HEALTH) CRIMINAL LAW) PALLIATIVE CARE IN NURSING HOMES) USE OF OPIOIDS FOR PAIN MANAGEMENT

March 5, 1999

Ms. Becky Sutton
Administrator
Hartley Hall Nursing Home
1006 Market Street
Pocomoke City, Maryland 21851

Dear Ms. Sutton:

I am writing to address concerns you have expressed about the legal context within which a nursing home provides palliative care to terminally ill residents. One general concern, as I understand it, is whether a nursing home has any regulatory obligations in this regard. A more specific concern is whether the use of opioids in the management of pain carries with it a risk of criminal prosecution for homicide if the resident died while receiving opioids. In brief, my responses are as follows: Under the State regulations applicable to nursing homes, every terminally ill nursing home resident should receive pain and symptom management that is consistent with sound medical practice and the resident's plan of care. Moreover, criminal liability for homicide cannot be imposed on health care providers who prescribe or administer clinically justified opioid analgesia for the purpose of relieving properly documented pain.

I

Regulatory Background

As a condition of licensure, all nursing homes are required to comply with standards for the care of patients adopted by the Secretary of Health and Mental Hygiene. §19-308(a) of the Health-General Article, Maryland Code. The administrator of a nursing home is "responsible ... for compliance with applicable laws and regulations." COMAR 10.07.02.07A(1). A resident's attending physician is required to "prescribe a planned regimen of total resident care which is adequate and appropriate to meet the needs of the resident." COMAR 10.07.02.10G. In addition, "pharmaceutical services shall be provided in accordance with accepted professional principles and appropriate federal, State, and local laws." COMAR 10.07.02.15A. Among the records to be kept for a resident is "documented evidence of assessment of the needs of the patient, of establishment of an appropriate plan

of initial and on-going treatment, and of the care and services provided." COMAR 10.07.02.20B(3).

The regulations require a care planning process intended to assess the medical needs of the resident. "The care plan shall address all of the resident's special care requirements necessary to improve or maintain the resident's status." COMAR 10.07.02.37B(1). Further, the interdisciplinary team completing the care plan shall "establish goals for each problem or need identified. The goals shall be realistic, practicable, and tailored to the resident's needs." COMAR 10.07.02.37B(2). Under the Nursing Home Residents Bill of Rights, a resident is entitled to "receive treatment, care, and services that are in an environment that promotes maintenance or enhancement of resident's quality of life." COMAR 10.07.09.08A(2). Finally, a nursing home is required to "develop and implement policies and procedures prohibiting ... neglect of residents," COMAR 10.07.09.15A, and "neglect" is defined to mean "failure to provide goods and services necessary to avoid physical harms, mental anguish, or mental illness." COMAR 10.07.09.02A(17).

While some commentators have suggested that rehabilitation, rather than palliation, is the traditional model for nursing home care,[1] the regulatory provisions cited above, separately and taken as a whole, require that nursing homes in Maryland respond with appropriate palliative care measures, including pain management, for residents.

According to a recent Institute of Medicine report, "Several studies of nursing home patients have reported that from 40 percent to over 80 percent of ... patients have pain." Marilyn J. Field and Christine K. Cassel (eds.), *Approaching Death: Improving Care at the End of Life* 128 (1997) (hereafter cited as *IOM Report*). For these patients, the regulatory requirements for decent care cannot be satisfied if pain is markedly under treated. Allowing pain, dyspnea, and other symptoms like constipation and nausea to remain poorly controlled would be inconsistent with improving or maintaining the resident's status and would create an environment that fails to promote maintenance or enhancement of the resident's quality of life. These are clear harms that, under the regulations, must be prevented.

II

Opioid Use in Pain Management

A. Clinical Considerations

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[1]*See e.g.*, Timothy S. Jost, *Public Financing of Pain Management: Leaky Umbrellas and Ragged S'afety Nets*, 26 J. of Law, Medicine & Ethics 290 (1998).

The literature on pain management establishes that opioid analgesics are often an essential component in the management of acute and chronic pain that fails to respond to nonopioid analgesics.[2] "[T]he analgesic effectiveness of the nonopioid drugs is limited by a ceiling effect, that is, escalation of the dosage beyond a certain level does not produce additional analgesia." Robert E. Enck, *The Medical Care of Terminally Ill Patients* 96 (1994). When the "ceiling effect" occurs, opioid analgesics are the next step.

Because of individual differences, the appropriate amount (and type) of opioids will vary from patient to patient; the therapeutic objective is to establish the amount needed to relieve documented pain, dyspnea, or other uncomfortable symptoms commonly experienced during the dying process. This amount will likely vary over time. According to the pertinent medical literature, determining the appropriate level of opioid dosing for particular patients requires careful attention to their clinical histories. For example, a dosing level that is appropriate for patients who have not been taking opioids may be ineffective for patients whose pain management regimen already includes opioids. Knowledgeable clinicians recognize that titration is essential to assure an appropriate level of opioids to manage the pain of particular patients. Careful titration, based on documented symptoms, is recognized as the key to the proper and effective use of opioids to relieve the pain of terminally ill patients.

