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February 12, 2001

Stephen C. Groft, Pharm.D.
Executive Director
White House Commission on Complementary and
Alternative Medicine Policy
6701 Rockledge Drive, Suite 1010
MS-7707
Bethesda, MD 20817

Dear Dr. Groft:

Thank you for your letter of January 29. In response, I have enclosed a copy of a recently published ACCP white paper on herbal products. Admittedly, herbals do not represent the breadth and depth of complementary and alternative medicine practices and products. Nevertheless, I believe you and the commission will find the white paper provides substantial information from ACCP's perspective relative to the issues and questions raised in your letter.

Please feel free to reproduce the white paper for use by the commission's members. I plan to attend at least a portion of the meeting later this month, and look forward to meeting you personally at that time.

Sincerely,

Enclosure

cc: Robert M. Elenbaas, Pharm.D., FCCP

ACCP WHITE PAPER

White Paper on Herbal Products

American College of Clinical Pharmacy

Lucinda G. Miller, Pharm.D., Anne Hume, Pharm.D., FCCP, Ila Mehra Harris, Pharm.D., Eric A. Jackson, Pharm.D., Tina J. Kanmaz, Pharm.D., Jacintha S. Cauffield, Pharm.D., Thomas W.F. Chin, Pharm.D., Maureen Knell, Pharm.D.

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In 1990, an estimated 427 million visits were made to alternative medical practitioners in the United States, exceeding the estimated 388 million visits to primary care physicians during the same period.[1] The number of visits had risen to 629 million in 1997, with growth mainly due to an increase in new individuals seeking practitioners of alternative medicine.[2] An estimated $27 billion was spent in 1997 on alternative medicine.[2]

Herbal and other natural products such as melatonin and megavitamins represent an area of great growth among alternative medical practices. Between 1990 and 1997, the use of herbal products increased 380% and megavitamin use increased 130%.[2] During this growth period, concerns have been raised about adequate research supporting efficacy claims and lack of uniform product standardization. The major issues surrounding the use of herbal products are discussed in this paper, and resources and recommendations for pharmacists to improve the informed use of these products by consumers are provided.

Overview of Complementary Medicine

"Complementary" medicine has been described by a variety of terms, including "integrative," "naturopathic," and "alternative."[1] In addition to herbal and megavitamin therapies, alternative medicine includes a broad range of therapies and practices, which are defined in Appendix 1. Relaxation techniques, herbal products, massage, chiropractic, spiritual healing, megavitamins, and self-help groups were the alternative medical therapies most frequently used in 1997.[2]

In one study, individuals chose alternative medical care, not because of dissatisfaction with conventional medicine, but because alternative therapies were more congruent with their personal beliefs and values.[3] Individuals using complementary therapies generally possess a high education and income level, although use crosses all socioeconomic categories.[1,2] The most commonly reported conditions for which alternative medicines are used are musculoskeletal complaints, including back and neck problems; arthritis; sprains; and strains. Allergies, as well as central nervous system complaints of fatigue, insomnia, anxiety and depression, also have prompted the use of alternative sources of medical care.[1,2] One report indicated that 60 million Americans over the age of 18 years have used herbs for general health maintenance and for colds, burns, headaches, allergies, rashes, insomnia and depression.[4] Complementary therapies usually are used as a supplement to conventional medical care, with only 4.4% of individuals relying exclusively on alternative medical care.[3] Patients have used complementary therapies to augment treatments for cancer and the acquired immunodeficiency syndrome. Also, a recent study of 101 caregivers found that over 55% tried at least one alternative

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therapy to improve memory in patients with Alzheimer's disease, and 20% tried over three treatments.[5]

While the media have acknowledged the widespread use of complementary medicine for common ailments in the United States, less than 40% of individuals using these therapies inform their health care providers, as they anticipate disparaging remarks if they reveal their use of these agents.[1,2] Conversely, many health care providers are reluctant to ask patients about alternative medicine use, creating a situation that has been described as "don't ask, don't tell."[2] The reason for the reluctance among health care professionals may be due in part to their inadequate knowledge about complementary medicine, particularly herbal products. Furthermore, many therapies originated long before the 20th century and usually outside the traditions of Western medicine[6] and thus lack evidence from the high-quality research methods that are the standard by which medical interventions are held. However, many herbal therapies do have unique pharmacologic actions that can benefit patients and spawn new research. The current paucity of evidence, particularly the absence of comprehensive knowledge on the constituents and activities of many herbal and natural products, raises concerns among health care providers as to whether some of these therapies pose an excessive public health care risk or result in delayed use of more effective therapies.

Introduction to Herbal Products

Over 20,000 herbal and other natural products are available in the United States.[7] The most commonly purchased products include echinacea, feverfew, garlic, ginseng, ginkgo, goldenseal, kava, St. John's wort, saw palmetto and valerian. Some products are used for health maintenance or for benign, self-limited conditions. However, others are used to self-treat serious illnesses, such as hawthorn for congestive heart failure, milk thistle for liver disease, or St. John's wort for depression.

During their growth in popularity over the last several years, the promotion of these products has undergone fundamental changes. In the past, herbal products were promoted to consumers primarily by mail-order companies and health food stores. More recently, chain drug stores and grocery stores have advertised herbal products aggressively to consumers in a manner similar to that for nonprescription drug products. The introduction of entire herbal product lines by traditional manufacturers, such as American Home Products, will likely increase this trend. For pharmacists and other health professionals confronted with inquiries from consumers about the health promotion claims of herbal products, it is important to acknowledge that some of these products have pharmacologically active chemical constituents, and, in essence, are drugs. Herbal products cannot be discounted as "natural" and hence, nontoxic entities, as many consumers believe. Although selected products may have therapeutically beneficial effects, many cause adverse effects[8] and drug interactions similar to those experienced with conventional agents.[9] In 1998, the American Association of Poison Control Centers received 6914 reports of adverse reactions from dietary supplements.[10] Between January 1993 and October 1998, the Food and Drug Administration (FDA) received 2621 reports of serious problems involving these products, including 184 deaths.[10] In contrast, in a study of 386 herb users, only 8% had experienced adverse effects.[11] Examples of adverse effects reported with some botanical products are shown in Table 1.[12–21]

The interaction potential of herbs with conventional drugs is a critical concern for drugs with narrow therapeutic indexes.[9] For example, many herbal products, such as garlic, ginger, ginseng, ginkgo, and feverfew, possess antiplatelet properties that can be additive when used with drugs known to affect hemostasis such as warfarin or heparin, albeit through different mechanisms.[22–26] Shankapulshpi, an Ayurvedic preparation used to treat epilepsy, increases the hepatic clearance and thereby decreases the serum concentrations and effectiveness of phenytoin when these agents are given concomitantly.[27] Recently, a significant interaction was identified in which St. John's wort reduced the area under the curve of the protease inhibitor indinavir by a mean of 57%, potentially leading to the development of indinavir drug resistance and treatment failure.[28] A comprehensive review of known and potential drug-herb interactions has been published recently.[9]

Safety Issues

Standardization is the process by which one or more active ingredients of an herb are identified, and all batches of the herb produced by a single manufacturer contain the same amount of active

Table 1. Examples of Adverse Reactions Associated with Herbal Products[a]

Organ System	Adverse Effect	Herbal Product
Immunologic	Allergic reactions	Royal jelly,[12] yohimbine[13]
Renal	Nephrotoxicity	*Radix aristolochia*[14]
Musculoskeletal	Rhabdomyolysis	Wormwood oil[15]
Hepatic	Hepatotoxicity	Chaparral,[16,17] comfrey,[18] sassafras[19]
Other	Mutagenicity	Frangula,[12] rhubarb, senna,[20] capsaicin[21]

[a]Not intended to be a comprehensive list.

ingredient.[29] Consumers expect the component ingredients of their nonprescription and prescription drug products to be standardized to ensure that each dose contains the requisite amount to elicit the desired effect. However, consumers either may not expect the same level of standardization for herbal products, or they assume they are standardized. One reason they may not expect the same level of product quality may be the commonly held perception by consumers that "natural is always good," and precise quantification is unnecessary. Also, many herbal medicine advocates propose that the therapeutic benefit of herbal products stems from the synergistic action of the several natural components in the herb. They argue that some constituents that are thought to be inactive may play a role in the pharmacokinetics of the active component,[30] and that a standardized extract would diminish or eliminate the beneficial effects of the heterogeneous botanical product. No evidence currently is available to support or refute this argument.

