Loyola University Chicago Law Journal

Volume 20
Issue 3 *Spring 1989 Health Care Law Symposium*

Article 5

1989

Risk Management in Home Health Care: Focus on Patient Care Liabilities

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I. INTRODUCTION

The delivery of health care has undergone drastic changes in the last twenty years. The hospital, once occupying a pivotal role in in-patient health care, has been relegated to a lesser, though nonetheless still important, position. Replacing hospitals in the scheme of health care delivery are alternative delivery systems, including home health care agencies.[1]

As an alternative delivery system, home health care agencies have proliferated. During the past five years, the number of Medicare-certified and non-Medicare-certified agencies have more than doubled.[2] Additionally, home health agencies have become the fastest growing category of Medicare-fund providers.[3] During 1983, home health care accounted for 1.7% of the nation's total health expenditures.[4]

Although providing care in the home is not a new idea,[5] the cur-

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1. M. MUNDINGER, HOME CARE CONTROVERSY: TOO LITTLE, TOO LATE, TOO COSTLY 365 (1983). For the purposes of this Article, home health care is defined as:

> [T]hat component of a continuum of comprehensive health care whereby health services are provided to individuals and families in their places of residence for the purpose of promoting, maintaining or restoring health, or of maximizing the level of independence, while minimizing the effects of disability and illness, including terminal illness. Service appropriate to the needs of the individual patient and family are planned, coordinated, and made available by providers organized for the delivery of home care through the use of employed staff, contractual arrangements, or a combination of the two patterns.

Id.

2. Tehan & Colegrove, *Risk Management and Home Health Care: The Time is Now*, 12 QRB 179 (1986) (citing J. Williams, Home Health Services: An Industry in Transition, Medicare Data (Oct. 1985)).

3. *Id.* (citing Note, *Home Health Care for the Elderly: Programs, Problems and Potential*, 22 HARV. J. ON LEGIS. 193, 200 (1985)). This growth has taken place despite the fact that Medicare payments to home health care agencies only total approximately 2% of Medicare's expenditures. *Id.*

4. *Id.*

5. The first community health nursing service was founded in Liverpool, England in the mid-19th century. In the United States, home health care nursing was carried out mainly by Visiting Nurse Associations and governmental-based public health depart-

rent growth and the present character of home health care delivery are unprecedented. Coinciding with the rapid growth of the industry has been the need of the home health care agency to deal with complex patient care issues, for example: patients on assisted ventilator support and the administration of chemotherapy in the home; organizational structuring concerns; and the constantly changing state and federal laws that impact on the delivery of health care. These and other novel factors have created a concern about controlling the potential legal liabilities faced by home health care agencies. Although it appears that alternative delivery systems in general, and home health agencies specifically, have been, for all practical purposes, spared the experience of defending medical liability cases,[6] it is certain that this state will not continue indefinitely.

Prudence dictates that the areas of legal liability be identified and a comprehensive risk management program, including an analysis, a plan of prevention, and an overall evaluation of identified potential liabilities, be established. A sound risk management program can be cost effective, improve the overall quality of care delivered, and, at the same time, protect the agency from lawsuits.

This Article will explore one potential area of legal liability for home health care agencies, that of patient care. Four major areas of patient care risk management are analyzed: scope of practice issues; documenting the care given; patient and family safety; and consent for treatment.

II. BACKGROUND: PATIENT CARE LIABILITIES

A. Scope of Practice Issues: The Statutory Basis For Nursing Practice

All health care delivery systems must be concerned that professionals administer care in accordance with state statutes and/or rules governing their practice. The home health agency is no different. What is unique to the home care industry is that the agency's employee's do their jobs in patient's homes rather than in

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ments during the first half of the 20th century. *See generally* S. STUART-SIDDALL, HOME HEALTH CARE NURSING: ADMINISTRATIVE AND CLINICAL PERSPECTIVES XV AND XVI (1986).

6. *Id.*; Crompton, *Alternative Delivery Systems, Risk Management and the Law*, 17 CUMB. L. REV. 357, 370-71 (1987). Of 25 alternative delivery system providers surveyed in Alabama, five of which were home health care agencies, 76% reported that no negligence actions had been filed against them, and 26% reported less than five actions against them. The two most common liability concerns were negligence and breach of confidentiality.

a central location. As a result, the agency faces different problems in monitoring and supervising the manner in which that care is being provided.[7] Even so, ensuring that professional practice statutes are adhered to must be a constant concern of the home health care agency.

Scope of practice concerns can be divided into two major areas: professional practice and para-professional practice.[8] Because a variety of health care actors can give home health care services, the agency must carefully control the respective practice issues and the interplay among the two major groups of providers.

The largest member group in the professional practice area is the nursing staff. Its composition and responsibilities are governed by various accreditation provisions, licensure requirements for the agency, and Medicare Conditions of Participation.[9] An additional external source of control over the nursing staff is a state's nursing practice act, which normally will define the scope of nursing practice, delineate the manner in which a nurse may be disciplined, and limit the practice of professional nursing and practical nursing to those who are licensed to do so.[10]

Both Medicare-certified agencies, which provide only skilled nursing care,[11] and non-certified agencies, which provide both

7. Crompton, *supra* note 6, at 370-71. Barhydt-Wezenaar, *Home Care and Hospice Care* in HEALTH CARE DELIVERY IN THE UNITED STATES 237, 241 (3d ed. 1986). Home care services include, but are not limited to, skilled nursing care, home health aide services, physician services, occupational, speech and physical therapy, and the provision of medical supplies and drugs.

8. Professional practice, for the purpose of this Article, is defined as the practice of nursing as it is defined in a state's practice act. Para-professional practices include those not licensed by the state and its nurse practice act as nurses. Examples include a home-health aide or homemaker.

9. 42 C.F.R. § 405.1201 (1987). Although a detailed analysis of the external requirements impacting on the nursing staff's role is beyond the scope of this Article, several accrediting requirements include the Joint Commission on the Accreditation of Health Care Organization's Standards for Home Care, the National League for Nursing ("NLN") criteria, the American Nurses' Association ("ANA") Standards of Home Health Nursing Practice, and state home health agency licensing laws.

10. *See infra* notes 11-24 and accompanying text.

