Chapter Seven

Facility Regulation and Quality Care of AD Patients

A. Nursing Home Regulation

1. *Current law*

All nursing homes must be licensed and, as a condition of licensure, must comply with State regulations.[1] These regulations, as adopted by the Secretary of Health and Mental Hygiene, are to set "reasonable ... standards of services" for, among other things, the care and medical supervision of patients.[2] In addition, nursing homes are obliged to comply with federal regulations as a condition of eligibility for payment by the Medicare and Medicaid programs.[3]

Nursing homes are subject to inspection at all times.[4] Inspections are carried out by surveyors, who are specially trained registered nurses employed by the Office of Health Care Quality ("OHCQ") in the Department of Health and Mental Hygiene. The objective of the survey process "is to assess whether the quality of care, as intended by the law and regulations, and as needed by the resident, is actually being provided in nursing homes."[5]

Nursing home regulations tend to identify quality of care with active interventions. The State regulations, for example, require "an active program of restorative nursing care aimed at assisting each patient to achieve and maintain his highest level of

independent function including activities of daily living."[6] This formulation would apply appropriately to many AD patients. For those with more advanced AD, however, a restorative model may well be inappropriate, and a palliative care approach far preferable (Shega, Levin, Hougham et al. 2003; Teno 2003).

Moreover, a palliative care approach might also be adopted to carry out a nursing home resident's advance directive. As discussed in Chapter 4 of this report, advance care planning can be a way for an individual with early AD to make health care choices applicable in the later stages of the disease. Under the regulations, "A resident has the right to consent to or refuse treatment, including the right to accept or reject artificially administered sustenance in accordance with State law."[7] OHCQ has rightly characterized a decisional advance directive as "'speak[ing]' for a resident at a time when she is unable, due to her medical condition, to communicate her wishes" (Office of Health Care Quality 2002). Consequently, OHCQ deems it a violation of the resident's rights when a nursing home (or hospital) provides an intervention that is refused in an advance directive.[8]

The Maryland Health Care Decisions Act recognizes a variety of situations in which a legally valid decision may be made to withhold or withdraw a feeding tube when a patient has advanced AD.

2. Nutrition and hydration.

The provision of nutritious, palatable food and adequate fluid intake is an obvious aspect of quality care in nursing homes. Both federal and State regulations require it.[9]

As we pointed out more than a decade ago, however, "nothing in these regulations ... mandates the administration of artificial sustenance."[10] The Maryland Health Care Decisions Act recognizes a variety of situations in which a legally valid decision may be made to withhold or withdraw a feeding tube when a patient has advanced AD.[11] Indeed, for an AD patient nearing the end of life, quality care implies

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caution in the use of feeding tubes, given their lack of demonstrated benefit and potential for harm (Abuksis, Mor, Segal et al. 2000; Callahan, Haag, Weinberger et al. 2000; Finucane and Christmas 2000; Finucane, Christmas, and Travis 1999; Gillick 2000; Kim 2001).

Data from 1999 indicate that, of Maryland nursing home residents with advanced cognitive impairment, 38 percent were tube fed (Mitchell, Teno, Roy et al. 2003). Although this number by itself is meaningless, because it does not reveal the decisional factors in individual cases, it does suggest the strong possibility that factors unrelated to the choice or best interest of the resident may play a role (Mitchell, Teno, Roy et al. 2003).

One possible extraneous factor is fear of regulatory consequences if a resident lost weight and a feeding tube was not used (Ersek and Wilson 2003). Indeed, the leader of a effort to introduce palliative care practices into several Maryland nursing homes identified precisely this fear: "[I]f a resident is losing weight, what is going on with the resident clinically may not be the first concern. The first question that comes to mind may be, 'What is the state survey agency going to do when they see this patient?' The assumption on the part of state regulators has been that any negative outcome, such as resident decline, is the result of inadequate care until proven otherwise" (Tuch, Parrrish, and Romer 2003).

To overcome this concern, the survey process should be carried out with an awareness of both the legal framework and the evidence-based clinical judgments that apply to decision making about the use of feeding tubes. For AD patients nearing the end of life, standard measures of malnutrition cannot be applied uncritically. For these patients, surveyors should not assume that a nursing home is deficient in its care solely because it did not respond to falling nutrition measures by inserting a feeding tube. The

policy goal should be to align survey standards with "quality end-of-life care, which emphasizes patient preferences and an acceptance of decline as part of the dying process" (Teno 2003).