One consequence of the lack of standardization is the variability in the quantity, or the complete absence, of the known or supposed active ingredient. Of 24 ginseng products assayed by a thin-layer chromatography spectrophotometric method, eight (33%) did not contain any detectable panaxosides, which are considered to be the active components.[31] The total panaxosides' content in the remaining products ranged from 0.26–6.85 mg/250-mg sample.[31] In a study of 44 feverfew products, 14 (32%) did not contain the minimum of 0.2% parthenolide content that is proposed, albeit disputed, as the necessary primary active ingredient and concentration. Another 10 products (22%) did not contain any detectable levels of parthenolide.[32]

Good manufacturing practices (GMPs), which are required for foods and drugs, are not required for herbal products. Good manufacturing practices ensure that products meet specific quality standards, are not adulterated or misbranded, and contain the correct ingredients and doses stated on the label.[33] Without GMPs, herbal products are at risk of adulteration and contamination.

The medical literature contains several examples of the adulteration of herbal and natural products with unlabelled ingredients and heavy metals. The FDA has received reports of bradycardia and heart block that were caused by ingesting plantain adulterated with digitalis.[34] This adulteration occurred when an inexperienced harvester mistook the digitalis-containing foxglove for the similar-appearing plantain. The product was sold for up to a year by several distributors before the problem was recognized.[34] Melatonin, in concentrations up to 7.11 μg/g, was found as an adulterant in feverfew, Huang-qin, and St. John's wort products.[35] A 41-year-old woman was reported to have an international normalized ratio of 11.5 after drinking hibiscus tea contaminated with warfarin.[36] A product known as "Sleeping Buddha," promoted for insomnia, was found to contain estazolam, a prescription benzodiazepine.[37] Lead intoxication occurred in a 59-year-old woman who consumed a Chinese herbal remedy that had a lead content of 0.5 mg/tablet.[38] Her intake of 30 tablets/day amounted to 15 mg/day of elemental lead, resulting in a 24-hour urinary lead content of 1044 μg. These examples illustrate the significant risk to the public for serious adverse health consequences, which could be eliminated by product standardization and GMPs.

An important prerequisite for establishing standards is the identification and quantification of active components. The active ingredient or the quantity necessary for effectiveness has not been determined for several products. For example,[39,40] Some manufacturers standardize St. John's wort according to its hypericin content, which is only 1 of 10 identified active components in this herb.[41]

Some herbal manufacturers have set standards for their products. For the Centrum herbal

product line, PharmaPrint—a patented process that incorporates chemical and biological specifications—ensures manufacturing consistency. The company that developed the process has 11 herbal products in development and has applications for investigational new drugs filed with the FDA for saw palmetto and St. John's wort.[42]

Deoxyribonucleic acid (DNA) fingerprinting is an analytical method using polymerase chain reactions to identify chemical components of herbal products. This methodology was recently made available by Univera Pharmaceuticals (Broomfield, CO) and can identify herbal and botanical ingredients based on their unique DNA characteristics.[43]

While some manufacturers have developed standardized extracts for their herbal products, many have not.[44] The American Herbal Products Association (AHPA) has not taken a position on whether all herbals should be standardized.[30] Furthermore, no governmental agency has imposed regulations to ensure uniformity. A regulatory framework for herbal products is being developed in England.[44] If a similar model were adopted in the United States, some level of standardization could be developed and should help to protect public safety. Standardizing the content of one active component, while maintaining the relative content of all other constituents, may be a satisfactory preliminary approach to achieve acceptable consistency among products.

Regulatory Issues

From a regulatory perspective, herbal products are classified as dietary supplements. Before 1994, herbals were regulated as foods or drugs, depending on their intended use. When Congress passed the Dietary Supplement and Health Education Act (DSHEA) in 1994, a separate classification was created for dietary supplements. Under this categorization, herbals are not considered foods or food supplements. Unlike drugs, herbs do not need to be proven safe and effective to be marketed. Thus, herbal products are not required to undergo the lengthy, rigorous, and expensive approval process that is required for drugs. This lack of regulations concerns many health care professionals and poses a significant risk for consumers.

The DSHEA of 1994 allows manufacturers of natural products to make claims regarding the ability of their products to alter structure or function, but not regarding diagnosis, treatment, cure, or prevention of disease.[45] New rules, implemented by the FDA in early 2000, ban implied, as well as expressed, disease claims.[46] For example, any claims that the consumer could misinterpret easily as treating or preventing disease no longer are allowed. In addition, the definition of disease changed so that common, minor symptoms of life stages (e.g., premenstrual symptoms, hot flashes associated with menopause, wrinkles, acne) no longer are considered diseases. Product claims are now allowed for these ailments.

Under the new FDA rules, a product may bear health maintenance claims (e.g., "maintains a healthy prostate"), but not disease claims (e.g., "treats benign prostatic hyperplasia"). Products claiming to diagnose, treat, prevent, or cure a disease will be classified as drugs and thus require proof of safety and efficacy.[47] Manufacturers must be able to provide evidence that a claim is not false or misleading. When manufacturers state that their products affect body structures or functions, the label must include the following disclaimer: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." In addition, companies must notify the FDA within 30 days after a product is on the market if it bears such a label.[45]

The DSHEA allows herbal products to remain on the market as long as they have not been proven to be unsafe. Whereas a drug must establish its safety before it can be marketed, herbal products can be marketed unless, or until, proven to be unsafe.[48] The possibility exists that considerable morbidity or mortality may occur before an herbal product is identified as dangerous and removed from the market.

The dietary supplement Cholestin was reclassified as a drug. It is a red rice yeast product claimed by its manufacturer (Pharmanex, Provo, UT) to lower low-density lipoprotein cholesterol and raise high-density lipoprotein cholesterol. The product was found to contain mevinolin, which is indistinguishable from lovastatin. Because the claims classify Cholestin as a drug, the product was ordered off the market by the FDA unless the standards for drugs were met.[47, 49] For now, the product remains on the market while the ruling is litigated.

In early 2000, the FDA published its Dietary Supplement Strategy (Ten Year Plan).[50] This plan

Table 2. General Description of Levels of Evidence

Level I	Randomized trials or meta-analyses in which lower limits of the confidence interval for the treatment exceed the minimal clinically important benefit
Level II	Randomized trials or meta-analyses in which lower limits of the confidence interval for the treatment overlap the minimal clinically important benefit
Level III	Nonrandomized concurrent cohort studies (studies with one group receiving the treatment and a concurrent group not receiving the treatment)
Level IV	Nonrandomized historic cohort studies (a study where outcomes from patients receiving a treatment are compared with a historic group with different treatment method)
Level V	Case series without controls

Adapted from reference 52.

sets forth the program goal, "By the year 2010, [the FDA will] have a science-based regulatory program that fully implements the Dietary Supplement Health and Education Act of 1994, thereby providing consumers with a high level of confidence in the safety, composition, and labeling of dietary supplement products." This plan addresses safety, including adverse event reporting, follow-up of significant adverse event reports, and GMPs; labeling; boundaries, including clarification of the differences between dietary supplements and drugs and the use of health claims for dietary supplements; and enforcement activities. It also strengthens the FDA's research and science capabilities for dietary supplement review and evaluation and provides a means for effective communication with stakeholders.