11. 49 Fed. Reg. 128, 272, 286 (1984). Other reimbursable services include physical therapy, speech pathology, medical social services, home health aides, and occupational therapy. *Id.* Examples of skilled nursing services include, but are not limited to, patient and family teaching, intravenous therapy, dialysis, and respiratory care. S. STUART-SIDDALL, *supra* note 5, at 5. *See also* A. HADDAD, HIGH TECH HOME CARE: A PRACTICAL GUIDE 4 (1987). Intravenous therapy involves introducing fluid and other necessary treatment, such as medications, into the patient's venous system when the patient may not be able to benefit from the treatment by mouth or when the medication cannot be administered by mouth, such as when chemotherapy is instituted. *Id.* at 8. Renal dialysis of a patient involves the use of a machine which functions as the patient's kidneys when the latter can no longer excrete urine from the body. The dialysis machine cleanses

skilled and un-skilled nursing services, must adhere to state nursing practice acts. Although nursing practice acts vary considerably from state to state,[12] all contain definitions of professional[13] and practical[14] nursing that determine for each state the scope of care possible.

In addition to complying with the definition of professional and practical nursing in a state, the registered professional nurse and the licensed practical nurse, or licensed vocational nurse as he/she is called in some states, also must adhere to the rules and regulations promulgated by the state agency formed to enforce the nursing act. For example, Illinois' Department of Professional Regulation, in conjunction with its Committee on Nursing, has adopted rules and regulations to implement the Illinois Nursing Act.[15] The Illinois rules enumerate specific tasks that a licensed practical nurse is permitted to perform concerning medication administration (after successfully completing an approved course in pharmacology and the administration of medicines), and contain

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the patient's blood from the impurities present in it due to the non-functioning of the kidneys and their inability to serve in this necessary role. TABER'S CYCLOPEDIC MEDICAL DICTIONARY 493-94 (16th ed. 1989).

12. For a comparison of nursing practice acts, see C. LABAR, STATUTORY DEFINITIONS OF NURSING PRACTICE AND THEIR CONFORMITY TO CERTAIN ANA PRINCIPLES (1983).

13. For example, the Illinois Nursing Act of 1987 defines professional nursing as follows:

> 'Professional nursing' includes all its specialties and means the performance for compensation of any nursing act, (1) in the nursing evaluation, observation, care and counsel of the ill, injured, or infirmed; (2) in the maintenance of health or prevention of illness of others; (3) the administration of medications and treatments as prescribed by a licensed physician, dentist or podiatrist; or (4) any act in the supervision or teaching of nursing, which requires substantial, specialized judgment and skill the proper performance of which is based on knowledge and application of the principles of biological, physical, and social sciences acquired by means of a completed course in an approved school of professional nursing. The foregoing shall not be deemed to include those acts of medical diagnosis or prescription properly performed only by physicians licensed in the State of Illinois . . . .

ILL. ANN. STAT. ch. 111, para. 3503(l) (Smith-Hurd Supp. 1989).

14. For example, the Illinois Nursing Act of 1987 defines practical nursing as follows:

> 'Practical nursing' means the performance, for compensation of acts in the care of the ill, injured, or infirmed, selected by and performed under the direction of a registered professional nurse, licensed physician, dentist, or podiatrist, requiring the basic nursing skill, judgment, and knowledge acquired by means of a completed course of study in an approved practical nursing education program.

ILL. ANN. STAT. ch. 111, para. 3503(j) (Smith-Hurd Supp. 1989).

15. ILL. ADMIN. CODE tit. 68, §§ 300.1 to 300.5 (1988). These rules and regulations are currently being revised, probably because of the recent passage of the Illinois Nursing Act of 1987.

standards of conduct for both the registered professional and licensed practical nurse. If breached, the standards of conduct could be grounds for disciplinary action. The standards include the proper delegation of professional responsibilities for the registered nurse, and require the licensed practical nurse to perform only those nursing activities permitted by law and for which she is educationally prepared.[16]

Thus, the nurses on staff at a home health care agency must be certain that they are performing in accordance with the state act and its rules and regulations. If required, a registered nurse must supervise the licensed practical nurse providing care in the home. The licensed practical nurse should not be performing tasks that only a registered nurse can properly do in a given situation.[17]

In addition to conforming to the nursing act, both professional registered nurses and licensed practical nurses must not violate any other state professional practice statutes, such as a state's medical practice act or its pharmacy act. All state medical practice acts require a person practicing medicine to have a license. Therefore, a registered or licensed practical nurse who performs medical care, as opposed to nursing care, can violate the medical practice act in those situations where the act requires a license to practice medicine. One area that is often troublesome for nurses in ensuring they are practicing nursing and not medicine centers on the administration of medications and treatments. Unless a state nursing practice act allows nurses to prescribe medications and/or treatments under certain conditions,[18] she/he may be charged criminally with practicing medicine without a license, and may face disciplinary action by the board of nursing or state agency. Nurses may also gain prescriptive authority by respective state boards of nursing and medicine or state agencies agreeing to allow nurses to prescribe medications and treatments by developing joint opinions on such practice.[19]

Similar concerns exist for the registered nurse and licensed prac-

16. *Id.* §§ 1300.42 to 1300.431.

17. For example, in Illinois a licensed practical nurse is not trained, as part of the required pharmacology course, to add medications to existing intravenous infusions or to start or add blood or blood components. *Id.* § 1300.44. Performing nursing activities outside the scope permitted by law and for which one is educationally prepared can result in actions by the Department against the licensed practical nurse for unethical, dishonorable, or unprofessional conduct. *Id.* §§ 300.43(e), 300.43(j).

18. As of 1986, 19 states allowed certain nurses to prescribe certain medications and drugs. See LeBar, *Filling in the Blanks on Prescription Writing*, AM. J. NURSING 30-34 (Jan. 1986).

19. For a discussion of joint practice statements and their effect on liability for negli-

tical nurse in relation to the state pharmacy act. In most states, a license is required to practice pharmacy. Although varying from state to state, the practice of pharmacy may be defined as "the compounding, dispensing, recommending or advising concerning contents and therapeutic values and uses" of drugs and medicines.[20] Therefore, nurses providing home care must not prescribe, recommend, or dispense drugs and medicines unless either the nursing act or joint opinions allows such conduct.

A second area of liability for the professional registered and licensed practical nurse involves the para-professionals who the nursing staff supervise, specifically the home health aide. Whenever the home health aide is providing "hands on" care, including ambulation assistance, personal care, and reporting any changes in the patient's condition, the registered nurse must supervise that aide, according to both the state nursing practice act, and, for those agencies that are Medicare certified, its Conditions of Participation.[21] The professional registered nurse must be certain not to assign to the home health aide those tasks that can only be done by a registered or licensed practical nurse, and they also must use the state nursing practice act's definition of those two areas of practice as a guide. For example, the licensing agency may view the permitting of a home health aide to administer medications or give an injection as assisting in the unauthorized practice of nursing. Most nursing practice acts impose criminal penalties on violators and contain a section under which a registered nurse or licensed practical nurse may be disciplined for assisting an individual to do so.[22] Delegation is just as important with the aide as it is when dividing tasks between licensed nursing personnel.

