

Standards



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Complementary and/or Alternative Therapy and Natural Health Products

Standards for Registered Nurses

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Introduction

Registered Nurses (RNs) in all areas of practice have encountered situations, questions or concerns related to ***complementary and alternative medicine (CAM)***¹ and ***natural health products (NHP)***. The purpose of this document is to provide direction for RNs who use CAM or NHPs as an adjunct within their nursing practice or who have clients who wish to or are using CAM and/or NHPs.

Canadians are increasingly using CAM therapies and NHPs. In 2005 the Natural Health Products Directorate at Health Canada did a random telephone survey and found that 71% of Canadians have used a NHP and 38% use them on a daily basis. Those who use NHP do so because of personal health concerns and a desire to maintain and promote personal health (Health Canada, 2005). A study in the U.S. (Barnes & Bloom, 2008) showed that 4 in 10 adults had used CAM in the past 12 months.

CAM is defined as practices or products that are not part of conventional medicine (Barnes & Bloom, 2008). Complementary therapies are used together with conventional medical treatments, while alternative therapies are used instead of conventional medical treatments. The term ***integrative medicine*** is also used. In integrative medicine, conventional therapies are combined with CAM where there is evidence of safety and effectiveness (Cady, 2009). Some therapies that are considered CAM within the Canadian context are thought of as conventional medicine in other cultures.

In the United States the National Center for Complementary and Alternative Medicine, a component of the National Institutes of Health (2010) has categorized complementary and alternative medicine into five domains;

1. **Mind-body medicine** use techniques that enhance the capacity of the mind to influence body function and symptoms. It includes hypnosis, visual imagery, meditation, art, music and dance as well as techniques that in the past were considered CAM but are now mainstream such as patient support groups and cognitive behavioral therapy.

¹ Words or phrases in bold italics are listed in the Glossary. They are displayed in bold italics upon first reference.

2. **Biologically based practices** include natural substances such as herbs, food, vitamins, probiotics and dietary supplements.
3. **Manipulative and body based methods** include massage, reflexology and chiropractic manipulation.
4. **Energy medicine** looks at healing from the perspective of energy fields. It would include therapies such as therapeutic touch, Reiki or electromagnetic based therapies.
5. **Whole medical systems** include homeopathy, traditional Chinese medicine and Ayurvedic medicine.

NHP's Regulatory Structure

NHP is a term used to refer to a group of health products including: vitamin and mineral supplements, herbal remedies and other plant-based products, traditional medicines (such as Chinese Medicines and Ayurvedic [Indian] Medicine), homeopathic medicines, fatty acids (such as omega 3, 6 and 9), probiotics and some personal care products such as antiperspirants, shampoos and mouthwashes. (Health Canada, 2009).

Natural health products are “manufactured”, sold or presented for use in:

- a. the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans
- b. restoring or correcting organic functions in humans, or
- c. modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health

(Health Canada, 2007)

The NHP regulation came into force on January 1, 2004. Under this regulation, all NHPs sold in Canada are required to have a pre-market assessment and authorization of their safety and effectiveness. All applicants must submit a listing of the product's medicinal and non-medicinal ingredients and those must appear on the product label. Those who manufacture, package, label or import a NHP must have a site license. This is to ensure that products in Canada are of high quality and made according to accepted or approved manufacturing practices in licensed facilities. All NHPs have a natural product number (NPN). This is an eight digit numerical code following the acronym NPN that is assigned to approved products marketed under the *Natural Health Products Regulation*.

Homeopathic medicines that are approved under these regulations have a homeopathic medicine number. It is an 8 digit numerical code following the acronym DIN-HM.

Health Canada has developed the Natural Health Products Database which is updated nightly. It can be accessed at <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/lnhpd-bdpsnh-eng.php>.