Postmarketing surveillance is an important component of monitoring the safety of herbal products. Reporting adverse events is facilitated through the FDA MedWatch system. In addition, the FDA developed the Special Nutritionals Adverse Event Monitoring System (SN/AEMS), which is a database of adverse events reported to the FDA that were associated with "use of a special nutritional product: dietary supplements, infant formulas, and medical foods." The SN/AEMS database is accessed through the Internet and searched online to determine whether a specific dietary supplement is associated with adverse effects. The usefulness of this system depends on the extent of reporting of adverse events associated with dietary supplements, including herbal products, from health professionals and consumers.

These new FDA measures are important in the regulation of dietary supplements; including herbal products. As these measures are implemented, consumers can place increasingly more confidence in the safety, composition, and labeling of herbal products, and health care professionals will be better able to counsel and monitor individuals who take such supplements.

Research Issues

Literature Retrieval

Research issues related to herbal therapy include considerations in retrieving the primary literature, using an evidence-based approach to evaluate studies, and in designing trials. The evaluation of any intervention, whether a surgical procedure, prescription drug, or herbal product, should begin with a thorough review of the literature. Because the National Library of Medicine does not consistently index articles on alternative medicine, the clinician using MEDLINE may not accomplish a satisfactory search. Still, a MEDLINE search is an important source of information. When necessary, MEDLINE searches may be supplemented by retrieving the references cited in the articles identified. EMBASE may index additional articles, and searching this database is strongly advised. Appendix 2 provides a bibliographic listing of reliable scientific sources of information on herbal products and alternative medicine.

Evidence-Based Evaluation

The current direction in medicine is practice based on evidence. While flaws and inferior science may have been accepted previously, treatment recommendations and decisions increasingly are expected to be determined by using evidence-based guidelines. The "test of time" or historical acceptance of alternative medicine, or of any element of medicine, is not a sufficient standard in today's society. The evaluation of herbal and other natural products as a health care modality should use the evidence-based approach.

In evidence-based medicine, treatment recommendations are determined by the level of

Table 3. Deficiencies and Problems Found Commonly in Studies of Herbal Products[a]

- Treatment arm used herbal products having several ingredients
- Inability to identify active ingredient of the herbal product
- Lack of standardized extracts, formulations, and doses
- Potential for adulterated or misbranded products
- Comparison of herbal products to subtherapeutic dosages of conventional medicine
- Many studies published in foreign languages only
- Small sample size
- Poorly defined inclusion or exclusion criteria
- Insufficient description of patient diagnosis using established criteria
- Short study duration for long-term chronic conditions
- Few pharmacoeconomic or outcomes-based studies

[a]These problems are not exclusive to herbal products but also occur frequently in trials of traditional drugs.

evidence available from clinical studies, which are judged by the quality of their design and methodology. In developing consensus statements on antithrombotic therapy, the American College of Chest Physicians incorporated a grading system of recommendations based on the levels of evidence from the clinical trials used.[51, 52] As summarized in Table 2, the levels of evidence range from level I (trials with the strongest design, such as randomized, controlled trials) to level V (case reports that provide useful information but no valid evidence for drug effectiveness).[52] As with other grading systems, limitations exist with the levels-of-evidence system, especially in the complexity of combining study results and applying results to patients with differing baseline characteristics or underlying risk factors. Nonetheless, using such a system can provide an initial approach to objectively evaluate studies of herbal products for level of evidence and determine a grade of recommendation.

Whereas some studies involving herbal products can be graded as having level I evidence, many published trials have weaker levels of evidence and rank as level III, IV, or V. Generally, many studies of alternative medicine therapies have flaws in study design, lack evidence of using standardized products, or fail to account for biases. Because many products were introduced to the United States from other countries and cultures, their studies are not published in the English language, adding to the difficulty in their evaluation. Many of the deficiencies are common to studies of conventional medicine, such as poorly defined exclusion or inclusion criteria and short treatment duration. However, unique to alternative medicine are problems such as product quality and standardization, as discussed previously. Other problems are listed in Table 3. Well-designed studies of some alternative therapies have been performed. Appendix 2 provides a comprehensive listing of information sources for these modalities. In particular, the Cochrane Library has a searchable collection of over 1500 randomized, controlled trials of alternative medicine interventions.

The Agency for Healthcare Research and Quality (formerly the Agency for Health Care Policy and Research) has issued a request for proposals for developing evidence-based reviews of various herbs. In response, the San Antonio Evidence-based Practice Center developed a team of national experts to review the literature addressing the use of garlic and milk thistle. Other teams have been assembled across the country to review other herbs. The results of this effort are anticipated to be published in the next few years.

Research with Herbal Products

Additional research is needed to satisfactorily determine the role of herbal products in health care. Well-designed, randomized, controlled clinical trials would best evaluate the efficacy, tolerability, and safety of herbal products, their comparative efficacy with conventional therapy, and potential drug interactions. Other areas needing research include assessing trends in usage, determining qualitative and quantitative standards for products, and evaluating long-term impacts on clinical outcomes, quality of life, and pharmacoeconomics. Because many individuals combine the use of herbal products with conventional medicine, as well as with other types of alternative medicine, research on these combined uses would be valuable.

The major barrier to research with herbal products and other types of alternative medicine is the relative lack of funding sources. Because most herbal and natural products cannot be patented, manufacturers have few incentives to fund large clinical trials. Increased regulations, as proposed by the FDA, as well as increased demands for clinical evidence by health care practitioners and educated consumers, may encourage manufacturers to conduct more clinical trials. In addition, many pharmaceutical manufacturers are planning to market herbal products and may be compelled to apply pharmaceutical testing and evaluation standards to herbal products. They may also be forced to fund studies evaluating the outcomes of combining alternative medicine with conventional therapies.

Both the National Center for Complementary and Alternative Medicine (NCCAM) at the National Institutes of Health (NIH) and the World Health Organization (WHO) have assisted or supported research in herbal products and other types of alternative medicine. Lobbying efforts by consumer groups and professional associations also can be an effective means to increase funding support for the scientific evaluation of all types of alternative medicine. Because the use of alternative medicines is a worldwide issue, large-scale global research efforts could be accomplished by collaboration, shared resources, and efficient use of the assets and expertise of each participating member. Private foundations that support medical research are another potential source of funding, and research objectives could be designed to meet foundation initiatives such as quality outcomes, cultural preferences for health care practices, use of health care resources, or self-care strategies with assessment of the need for referrals into health care systems.

The Role of Pharmacists

Millions of Americans take herbal products, and few inform their primary care providers. Many pharmacies sell herbal products, and pharmacists frequently are asked by both patients and other health care providers about the use of these products. The quality of the information on herbal products provided by pharmacists is unknown.

The basis for pharmacist involvement with herbal products is an extension of their established roles in pharmaceutical care, clinical pharmacy practices, and collaborative health care teams. The pharmacist plays a key role in providing care to patients who are taking or contemplating taking herbal products. The variability in the degree of scientific evidence on efficacy and safety available to support the use of herbal products makes it even more imperative that pharmacists assume an active role in this area of practice.

Ideally, pharmacists should stock only those products that were manufactured with conformity to GMP guidelines. This information is not available from manufacturers, but should be. In addition, products containing only the part of the plant that was proven in clinical trials to be effective should be stocked. Herbal and natural products with questionable or unproven efficacy or those known to be harmful should not be inventoried, recommended, or sold. Pharmacists employed by large corporations may need to develop special strategies to maintain the quality of products offered for sale. Pharmacists are in an ideal position to be involved in the care of patients taking herbal products, to monitor for adverse events, and to ensure that appropriate outcomes are met.

