House Aging & Older Adult Services Committee

Public Hearing on Proposed Assisted Living Regulations

September 18, 2008
418 Main Capitol
9:30 a.m.

PA Association for Justice (formerly the Trial Lawyers Association)

Clifford A. Rieders, Esquire
161 West Third Street
P.O. Box 215
Williamsport, PA 17703-0215
(570) 323-8711
crieders@riederstravis.com
www.riederstravis.com

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1. Act 2007–56 enacted in Pennsylvania on July 25, 2007

1.1 In enacting Act 56, the General Assembly found it in the best interests of all Pennsylvanians that a system of licensure and regulation be established for assisted living residences in order to ensure accountability and availability of long-term care for adults.

2. Informed Consent

2.1 Section 1001 – Statutory Definitions

"Informed consent agreement" means a formal, mutually agreed upon, written understanding which:

(1) results after thorough discussion among the assisted living residence, staff, the resident, and any individuals the resident wants to be involved; and

(2) identifies how to balance the assisted living residence's responsibilities to the individuals they serve with a resident's choices and capabilities with the possibility that those choices will place the resident or other residents at risk of harm.

2.2 Regulations Pursuant to Statute

Section 1021 of the statute provides for regulations to carry out the statute. Section 1021(2)(vii) Create standards for informed consent agreements that promote aging in place which include written acknowledgement of the risks that residents assume while directing their own care and which release the facility from liability for adverse outcomes resulting from actions consistent with the terms of the informed consent agreement. Such informed consent agreements shall only be entered into upon the mutual agreement of the resident and the assisted living residence.

2.3 Mcare Act Background

Informed consent is defined in Chapter 5 of the Mcare Act 40 P.S. § 1303.501, *et seq.*, in the following manner:

"Informed consent." The consent of a patient to the performance of a procedure in accordance with § 504.

§ 504. Informed consent, 40 P.S. § 1303.504 reads, in its entirety, as follows:

Section 504. Informed consent

(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.

(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.

2.4 The Law of Informed Consent

A patient's understanding is vital before an informed consent can be effective.

Informed consent is frequently misunderstood by the laypublic. Informed consent is not the same as assumption of the risk. Informed consent is not intended to relieve an actor from a negligent act, one which represents a breach in the standard of due care.

Informed consent is intended to assure that a person does not undergo a procedure that they have not agreed to, but which procedure or conduct is otherwise proper, legal, and within the standards of due care.

For a comprehensive analysis of this topic, see Pennsylvania Medical Malpractice Law & Forms, 2008 edition, Clifford A. Rieders, pajustice.org, copyright 2008, p. 261, *et seq.*

A physician is bound to disclose risks which a reasonable person would consider material to his/her decision whether or not to undergo treatment. *Sauro v. Shea*, 390 A.2d 259 (Pa. Super. 1978).

A physician is precluded from administering to or operating upon a mentally competent adult patient in non-emergency situations without his consent. In order for a consent to be valid, the physician is duty bound to apprise the patient "of such important matters as the nature of the therapy, the seriousness of the situation, the disease and the organs involved and the potential results of the treatment." *Festa v. Greenberg*, 511 A.2d 1371, 1373 (Pa. Super. 1986), citing *Salis v. United States*, 522 F.Supp. 989, 997 (M.D. Pa. 1981), abrogation on other grounds recognized, *MacDonald v. United States*, 767 F.Supp. 1295 (M.D. Pa. 1991), summarizing *Gray v. Grunnagle*, 423 Pa. 144, 223 A.2d 663 (Pa. 1966).

Pennsylvania has adopted the "prudent patient" standard in informed consent cases. *Cooper v. Roberts*, 286 A.2d 647 (Pa. Super. 1971). A patient's right to know all material facts pertaining to proposed treatment cannot be dependent upon the self-imposed standards of the medical profession. In determining whether a physician breaches a duty to his patient to apprise him of material risks involved in a recommended medical procedure and available alternatives, the standard of care is not what a reasonable medical practitioner would have done in the situation, but rather whether the physician disclosed those risks which a reasonable person would have considered material to his decision whether or not to undergo treatment. *Festa v. Greenberg*, 511 A.2d at 1375. *See also, Weiss v. Green*, 129 F.Supp.2d at 756, *et seq.*

The doctrine of informed consent, whether involving non-consensual surgery or a lack of informed consent, sounds in battery, not negligence. *Montgomery v. Bazaz-Sehgal*, 798 A.2d 742, 744 (Pa. 2002).