The home health care agency also faces potential liability when allegations of the unauthorized practice of a health care professional surface. State nursing practice acts contain provisions prohibiting an employer from employing unlicensed individuals to practice nursing or practical nursing.[23] Research conducted in 1983 in ten states[24] indicated that out of thirty-six violations relat-

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gent care in California, see Kelly & Garrick, *Nursing Negligence in Collaborative Practice: Legal Liability in California*, 12 L., MED. & HEALTH CARE 260 (1984).

20. ILL. ANN. STAT. ch. 111, para. 4123(d) (Smith-Hurd Supp. 1989).

21. 42 C.F.R. § 405.1201 (1987).

22. The state nursing practice acts of Illinois, Nevada, Nebraska, and New York contain such a provision. For a review of state nursing practice acts, see C. LEBAR, ENFORCEMENT OF THE NURSING PRACTICE ACT (1986).

23. As of 1986, 13 state practice acts contained such provisions. *Id.* at 18-20.

24. These states included Arizona, Illinois, Minnesota, Mississippi, New Jersey, Missouri, Oklahoma, South Carolina, Utah, and Virginia. *Id.* at 34.

ing to the category of nursing licensure, practicing without a current license (29) and exceeding the scope of practice (2) were two of the most frequent incidents in that category handled by those state licensing bodies.[25] The licensure violations accounted for nine percent of the total actions taken during that year in the states studied.[26]

B. Documentation of Patient Care Given

Documentation of patient care given is vitally important to any health care delivery system, not only in terms of reimbursement, but also to reduce liability. Professional and para-professional staff must document completely, clearly, accurately, and timely in the home care record the care given, patient reaction to that care, communication to other health professionals (particularly the physician), and changes in the patient's condition. Although not all inclusive, this and other information are necessary to verify that care was provided in a safe, effective manner and was consistent with the professional's standard of care.[27]

There are, however, additional reasons why the home health agency and its staff must be concerned with documentation, and these reasons arise due to the unique nature of providing health care in the patient's home. Because home health care is provided by a multi-professional and para-professional team, services must be coordinated. If all services are rendered by one home care agency, coordination is feasible. Most often, however, several agencies may be providing care to the patient, and each will need to document that care in the record. Gaps in documentation, duplication, or the absence of documentation are possible risks that the agency must anticipate and plan to avoid.

The home care agency may encounter other unique problems

25. *Id.*

26. *Id.*

27. Connaway, *Documenting Patient Care in the Home — Legal Issues for Home Health Nurses*, 3 HOME HEALTHCARE NURSE 6 (Sept.-Oct. 1985). The decision in Collins v. Westlake Community Hospital, 57 Ill. 2d 388, 312 N.E.2d 614 (1974) illustrates the importance of documentation. In *Collins*, a six-year-old boy was hit by a car and his leg was fractured. His leg was casted, and he was admitted to Westlake Hospital and placed in traction. The physician ordered that his patient's toes be observed closely and the observance recorded. Although the nurses testified that they did observe his condition, it worsened, and the affected leg had to be amputated. The medical record was devoid of any documentation concerning the assessment of the child's affected leg for a least a seven-hour period. The supreme court reversed the directed verdict rendered in favor of the defendant, stating that if there was no record of the assessments, the jury could have inferred that they were not made. *Id.* at 395, 312 N.E.2d at 617.

because physicians are almost never on-site. All communications with physicians must be done by telephone. Although telephone orders from physicians are acceptable, the documentation of physicians' orders and other communications with physicians, as well as other health care providers, must be made carefully. The inability of supervisors to oversee the care provided in every home also raises documentation concerns peculiar to the home care setting. Nevertheless, the agency must ensure that its supervisors sufficiently monitor the staff to guarantee that patients receive adequate and non-negligent care.

Patient and family teaching, a vital component of home health care nursing, must also be well-documented in the patient's medical record. Although no reported cases have occurred in which a plaintiff alleged negligent teaching by a home health care nurse, several have been reported in the acute care setting, mainly in the emergency department.[28] *Crawford v. Earl K. Long Hospital*[29] involved the lack of documentation in the emergency room record despite adequate instructions given orally by the emergency room nurse.[30] Because the nurse failed to record her instructions in the record, the deceased patient's administrator successfully alleged that no instructions were given. Thus, the case was kept alive until the judgment in favor of the hospital was upheld by the appellate court.[31]

Although educating patients and their families is an important part of home care nursing, controversy exists over whether a physician's order is necessary before nurses may instruct patients.[32] If

28. *See, e.g.*, Crawford v. Earl K. Long Memorial Hosp., 431 So. 2d 40 (La. Ct. App. 1983); LeBlanc v. Northern Colfax County Hosp., 100 N.M. 494, 672 P.2d 667 (N.M. Ct. App. 1983).

29. 431 So. 2d 40 (La. Ct. App. 1983).

30. *Id.* at 41.

31. *Id.*

32. The debate centers on whether teaching, especially about medication doses and alterations or treatment issues, is within the definition and scope of practice of nursing or must be ordered by a physician. *See* J. JACKSON & E. JOHNSON, PATIENT EDUCATION IN HOME CARE: A PRACTICAL GUIDE TO EFFECTIVE TEACHING AND DOCUMENTATION 6-7 (1988). Most state nursing practice acts include teaching in their definition of nursing practice. C. LABAR, *supra* note 12. The best known case dealing with this issue is Tuma v. Board of Nursing, 100 Idaho 74, 593 P.2d 711 (1979), where nurse Tuma discussed the alternative treatment of Laetrile with her patient who was scheduled for chemotherapy. The physician, unhappy that the discussion had taken place, reported Tuma to the board of nursing, which suspended her license for six months. *Id.* at 76-77, 593 P.2d at 713-14. Upon review by the Idaho court of the Board's decision, her license was restored. *Id.* at 83, 593 P.2d at 720. The court did state, however, that Tuma should have discussed her decision to share the Laetrile treatment option with the physician before doing so with the patient. *Id.*

not approved or ordered by the physician, but documented as having been done, the agency and nurse may face problems with the state's licensing agency for the unauthorized practice of medicine if the teaching involved alteration of medicines, drugs, or other treatments.