Drug Histories

Because they are not classified as drugs and are not considered drugs by their users, herbal products frequently are not mentioned during drug interviews or listed voluntarily on drug lists. All drug histories should include questions about the use of herbal and other natural products. The "don't ask, don't tell" policy is not acceptable for pharmacists. Many consumers expect pharmacists and other health professionals to be skeptical, and even hostile, about the use of herbal products.[1] To encourage consumers to discuss their use, inquiries should be conducted in an open and nonjudgmental fashion similar to the manner of inquiring about other over-the-counter products.

Inquiries should address the specific health care purpose for which the patient is using, or is considering using, an herbal product. Common reasons for use include health promotion; disease prevention; poor outcomes and limited treatment options for a serious illness; exhaustion of conventional therapies; dissatisfaction with, or lack of efficacy of, conventional therapies; significant side effects or risks associated with conventional medicine; belief that herbal and natural products are better or safer; preference

for personal involvement in the decision-making process; and cultural or spiritual preference.[3]

Pharmacists, other health professionals, and consumers must be vigilant in detecting and reporting suspected serious adverse events from prescription drugs, over-the-counter agents, and natural products to the FDA's MedWatch program. The SN/AEMS is a valuable way to detect emerging serious problems resulting from the use of natural products, but only if professionals and consumers are proactive in reporting problems.

Patient Education

Pharmacists should maintain accurate information about herbal products and use this expertise when advising consumers.[53] Pharmacists should strive to provide unbiased evaluations and to correct any misconceptions about the benefits and toxicities of these products in a manner similar to that done for over-the-counter and prescription agents.[54] Suitable resources, such as those listed in Appendix 2, can assist pharmacists in this role.

For the consumer using herbal products, the pharmacist should determine if the patient's herbal therapy is appropriate or if other therapies, conventional or otherwise, would provide better alternatives. The pharmacist should review the patient's drug regimen (including prescription, over-the-counter, and herbal and natural products) and disease states for potential or actual drug-related problems. Assisting the patient in streamlining a regimen of herbal and conventional therapies may result in eliminating products with similar effects or those that have not provided a benefit following a therapeutic trial. For example, it may be more economical to use saw palmetto in place of finasteride if a standardized, reputable saw palmetto product is available. Combinations of certain herbal products and conventional drugs may cause synergy of similar adverse events or may result in significant drug interactions.

For the consumer who is contemplating the use of herbal products, pharmacists should provide advice about the risks, as previously highlighted. In addition to efficacy and safety, factors such as cost and adherence should be considered, especially if the patient is taking other drugs. Care should be exercised if the patient is pregnant. Allergies should be reviewed carefully, with special caution for those who have plant and pollen allergies. Caution should be taken when little is known about the short-term or long-term effects of any product. Without the pharmacist working with the patient who plans to take herbal products, the patient may do so independently, with potentially adverse outcomes.

A major challenge is the patient who chooses to use herbal products as a substitute for conventional therapy without the knowledge and approval of the primary care provider. In this situation, the pharmacist can play a key role in educating the patient about the potential for delaying the initiation of proven therapy, or not allowing adequate time for a therapeutic trial.[55] Pharmacists need to establish rapport with their patients, maintain regular contact and follow-up, and, most important, encourage the use and continuation of therapies that have been effective.

With Medicare and many states requiring patient counseling and education, pharmacists must be able to recognize potential interactions, including those involving herbal products.[56] Liability issues involving alternative medicine are yet to be fully determined. However, by documenting that objective information on both risks and benefits was presented and that an informed decision was made by the patient, pharmacists should be able to demonstrate actions that were in the best interest of their patients. If high-quality studies of a particular herbal product are not available, the process for making therapy recommendations is the same as that for conventional medicine. Pharmacists play a critical role in educating patients and health care providers about the evidence available regarding efficacy and potential adverse effects, and in making recommendations consistent with that evidence.

To assure comprehensive care is maintained, the patient should inform, or permit the pharmacist to inform, the primary care provider that the patient is, or will be, taking alternative medicines.[56] Pharmacists who sell herbal products must avoid conflicts of interest when advising patients about these products. As with other nonprescription products, recommendations must be made in an unbiased manner based on the potential for benefit to the patient.

Pharmacist Participation in the Health Care Team

By keeping fully informed about herbal products, the pharmacist can be a valuable source of information for conventional and alternative

medical providers. The pharmacist should provide updates to the health care team on commonly used herbal products and serve as a resource for questions from the team members. Working closely with each patient's primary care providers, the pharmacist can provide expertise to identify and distinguish between side effects induced by conventional agents and plant-derived products. The management of side effects caused by these products and recommendations for treatment options are additional aspects of the pharmacist's role.

The pharmacist also should collaborate with the health care team in conducting research on the use of botanical agents. Pharmacists should encourage and share the responsibility for publishing these research results.

Pharmacists no longer can ignore the significance of herbal products and other types of alternative medicine in their daily practices. Staying informed and educating others should be an integral part of all pharmacists' responsibilities in providing complete pharmaceutical care to patients.

Pharmacy Education

Since the late 1970s, the formal education of pharmacy students about herbal and natural products has declined steadily. Courses in pharmacognosy, formerly required for all pharmacy students, were deleted during periods of curricular changes and as pharmacognosy faculty retired. A survey of 77 colleges of pharmacy conducted in 1997 revealed that 74% of the schools offered one pharmacognosy course averaging almost 3 credit hours, with one-third of the time devoted to herbal products.[57] However, in two-thirds of the schools, the course was an elective offering, hence limiting student exposure. A survey addressing the broader topic of alternative medicine recently reported similar findings.[58]

Although the new accreditation standards of the American Council on Pharmaceutical Education require instruction on self-care topics, herbal products and the broader topic of alternative medicine are not mentioned specifically.[59] The best approach to teaching herbal and natural products is unknown, but integrating core information across the curriculum into courses such as medicinal chemistry, pharmaceutics, and therapeutics is recommended. Discussions of herbal and natural products in therapeutics courses should emphasize the findings and limitations of current research in the medical literature and the levels of evidence supporting or refuting their use, just as they do for conventional treatments. Discussions of drug-induced diseases such as nephrotoxicity and hepatotoxicity should include herbal and other natural product causes. Courses would be enhanced by the participation of faculty with clinical expertise in the area of herbal medicine.

In addition to integration across the curriculum, specific courses might be designed to attain higher skill levels. For example, courses might emphasize the psychological aspects of self-care and factors that motivate patients to use herbal and natural products. In professional practice laboratory courses, students should be taught communication techniques that encourage consumers to talk about their use of these products and that develop nonjudgmental, supportive approaches to promote open and honest communication. Students must be made aware of their professional responsibility to public health by discouraging the use of dangerous products, whether herbal or nonherbal in origin.

For practicing pharmacists to fulfill their roles as educators on the use of herbal and natural products and contribute to the well-being of public health, continuing education and skills should focus on four core areas: (1) Pharmacists should have a thorough knowledge of common herbal and natural products in terms of their derivation, safety and efficacy, and drug interactions; (2) All pharmacists should have the ability to triage individuals in an ambulatory environment to determine those conditions for which self-care might be appropriate or, at a minimum, not detrimental; (3) The pharmacist must have effective oral communication skills that incorporate an appreciation for the health beliefs of culturally and ethnically diverse populations; and (4) Pharmacists must possess the technologic and critical appraisal skills for retrieving and evaluating relevant lay information and scientific literature on herbal topics.