RECOMMENDATION 7-1: Surveyors should be provided with suitable training regarding the use of feeding tubes for patients with AD, including the clinical indications and legal criteria justifying the withholding or withdrawal of a feeding tube.

This serious shortfall in pain management is inconsistent with quality care, for "uncontrolled pain significantly interferes with all aspects of a patient's functioning" **(Institute of Medicine 1997, at 76).**

3. *Pain assessment and management.*

Nursing home residents all too often experience moderate or excruciating pain that is neither properly assessed nor properly treated (Bernabei, Gambassi, Lapane et al. 1998; Sengstaken and King 1993; Teno, Weitzen, Wetle et al. 2001). For example, researchers from Brown University's Center for Gerontology and Health Care Research found that the rate of moderate or excruciating pain among Maryland nursing home residents who are terminally ill was 42.9%; the rate of persistent severe pain was 38.5%.[12] Given that nursing home residents with AD often cannot respond directly to questions about pain, one can safely conclude that persistent pain in this population is not well recognized or treated (Ferrall, Ferrell, and L. Rivera 1995; Teno, Bird, and Mor undated, at 18).

This serious shortfall in pain management is inconsistent with quality care, for "uncontrolled pain significantly interferes with all aspects of a patient's functioning" (Institute of Medicine 1997, at 76). Teno and colleagues from Brown University summarized as follows the "high price" of unrelieved pain:

> The presence of pain in elderly patients and nursing home residents has been associated with depression, decreased socialization, sleep disturbance, impaired ambulation, and increased health care use and costs .... Many geriatric conditions are worsened by the presence of pain including deconditioning, gai[t] disturbances, falls, slow rehabilitation, polypharmacy, cognitive dysfunction, and malnutrition (Teno, Bird, and Mor undated, at 8).

A consensus among experts suggests that government and the private sector alike should pursue quality improvement efforts in pain and symptom management, especially for people with AD **(Joint Conference on Legal/Ethical Issues in the Progression of Dementia 2001).**

In addition, the perception that a loved one is in pain surely adds to the stress on care givers (Schulz, Mendelson, Haley et al. 2003). To avoid these harms, a consensus among experts suggests that government and the private sector alike should pursue quality improvement efforts in pain and symptom management, especially for people with AD (Joint Conference on Legal/Ethical Issues in the Progression of Dementia 2001).

Appropriate attention to pain and symptom management is more than an ethical aspiration. This Office has advised that a nursing home violates its regulatory obligations if it fails to provide pain and symptom management that reflects sound medical practice and a resident's plan of care,[13] and the Office of Health Care Quality has made identification of shortfalls in pain management a survey priority. A resident's attending physician has a duty, among other things, to "properly define and describe resident symptoms and problems ..." and to "determine appropriate services for a resident ...."[14] In translating this general obligation into an effective plan for pain assessment and treatment, the attending physician may benefit from the knowledge and experience of the facility's medical director (Feinsod,Prochada, Anneberg et al. 2000).

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RECOMMENDATION 7-2: The Office of Health Care Quality should continue to emphasize to its licensees that its surveys will give priority attention to evidence of appropriate pain assessment and management and should train its surveyors to be particularly vigilant about this aspect of quality care.

RECOMMENDATION 7-3: The associations representing nursing homes should give priority to educational efforts to convey best practices in pain assessment and management, with particular emphasis on tools that permit pain in people with AD to be measured and documented (by, for example, consistent observation of well-defined aspects of breathing, vocalization, facial expression, and body language).

B. Assisted Living Regulation

1. *Current law*

The essence of assisted living is captured by the Maryland Code's definition of "assisted living program":

> A residential or facility-based program that provides housing and supportive services, supervision, personalized assistance, health-related services, or a combination thereof that meets the needs of individuals who are unable to perform or who need assistance in performing the activities of daily living or instrumental activities of daily living in a way that promotes optimum dignity and independence for the individuals.[15]

Under basic consumer protection principles, advertising claims should be supported by actual practice.