A claim based upon a lack of informed consent involves a battery committed upon a patient by a physician, an action which is distinct from a claim of consented-to, but negligently performed, medical treatment. *Id.* at 748-749. Since surgery performed without a patient's informed consent constitutes a technical battery, negligence principles generally do not apply. A claim involving a surgical procedure performed without any consent at all is also a battery. A claim concerning a lack of consent for surgery can be maintained with no allegations of negligence with respect to the actual performance of the procedure. A lack of informed consent or a lack of consent claim is actionable even if the subject's surgery was properly performed and the overall result is beneficial. *Id.* at 749. Clearly, this should be part of a trial court's charge to the jury.

Most Superior Court panels have understood that a failure to give informed consent is an action that sounds in battery and not negligence. *Foflygen v. R. Zemel, M.D., P.C.*, 615 A.2d 1345 (Pa. Super. 1992).

Act 56 breaks new ground in that previously hospitals and other such facilities were not required to provide informed consent; the obligation was that of the individual health care provider. *Valles v. Albert Einstein Medical Center*, 805 A.2d 1232 (Pa. 2002). The court reasoned that a medical facility could not maintain control over informed consent aspect of the physician-patient relationship. Since informed consent flows from discussions each patient has with his physician, the court declined to inject an element of hospital responsibility into the highly individualized and dynamic relationship.

3. Expert Testimony

It is well established in Pennsylvania that in informed consent cases, expert testimony is not necessary to establish the medical community's standard of disclosure. The question of whether a physician discloses risks which a reasonable person would deem material is for the trier of fact.

Montgomery v. Bazaz-Sehgal, 798 A.2d 742, 744 (Pa. 2002) teaches that expert testimony is necessary to establish damages for mental injuries. The court, by its logic, suggests that mental injuries are those which typically arise from a lack of informed consent and are fully permitted. The law is well-established that expert testimony is not necessary where the cause of an injury is clear and where the subject matter is within the experience and comprehension of lay-jurors. *Id.* at 752. Laypersons are certainly capable of comprehending, without the assistance of an expert, mental and emotional damages and determining whether those difficulties were occasioned by the unwanted and unexpected implantation of a penile prosthesis.

It is necessary to have an expert witness to establish the existence, magnitude and other relevant scientific characteristics of the risks of a recommended medical procedure and viable alternatives. This in no way modifies the rule in Pennsylvania that

expert medical testimony is not required to establish the scope of a physician's duty to disclose; it remains for the trier of fact to determine the materiality of these risks.

The determination as to what is material is a consideration left to the trier of fact. *Moure v. Raeuchle*, 604 A.2d 1003 (Pa. 1992). An expert may not opine on the ultimate issue as to what a reasonable patient would do or consider under certain circumstances. *Sagala v. Tavares*, 533 A.2d 165 (Pa. Super. 1987). *McSorley v. Deger*, 905 A.2d 524 (Pa. Super. 2005) (question is for the jury to determine whether a doctor's actions are within consent provided). Expert testimony and necessity in *McSorley*.

To establish materiality, it is incumbent upon the plaintiff to present expert testimony establishing both the nature of the harm attendant to a medical procedure and probability of that harm occurring. *Moure*, cited by *Zeid v. Castillo*, 36 Pa. D.&C.4th 281 (Phila. Co. 1997), aff'd, 711 A.2d 1047 (Pa. Super. 1997) (table).

Probability of risk has been referred to as frequency in magnitude of the risk, and usually requires expert testimony. *Zeid* at 284, citing the Superior Court cases aforementioned.

The Superior Court attempted to address what is left to the trier of fact versus what must be testified to by an expert in informed consent cases when it authored *Neal v. Lu*, 530 A.2d 103, 112 (Pa. Super. 1987).

> We concluded in *Festa* that even though the ultimate assessment of materiality is for the fact finder to make, expert testimony is nevertheless necessary on the important secondary issues that lie outside the knowledge of the lay person. (citations omitted). Thus, only an expert is able to explain the harms that can arise from the procedure in question and estimate the likelihood that those harms will occur. Only an expert, moreover, can identify viable alternative treatments and discuss the risks involved. Overruled on other grounds by *Gouse v. Cassel*, 532 Pa. 197, 615 A.2d 331 (1992) (that part of the decision requiring actual injury in informed consent cases has been abrogated).