Summary

Individuals increasingly are taking a more active role in their health care, and herbal products have emerged as a common choice among self-care therapies. Pharmacists are active participants in the care of patients who are taking herbal products. Currently, most pharmacists are not educated adequately about herbal products

and other types of alternative medicine. Furthermore, good information about many of these products is not available. These combined factors present a challenge for pharmacists as they seek to provide optimal care and counseling to patients who use herbs or supplements. We recommend the following actions to place pharmacists in better positions as effective agents protecting public safety:

- Regulations should be implemented at a federal level to require basic levels of standardization and quality control in the manufacture of herbal products.
- Indexing terms in medical bibliographic systems should be expanded to target herbal products.
- Funding should be increased for scientific research evaluating herbal products.
- Pharmacy schools should include a competency statement in their curricula regarding herbal medicines.
- Continuing education in herbal products should be available and encouraged for all pharmacists.

Pharmacists should approach the use of all therapeutic interventions with scientific rigor, whether they are traditional or complementary in nature. Patients will benefit as more information is known and widely disseminated. By actively embracing the responsibility for counseling individuals on the appropriate use of herbal products, pharmacists will become a recognized source of expert information in this rapidly growing area, yielding important improvements in the quality of care.

Acknowledgments

The thoughtful reviews of Geraldine Anastasio, Pharm.D., and Marc Israel, Pharm.D., are gratefully acknowledged.

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Appendix 1. Glossary and Short Descriptions of Other Alternative Medicine Practices

Acupuncture: practice of piercing specific areas of the body with needles to relieve discomfort associated with painful disorders, to induce surgical anesthesia, or for therapeutic purposes. This procedure originally was introduced and practiced in China.[60]

Alexander therapy: therapy designed to increase awareness and voluntary inhibition of personal habitual patterns of rigid musculoskeletal constrictions.[61]

Aromatherapy: use of fragrances and essences from plants to affect or alter a person's mood or behavior and to facilitate physical, mental, and emotional well-being. The essential oils in plants contain chemicals, many of which have therapeutic properties and have been used historically in Africa, Asia, and India.[60]

Ayurvedic medicine: traditional Hindu system of medicine that is based on customs, beliefs, and practices of the Hindu culture. Ayurveda means "the science of life."[60]

Balneotherapy: therapy by hot or warm baths in natural mineral waters or spas. It includes not only bathing in, but also drinking, the waters. It does not include whirlpool baths.[60]

Biofeedback: use of instrumentation to give immediate and continuing signals of change in bodily function of which a person is usually unaware.[60]

Chiropractic: system that is said to use the recuperative powers of the body and the relationship between musculoskeletal structures and functions of the body, particularly of the spinal column and the nervous system, in the restoration and maintenance of health.[60]

Curanderismo: Latin-American, community-based folk system of medicine that consists of two components. The first, humor model, classifies activity, food, drugs, and illness as having characteristics of hot or cold, and dry or moist. Good health is maintained by achieving a balance between these characteristics. The second component involves the treatment of folk illnesses.[62]

Hydrotherapy: external application of water for therapeutic purposes. It is differentiated from balneotherapy by emphasizing the use of plain water, whereas balneotherapy emphasizes the use of mineral water.[60]

Hypnosis: state of increased receptivity to suggestion and direction, induced by the influence of another person.[60]

Massage: systematic application of petrissage, effleurage, friction, percussion, stroking, static pressure, vibration, or other manual manipulations to the soft tissues (muscles, ligaments, tendons, fascia) of the body. These techniques include, but are not limited to, Rolfing, Trager, Bidegewebsmassage, Neuromuscular Therapy Hellerwork, acupressure, myofascial release, strain-counterstrain, positional release, shiatsu, and the manual stimulation of trigger points.[63]

Meditation relaxation techniques: mental exercises such as concentration or visualization, postural modifications, and breathing exercises designed to reduce mental and/or physical arousal. These techniques include meditation, Jacobsen exercises, the Mitchell method, autogenic training, visualization and imagery.[61]

Osteopathy: a system of therapy and medicine based on the theory that the normal body is a vital mechanical organism whose structural and functional states are of equal importance and is capable of making its own remedies against infections and toxic conditions when there are favorable environmental circumstances and adequate nutrition.[60]

Qigong (pronounced "chee gong"): in Chinese, "qi" means energy and "gong" means a skill or practice. Together they translate as "a skill or practice of cultivating energy." Qigong is a Chinese practice of self-care that involves the combination of specific regulation of body movement and posture through physical exercise with meditation involving careful regulation of breath and deep relaxation states. It is done to enhance the mind-body connection and thus promote health.[64,65]

Reflexology: manual stimulation of points on the foot thought to correspond to the organs and structures of the body.[61]

Therapeutic touch: a method developed in the 1970's by Dora Kunz and Dolores Krieger (from the New York University Nursing School), wherein the healer's hands are placed, in a systematic way, on or near the patient to facilitate palliative relief or cure.[63]

Tai chi: an ancient Chinese system of exercise or an "art for life." The practice stimulates the nervous system, increases blood circulation and glandular activity, strengthens muscles, and exercises the joints. The movements are circular and gentle, done in an even, slow tempo, synchronized with the breath.[66]

Vegan diet: diet that excludes all animal products such as flesh foods, milk, cheese, eggs, butter, and honey.[66]

Vegetarian diet: diet that excludes flesh foods such as meat, fish, fowl and their derivatives. It is sometimes called lacto-ovo vegetarian because it includes milk and eggs.[66]

Yoga: orthodox system of Hindu philosophy, which includes exercise for attaining bodily or mental control and well-being.[60]

Appendix 2. Sources of Information on Herbal Medicines and Alternative Therapies

Journals

These journals specifically or regularly address alternative therapies and include original research. The reader is referred to Ulrich's International Periodicals Directory, 38th edition (New Providence, NJ: RR Bowker, 2000) for more detailed information. All journals listed are active. The year refers to year of first publication.

English Language, Peer-Reviewed

Alternative Medicine Review, 1996 (academic/scholarly publication)
Alternative Therapies in Clinical Practice, 1994 (academic/scholarly publication)
Alternative Therapies in Health and Medicine, 1995 (academic/scholarly publication)
American Journal of Chinese Medicine, 1973 (abstracting and indexing service, academic/scholarly publication)
Australian Journal of Medical Herbalism, 1989 (academic/scholarly publication)
Australian Traditional Medicine Society Journal, 1998 (academic/scholarly publication)
British Journal of Phytotherapy, 1990 (academic/scholarly publication)
European Journal of Herbal Medicine, 1994 (academic/scholarly publication)
Focus on Alternative and Complementary Therapies, 1996 (academic/scholarly publication)
Forschende Komplementaermedizin/Research in Complementary Medicine, 1994 (online edition, academic/scholarly publication)
HealthInform, 1995 (newsletter, abstracting and indexing service, academic/scholarly publication)
Journal of Alternative and Complementary Medicine: Research on Paradigm, Practice and Policy, 1993 (academic/scholarly publication)
Journal of Herbal Pharmacotherapy, first issue slated for fall, 2000 (academic/scholarly publication)
Journal of Interprofessional Care, 1984 (academic/scholarly publication)
Planta Medica, 1935 (academic/scholarly publication)

Non-English Language, Peer-Reviewed

Hebei Zhongyi/Hebei Traditional Medicine, 1979 (Chinese, academic/scholarly publication)
Tijdschrift Voor Integrale Geneeskunde, 1984 (Dutch, academic/scholarly publication)
Zhongguo Yaoxue Wenzhai/Chinese Pharmaceutical Abstracts, 1982 (text in Chinese, index in English, abstracting/indexing, academic/scholarly publication)

Non-Peer-Reviewed or Peer Review Status Unknown

Alternative and Complementary Therapies, 1994
Complementary Therapies in Medicine,1993 (academic/scholarly publication)
Complementary Therapies in Nursing and Midwifery, 1995 (academic/scholarly publication)
HerbalGram, 1979
Phytomedicine, 1994 (academic/scholarly publication)

Databases

The Research Council for Complementary Medicine (RCCM) home page has more details on most of the following. The RCCM's Internet address is provided in Web site section below.