Each licensed product listed in the database provides the following information:

1. product name
2. product license holder
3. natural product number (NPN) or homeopathic medicine number (DIN-HM)
4. product's medicinal ingredients
5. product's non-medicinal ingredients
6. product's dosage form
7. product's recommended use or purpose (i.e. its health claim or indication)
8. risk information associated with the product's use (i.e. cautions, warnings, contraindications and known adverse reactions)

Authority to Provide Complementary/Alternative Therapy

An important distinction between CAM therapies and NHPs is that CAM therapies are generally provided by a CAM practitioner while NHPs are usually self-selected by the consumer (Smith & Simpson, 2003). In some cases, the CAM practitioner is a member of a regulated profession. However, many therapies that fall under CAM including aromatherapy, craniosacral therapy, Ayurvedic medicine, iridology, therapeutic touch and Reiki are performed by a variety of individuals who may or may not be regulated health professionals. Regulated practitioners are governed by a professional college, meet minimum requirements to practice, and are subject to formal mechanisms to be held accountable for their practice. Unregulated providers may or may not have met a minimal educational standard to practice and are not accountable to a regulatory body that can assess and determine the appropriateness of practice.

Many RNs are interested in the use of CAM and NHP in their practice because of their emphasis on a holistic and natural approach to care. This holistic approach to care focuses on the mind-body-spirit connection. Florence Nightingale believed that "...nursing is putting us in the best possible conditions for Nature to restore or to preserve health – to prevent or to cure disease or injury" (Nightingale, 1954, p. 334). It was her belief that individuals are central to their own healing.

An RN has the authority to provide therapy if:

- a. The therapy is within the scope of nursing practice (refer to CARNA *Scope of Nursing for Registered Nurses*, 2011 and professional legislation and regulation including restricted activities authorization (refer to CARNA document *Health Professions Act: Standards for Registered Nurses in the Performance of Restricted Activities*, 2005).
- b. There are policies and procedures in place in the practice setting that support the use of the therapy as part of a client's individualized plan of care.

The process outlined on pages 5-7 of the CARNA document *Health Professions Act: Standards for Registered Nurses in the Performance of Restricted Activities* (2005) can be used by CARNA regulated members to determine if specific CAM or NHP interventions would be appropriate as an adjunct to nursing practice in a particular setting (see Appendix A).

Those nurses in self-employed practice who wish to use complementary/alternative therapies as an adjunct to their nursing practice must submit documentation about their nursing practice to the Registration Committee for approval. Complementary and alternative health-care therapies by themselves do not constitute nursing practice. RNs in self-employed practice must follow the guidelines outlined in the CARNA document *Self-Employment for Nurses: Position Statement and Guidelines* (2010). This document states:

The use of the protected titles of registered nurse or 'RN' and nurse practitioner or 'NP' is authorized in the *Registered Nurses Profession Regulation* (2005).

Registered nurses and nurse practitioners may use the title 'RN' or 'NP' with the promotion of their approved nursing practice. Using the title 'RN' or 'NP' in marketing approved professional services helps the consumer make an informed decision when choosing a health service provider.

Registered nurses cannot use the title 'RN' or 'NP' in association with the endorsement or promotion of products or services. Endorsement of a product or service occurs when

a nurse uses their credentials to lend credibility to a commercial product or service (CNO, 2009). The endorsement of a product or service without providing information about other options could mislead the public and may be considered a conflict of interest.

When a client is making decisions regarding particular products or services, the self-employed nurse must provide information on a range of options to support the client in making informed choices. The client should be informed of the potential benefits and risks, intended effects and possible adverse effects of the products and available options. (CARNA, 2010b).

Standards for Complementary and Alternative Health Care and Natural Health Products in Nursing Practice

The following standards provide direction to RNs in making decisions about care that involves CAM and NHP as an adjunct within their nursing practice. These standards build upon the *Nursing Practice Standards (2005)*, which are applicable to all practice settings and provide information to the public as to what they can expect from RNs.