C. Safety of Patient and Family in the Home

The use of high-tech equipment in home care is increasing on a regular basis. Although patients with poliomyelitis who were dependent upon respirators[33] have been cared for in the home for years,[34] the use of other types of highly technical equipment by home care providers has grown dramatically. This growth is probably due to a number of factors, including the advent of the home hospice movement in the United States,[35] Diagnostic Related Groupings,[36] and other cost containment measures aimed at curtailing the spiraling costs of providing care, especially in the long-term and institutional setting. In addition, recent scientific and technological advances in the development of health care equipment have aided this growth. Currently, the common advanced therapies provided by home health care agencies include dialysis, intravenous therapy, respiratory care,[37] biotelemetry services,[38]

33. Poliomyelitis, inflammation of the gray matter of the spinal cord, often results in a paralysis or weakness of muscle groups, including those involved in breathing. TABER'S CYCLOPEDIC MEDICAL DICTIONARY 1438-39 (16th ed. 1989). A respirator or ventilator is a machine that takes over the breathing function of an individual when that person cannot breathe naturally and, therefore, needs mechanical help to do so. *Id.* at 1587-88.

34. A. HADDAD, *supra* note 11, at 1 (citing Affeldt, *Prognosis for Respiratory Recovery in Severe Poliomyelitis*, 38 ARCHIVES PHYSICAL MED. & REHABILITATION 290 (1957)).

35. Hospice care is tailored for terminally ill patients and their families to aid the dying person in meeting death with dignity. Hospice programs exist in both institutional and home settings, the latter being helped greatly by the Consolidated Omnibus Budget Reconciliation Act of 1985, which made the Medicare hospice benefit a permanent one. Barhydt-Wezenaar, *supra* note 7, at 259. Because the focus of hospice care is the terminally ill patient, a variety of diagnoses are seen, including cancer, end-stage cardiac disease, and amyotrophic lateral sclerosis ("Lou Gehrig's Disease"). *Id.* at 258 (citing Maloney, *How Hospices Ease Last Days of the Dying*, U.S. NEWS & WORLD REPORT, Feb. 11, 1985, at 70).

36. Diagnostic Related Groupings ("DRGs") were initiated to aid in reducing the costs of health care paid by third-party payors, such as insurance companies. DRGs limit reimbursement to health care providers to a fixed amount per diagnosis, rather than reimbursing the provider for the actual costs of care provided to the patient. Although many private third-party payors utilized DRGs before 1982, Medicare began doing so in 1982. *See generally* P. GRIMALDI & J. MICHELETTI, DIAGNOSTIC RELATED GROUPS: A PRACTITIONER'S GUIDE (1983).

37. Respiratory care in the home involves many treatments, including the utilization of oxygen, inhalation therapy, and ventilator support. A. HADDAD, *supra* note 11, at 5.

38. Biotelemetry is the use of electrical equipment to measure, transmit, and receive

and parenteral/enteral nutritional therapy.[39]

The use of highly technical equipment in the home raises many concerns, one being the safety of the patient and the family. Not only must nursing personnel be skilled in providing care with the use of the equipment, they must teach and train any para-professionals who will be working with the equipment to do so in a safe manner. Similarly, family members who are involved as care-givers need to be trained to use that same equipment. Thus, liability for negligent teaching, should an injury occur to the patient due to a failure to properly teach or train others, is a concern for the home health care agency.

Equipment failure is another safety concern for the agency. The presence of additional equipment and personnel in the institution allows for swift resolution of equipment difficulties. In the home, however, equipment failure is more likely to result in injury or death because of the lack of additional equipment and staff support.

Concurrent with the growth of highly technical equipment in the home is the growth of the types of treatments administered in the home setting. Even chemotherapy is administered in the home.[40] The use of chemotherapy in the home setting for cancer patients has been supported by three factors: the benefit of continuous infusion of chemotherapeutic agents; the decreased cost of providing the care in the home; and the psychological benefit to the patient of receiving care in the home versus the hospital setting.[41] Nevertheless, the agency should consider its potential liability in deciding to render chemotherapy in the home. For example, the registered

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bodily conditions when the individual being monitored is not immediately present. Monitoring cardiac functioning is often done by this method. TABER'S CYCLOPEDIC MEDICAL DICTIONARY 212 (16th ed. 1989). The patient may be placed on a cardiac monitor in the hospital or home setting, and a constant evaluation of cardiac status can occur by the health care provider without requiring the health care provider to be in the same physical location as the patient.

39. A. HADDAD, *supra* note 11, at 4. Parental therapy is the introduction of a nutritive material into the body by a route other than through the intestinal tract. In contrast, enteral therapy introduces the nutritive substance into the intestine. Common examples of both include the use of a catheter inserted into a vein and a feeding tube which carries the nutritive substance directly into the digestive system. *Id.* at 7.

40. Chemotherapy is the administration of chemical reagents that have a toxic effect on the underlying disease-causing micro-organism. TABER'S CYCLOPEDIC MEDICAL DICTIONARY 335 (16th ed. 1989). Chemotherapy is most often used for patients suffering from cancer that has spread throughout the body, and includes antineoplastic agents, which hinder the formation of new, malignant cells, and cytotoxic agents, which, when introduced into the body, destroy cells or prevent their multiplication. *Id.* at 115, 452.

41. Garvey, *Current and Future Nursing Issues in the Home Administration Of Chemotherapy*, 3 SEMINARS IN ONCOLOGY NURSING 142 (1987).

nurse administering the chemotherapy must carefully handle the chemotherapy to ensure her own safety and to safeguard against exposing family members to the antineoplastic agent(s). Similarly, the agency must devise safe procedures for handling used equipment, storing cytotoxic agents, and preparing the drugs.[42]

The control of infections, especially nosocomial infections,[43] is a vital component of any health care delivery system. Infection control is particularly important today with the increased incidence of Hepatitis[44] and AIDS.[45] Home health care is a significant factor in the lives of persons affected by HIV[46] because the care that is needed extends far beyond any initial hospitalization that occurs. The home health nurse must not only be concerned with her own safety and the safety of the para-professional staff, but also with minimizing the risk of infecting family members. In addition, the risk of exposing a patient whose immunological defenses[47] are compromised, such as the patient with AIDS or the patient receiving chemotherapy, to other possible infectious diseases creates additional infection control concerns for the home care agency.

D. Consent for Treatment / Refusal of Treatment

The right of a competent adult, or for one's legally appointed guardian, to give his informed consent for treatment has received support in courts and legislatures. Medicare regulations affecting long term care have required the informed consent of nursing home residents for some time.[48] The right to be fully informed of care and treatment, changes in that care, and the ability to participate in its planning will be required of home health agencies.[49]

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42. *Id.* at 144.