Zeid at 284.

Zeid involved the probability of harm of laser removal of tattoos. The court found the response posed by plaintiff's expert unclear in assessing the magnitude of the risk. It was held that plaintiff's expert was unable to precisely assess the risks, thus resulting in conjecture concerning probability and making his expert opinion non-conclusive and speculative.

In sum, the determination of what a material risk is, is a question for the jury, but expert information must be supplied as to the nature of the harm attendant to the procedure, and the probability of that harm occurring.

Under Pennsylvania's common law doctrine, informed consent has not been required in cases involving non-surgical procedures. *Stalsitz v. Allentown Hosp.*, 814 A.2d 766, 772 (Pa. Super. 2002). The general rule is that informed consent only applies to surgical procedures, and only to physicians performing those procedures. *Id.* At 775. The trial court properly granted a demurrer with regard to the physician's duty to obtain informed consent for an angiogram, since that procedure involved the injection of a dye and will be considered non-surgical. *Id.* at 777, 778. Likewise, the court concluded that the demurrer was properly granted with regard to the claim that the doctors were obligated to obtain informed consent for the angioplasty, since it was undisputed that a different doctor perform the procedure. Further, the court found itself unable to define the angioplasty as surgical or non-surgical. Since the jury found that substantial factor did not exist, a new trial was said not to be warranted on the question as to whether informed consent was necessary for the procedure. Since this was a pre-statutory informed consent case under 40 P.S. § 1301.811-A(a)(2)-(3), common law dictated that this was a battery case and the substantial factor question should not even have gone to the jury on informed consent.

The purpose of this background is to demonstrate that the statute and the regulations pursuant thereto breaks new ground in that an institution is required to give informed consent and the informed consent in no way relieves the institution or the people that work there from negligence. The concept under the statute is to relieve the institution and the people who work at the institution from responsibilities, but not from neglect, where a resident executes a valid document in order to take over his or her own care.

The statute was careful to use the term "adverse outcomes" rather than release of a facility from liability for lack of due care or negligence.

4. Regulatory Issues

§ 2800.16. Reportable incidents and conditions

(a) A reportable incident or condition includes the following:
  (1) The death of a resident.
  (2) A physical act by a resident to commit suicide.
  (3) An injury, illness or trauma requiring treatment at a hospital or medical facility. This does not include minor injuries such as sprains or minor cuts.
  (4) A violation f a resident's rights in §§ 2800.41 – 2800.44 (relating to resident rights).
  (5) An unexplained absence of a resident for 24 hours or more, or when the support plan so provides, a period of less than 24 hours, or an absence of a resident from a special care unit.

(6) Misuse of a resident's funds by the residence's staff persons or legal entity.
(7) An outbreak of a serious communicable disease as defined in 28 Pa. Code § 27.2 (relating to specific identified reportable diseases, infections and conditions).
(8) Food poisoning of residents.
(9) A physical or sexual assault by or against a resident.
(10) Fire or structural damage to the residence.
(11) An incident requiring the services of an emergency management agency, fire department or law enforcement agency, except for false alarms.
(12) A complaint of resident abuse, suspected resident abuse or referral of a complaint of resident abuse to a local authority.
(13) A prescription medication error as defined in § 2800.188 (relating to medication errors).
(14) An emergency in which the procedures under § 2800.107 (relating to emergency preparedness) are implemented.
(15) An unscheduled closure of the residence or the relocation of the residents.
(16) Bankruptcy filed by the legal entity.
(17) A criminal conviction against the legal entity, administrator or staff that is subsequent to the reporting on the criminal history checks under § 2800.51 (relating to criminal history checks).
(18) A termination notice from a utility.
(19) A violation of the health and safety laws under § 2800.18 (relating to applicable laws).
(20) An absence of staff or inadequate staff to supervise residents.

(b) The residence shall develop and implement written policies and procedures on the prevention, reporting, notification, investigation and management of reportable incidents and conditions.

(c) The residence shall report the incident or condition to the Department's assisted living residence office or the assisted living residence complaint hotline within 24 hours in a manner designated by the Department. Abuse reporting must also follow the guidelines in § 2800.15 (relating to abuse reporting covered by law).

(d) The residence shall submit a final report, on a form prescribed by the Department, to the Department's assisted living residence office immediately following the conclusion of the investigation.