AMED (Alternative and Allied Medicine Database). Produced and updated monthly by the British Library's Medical Information Centre, this database contains 65,000 references from 400 journals on alternative and complementary medicine. Online searches are available through Datastar or MIC-KIBIC. The database is also available on floppy disk and in printed format as the Complementary Medicine Index from the British Library Medical Information Service, Boston Spa, United Kingdom. More details are available from the British Library (01937 546 039).

CISCOM (Centralised Information Service for Complementary Medicine). This RCCM database of research references and abstracts combines data from MEDLINE, AMED, other specialized European databases and in-house citation tracking. There is no direct access to the database, but mediated searches can be arranged by calling the RCCM (+44 0207 833 8897). Fees for use of the service start at £15 (UK) and depend on the scale and complexity of the request. Data are provided in printed or electronic format. A special feature of the CISCOM database is a large collection of randomized, controlled trials, including the full registry of the Cochrane Complementary Medicine Field.

The Cochrane Library. This database provides rapid access to regularly updated systematic reviews of the effects of health care (Cochrane Database of Systematic Reviews [CDSR]), structured abstracts of quality-assessed, previously published reviews (Database of Abstracts of Reviews of Effectiveness [DARE]), references to controlled trials (Cochrane Controlled Trials Register [CCTR]), and references to articles on the science of reviewing research and sources of further information (Cochrane Review Methodology Database [CRMD]). This evidence-based medicine database is developed and maintained by Collaborative Review Groups and is more likely to provide useful information on alternative therapies, including herbs, than is MEDLINE. Subscription information is provided on the Cochrane Library Web site listed in the Web site section below.

Appendix 2. Sources of Information on Herbal Medicines and Alternative Therapies (continued)

Databases (continued)

Cochrane Complementary Medicine Field. This section of the Cochrane Library was established to meet the growing need for evidence-based research in alternative medical practices. The primary aim of the database is to compile randomized, controlled trials of alternative medicine interventions, particularly from journals that specialize in this area. The full registry of this database is included in CISCOM (listed above). However, a fee is required for a mediated search of CISCOM. Sometime in the near future, this database will be added to the CCTR of the Cochrane Library. This database is only available to subscribers of the Cochrane Library.

EXTRACT. This database contains annotated and codified information about the chemistry, pharmacology, and therapeutics of medicinal plants. More information is available from the Simon Mills Centre for Complementary Health Studies, University of Exeter, Streatham Court, Rennes Drive, Exeter EX4 4PU, United Kingdom (+44 01392 264498 weekdays).

NAPRALERT (Natural Products Alert). This database contains 125,000 entries on natural products used worldwide, including chemical, pharmacologic, and ethnomedical information, and is updated monthly by Scientific and Technical Information Network. Summary information can be found at http://info.cas.org/ONLINE/DBSS/napralertss.html.

Natural Medicines Comprehensive Database. This extensive database, maintained by the editors of the *Pharmacist's Letter/Prescriber's Letter*, contains information on over 1000 herbs and dietary supplements with an index containing over 7000 brand names. Each herb/supplement listing includes 15 categories of information that address the most common questions faced by practitioners. The database is well referenced and is available as an electronic version (http://www.NaturalDatabase.com/) and print version (refer to the books section of this appendix). The Web version is continuously updated and allows more sophisticated searching than does the print version. It also contains a more extensive brand name index.

Web Sites

Research Council for Complementary Medicine (RCCM): http://www.rccm.org.uk/. The home page contains a comprehensive listing and descriptions of bibliographic databases, indexes, and journals related to alternative medicine. The RCCM is a resource for health care professionals only; they do not serve the lay public. CISCOM is the RCCM's database. Unfortunately, on the completion of existing commitments, the RCCM will cease to operate. At the time of this writing, the home page was still accessible.

American Botanical Council (ABC): www.herbalgram.org. The home page provides access to information on ordering HerbalGram (see journals), The Complete German Commission E Monographs (see books), and an herb book catalog.

NIH's National Center for Complementary and Alternative Medicine (NCCAM): http://nccam.nih.gov/. The NCCAM facilitates research and evaluation of alternative medical practices and disseminates this information to both health professionals and the public. From their home page one can access general information on alternative medicine, a listing of program areas, calendar of events, and the CAM Citation Index. The CAM Citation Index consists of more than 180,000 bibliographic citations from 1963–1998 extracted from the National Library of Medicine MEDLINE database. This database allows one to search or browse the database, which is organized by CAM system, disease, or method. This database is limited by using MEDLINE, which has only 23 subject headings for alternative medicine and is not as extensive as CISCOM or the Cochrane Library.

The Cochrane Library: www.cochrane.co.uk. This Web site contains information about the Cochrane Library and how to access it. Only abstracts are available free from the Internet. A subscription is required for the other services.

Center for Food Safety and Applied Nutrition: http://vm.cfsan.fda.gov/. This Web site has a section on dietary supplements, including information on the Dietary Supplement Health and Education Act (DSHEA) and the Special Nutritionals Adverse Event Monitoring System.

International Bibliographic Information on Dietary Supplements (IBIDS): http://dietary-supplements.info.nih.gov/databases/ibids.html. IBIDS is a database of published, international, scientific literature on dietary supplements, including vitamins, minerals, and selected herbal and botanical supplements. It is produced by two government agencies, NIH's Office of Dietary Supplements and the U.S. Department of Agriculture's Food and Nutrition Information Center, and currently contains 328,000 citations and abstracts.

Micromedex Internet Healthcare Series: http://micromedex/mdxdocs/mdxhome.html. Micromedex is developing a reliable, comprehensive source of information for alternative medicine at this Web site. The AltMedDex System was introduced in February 1999 and will contain more than 50 evidence-based monographs on herbal, vitamin, and other dietary supplements. The clinically focused, scientific information also will contain guidelines and recommendations to assist clinicians in making appropriate therapy choices and decisions.

Books

PDR for Herbal Medicines, 2nd ed. Montvale, NJ: Medical Economics, 2000.

PDR for Nonprescription Drugs and Dietary Supplements, 20th ed. Montvale, NJ: Medical Economics, 1999.

Bisset NG. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis. Washington, DC: MedPharm Scientific Publishers, 1994.

Blumenthal M, Busse WR, Goldberg A, et al, eds. The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicine. Austin, TX: American Botanical Council, 1998.

Bratman S, Kroll D. Clinical Evaluation of Medicinal Herbs and Other Therapeutic Natural Products. Rockland, CA: Prima Health Publishing, 2000 (updated quarterly).

Appendix 2. Sources of Information on Herbal Medicines and Alternative Therapies (continued)

Books

DerMarderosian A, ed. The Review of Natural Products. St. Louis, MO: Facts & Comparisons, Inc, 1999 (updated monthly).

DeSmet PAGM, Keller K, Hansel R, Chandler RF. Adverse Effects of Herbal Drugs, Volumes 1, 2, and 3. New York: Springer-Verlag, 1992, 1993, and 1997, respectively.

European Scientific Cooperative on Phytotherapy, Fascicule 1 and 2. Center for Complementary Health Studies, University of Exeter, Exeter, UK, 1996 and 1997, respectively.

Foster S, Tyler VE. Tyler's Honest Herbal: A Sensible Guide to the Use of Herbs and Related Remedies, 4th ed. New York:. The Haworth Herbal Press, 1999.