Standards when CAM and/or NHPs are used as an adjunct to nursing practice

1. Use of CAM and/or NHPs
 - The RN must have the necessary competence (knowledge, skill, judgment and attitudes) to provide the therapy in a safe, competent and ethical manner.
 - Policy in the practice setting must support the use of CAM. Employer policy might include identification of required education and competencies, experience, informed consent, documentation and supervision requirements.
 - The RN must have successfully completed appropriate educational or certificate programs from credited sources to prepare themselves to provide the therapy. In some situations (e.g. acupuncture), licensure with another regulatory body may be necessary.

- The RN must use reliable sources of information and examine the evidence to determine that the therapy is safe and effective including consultation with a pharmacist or other health care providers as necessary. All pharmacies are required to have a NHP reference.
 - The RN must use their knowledge and critical judgment to identify risks and expected outcomes, and to determine if the therapy is appropriate to the client situation.
 - The RN must be aware of the intended effects, possible side effects, interactions with other therapies, adverse reaction reporting requirements of Health Canada and be prepared to provide care in relation to any expected or unexpected effects of the therapy – including plans for backup care if it is needed.
 - Nursing care related to CAM therapies must be documented in the client record. Documentation would include:
 - ◆ nursing history and assessment of the use of CAM and NHPs,
 - ◆ discussion regarding the history of the condition,
 - ◆ risks and benefits of conventional treatment,
 - ◆ client or families decision not to proceed with conventional therapy,
 - ◆ risks and benefits of a proposed CAM therapy and families response to that, and
 - ◆ planning, intervention, and evaluation of care and the therapy.
 - The RN must assess clients respecting the use of CAM and/or NHPs and encourage their clients to inform their other health-care providers of CAM they engage in and NHPs they are using.
2. Administration of NHPs
- There must be policies and procedures in place that support the administration of NHPs.
 - RNs only administer NHPs that are legal in Canada. NHPs that are administered must have an eight-digit product license number that is preceded by the letters 'NPN'. Homeopathic medicines will have the eight-digit number preceded by the letters 'DIN-HM'. These labels provide

assurance that the product has been reviewed and approved by Health Canada for safety and efficacy (Health Canada, 2004).

- The RN who administers NHPs must be aware of the intended effects, possible side effects and be prepared to provide care in relation to expected or unexpected effects of the NHP.

3. Informed consent

- The client must be informed of the potential benefits and risks, intended effects and possible side effects of the therapy and other available options. RNs use current and updated resources.
- There must be informed consent by the client as outlined in the InfoLAW® from the Canadian Nurses Protective Society (CNPS, 1994; CNPS, 2004) as well as compliance with employer policy for consent.

CAM and NHPs Initiated by Clients

With the increase in access to information, clients are increasingly managing their own health. Many are searching for therapies that will relieve the symptoms of chronic or acute illness. Others have cultural practices and values that are different from mainstream North American health care. In situations where clients want to explore or have made a personal decision to initiate CAM and/or NHPs, the RN must:

1. be non-judgmental in supporting the client's exploration of the therapies
2. recognize the client's autonomy in decision-making
3. assist the client to find accurate, reliable sources of information on CAM therapies, NHPs and conventional treatment in order that the choices made by the client are informed choices. This includes providing information on potential risks, benefits, costs and limitations of the therapy, the federal NHP regulation and/or referral to other health care providers such as pharmacists or physicians
4. assess the use of CAM and/or NHPs in the client's care and encourage them to inform all health-care providers, including primary care providers such as physicians and NPs, of the CAM they are engaged in and NHPs they are using

Risk Factors to Consider

Parkman (2002) has identified several risk factors in relation to CAM and NHPs that may be important to consider when assessing clients and families and developing a plan of care. These risk factors include:

- clients who have rejected conventional care for an acute or chronic illness and have placed all their hope in CAM or NHPs with little knowledge of the efficacy of the CAM therapies or NHPs
- clients who have delayed treatment for a treatable illness on the basis of self-diagnosis without a medical evaluation of the health problem
- clients who have spent considerable monies for therapies not covered by insurance and as a result are at risk for financial hardship or difficulty
- clients who independently mix CAM and/or NHPs with prescribed conventional therapies without knowledge of the contraindications and associated risks
- women of child-bearing age or who are pregnant using herbal or nutritional supplements without the guidance of a health-care professional
- clients in emergency departments or clinics with atypical symptoms or failure to respond to prescribed therapy

Conclusion

As CAM and use of NHPs increases, it is important for RNs to have an understanding of these therapies and products. Clients have the right to make their own personal decisions related to their care. RNs provide appropriate information so choices and decisions are informed.

Examples

The following scenarios are provided to give examples of how the standards can be used to make decisions with respect to complementary/alternative therapy.

Robert is a home care nurse caring for a client who has colon cancer. The client has undergone chemotherapy and the outcome is uncertain at this point. The client has difficulty with pain, is anxious about the outcome of treatment, and has shown signs of depression. On recent visits, Robert noted that the client has been making comments with respect to CAM and NHPs. Knowing that many clients do not inform their mainstream health-care providers that they are using alternative therapies, Robert explores this further on his next visit. He discovers that the client has been using some herbal remedies and is considering going to a clinic in Europe for treatment. The treatment at the European clinic requires injections when he comes home.

In addressing this client situation, Robert used the CARNA document *Ethical Decision-Making for Registered Nurses in Alberta: Guidelines and Recommendations* (2010) for guidance with the ethical concerns. He also used the document *Alternative and/or Complementary Therapy and Natural Health Products: Standards for Registered Nurses* (2011).

According to the principle of autonomy, clients have the right to make their own decisions and choices with respect to health care. RNs, to the extent possible, provide clients with the information they need to make informed decisions related to their health and well-being in an open, accurate and transparent manner (CNA, 2008). In this situation, Robert explored with the client information and evidence on the particular NHPs that he uses or is considering using, as well as other treatment options, and encouraged the client to seek information from the physician or a pharmacist as to the effects and interactions of both the conventional medications and the NHPs. He also suggested the client check for information from Health Canada concerning the regulation status of the NHPs. The client agreed to monitor the effects of the therapies and medications. Together, they decided on how and what should be monitored. Robert discussed with the client other CAM therapies that have been approved for use in this practice setting, including guided imagery, massage, and Therapeutic Touch.

The client had very little information on the nature of the injections he was to have after treatment in the European clinic. He and Robert discussed at length the information the client should seek while there. Robert made it clear that he could not administer an injection of a substance he did not know. If the client insisted on having the injection,

Robert agreed to teach a family member to give the injection safely. The family understood that while Robert would support the family in their choice, he could not as an RN, administer an unknown substance, or engage in therapy not approved by his employer or authorized for use in Canada.

Anne is a nurse who has taken the appropriate massage therapy education and has become a certified massage therapist. She works on a surgical unit and believes that massage could be used to help relieve pain, decrease anxiety and increase relaxation.

Anne knew that while massage therapy may assist in relieving pain and decreasing anxiety, the dilation of blood vessels and increased circulation may be of risk to clients with cardiac or renal problems. She first reviewed the policies and procedures within the practice setting to see if massage therapy was approved as a modality of care. If she performed massage and something untoward happened, the employer may not provide liability protection if she was acting outside of her job description and the policies of the practice setting. In this practice setting, there was no policy statement, so Anne approached the manager and discussed the process for approval. Relevant research on potential benefits and risks was carefully examined. Policies and guidelines were developed to guide employees who have the education and certification for massage therapy to engage in therapeutic massage when appropriate.

Jane is a RN working in home care. Her caseload includes individuals from a number of different cultural groups, as well as First Nation Canadians. She has encountered an increasing number of questions about the use of NHPs as well as CAM therapies from all cultural groups.