43. Nosocomial infections are those that are acquired in an institution, as opposed to those acquired elsewhere. *See* Chavigny & Helm, *Ethical Dilemmas and the Practice of Infection Control*, 10 L., MED. & HEALTH CARE 168 (1982).

44. Hepatitis is an inflammation of the liver caused by many agents, including viruses. TABER'S CYCLOPEDIC MEDICAL DICTIONARY 816 (16th ed. 1989).

45. The disease is also referred to as AIDS/AIDS-Related Complex ("ARC") or HIV infection. Patients with the disease are often called People With Aids or PWAs. A. LEWIS, NURSING CARE OF THE PERSON WITH AIDS/ARC 1 (1988). AIDS is defined as an immunodeficiency syndrome caused by the HIV virus. *See infra* notes 46 and 47.

46. HIV stands for the Human Immunodeficiency Virus which permits opportunistic infections and malignancies to form in the body. TABER'S CYCLOPEDIC MEDICAL DICTIONARY 53 (16th ed. 1989).

47. Immunological defenses are those mechanisms in the body that protect the individual from disease, especially infectious diseases. *Id.* at 894.

48. 42 C.F.R. § 405.1121(k) (1987).

49. Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 4001-4307, 101 Stat. 1330 (1987).

Most states have passed consent statutes, both specific to the nursing home setting and in relation to health care delivery generally, that support this right as well. And, with cases such as *Schloendorff v. Society of New York Hospital*,[50] *Salgo v. Stanford University Board of Trustees*,[51] and *Canterbury v. Spence*,[52] the right has become firmly rooted.

The right of informed refusal for treatment has traveled a much rockier course in courts and legislatures than has informed consent. Many of the early cases, such as *In re Quinlan*[53] and *In re Dinnerstein*,[54] presented the question of whether a guardian could refuse treatment for the patient. Many courts have held that a guardian could do so. Recent decisions have continued to underscore this right, and also have expanded the ability to refuse treatment to include refusing life-saving treatment, including food and fluids.[55]

State legislatures have adopted advance directive statutes, such as living will acts and durable power of attorney statutes,[56] to pro-

50. 211 N.Y. 125, 105 N.E. 92 (1914). The *Schloendorff* case is often cited as the "foundation of the modern doctrine of informed consent." A. ROSOFF, INFORMED CONSENT: A GUIDE FOR HEALTH CARE PROVIDERS 315 (1981). With Judge Cardozo presiding, the court held that every human, competent adult has a right to determine what will be done to his body and, when a surgeon performs surgery without the consent of the patient, that surgeon is liable for assault and subsequent damages. *Schloendorff*, 211 N.Y. at 129-30, 105 N.E. at 93.

51. 154 Cal. App. 2d 560, 317 P.2d 170 (1957). The *Salgo* court held that in order for consent for treatment to be valid, the patient giving consent must understand the treatment being consented to and its inherent risks. *Id.*

52. 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972). The *Canterbury* court held that the standard that would be examined in determining whether a physician explained the treatment to be undertaken adequately so that the patient's consent was truly "informed" would be what the patient would want to know, rather than what another physician in the same or similar circumstances would reveal. *Id.* at 780.

53. 70 N.J. 10, 355 A.2d 647, *cert. denied sub. nom.* Garger v. New Jersey, 429 U.S. 922 (1976), *overruled in part, In re* Conroy, 98 N.J. 321, 486 A.2d 1209 (1985).

54. 6 Mass. App. Ct. 466, 380 N.E.2d 134 (1978).

55. *See, e.g.*, Bouvia v. Superior Court, 179 Cal. App. 3d 1127, 225 Cal. Rptr. 297 (1986); Barber v. Superior Court, 147 Cal. App. 3d 1006, 195 Cal. Rptr. 484 (1983); *In re* Requena, 213 N.J. Super. 443, 517 A.2d 869 (1986) (per curiam). *See generally* Oberman, *Withdrawal of Life Support: Individual Autonomy Against Alleged State Interests in Preserving Life*, 20 Loy. U. Chi. LJ. 797 (1989).

56. *See* ILL. ANN. STAT. ch. 110, paras. 701, 804-1 (Smith-Hurd 1988). Living will acts and durable powers of attorney, also called advance directives, allow an individual to direct health care providers as to what treatment he wants initiated, withdrawn, or withheld in the event the person cannot speak for himself. The living will usually is operative in terminal situations, and it directs health care providers to withdraw or withhold treatments. A durable power of attorney for health care decisions, on the other hand, allows the person to appoint an agent to make decisions for him. It becomes operative upon any event the person so selects (not just a terminal condition), and can be used to continue or limit treatment. These legal mechanisms allow an individual to avoid the costly and

vide additional legal mechanisms for the individual to make treatment choices in advance of a physical or mental inability to do so. Advance directives vary from state to state, and legal challenges have included whether these are the sole means by which people may express their wishes concerning treatment or non-treatment[57] and whether a document which is not in conformity with the state statute can be honored.[58]

Because home health care agencies provide care to a variety of patients, including those who are terminally ill or suffering from diseases that may result in death, the importance of providing care with input from the patient is necessary. Providing care in conformity with a patient's wishes is easily followed, perhaps when there is no question about an advanced directive's validity or when one is present. Home health agency personnel, however, may be confronted with a home care situation where no advance directives have been executed or where the family is in disagreement over treatment the patient has elected to be performed or withheld. When the patient is a minor and the parents have decided that no life-sustaining treatment should be instituted, special concerns are raised. The home health care agency must anticipate the many situations it and its personnel will confront in the home surrounding consent and the refusal of treatment.

III. Risk Management Approaches to Decreasing Liability

A. Basic Concepts

The concept of risk management in health care is not new. In the acute care setting — the hospital — its importance gained in response to the medical malpractice crisis from 1973 to 1975 and the subsequent insurance crisis in which the insurance industry retreated from underwriting policies as payment for claims.[59] Risk

sometimes lengthy process of petitioning for the appointment of a guardian over the person to make such decisions. Nevertheless, the guardianship process still can be helpful, especially when the patient can no longer make treatment choices and has no advance directives. *See* M. Kapp, Working With Substitute Decisionmakers in Preventing Malpractice In Long Term Care: Strategies For Risk Management 113-37 (1987).

57. *See* Corbett v. D'Alessandro, 487 So. 2d 368 (Fla. Dist. Ct. App.), *review denied*, 492 So. 2d 1331 (Fla. 1986).