Huang KC. The Pharmacology of Chinese Herbs, 2nd ed. New York: CRC Press, 1999.

Jellin JM, Batz F, Hitchens K. Pharmacist's Letter/Prescriber's Letter Natural Medicines Comprehensive Database. Stockton, CA: Therapeutic Research Faculty, 1999.

McGuffin M, Hobbs C, Upton R, Goldberg A. American Herbal Products Association's Botanical Safety Handbook. New York: CRC Press, 1997.

Miller LG, Murray WJ. Herbal Medicinals: A Clinician's Guide. New York: The Haworth Herbal Press, 1998.

Newall CA, Anderson LA, Phillipson JD. Herbal Medicines: A Guide for Health-Care Professionals. London: The Pharmaceutical Press, 1996.

Randall JL, Lazar JS, eds. Complementary and Alternative Therapies in Primary Care. Primary Care Clinics in Office Practice 1997(Dec);24(4).

Robbers JE, Tyler VE. Tyler's Herbs of Choice: The Therapeutic Use of Phytomedicinals. New York: The Haworth Herbal Press, 1999.

Schulz V, Hansel R, Tyler VE. Rational Phytotherapy: A Physicians' Guide to Herbal Medicine, New York: Springer, 1997.

Miscellaneous

The following article in the library science literature may be helpful in conducting a literature search in alternative medicine. It provides a detailed discussion on conducting electronic database searches, including specific examples of terms and strategies to use when searching MEDLINE, EMBASE, BIOSIS Previews, and SciSearch. In addition, the article discusses AMED, International Pharmaceutical Abstracts (IPA), NAPRALERT, and The Cumulative Index to Nursing and Allied Health (CINAHL).

Snow B. Alternative Medicine Information Sources. Database 1998 (June/July);21:18–29.

Inclusion in this list does not represent endorsement by the authors.

Tab 14

White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland 20817 tel: 301-435-7592 fax: 301-480-1691
E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

January 29, 2001

Mr. Tom Dolan, President
American College of Healthcare Executives
Suite 1700
One North Franklin Street
Chicago, IL 60606-3491

Dear Mr. Dolan:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

The Commission will meet on February 22-23 to discuss complementary and alternative medicine in terms of education and training of health care practitioners, quality of care, and accountability. To accomplish its goal, the Commission needs your organization's input before it begins its deliberations. Therefore, we would very much appreciate receiving your advice and comments on these issues by **February 13, 2001**, preferably by e-mail or otherwise by fax, so that the Commissioners have enough time to review them before the February 22-23 meeting.

The questions that follow were developed to guide the Commission's deliberations.

1. Do you provide any training in complementary and alternative medicine (CAM) in your undergraduate, graduate, or continuing education curricula? If no, please explain why not. If yes, please answer the following:

- What CAM modalities or therapies are offered in your curricula?
- Approximately how much time is devoted to CAM?
- Is there any discussion of CAM as a different approach to healing?
- What are the barriers/incentives to inclusion of CAM in your curricula?

2) What policy recommendations can you make to facilitate the inclusion or expansion of CAM in your curricula?

3) Should questions regarding CAM be included in national board exams?

4) What should members of your profession know about CAM or about making referrals to CAM practitioners? How should that level of knowledge be determined?

5) Is malpractice a concern in terms of offering or not offering referrals for patients for CAM practices and products?

6) Are there any risks associated with CAM that may be of concern to your practitioners? If so, can you suggest any ways that they can be minimized?

7) Do you have any other thoughts or suggestions that may assist the Commission in formulating their recommendations?

Thank you for your invaluable assistance. Please send your written comments to Ms. Corinne Axelrod *(e-mail: axelrodc@mail.nih.gov, fax: 301-480-1691, phone:301-435- 7592),* and contact her with any questions you may have.

The February meeting will be held in the Hubert H. Humphrey Building, 200 Independence Avenue, in Washington, DC. You are welcome to attend.

Sincerely,

Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on
Complementary and Alternative
Medicine Policy

Chang, Michele (NCCAM)

Subject: FW: White House Commission

I am responding to your request about ACHE's involvement in CAM. As a bit of background, ACHE is an international professional society of nearly 30,000 healthcare executives. The College is known for its prestigious credentialing and educational programs. The College is also known for its journal, Journal of Healthcare Management and magazine, Healthcare Executive, as well as ground breaking research and career development and public policy programs.

I am sending to Stephen Groft a copy of a journal, Frontiers of Health Services Management which was recently published on the subject of CAM.

Please contact me if you have any questions.

Karen Hackett, FACHE
Executive Vice President & Chief Operating Officer
ACHE

Tab 15

White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland 20817 tel: 301-435-7592 fax: 301-480-1691
E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

January 26, 2001

Ms. DeeAnne Williams, C.N.M.
Executive Director
American College of Nurse-Midwives
818 Connecticut Avenue
NW, Suite 900
Washington, D.C. 20006

Dear Ms. Williams:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

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6) Are there any risks associated with CAM that may be of concern to your practitioners? If so, can you suggest any ways that they can be minimized?

7) Do you have any other thoughts or suggestions that may assist the Commission in formulating their recommendations?

Thank you for your invaluable assistance. Please send your written comments to Ms. Corinne Axelrod *(e-mail: axelrodc@mail.nih.gov, fax: 301-480-1691, phone:301-435- 7592),* and contact her with any questions you may have.

The February meeting will be held in the Hubert H. Humphrey Building, 200 Independence Avenue, in Washington, DC. You are welcome to attend.

Sincerely,

Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on
Complementary and Alternative
Medicine Policy

From: Deanne Williams [mailto:Dwilliam@acnm.org]
Sent: Sunday, February 04, 2001 4:58 PM
To: Axelrod, Corinne (NCCAM)

January 29, 2001 via e-mail

As Executive Director of the American College of Nurse-Midwives (ACNM), I am responding to your request for information about the CAM content which is included in the education of certified nurse-midwives (CNMs) and certified midwives (CMs). The ACNM is the professional organization representing CNMs and CMs. We have established standards for the education, certification and practice for these professionals who provide primary health care to women and are licensed to practice in 50 states plus the District of Columbia. All graduates of ACNM DOA accredited education programs are eligible to take the national certification exam which serves as the entry-to-practice exam required for state licensure. All education programs are post baccalaureate and over 70% of our members have earned a master's degree. The ACNM Division of Accreditation is recognized as an accrediting agency by the U.S. Dept of Education.

Complementary and alternative medicine is included in the education and continuing education activities supported by ACNM. For example, the ACNM Core Competencies for Basic Midwifery Practice which delineate the fundamental knowledge, skills and behaviors expected of a new practitioner include "management techniques and therapeutics including complementary therapies" to facilitate health and treat common health problems. Complementary therapies refer to those therapeutic measures for which there is some evidence of safety and effectiveness. The core competencies do not contain a list of these therapies. Because the core competencies have such a strong influence over the education of all who enter our profession, it is hard to identify a policy that could do more to facilitate the inclusion of CAM in program curricula. The national board exam is managed by a separate entity which utilizes the core competencies and a task analysis to determine the content of the exam. Thus, one would expect to see some questions on CAM in the exam, but I cannot tell you how many.

Because there are 45 accredited education programs across the country, I cannot tell you how much time each program devotes to CAM. I am aware that this is an area of great interest to many of our members. While midwives have worked as part of the medical profession for many years, our emphasis on informed decision making and focus on the provision of individualized care, probably makes it more comfortable for consumers who subscribe to CAM to seek our services. In addition, our critical review of what is promoted as routine maternity and/or women's health care, has also led many to at least consider CAM as worthy of respect.

