mental Health Care Access
By Larissa Morgan

Millions of Pennsylvanians struggle to access mental health care. Many residents forgo care due to high out-of-network health insurance costs, and more than a million of the state’s residents live in areas that lack mental health professionals altogether. The shortcomings in the current mental health system are reflected in the mental health crisis growing in Pennsylvania public schools; the opioid epidemic plaguing cities, suburbs and rural communities; and the high rates of individuals suffering from mental illness in the justice system.

The COVID-19 pandemic exacerbated these mental health challenges due to social isolation, financial hardship, and severe illness, among other stressors.

However, throughout the pandemic, Pennsylvania lawmakers have responded with legislation to address these growing challenges. A wave of recently introduced legislation aims to expand access to mental health services, particularly for vulnerable populations throughout the commonwealth.

Telehealth has served as an essential delivery of care method throughout the COVID-19 pandemic. Given its importance, Gov. Tom Wolf recently extended the COVID-19 waiver that allows patients to receive mental health services via telehealth. At the same time, the Pennsylvania House of Representatives is reviewing H.B. 2419 — legislation that would permit psychiatric services to be conducted entirely through telehealth, thereby amending a statute requiring half of psychiatric services to be delivered on-site.

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Increased Mental Health Care Access
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According to the bill’s primary introducer, Rep. Tina Pickett, for populations who lack transportation or live in communities with a shortage of psychiatrists, this legislation would address those barriers while simultaneously confronting the increased demands for psychiatric care in the state.6

In addition to increasing accessibility to mental health care through telehealth, a package of bills seeks to improve mental health services in Pennsylvania public schools. H.B. 2022 would amend the Public School Code to permit schools to contract with third-party providers to offer mental health services — such as crisis management, suicide prevention and anxiety counseling — in public schools. Meanwhile, H.B. 2023 would charge the Pennsylvania Department of Education (PDE) with establishing a model curriculum on mental health education for public schools to combat stigma surrounding mental illness among students. Finally, a third bill, H.B. 2024, would direct the PDE to implement a study to better understand existing mental health education in public schools and use its findings to improve current curricula.

Other legislation focuses on creating networks that address barriers in finding care and services. For example, H.B. 404 would create a statewide children’s mental health ombudsman, who would work to advocate for children’s mental health and identify existing barriers to treatment, among other initiatives. Similarly, to streamline mental health services across schools, Pennsylvania residents and providers, lawmakers are considering H.B. 409, which would establish a publicly accessible mental health clearinghouse, including a list of resources and providers across the state.

As Pennsylvania lawmakers continue to prioritize mental health in their legislative agendas, the Mental Health Law Subcommittee of the Pennsylvania Bar Association will monitor these bills and advocate on behalf of legislation that fosters an accessible, equitable mental health system. The Mental Health Law Subcommittee invites you to join us if you are interested in our efforts to foster dialogue and implement initiatives on pressing mental health issues facing Pennsylvanians and members of the legal community.

For more information about the Mental Health Law Subcommittee and its efforts, please contact Larissa Morgan at larissa.morgan@faegredrinker.com or Rose Constantino at rco100@pitt.edu.

We look forward to hearing from you!

Larissa Morgan is a health care associate at Faegre Drinker Biddle & Reath LLP. Her practice focuses on a wide range of regulatory and transactional matters, including digital health regulation, Medicare and Medicaid compliance, and strategic transactions and affiliations. Larissa has written extensively on health care regulation and bioethics topics. Her work has been published in the Journal of the American Medical Association Pediatrics and was cited by the Centers for Disease Control and Prevention. She is a co-chair of the PBA Health Care Law Committee’s Mental Health Law Subcommittee.
Hello, it’s me, your friendly, neighborhood PBA legislative counsel here to provide you with a legislative update and to say goodbye.

This legislative session has been an odd one. In my five and a half years at the PBA, I have never seen a session like it. It started off with a bang in January 2021, and things have not slowed down since. Despite this atypical session, budget season (which just concluded as I am writing this) was pretty typical in that there were plenty of back-and-forth negotiations over money, and a completed budget was over a week late. It ultimately included a $45.2 billion spending plan with historic investments in education and public safety, cuts in the state corporate net income tax, and an investment in mental health programs, just to name a few.

While it is always good to have a completed budget, we in the PBA Legislative Department like budget season for another reason — non-budget-related bills move while the legislators are in Harrisburg working on the budget! An example of one such bill is a PBA initiative, House Bill 2057, which originates from our Business Law Section. As Fred has noted in another column, this bill would significantly modernize the Business Corporation Law as well as amend related provisions of Title 15 of the Pennsylvania Consolidated Statutes. After receiving first consideration in the House back in November 2021, House Bill 2057 had significant movement in June by unanimously passing the House in late June. It has been assigned to the Senate Finance Committee, where we hope there will be movement on the bill when the General Assembly returns in the fall.

Another bill we support that had some movement this budget season is House Bill 2525, which would amend the Criminal History Records Information Act (CHRIA) to permit parties to obtain investigative materials from law enforcement for civil litigation. After having passed the House back in April, House Bill 2525 received first and second consideration in the Senate in June and is now assigned to the Senate Appropriations Committee.

As a final budget season update, I am happy to report that this was the first time in six years that funding for the judiciary was increased. In addition, there was a reauthorization through July 31, 2023, of statutory surcharges, collectively known as Act 49, which account for 15% of the annual judicial operations budget. Lastly, there was another annual suspension of the $15 million diversion from the Judicial Computer System Fund.

Specifically, as to healthcare law, there has been some legislative movement I would like to update you on. House Bill 245, which would provide updates to international medical graduate requirements, was signed into law in April as Act 16 of 2022. Similarly, House Bill 889, which would update international nursing licensure exam requirements, was signed into law in June as Act 22 of 2022. Lastly, House Bill 2401, signed into law as Act 30 of 2022, amends the Health Care Facilities Act to extend regulatory waivers that went into effect over the course of the COVID-19 pandemic.

Now that you are up to date on recent legislative developments, I want to take this opportunity to say thank you and goodbye. When you are reading this, I will no longer be legislative counsel for the PBA. It has been a pleasure serving the interests of the PBA through my role as legislative counsel. While I will no longer lobby for the PBA, I plan to stay actively involved as a PBA member, so I hope to see you soon.

For additional information about the PBA’s legislative program, contact Director of Legislative Affairs, Fred Cabell, at fred.cabell@pabar.org.