58. *See In re* Estate of Prange, 166 Ill. App. 3d 1091, 520 N.E.2d 946 (1st Dist.), *judgment vacated and opinion withdrawn*, No. 66947 (Ill. May 19, 1988).

59. Tehan & Colegrove, *supra* note 2, at 179. The malpractice and insurance crisis occurred when financial losses due to malpractice, workers' compensation, and other forms of tort liability reached an all-time high. State legislatures passed reforms to limit

management in home care is relatively new. Even so, liability insurance coverage for home care agencies is difficult to obtain, and many insurance carriers will not issue a policy unless the agency has adopted a formal system of reporting risks.[60]

Because a good risk management program can aid in the procurement of liability insurance, improve patient care, and decrease financial loss for the agency, a sound risk management program is crucial for the home health agency. Although it is clear that not all risks can be controlled or eliminated, the program should include four basic components: "risk identification, risk analysis, risk treatment, and risk evaluation."[61]

The first component, risk identification, not only includes the earmarking of potential risks based on the services to be provided, but also requires that the agency receive input from personnel in the form of "incident" or "occurrence" reports.[62] A well-developed policy about the use of occurrence reports, their importance to the agency, that they are not punitive in nature but are to help evaluate and, where needed, change patient care to ensure that it is being carried out properly and in accordance with standards of care, can increase their usefulness to the agency and its personnel. In addition, agency staff should be aware of the fact that an incident report can greatly aid the agency in preparing a case for trial should a suit be filed.[63]

Risk analysis, on the other hand, deals with the probability that a loss will occur, and looks at the number of losses, their fre-

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the ways in which such suits could be filed and to limit damage awards paid to injured plaintiffs. The immediate "crisis" appears to be over; however, there is a continuing concern in the insurance, legal, and medical communities over balancing financial loss (from the insurance industry), protecting access to the court system (from the legal arena), and avoiding inclusion in lawsuits (from the medical community). See Kraus, *Risk Management in the Future* in HEALTH CARE RISK MANAGEMENT: ORGANIZATION AND CLAIMS ADMINISTRATION 259-75 (1986).

60. Kraus, *supra* note 59, at 259-75. The discussion of insurance in this Article focuses on professional liability insurance. A home health agency has other insurance needs as well, including first-party insurance (fire and dishonesty insurance), third-party insurance (automobile and umbrella liability insurance), and life and health insurance for all employees. *See* Gill & Nels, *Insurance* in HANDBOOK OF HEALTH CARE RISK MANAGEMENT 183, 186-99 (1986).

61. Salman, *Risk Management Processes and Functions* in HANDBOOK OF HEALTH CARE RISK MANAGEMENT 149, 153 (1986).

62. *Id.* at 156. Incident or occurrence reports are utilized when an unexpected or unnatural consequence of the patient's treatment or disease takes place during treatment and is not a desirable result of optimal medical management. An example of an incident requiring a report to be filled out is when the wrong medication was given to a patient. *Id.*

63. *Id.* at 164.

quency, and the overall effect the losses would have on the agency, both "financially and clinically."[64] The analysis can take the form of a statistical or mathematical evaluation, the utilization of a risk management committee, or a combination of the two.

The third component, risk treatment, involves controlling risks/losses and risk financing.[65] Controlling risks or losses can be managed in a number of ways. One way in which it can be achieved is by emphasizing loss prevention, in other words, by instituting a system that attempts to prevent losses before they occur.[66]

When attempting to reduce risks in patient care, the focus must be on the agency staff members who provide the care. Concerning the four major areas of potential liability discussed in this Article, the home care agency can institute preventative measures to help control the risks of providing care.

B. Policies and Procedures and Job Descriptions

The first undertaking for the home care agency is the development of patient care policies and procedures. Policies and procedures serve as guidelines for patient care, provide a ready resource for the staff when unfamiliar with a procedure, and stand as a measure of control in terms of what is acceptable practice in the agency.[67] Because policies and procedures must be based on accepted standards of practice generally, many external sources exist to guide the home care agency in developing patient care policies and procedures.[68] Conformity with standards of care is essential because an agency's policies and procedures can be introduced into evidence in a professional negligence action to prove adherence to the agency's patient care requirements.[69] Moreover, accreditation bodies, including Medicare and the Joint Commission on the Accreditation of Health Care Organizations, require that policies and procedures be reviewed and evaluated.[70]

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64. *Id.* at 165.

65. *Id.* at 174.

66. *Id.*

67. Mech, *Quality Assurance and Documentation* in LEGAL ISSUES IN NURSING 453-54 (1987).

68. Some of those standards include, but are not limited to, those listed in American Nurses' Association Standards of Home Health Nursing Practice (1986); American Nurses' Association Standards and Scope of Hospice Nursing Practice (1987); National League for Nursing, Position Statement on Ensuring Quality in Home Health Care (1986).

69. Darling v. Charleston Community Hosp., 33 Ill. 2d 326, 211 N.E.2d 253 (1965), *cert. denied*, 383 U.S. 946 (1966).

70. 42 U.S.C. § 1395x(o)(2) (1982); 42 C.F.R. §§ 405.1222(a), 405.1229 (1987); Joint

Similarly, job descriptions need to be drafted and kept current with agency policy. Like policies and procedures, job descriptions provide a means of ensuring that only qualified staff are hired to care for patients, define respective patient care responsibilities, and fulfill accreditation requirements. Job descriptions can stand as proof that agency requirements concerning staffing were met should that question be raised in a professional negligence suit.[71]

In relation to scope-of-practice issues, the home health care agency must ensure that job descriptions are clear, well-defined, include any educational and experience requirements necessary to fulfill the respective positions in the agency, and meet respective federal and state regulations, licensing requirements, and accreditation standards.[72] Furthermore, the job description should be consistent with adopted policies and procedures concerning patient care. For example, because home health nurses must function on an independent basis when providing care, their educational preparation must support the ability to function in an expanded role. Thus, if an agency decides that a registered nurse with an associate degree can provide care in the home without nursing supervision, the agency is taking a risk in terms of potential liability for not providing adequately trained nursing personnel to deliver care to patients.

Adopted policies and procedures can also limit risks in terms of scope of practice issues by including in them only those tasks that respective nursing personnel can properly carry out. Listing the functions a licensed practical nurse can perform in the agency will support the authorized practice of nursing in the agency. Developing a policy mandating that only appropriately licensed nursing staff can administer medications and treatments conforms to Medicare Conditions of Participation[73] for Medicare-certified agencies,

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Commission on the Accreditation of Health Care Organizations Accreditation Manual for Hospitals HC 3 (1988).