The list of licensed assisted living facilities in Maryland is 100 pages long, covering more than 1100 sites with sizes ranging from homes with but one bed to facilities with more than 100 beds.[16] It has been estimated that 18,000 to 20,000 Marylanders reside in these facilities,[17] of whom perhaps two-thirds have AD.[18]

Assisted living programs must be licensed for one of three levels of care and are subject to the Department's quality standards.[19] Under the Department's regulations, people with AD (like other assisted living residents) are to be assessed for their physical condition, medical status, and level of functioning.[20] A resident would ordinarily enter a program licensed for a level of care that corresponds to the resident's needs, unless the Department grants a "resident-specific level of care waiver."[21]

Overall issues concerning the regulation of assisted living, which are numerous, complex, and contentious (Assisted Living Workgroup 2003), are beyond the scope of this report. Importance guidance on these issues is likely to come from the work of the Assisted Living Advisory Workgroup within the Department of Health and Mental Hygiene. Its final report is nearing completion and will include recommendations, among others, on "quality standards for specialized assisted living facilities, including facilities with Alzheimer's units."[22] We limit our consideration to one specific topic recently addressed by the Maryland General Assembly.

2. Advertising of special AD care.

Many assisted living facilities, especially larger ones, advertise that they offer special care for people with AD. For example, one multi-site provider speaks of facilities for people with mild AD that offer "special attention to physical building layout, safety, and decor." This provider also offers facilities for people with more advanced AD, which are said to reflect

expert help in the design of "every detail of the program from decor to activity, therapy and dietary programs." Claims like these are intended to reassure family members that their loved ones can "age in place" and yet receive appropriately tailored (albeit more costly) services as AD takes its toll over time.

Under basic consumer protection principles, advertising claims should be supported by actual practice. To help prospective residents and their family members understand what underlies claims about special AD care, a statute that became effective on October 1, 2002, requires that a facility with an "Alzheimer's special care unit or program" disclose a written description of the unit.[23] This description is to include, among other elements, the facility's "assessment and care planning protocol," staffing patterns, special design features, and "any services, training, or other procedures that are over and above those that are provided in the existing assisted living program."[24] We are unaware of any data, however, on the extent to which there is genuine consistency among advertising claims, representations in disclosure statements, and actual practice.

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RECOMMENDATION 7-4: As resources permit, the Office of Health Care Quality should conduct or sponsor a study to determine whether advertising claims about special AD care are consistent with descriptions in disclosure statements and whether both are consistent with services actually delivered.

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Endnotes

1. Health-General Article, §§ 19-318(a) and 19-327(a)(2).

2. Health-General Article, § 19-308(a).

3. 42 C.F.R. § 483.1(b).

4. COMAR10.07.02.05A.

5. 42 C.F.R. § 488.110.

6. COMAR10.07.02.12S.

7. COMAR10.07.09.08C(11).

8. The decision of an administrative law judge upholding OHCQ's finding of a deficiency and imposing of a $10,000 civil penalty is available at the following address: www.dhmh.state.md.us/ohcq/ download/alj.pdf (accessed August 7, 2003).

9. 42 C.F.R. § 483.35; COMAR 10.07.02.13E.

10. 73 Op. Att'y Gen. 162, 206 (1988).

11. Op. Att'y Gen. No. 00-029 (November 16, 2000).

12. http://www.chcr.brown.edu/dying/mdprofile.htm#Pain (accessed August 7, 2003).

13. Letter from Assistant Attorney General Jack Schwartz to Ms. Becky Sutton (March 5, 1999), available at http://www.oag.state.md.us/Healthpol/pain.pdf (accessed August 7, 2003).

14. COMAR10.07.02.10G(2) and (3)(a).

15. Health-General Article, § 19-1801(1).

16. http://www.dhmh.state.md.us/ohcq/listings/web_alp.pdf (accessed August 7, 2003).

17. http://www.manpha.org/ (accessed August 7, 2003).

18. Unpublished data from the Maryland Assisted Living Study, conducted by researchers at the Johns Hopkins University. Available at: http://www.dhmh.state.md.us/ohcq/alwrkgrp/ june9.htm (accessed January 4, 2004).

19. Health-General Article, § 19-1805(a)(2) and (5).

20. COMAR10.07.14.09.

21. COMAR10.07.14.09A and 10. To obtain a waiver, an assisted living facility "must demonstrate that it has the capability of meeting the needs of the resident ...." COMAR10.07.14.10B.

22. Chapter 102 of the Laws of Maryland 2003, Section 4.

23. Health-General Article, § 20-109(c) and (d). Under proposed regulations, the description would be disclosed to "the family or other party responsible for any resident before admission of the resident to the Alzheimer's special care unit or program," as well as to any other person on request. Proposed COMAR 10.07.14.06E(2), published for comment at 30 Md. Reg. 429 (March 21, 2003).

24. Health-General Article, § 20-109(e).