Some health care providers and patients have avoided opioid analgesics because of a fear of addiction. There is a recognized difference, however, between drug tolerance and dependence, on the one hand, and drug addiction, on the other hand.[3] Tolerance is a normal *physiological* change that a person develops after frequent doses of opioids and certain other medicines. Opioid dependence, also *physiological* in nature, is the state of being tolerant to opioids; it is a normally expected condition in a person being treated with opioids and can be ameliorated by appropriate medical and pharmacological management. By contrast, addiction is a *psychological and behavioral syndrome* characterized by loss of control over drug use, compulsive drug use, and continued drug use despite the harm that the use causes. Although drug addiction is a grave social problem, drug tolerance and dependence experienced by terminally ill patients with accompanying pain is not an issue of addiction.

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[2]*See generally, e.g.*, Agency for Health Care Policy and Research, *Management of Cancer Pain* (1994); American Pain Society, *Principles of Analgesic Use in the Treatment of Acute Pain and Cancer Pain* (3d ed. 1992), Russell K. Portenoy, *Palliative Care of the Elderly Oncology Panent: Focus on Pain Management*, 11 Oncology Case Reports and Review, No. 3 (1996).

[3]*See* Maryland Board of Physician Quality Assurance, *Prescribing Controlled Drugs*, 4 Maryland BPQA Newsletter No. 1, at 2 (March 1996). *See generally* IOM Report at 193.

B. Criminal Liability

"At the common law, to which the inhabitants of Maryland are entitled, ... homicide is the killing of a human being by another human being; criminal homicide is homicide without lawful justification or excuse; and criminal homicide with malice aforethought is murder ...." *Jackson v. State*, 286 Md. 430, 435, 408 A.2d 711 (1979). A health care provider or other person who administers a drug to a patient in order to kill the patient would be chargeable with murder. See 78 *Opinions of the Attorney General* (1993) [Opinion No. 93-036, at 2 (September 8, 1993)].

A health care provider, however, who prescribes or administers opioids for the purpose of relieving pain or other symptoms, following appropriate medical practice in terms of titration and documentation, is not guilty of criminal homicide, even if the patient dies during the course of treatment. First, opioid use might not have actually contributed to the death. Although respiratory depression can be a side effect of opioid therapy, it "usually occurs with the acute administration of morphine to an opioid-naive patient. Rarely, patients being treated chronically with opioids develop respiratory depression ...." Enck, *The Medical Care of Terminally III Patients* at 105. Therefore, prosecutorial concerns about potential criminal misconduct should not be based solely on opioid levels in the blood. A level of opioids that appears high in the abstract must be considered in its clinical context.

Second, even if respiratory depression from opioid use was a cause of death, that unwanted, albeit foreseeable, side effect does not give rise to criminal liability when the intent underlying the opioid administration is a therapeutic one) to provide palliative care in accordance with proper clinical standards. As the Supreme Court observed in a related context, "just as a State may prohibit assisting suicide while permitting patients to refuse unwarranted life-saving treatment, it may permit palliative care related to that refusal, which may have the foreseen but unintended 'double effect' of hastening the patient's death." *Vacco v. Quill*, 117 S. Ct. 2293, 2301 n. ll (1997). Indeed, serious constitutional issues would arise "were State law to prevent the provision of palliative care, including the administration of drugs as needed to avoid pain at the end of life ...." *Washington v. Glucksberg*, 117 S. Ct. 2302, 2312 (Breyer, J. concurring). *See also* 117 S. Ct. at 2303 (O'Connor, J. concurring). As one scholar observed in a study of this topic, "physicians and nurses who provide good palliative care to patients have little to fear from the criminal law." Ann Alpers, *Criminal Act or Palliative Care? Prosecutions Involving the Care of the Dying*, 26 J. of Law, Medicine & Ethics 308, 311 (1998).

III

Conclusion

Nursing homes that competently use opioids and other analgesics to control pain in terminally ill patients meet their regulatory responsibilities and do not risk criminal liability for homicide, even if a resident dies while receiving opioid analgesia, so long as the opioids have been provided in accordance with good clinical practice. Indeed, nursing homes that currently do not have that competence should take steps to acquire it, so as to meet their regulatory obligations toward patients in their final stage of life.[4]

I hope that this letter responds to your concerns and reinforces your desire to provide the best possible care to all of your residents.

Very truly yours,

Jack Schwartz
Assistant Attorney General
Director, Health Policy Development

[4]For example, many nursing homes choose to work with hospices in their communities to develop comprehensive end-of-life care plans that include clinically appropriate pain management for their terminally ill residents. *See generally* National Hospice Organization, *Nursing Home Task Force Report* (1998).