(e) If the residence's final report validates the occurrence of the alleged incident or condition, the affected resident and other residents who could potentially be harmed or his designated person shall also be informed immediately following the conclusion of the investigation.

(f) The residence shall keep a copy of the report of the reportable incident or condition.

Comments: The Mcare definition of serious event is excluded. It should be included. Subsection (a)(3) should define a serious bodily injury in a way that Mcare does; an occurrence or happening which is unanticipated by a reasonable patient and requires medical care. The definition in the regulations is an injury, illness or trauma requiring treatment at a hospital or medical facility. This may be too narrow. It would be useful if consistent definitions were used in differing pieces of legislation. The concept of an "unanticipated" event is inclusive and is to be viewed from the position of the resident or family member.

§ 2800.17 Confidentiality of Records.

Resident records shall be confidential, and, except in emergencies, may not be accessible to anyone other than the resident, the resident's designated person if any, staff persons for the purpose of providing services to the resident, agents of the Department and the long-term care ombudsman without the written consent of the resident, an individual holding the resident's power of attorney, for health care or health care proxy or a resident's designated person, or if a court orders disclosure.

Comments: We believe that records should be made available free of charge for the resident or the resident's representative where there has been a serious event. That is not currently the law but is something we should be encouraging. In discussions with a number of well informed individuals associated with the Department of Public Welfare, it was noted that a residence must comply with applicable Federal, State and local laws, ordinances and regulations. Presumably, this would include State laws with respect to costs for records. However, a resident is typically in a different situation than a non-resident in terms of their ability to afford records and perhaps even to understand them. Perhaps the Ombudsman would be in a position to request the records without cost for good cause. It should be noted that copying services typically make a profit, part of which they kick back to the entities for whom they work.

§ 2800.19 Waivers.

(a) A residence may submit a written request for a waiver of a specific requirement contained in this chapter. The waiver request must be on a form prescribed by the Department. The Secretary, or the Secretary's appointee, may grant a waiver of a specific requirement of this chapter if the following conditions are met:

(1) There is no jeopardy to the residents.

(2) There is an alternative for providing an equivalent level of health, safety and well-being protection of the residents.

(3) Residents will benefit from the waiver of the requirement.

(b) The scope, definitions, applicability or residents' rights, assisted living service delivery requirements, special care designation requirements, disclosure requirements, complaint rights or procedures, notice requirements to residents or family, contract requirements, reporting requirements, fire safety requirements, assessment, support plan or service delivery requirements under this chapter may not be waived.

(c) At least 30 days prior to the submission of the completed written waiver request to the Department, the residence shall provide a copy of the completed written waiver request to the affected resident and designated person to provide the opportunity to submit comments to the Department. The residence shall provide the affected resident and designated person with the name, address and telephone number of the Department staff person to submit comments.

(d) The residence shall discuss the waiver request with the affected resident and designated person upon the request of the resident or designated person.

(e) The residence shall notify the affected resident and designated person of the approval or denial of the waiver. A copy of the waiver request and the Department's written decision shall be posted in a conspicuous and public place within the residence.

(f) The Department will review waivers annually to determine compliance with the conditions required by the waiver. The Department may revoke the waiver if the conditions required by the waiver are not met.

Comments: The regulations never state that a waiver cannot be completed by someone who is incompetent or otherwise not in a condition to understand the terms and conditions. The regulations should state that the waiver must be initiated by the resident. The regulations should state that there is a period of rescission. Without these protections, the waiver provision can be misused by a facility which prepares the document.

In discussions with the Department of Public Welfare, it was noted that a waiver should never be initiated by the resident. It does not appear that this is clear in the regulations, and we believe that should be clarified.

§ 2800.26 Quality Management

(a) The residence shall establish and implement a quality management plan.

(b) The quality management plan must address the periodic review and evaluation of the following:

(1) The reportable incident and condition reporting procedures.

(2) Complaint procedures.

(3) Staff person training.

(4) Licensing violations and plans of correction, if applicable.

(5) Resident or family councils, or both, if applicable.

(c) The quality management plan must include the development and implementation of measures to address the areas needing improvement that are identified during the periodic review and evaluation.

Comments: This regulation should refer to regulations which indicate the right to review the quality management plan, who will approve the plan, how the resident is informed of the procedure, how the complaint will be addressed, and in what time frame. There also should be a non-retaliation provision.

