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Mowery, Brian

From: Smith, Elaine
Sent: Wednesday, July 08, 2009 4:26 PM
To: Mowery, Brian
Cc: White, William; Sanchez-Roberts, G. Yvette
Subject: FW: Proposed Rulemaking - Dept of Public Welfare

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INDEPENDENT REGULATORY
REVIEW COMMISSION

For the grid... thanks.

From: Debbie Bueno <dbueno@riederstravis.com>
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Sent: Wed Jul 08 15:56:12 2009
Subject: Proposed Rulemaking - Dept of Public Welfare

PROPOSED RULEMAKING
Control Copy 6/24/2009

DEPARTMENT OF PUBLIC WELFARE
[55 PA. CODE CH. 2800]
Assisted Living Residences

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Re: Comments

I will limit my comments to those aspects of the proposed regulations that appear to have legal consequences.

§ 2800.16 Reportable Incidents and Conditions.

Prior Comment.

The Mcare definition of serious event is excluded. It should be included. Subsection (a)

7/9/2009

(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.

Additional Comment.

The above paragraph is from my original Comments. This has not been addressed at all. There has been some improvement in Subsection (20) which defines inadequate care as "defined by the respective residents support plans." Those plans obviously can be deficient.

Subsection (c) adds a requirement to notify the resident's family and the resident's designated person, which is good.

§ 2800.17 Confidentiality of Records.

Prior Comment.

I 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.

Additional Comment.

This has not been addressed at all.

§ 2800.19 Waivers.

Prior Comment.

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.

Additional Comment.

My concerns have not been addressed except with regard to posting of the waiver, some definitional formalities and revocation of a "standing" waiver.

§ 2800.26 Quality Management

Prior Comment.

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.

Additional Comment.

My suggestion has not been addressed except to assure compliance "with law and the relevant standard of care" which is a worthy addition.

§ 2800.30 Informed Consent Process.

Prior Comment.

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

The regulation permits the licensee to request the initiation of an informed consent process when it believes that the facility or the staff members are at imminent risk of substantial harm by the residents who wish to exercise independence. It appears that this entire scheme is productive of confusion and overreaching. There does not appear to be a problem with rules and regulations which prohibit a resident from putting staff at the institution at imminent risk of substantial **physical** harm. However, a system which gives discretion to the institution to go through the informed consent procedure when in its own subjective judgment feels that it is at risk of substantial harm (what kind of harm?) is productive of problems.

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 I 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 a 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 recision 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.

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 I 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...", I 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. I 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.

I 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.

Additional Comment.

Not all of the changes have been accepted, although some important ones have been made. For example a recision period has been added and Subsection (j) Liability has been improved so as to assure that the informed consent agreements have nothing whatsoever to do with liability issues. The manner of describing self-directed care has been clarified.

The burden of showing informed consent should be addressed and placed on the facility.

§ 2800.41, et seq. Resident Rights

Prior Comment.

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

Additional Comment.

This has not been addressed.

§ 2800.44

Prior Comment.

It is my 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.

Additional Comment.

Subsection (h) clarifying that this section does not in any way affect the right of the resident to file suit or a claim for damages is very appropriate and helpful.

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