71. In Darling v. Charleston Community Hospital, 33 Ill. 2d 326, 211 N.E.2d 253 (1965), *cert. denied*, 383 U.S. 946 (1966), the Illinois Supreme Court held that an institution's own policies and procedures could be introduced into evidence to prove conformity with them when negligence was alleged. Job descriptions can also be used in this manner. *See* National League for Nursing/American Public Health Association, Criteria and Standards Manual for Accreditation for Home Health Agencies and Community Nursing Services (7th ed. 1980); National League for Nursing/American Public Health Association, Policies and Procedures for Accreditation of Home Health Agencies and Community Nursing Services (1980).

72. *See supra* notes 66-68. *See also* Keating & Kelman, *Administration and Management of Home Care Agencies* in HOME HEALTH CARE NURSING: CONCEPTS AND PRACTICE 39, 51 (1988).

73. 42 C.F.R. § 405.1223(c) (1987).

and eliminates the concern that the agency supports the unauthorized practice of nursing. Similarly, adopting a policy concerning the use of physician-developed standing orders and written protocols[74] specific to individual nursing staff when providing care may also help the agency conform to the nursing practice act in its state.[75] Finally, a carefully drafted policy concerning the delegation of care can assist both the agency and nursing staff to conform their actions to the applicable laws and regulations.

Policies and procedures concerning the documentation of patient care are essential. At a minimum, the policies and procedures should include the following requirements:

1) that a medical record be kept on every patient, that entries in the medical record be objective, factual, complete, and be based on observations and clinical signs and symptoms;
2) that written entries be printed in black ink or typewritten;
3) that all entries be dated and timed;
4) that provisions for documenting "late entries" or "addition to entries" are present;
5) that only accepted agency abbreviations are used;
6) that specific guidelines for the correction of errors in the record are present;
7) that the manner in which physician's orders are obtained, recorded, and countersigned are clearly spelled out; and
8) that all communications between and among health care providers, including contacts with the physician, be included in the patient record.

74. Standing orders are orders written by a physician concerning medical treatment and/or the administration of medications for the nurse to follow when it is not possible to obtain the order directly due to time constraints (for example, in an emergency) or when a physician is not readily available. They do not, however, take the place of consultation with the physician concerning the condition of the patient or the care given. C. NORTHROP & M. KELLY, CRITICAL CARE NURSING, LEGAL ISSUES IN NURSING 126 (1987). Written protocols, utilized to guide the nurse when the physician is not readily available, are developed by the physician and aid the nurse in providing care within the scope of the nursing practice act. *Id.*

75. The use of physician-developed standing orders and written protocols was tested in Sermchief v. Gonzales, 660 S.W.2d 683 (Mo. 1983). In *Sermchief*, two nurse-practitioners were alleged to be practicing medicine without a license by the Board of Healing Arts, despite their use of standing orders and written protocols for, among other things, the provision of birth control devices and medications. *Id.* at 684. The Missouri Supreme Court, reversing and remanding the trial court's decision, said the utilization of physician-based standing orders and written protocols constitutes a nursing diagnosis as opposed to a medical diagnosis. *Id.* at 689. At the heart of the controversy was the definition of nursing in the Missouri Nurse Practice Act. *Id.* at 687. For an analysis of this and another case impacting on nurse practitioners, see Brent, *The Nurse Practitioner After Sermchief and Fein: Smooth Sailing or Rough Waters?*, 21 VAL. U.L. REV. 221 (1987).

In addition, the policies and procedures generally should require that all aspects of the care given to the patient be reflected in such patient's medical record.[76] Standardized, written teaching forms should decrease the agency's and staff's exposure to liability for patient and family teaching.[77]

Policies and procedures concerning patient and family safety in the home must begin with an infection control policy. Use of the Center for Disease Control's ("CDC") Universal Precautions[78] as a basis for good infection control procedures for all patients and their families, not just those with an identified infectious disease, is vital.

The administration of chemotherapeutic agents in the home mandates well-reasoned policies that consist of, but are not limited to, the use of latex surgical or thick polyvinyl gloves during the preparation and administration of the agent(s), guidelines for proper storage of the agent(s), including temperature requirements, and the avoidance of skin contact with the excreta[79] of those receiving antineoplastic drugs.[80]

The presence of highly technical equipment in the home necessitates policies and procedures to educate the patient and his family about the use of such equipment so that the patient and family can competently provide care without risking injury to the patient. Furthermore, the use of highly technical equipment requires that an initial evaluation of the home environment be made prior to the

76. S. MILLER, DOCUMENTATION FOR HOME HEALTH CARE: A RECORD MANAGEMENT HANDBOOK 2 & 3 (1986). *See also* W. ROACH, S. CHERNOFF & C. ESLEY, MEDICAL RECORDS AND THE LAW (1985); Connaway, *supra* note 27, at 6.

77. Several reference texts exist for patient teaching and its documentation. *See generally* J. JACKSON & E. JOHNSON, PATIENT EDUCATION IN HOME CARE: A PRACTICAL GUIDE TO EFFECTIVE TEACHING AND DOCUMENTATION (1988); P. LAZES, L. KAPLAN & G. GORDON, THE HANDBOOK OF HEALTH EDUCATION (2d ed. 1987).

78. Center for Disease Control, Recommendation for Preventing Transmission of Infection with Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus during Invasive Procedures, 34 MORBIDITY & MORTALITY WEEKLY REV. 682 (1985); Center for Disease Control, Recommendations for Preventing Transmission of Infection with Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus during Invasive Procedures, 35 MORBIDITY & MORTALITY WEEKLY REV. 221 (1986); Center for Disease Control, Update on Hepatitis B Prevention, 36 MORBIDITY & MORTALITY WEEKLY REV. (1987).

79. Excreta is defined as any excreted matter, including but not limited to sweat, urine, and feces. THE RANDOM HOUSE COLLEGE DICTIONARY 461 (1st ed. 1984).