§ 2800.30 Informed Consent Process.

(a) *Initiation of process.*

(1) When a licensee determines that a resident's decision, behavior or action creates a dangerous situation and places the resident, other residents or staff members at imminent risk of substantial harm by the resident's wish to exercise independence in directing the manner in which they receive care, the licensee may initiate an informed consent process to address the identified risk and to reach a mutually agreed-upon plan of action with the resident or the resident's designated person. The initiation of an informed consent process does not guarantee that an informed consent agreement, which is agreeable to all parties, will be reached and executed.

(2) When a resident wishes to exercise independence in directing the manner in which the resident receives care, the resident may initiate an informed consent process to modify the support plan and attempt to reach a mutually agreed upon plan of action with the licensee. A cognitively impaired resident shall be eligible for an informed consent agreement only if the resident's legal representative is included in the negotiation of the informed consent agreement and executes the agreement.

(b) *Notification.*

(1) When the licensee chooses to initiate an informed consent process, the provider shall do so by notifying the resident and, if applicable, the resident's designated person in writing and orally. The notification must include a statement that the long-term care ombudsman is available to assist in the process and include the contact information for the ombudsman. For cognitively impaired residents, the ombudsman

shall be automatically notified by the licensee. Notification shall be documented in the resident's file by the licensee.

(2) When a resident or, if applicable, the resident's legal representative chooses to initiate an informed consent negotiation, the resident or the resident's legal representative shall do so by notifying the licensee in writing or orally. Notification shall be documented in the resident's file by the licensee.

(c) *Resident's involvement.* A resident who is not cognitively impaired shall be entitled, but is not required, to involve his legal representative and physician, and any other individual the resident wants involved, to participate or assist in the discussion of the resident's wish to exercise independence and, if necessary, in developing a satisfactory informed consent agreement that balances the resident's choices and capabilities with the possibility that the choices will place the resident or other residents at risk of harm.

(d) *Informed consent meeting.*

(1) In a manner the resident can understand, the licensee shall discuss the resident's wish to exercise independence in directing the manner in which he receives care. The discussion must relate to the decision, behavior or action that places the resident or persons other than the resident in imminent risk of substantial harm and hazards inherent in the resident's action. The discussion must include reasonable alternatives, if any, for mitigating the risk, the significant benefits and disadvantages of each alternative and the most likely outcome of each alternative. In the case of a resident with a cognitive impairment, the resident's legal representative shall participate in the discussion.

(2) A resident may not have the right to place persons other than himself at risk, but, consistent with statutory and regulatory requirements, may elect to proceed with a decision, behavior or action affecting only his own safety or health status, foregoing alternatives for mitigating the risk, after consideration of the benefits and disadvantages of the alternatives including his wish to exercise independence in directing the manner in which he receives care. The licensee shall evaluate whether the resident understands and appreciates the nature and consequences of the risk, including the significant benefits and disadvantages of each alternative considered, and then shall further ascertain whether the resident is consenting to accept or mitigate the risk with full knowledge and forethought.

(e) *Successful negotiation.* If the parties agree, the informed consent agreement shall be reduced to writing and signed by all parties, including all individuals engaged in the negotiation at the request of the resident, and shall be retained in the resident's file as part of the service plan.

(f) *Unsuccessful negotiation.* If the parties do not agree, the licensee shall notify the resident, the resident's legal representative and the individuals engaged in the

The term "cognitively impaired" in Section (a)(2) is utilized but the definition needs to be more broad. That term is a medical determination and the provision should apply in all certain circumstances, even physical disability.

There should be a rescission period.

The informed consent meeting (d)(1) once again uses the terminology "imminent risk of substantial harm" but we believe the language should be "imminent risk of substantial physical harm" otherwise the terminology has no meaning. The institution could think itself in "substantial harm" under variety of circumstances that are not particularly reasonable. Also an objectively reasonable standard should be imported.

After discussing the matter with the Department of Public Welfare, it appears that there is a need to define "independence in directing the manner in which they receive care...." It is at this place that the right of rescission should be inserted, and there appears to be agreement on this point.

Perhaps most importantly, the regulation should specifically set forth the informed consent language, mandating the form, size, type and content.

A checklist of requirements to show whether the informed consent regulations have been satisfied should be promulgated by the Department, which also appears to be agreeable to those writing the regulations.

The burden of showing informed consent should be on the facility, and once again we believe the regulation drafters will be receptive to that concept.