In talking to her colleagues, Jane realized that others were also concerned about their level of knowledge of various cultural practices and values, information on various CAM therapies and NHPs being used, and ethical dilemmas related to complementary and alternative therapy. At the next staff meeting, they identified this as an issue and planned to set aside some in-service and staff meeting time to address it. The nurses divided into three groups. Jane's group began a literature review on CAM therapies and NHPs and eventually created a resource manual. The manual included information and research on various CAM therapies and NHPs being used. They also examined federal regulations as it relates to NHPs. One group identified several ethical issues. They consulted with CARNA and resources within their organization that addressed ethical concerns. A half-day workshop was organized in which they worked through some of the ethical dilemmas that faced them. The third group examined in more depth some of the

varying cultural health-care practices and beliefs of the population in their area. They developed a series of seminars involving community members. One of their goals was to explore how they could honour and respect traditional healers and practices and maintain CARNA standards.

Joan is interested in setting up a holistic self-employed practice. She is very interested in lifestyle management and health promotion. Joan has taken the certification courses for Therapeutic Touch. Joan has a part-time position in oncology at her local hospital.

Joan contacted CARNA for information on self-employed practice and standards for CAM. She reflected upon the discussion related to knowledge and consent to treatment and realized that, although she had done the certification for Therapeutic Touch, she was a beginning practitioner. Joan decided to work with another Therapeutic Touch practitioner for six months in order to gain experience through mentoring.

There were several clients on Joan's unit who were interested in having Therapeutic Touch when they returned home. She knew she couldn't promote her own business, and discussed how to approach this with her manager. They established a resource list for Therapeutic Touch which could be provided by staff to clients who were interested. It included a reading list, policy within the hospital, and a list of practitioners or businesses where Therapeutic Touch could be accessed outside of the hospital. The list included her own information. For those clients who asked, she provided the general resource list. She was careful to discuss several resources and did not specifically recommend her own practice.

Darlene is the manager on an acute care general surgical unit. They recently had an incident where a client had not informed his physician that he was taking NHPs in addition to his prescribed medication. The client's life was at risk during surgery due to uncontrolled bleeding.

Darlene and the risk management team discussed this incident from the perspective of client safety and medical error. They noted in the literature that many clients do not inform health-care providers that they are engaging in CAM or taking NHPs. To address this situation it was decided to develop an assessment tool and teaching plan for the pre-op clinic so that clients and families could be supported in sharing this information with all health-care providers including their physicians. It is important for clients to understand problem interactions between prescribed medications and the NHP and known contraindications to the NHP.

Darlene and her nursing staff adapted the assessment tool and teaching plan for use on the unit as a number of clients having emergency surgery have not attended the pre-op clinic. The clinical educator, together with the pharmacist, developed an in-service for staff to increase their knowledge as part of the implementation of the assessment tool and teaching plan.

As the use of CAM and NHPs grows Darlene and her staff have noted that some clients will request that staff administer NHPs they have been taking at home or have a CAM provider visit them in hospital to perform a treatment. This has been addressed on a case-by-case basis. The necessity for hospital policy has become clear and Darlene has raised this as an issue to be addressed at the next meeting of the clinical managers.

Glossary

Complementary and Alternative Medicine (CAM) – Practices that are not generally considered part of conventional medicine (Barnes & Bloom, 2008). Complementary therapies are used together with conventional medical treatments, while alternative therapies are used instead of conventional medical treatments.

Natural Health Products (NHPs) – NHPs include vitamins, minerals, essential fatty acids and homeopathics, etc. These products are used to prevent, diagnose or treat disease, restore or correct function, or maintain or promote health. NHPs may be derived from plants, animals or micro-organisms. (Health Canada, 2003).

Integrative Medicine – Conventional medical treatments that are used with CAM where there is evidence of safety and effectiveness (Cady, 2009).