80. Barry & Booher, *Promoting the Responsible Handling of Antineoplastic Agents in the Community*, 12 ONCOLOGY NURSING F. 41, 44 (1985). Of 16 facilities surveyed, three of which were home care agencies, only two had written guidelines for the administration of chemotherapy. Neither of the two was a home health care agency. *Id.* at 44.

actual provision of care.[81] The agency should assess such factors as the location of electrical sockets, size of rooms, and the home environment in general. Such an evaluation can be an effective risk management tool and can be beneficial to the hospital and its nurses in the discharge planning process, or by the agency nurse prior to beginning care.[82]

The equipment the agency uses must be able to endure extended periods of use. Additionally, the agency should devise clear and concise policies concerning equipment maintenance.[83]

The importance of the right of informed consent and refusal for treatment demands that agencies develop policies to protect this right. The policies should follow statutory requirements and case precedent. They should address the following:

1) informed consent and refusal procedures, including documentation in the record;
2) the nursing staff's role, especially the registered nurse, in notifying the attending physician and others of the presence of a living will or other advance directive;
3) the need to obtain orders from the physician before care is withdrawn or withheld; and
4) procedures for obtaining consent or refusal when a guardian is present or the patient is a minor.

C. Orientation and In-Service Programs

Because a good risk management program depends upon the identification of risks and strategies to avoid the risks, an integral part of any risk avoidance plan is to provide adequate orientation to all staff concerning the agency. The home care agency should require that all employees successfully complete an orientation program before being assigned to care for a patient in the home. In addition, the agency can further support competency in patient care by requiring a preceptor to work with the new employee for

81. A. HADDAD, *supra* note 11, at 76.

82. *Id.* The discharge planning process, performed by discharge planners, most often occurs when a patient is referred from the hospital or other facility in anticipation of discharge from the facility. Although discharge planners may be social workers or registered nurses and function under various models, the best risk management approach, in this author's opinion, is for the discharge planner to be a registered nurse or, at a minimum, involve a registered nurse who assesses "post-hospital needs and documents the care process in detail in order for this process to be transferred to the home setting." *See* Drew, Biordi & Gillies, *How Discharge Planners and Home Health Nurses View Their Patients*, 19 NURSING MANAGEMENT 66, 66 (Apr. 1988).

83. Keating & Kelman, *supra* note 72, at 92. The policies should include cleaning and repair of broken equipment and identify who is to be notified when a return of equipment is necessary. *Id.*

an initial period of time after orientation.[84] Nevertheless, an agency's obligation to ensure safe practice by its staff simply is not complete by merely providing a good orientation program. In-service programs are vital to educate the entire staff on new or changing health care delivery issues and concerns.

D. Quality Assurance Program

A health care delivery system's quality assurance program is "designed to protect patients, improve the provider's care, and to assure compliance with optimally achieved standards."[85] Risk management programs and quality assurance programs, although separate, share the common concern of identifying substandard care, even though from two different perspectives.[86] In providing home health care, risk management is an integral part of the agency's quality assurance plan, and must be operational for the overall improvement of patient care.[87] A quality assurance program must be well-planned, emphasizing the monitoring and evaluating of the structure, process, and outcomes in the home care agency.[88] A quality assurance program should provide for the review of agency policies and procedures, the referral/intake process, client satisfaction, and continuity of care.[89] The agency should form a quality assurance committee to carry out the mandate of its quality assurance program, and should include as members a physician, the agency director, and at least one registered nurse.[90] An

84. *See* Plesse & Lederer, *Preceptors: A Resource for New Nurses*, 12 SUPERVISOR NURSE 35 (1981); Bueno, Barker & Christmyer, IMPLEMENTING A COMPETENCY BASED ORIENTATION PROGRAM, 5 NURSE EDUCATOR 16 (May-June 1980); D. BOWER, L. LINC & D. DENEGA, EVALUATION INSTRUMENTS IN NURSING (1988). A preceptor is usually a seasoned staff member who works with a new employee until the latter is competent to work on his or her own.

85. Salman, *Quality Assurance and Risk Management* in HANDBOOK OF HEALTH CARE MANAGEMENT 415 (1986).

86. *Id.* Risk management's focus is narrower than that of quality assurance, with its primary focus being the protection of the agency's financial and social resources. *Id.* Quality assurance must constantly evaluate standards of care as advances in health care occur. Risk management, however, may be satisfied simply to meet the standard, without regard for the margin of achievement. *Id.* at 414.

87. Quality assurance is mandated by Medicare in its Conditions of Participation. *See* 42 U.S.C. § 1320(c) (1982); National League for Nursing ("NLN") accreditation requirements; The National HomeCaring Council (National Homecaring Council, Interpretation of Standards 14 (1981)).

88. S. MILLER, *supra* note 76, at 170.

89. *Id.* at 181-83.

90. *Id.* at 177. The registered nurse in home health care can play an important role as a member of the quality assurance committee. *See* Brent, *Quality Assurance and the Home Health Nurse: Taking an Active Role*, 6 HOME HEALTHCARE NURSE 6 (July-Aug. 1988).

inter-disciplinary approach is necessary because the committee "influences the kinds of problems that are identified, how they are defined, what kinds of solutions are proposed, and how the committee will function in relation to the rest of the organization."[91]

E. Open Channels of Communication Between Agency Administration and Staff

Home health care agency policies, procedures, and overall philosophy should encourage and enhance the open exchange of information pertaining to patient care at all times, not only when a problem arises. Fostering the sharing of concerns and difficulties inherent in the provision of patient care can aid in the resolution of such concerns and difficulties before they either become a risk the agency must address or influence the quality of care provided by the agency's staff. This approach is consistent with quality assurance mandates that evaluation take place on a regular basis. In addition, the sharing of concerns and differences ensures that the last step in the risk management program, that of risk evaluation, is met.

IV. CONCLUSION

Home health care agencies stand at the crossroads of fascinating times. Rarely involved in litigation to date, agencies enjoy a sense of comfort and satisfaction. Regardless of whether this protection will continue, home health care agencies have an obligation to be accountable to those to whom they provide care. A good risk management program can foster that accountability and, at the same time, insist that the care provided is quality care. Indeed, the consumer of health care expects no less.[92]

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91. S. MILLER, *supra* note 76, at 177.

92. As one commentator noted:

> We have granted the health professions access to the most secret and sensitive places in ourselves and entrusted to them matters that touch on our well-being, happiness and survival. In return, we have expected the professions to govern themselves so strictly that we need have no fear of exploitation or incompetence. The object of quality assessment is to determine how successful they have been in doing so; and the purpose of quality monitoring is to exercise constant surveillance so that departure from standards can be detected early and corrected.

Haffner, Jonas & Pollack, *Regulating the Quality of Patient Care* in HOSPITAL QUALITY ASSURANCE: RISK MANAGEMENT AND PROGRAM EVALUATION 3 (1984) (quoting Donabedian, The Quality of Medical Care D.H.E.W. Pub. No. 78-1232 (P-H), Health: United States, 1978, at 111).