With respect to language "wish to exercise independence directing the manner in which they receive care....", we believe the definition ought to apply only where a resident specifically requests care not provided for by the institution, in contravention of medical advice and where the guardian or person with a power of attorney agrees. In other words, independence in directing receipt of care should not apply at all, except for the situation noted or the temptation for overreaching on the part of certain facilities will be very great indeed. We do not believe this is inconsistent with the statute.

With respect to liability section, 2800.40(i), stating that execution of an informed consent agreement shall not constitute a waiver of liability "beyond the scope of the agreement or with respect to acts of negligence or tort," there is concern because the language "beyond the scope of the agreement" should be tied in with the informed consent agreement. The language could be tightened up considerably.

We would suggest the following:

(i) Liability. The execution of informed consent agreement does not constitute any waiver of liability, nor shall it be considered to affect or relate to any claim with respect to acts of negligence, tort, products defect, breach of fiduciary duty,

contract violation, or any other claim or cause of action. An informed consent agreement does not relieve a licensee of liability for violation of statutory or regulatory requirements promulgated under this chapter, nor does it affect the enforceability of regulatory provisions including those provisions governing admission or discharge or the permissible level of care in an assisted living residence. The informed consent is merely a manner of describing self-directed care in those limited instances where it shall be permitted as applicable. The execution of said agreement has no bearing on any suit or claim for damages.

§ 2800.41. Notification of rights and complaint procedures.

(a) Upon admission, each resident and, if applicable, the resident's designated person, shall be informed of resident rights and the right to lodge complaints without intimidation, retaliation or threats of retaliation by the residence or its staff persons against the reporter. Retaliation includes transfer or discharge from the residence.

(b) Notification of rights and complaint procedures shall be communicated in an easily understood manner and in a language understood by or mode of communication used by the resident and, if applicable, the resident's designated person.

(c) The Department's poster of the list of resident's rights shall be posted in a conspicuous and public place in the residence.

(d) A copy of the resident's rights and complaint procedures shall be given to the resident and, if applicable, the resident's designated person upon admission.

(e) A statement signed by the resident and, if applicable, the resident's designated person acknowledging receipt of a copy of the information specified in subsection (d), or documentation of efforts made to obtain signature, shall be kept in the resident's record.

Comments: Once again, we would suggest specific wording of the rights and posting thereof in a conspicuous place.

§ 2800.44 Complaint procedures.

(a) Prior to admission, the residence shall inform the resident and the resident's designated person of the right to file and the procedure for filing a complaint with the Department's Assisted Living Residence Office, local ombudsman o9r protective services unit in the area agency on aging. Pennsylvania Protection & Advocacy, Inc. or law enforcement agency.

(b) The residence shall permit and respond to oral and written complaints from any source regarding an alleged violation of resident rights, quality of care or other matter without retaliation or the threat of retaliation.

(c) If a resident indicates that he wishes to make a written complaint, but needs assistance in reducing the complaint to writing, the residence shall assist the resident in writing the complaint.

(d) The residence shall ensure investigation and resolution of complaints. The residence shall designate the staff person responsible for receiving complaints and determining the outcome of the complaint.

(e) Within 2 business days after the submission of a written complaint, a status report shall be provided by the residence to the complainant. If the resident is not the complainant, the resident and the resident's designated person shall receive the status report unless contraindicated by the support plan. The status report must indicate the steps that the residence is taking to investigate and address the complaint.

(f) Within 7 days after the submission of a written complaint, the residence shall give the complainant and, if applicable, the designated person, a written decision explaining the residence's investigation findings and the action the residence plans to take to resolve the complaint. If the resident is not the complainant, the affected resident shall receive a copy of the decision unless contraindicated by the support plan. If the residence's investigation validates the complaint allegations, a resident who could potentially be harmed or his designated person shall receive a copy of the decision, with the name of the affected resident removed, unless contraindicated by the support plan.

(g) The telephone number of the Department's Assisted Living Residence Office, the local ombudsman or protective services unit in the area agency on aging, Pennsylvania Protection & Advocacy, Inc., the local law enforcement agency, the Commonwealth Information Center and the assisted living residence complaint hotline shall be posted in large print in a conspicuous and public place in the residence.

Comments: It is our view there should be a section, once again, indicating that this does not in any way affect the right to file a suit or a claim for damages where that is appropriate.