Note that the terms “complementary” and “alternative” therapy are often used interchangeably but they are different.

The naming of particular therapies in the document does not in any way indicate the College and Association of Registered Nurses of Alberta (CARNA) endorsement of the complementary or alternative therapies. They are merely examples.

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Appendix A

From the CARNA document *Health Professions Act: Standards for Registered Nurses in the Performance of Restricted Activities* (2005):

2. Guidelines for Determining if a Specific Intervention Should Become a Part of Registered Nursing Practice

A number of health professionals may be authorized to perform a specific restricted activity. Factors influencing which health professional will perform the restricted activity intervention in a given situation include:

- authorization by the professional's regulatory college to perform the restricted activity
- needs of the client
- context of care including the acuity/stability/complexity of the client
- service delivery model
- knowledge and competency of the health-care professional
- availability of health professionals in the practice setting
- continuity of care within the setting

The practice of registered nurses (RNs), like that of other health-care professionals, is constantly evolving. In the assessment of client care and nursing practice, employers and RNs may identify interventions/tasks within a restricted activity authorized for RNs that they are not currently performing. Assessment of the clinical situation may indicate that it would be reasonable for an RN to perform that restricted activity intervention. The following guidelines have been identified to provide assistance to administrators, managers and RNs in determining if interventions within a restricted activity category should be incorporated as a part of RNs' practice in that particular practice setting.

1. **Assessment of Client Need, Intent and Purpose of the Restricted Activity Intervention**

The determination of whether or not an RN performs a specific intervention/task within a restricted activity category must be mutually agreed upon between RNs and other health-care professionals in the practice setting. The determination should be supported by institutional policy, be the same on any shift and driven by the needs of the client, not by the desire for convenience of health-care professionals. For example, the RN may be the only available provider in a practice setting during the night shift who has a competency in a particular restricted activity intervention. If the RN is not allowed to perform this intervention on a day shift, they should not be allowed to perform it on nights. Additionally, if the person was not competent to provide the intervention, it does not matter if they are the only available provider – they must not perform the activity.

2. Knowledge and Skill to Perform the Restricted Activity Intervention Safely

The responsibility for attaining and maintaining competence in the restricted activity intervention is held jointly by RNs and their employers. One of the important factors to consider when decisions are made as to whether or not a particular restricted activity intervention should become a part of nursing practice is the opportunity to maintain competence.

The RN is expected to:

- identify his/her own learning needs with respect to the restricted activity intervention
- practise only within his/her areas of competence, and
- utilize available educational resources to attain and maintain competency in the activity

Employers have the responsibility to:

- provide orientation and staff development programs based on identified learning needs related to the goals of the organization, and
- ensure the provision of the necessary resources for RNs to attain and maintain competency in the restricted activity interventions required by the needs of clients in the practice setting

RNs and employers share responsibility for collaborating on the ongoing evaluation of the need for and the performance of all interventions, including the competence of the practitioners involved. Employers will need to strive for consistent methods to evaluate RN competence.

3. Identification and Establishment of Policies and Procedures to Facilitate Safe and Competent Performance of the Activity

The development and implementation of evidence-based policies and procedures is critical to support safe and competent performance of restricted activity interventions. As part of this process there must be mutual agreement by the professionals involved in the practice setting that this intervention will become a part of nursing practice.

In any practice setting, RNs have both the right and the professional obligation to question policies and procedures inconsistent with therapeutic client outcomes, current practices and safety standards. Accordingly, where the performance of a particular restricted activity intervention in a specific practice setting is not consistent with therapeutic client outcomes, current practices and/or safety standards, RNs have the professional responsibility to refuse the acceptance of such a restricted activity intervention, and to communicate their concern to the employer. Employers have the responsibility to address the concerns outlined with respect to the proposed restricted activity intervention. In such instances, the particular restricted activity intervention should only be incorporated as a part of registered nursing practice when all concerns of the parties affected have been satisfactorily addressed.