SUMMARY

The bill and the regulations represent a tremendous advance in care for senior Pennsylvanians. However, we must be careful not to provide with one hand while taking away with the other. The purpose of the statute and the regulations is to enhance care for residents, including their legal rights. Part of the overall care and management in a residential facility are to protect and insure the legal rights of those often in a weak position to do so themselves.

The informed consent process must not turn into a "get out of jail free" card for residential facilities. The failures of such facilities is the reason the statute and the regulations have come into place.

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(1) results after thorough discussion among the assisted living residence, staff, the resident, and any individuals the resident wants to be involved; and

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What informed consent agreements are not:

1. They do not relieve the entity from duty of due care.
2. In the law, informed consent, when violated, represents a species of battery.
3. Informed consent agreements, as used in Act 53, is different than used in the law of negligence and should not be confused.

2.3 Mcare Act Background

Section 504 – Informed Consent

(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:

* * *

(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.

2.4 The Law of Informed Consent

The doctrine of informed consent, whether involving non-consensual surgery or a lack of informed consent, sounds in battery, not negligence. *Montgomery v. Bazaz-Sehgal*, 798 A.2d 742, 744 (Pa. 2002).

Expert Testimony

It is well established in Pennsylvania that in informed consent cases, expert testimony is not necessary to establish the medical community's standard of disclosure. The question of whether a physician discloses risks which a reasonable person would deem material is for the trier of fact.

Regulatory Issues

Section 2800.16 – Reportable incidents and conditions

(a) A reportable incident or condition includes the following:

* * *

(3) An injury, illness or trauma requiring treatment at a hospital or medical facility. This does not include minor injuries such as sprains or minor cuts.

Regulatory Issues

The Mcare definition of serious events is excluded. It should be included. Subsection (a)(3) should define a serious bodily injury in a way that Mcare does; an occurrence or happening which is unanticipated by a reasonable patient and requires medical care. The definition in the regulations is an injury, illness or trauma requiring treatment at a hospital or medical facility. It would be useful if consistent definitions were used in differing pieces of legislation. The concept of an "unanticipated" event is inclusive and is to be viewed from the position of the resident or family member.

Regulatory Issues

Section 2800.17 – Confidentiality Records

We believe that records should be made available free of charge for the resident or the resident's representative where there has been a serious event.

Regulatory Issues
Section 2800.19 - Waivers

(a) A residence may submit a written request for a waiver of a specific requirement contained in this chapter. The waiver request must be on a form prescribed by the Department. The Secretary, or the Secretary's appointee, may grant a waiver of a specific requirement of this chapter if the following conditions are met:

* * *

The regulations never state that a waiver cannot be completed by someone who is incompetent or otherwise not in a condition to understand the terms and conditions.

Regulatory Issues

Section 2800.26 – Quality Management

(a) The residence shall establish and implement a quality management plan.

(b) The quality management plan must address the periodic review and evaluation of the following:

- (1) The reportable incident and condition reporting procedures.
- (2) Complaint procedures.
- (3) Staff person training.
- (4) Licensing violations and plans of correction, if applicable.
- (5) Resident or family councils, or both, if applicable.

(c) The quality management plan must include the development and implementation of measures to address the areas needing improvement that are identified during the period review and evaluation.

Regulatory Issues

Section 2800.26 – Quality Management

This regulation should refer to regulations which indicate the right to review the quality management plan, who will approve the plan, who the resident is informed of the procedure, how the complaint will be addressed, and in what time frame. There also should be a non-retaliation provision.

Regulatory Issues

Section 2800.30 – Informed Consent Process

(a)(1) When a licensee determines that a resident's decision, behavior or action creates a dangerous situation and places the resident, other residents or staff members at imminent risk of substantial harm by the resident's wish to exercise independence in directing the manner in which they receive care, the licensee may initiate an informed consent process to address the identified risk and to reach a mutually agreed-upon plan of action with the resident or the resident's designated person.

Regulatory Issues

Section 2800.30 – Informed Consent Process

(a)(2) When a resident wishes to exercise independence in directing the manner in which the resident receives care, the resident may initiate an informed consent process to modify the support plan and attempt to reach a mutually agreed upon plan of action with the licensee. A cognitively impaired resident shall be eligible for an informed consent agreement only if the resident's legal representative is included in the negotiations of the informed consent agreement and executes the agreement.

This process is not limited to a person who is competent.