In 1999, the Journal of Nurse-Midwifery (now Journal of Midwifery and Women's Health), which is the official ACNM journal, devoted an entire issue to a home study program titled: Complementary/Alternative Therapies in Women's Health. At the ACNM Annual Meeting, it is not unusual to find several presentations that address specific CAM therapies. In addition, CAM may be mentioned in many of the presentations as it is relevant to the clinical topic.

I am not aware that malpractice is a concern in terms of offering or not offering referrals for

CAM practice or products. I do know that many of our members have called for meticulous and evidence based decision-making in this area. Since many midwifery clients are pregnant, the effect of CAM on the mother and developing fetus are primary concerns. Lack of evidence of safety in this area is a problem.

Finally, the ACNM wants to emphasize that midwifery care should not be classified as an alternative therapy. While receiving care from a CNM or CM is an alternative to receiving care from a physician, midwifery as practiced by CNMs and CMs is a well-established profession taught in programs that are affiliated with institutions of higher education. The primary difference between midwifery and medicine can be found in the philosophy of care, not in the knowledge base or content of care. There is ample evidence to document that the outcome of care with a CNM is equivalent to that of a physician.

I wish you well in your deliberations and will be happy to provide additional information if needed.

Sincerely,

Deanne R. Williams, CNM, MS, FACNM
Executive Director

Tab 16

White House Commission on Complementary and Alternative Medicine Policy

6701 Rockledge Drive, Suite 1010, MS-7707, Bethesda, Maryland 20817 tel: 301-435-7592 fax: 301-480-1691
E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

January 26, 2001

Mr. Eric Scharf, C.A.E.
Executive Director
American College of Nurse Practitioners
503 Capitol Ct NE, #300
Washington, D.C. 220002

Dear Mr. Scharf:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

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7) Do you have any other thoughts or suggestions that may assist the Commission in formulating their recommendations?

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Sincerely,

Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on
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Medicine Policy

Tab 17

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January 26, 2001

Stanley Wallach, M.D.
Executive Director
The American College of Nutrition
300 South Duncan Avenue, Suite 225
Clearwater, Florida 33755

Dear Dr. Wallach:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

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Sincerely,

Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on
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Tab 18

White House Commission on Complementary and Alternative Medicine Policy

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January 26, 2001

John S. Zapp, D.D.S.
Executive Director
American Dental Association
211 E. Chicago Avenue
Chicago, Il 60611

Dear Dr. Zapp:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

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Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on
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Medicine Policy

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White House Commission on Complementary and Alternative Medicine Policy

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E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

January 29, 2001

Mr. John H. Graham IV, CEO
American Diabetes Association
1701 North Beauregard Street
Alexandria, VA 22311

Dear Mr. Graham:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

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White House Commission on
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Tab 20

White House Commission on Complementary and Alternative Medicine Policy

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January 26, 2001

Mr. Todd Ketch
Director, Government Relations
American Dietetic Association
1120 Connecticut Avenue, NW, Suite 480
Washington, D.C. 20036

Dear Mr. Ketch:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

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Executive Director
White House Commission on
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E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

January 26, 2001

Ms. Stephanie Reed
American Nurses Association
600 Maryland Avenue, SW
Suite 100 West
Washington, DC 20024

Dear Ms. Reed:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

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Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on
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Chang, Michele (NCCAM)

Subject: FW: White House Commission

Confirming my conversation this morning with Ms. Corinne Axel of the Commission's staff, I am writing in response to the Commission's invitation to the American Nurses Association to present testimony during the meeting scheduled for February 22-23.

As I indicated to Ms. Axel, ANA does not have a formal policy on complementary and alternative medicine and will not be able to present testimony as requested. However, many registered nurses are involved in the practice of these therapies, and we agree that it would be appropriate for the Commission to seek comment from nursing specialty organizations whose members are particularly knowledgeable in this area.

ANA suggests particularly that you contact:

American Holistic Nurses Association
P. O. Box 2130
Flagstaff, AZ 86003-2130
Phone: 800-278-2462
Website: www.ahna.org

Oncology Nursing Society
501 Holiday Drive
Pittsburgh, PA 15220
Phone: 412-921-7373
Fax: 412-921-6565
Website: www.ons.org

I hope this information is helpful. ANA appreciates your invitation, and we will look forward to the Commission's recommendations.

Stephanie Reed
Associate Director
ANA Government Affairs

Tab 22

White House Commission on Complementary and Alternative Medicine Policy

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E-mail: whccamp@mail.nih.gov Website: www.whccamp.hhs.gov

January 26, 2001

Mr. Joe Isaacs, C.A.E.
Executive Director
American Occupational Therapy Association
4720 Montgomery Lane
P.O. Box 31220
Bethesda, MD 20824-1220

Dear Mr. Isaacs:

I am writing this letter on behalf of the White House Commission on Complementary and Alternative Medicine Policy, established by the President in March of 2000. In carrying out its mandate, the Commission is addressing: (1) coordinated research on complementary and alternative medicine (CAM) practices and products; (2) appropriate education and training of CAM and conventional health care practitioners; (3) dissemination of reliable information on CAM to health care providers and the general public; and (4) delivery and public access to CAM services. Additional information on the Commission is available at its Web site at <http://www.whccamp.hhs.gov>.

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Sincerely,

Stephen C. Groft, Pharm. D.
Executive Director
White House Commission on
Complementary and Alternative
Medicine Policy

Thank you for your recent communication to our Executive Director, Joe Isaacs, requesting information from the American Occupation Therapy Association, Inc. (AOTA) to assist the White House Commission on Complementary and Alternative Medicine. I am responding on his behalf. We are grateful for the opportunity to further the deliberations of the Commission and its important undertaking.

AOTA represents the professional interests of almost 50,000 occupational therapists, occupational therapy assistants and students of occupational therapy. Occupational therapy practitioners provide important health and rehabilitation services to people of all ages who, because of illness, injury, developmental or psychological impairment, need specialized intervention to regain, develop, or build skills necessary for independent functioning. The focus of occupational therapy is on an individual's ability to effectively engage in performance areas that are purposeful and meaningful, such as activities of daily living (ADLs), work and other productive activities. Occupational therapists evaluate and treat sensorimotor, cognitive and psychosocial problems that may interfere with an individual's performance abilities while taking into account the performance context, such as environmental factors.

Occupational therapists and occupational therapy assistants must complete accredited entry-level academic programs and a supervised fieldwork experience. Both must graduate from educational programs accredited by the American Occupational Therapy Association's Accreditation Council in Occupational Therapy Education (ACOTE), which is recognized as the accrediting agency for occupational therapy by the United States Department of Education (USDE) and the Council on Higher Education Accreditation (CHEA). Following successful completion of course and clinical work, both the occupational therapist and the occupational therapy assistant must pass entry-level certification examinations administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

For the Commission's information, I have enclosed copies of the ACOTE accreditation standards for both technical and professional levels in occupational therapy. Although complementary and alternative medicine is not specifically addressed in occupational therapy curricula, we believe from discussions with educators that there is discussion of complementary and alternative medicine and its relationship to occupational therapy ongoing at some occupational therapy education programs. Anecdotal reports and references in the professional literature indicate that some occupational therapists are also incorporating use of complementary and alternative medicine techniques such as meditation, Tai Chi, acupressure, and yoga in their interventions plans. Beyond these indicators, we do not have substantial information to share with the Commission on the specific questions you posed.

However, the Association's ACOTE Educational Standards Review Committee would welcome recommendations from the Commission about educating occupational therapy students about complementary and alternative medicine for their consideration in developing future versions of the ACOTE Standards. In addition, the Association welcomes any suggestions for educating practitioner members of the Association about the role of and appropriate referrals to complementary and alternative medicine practitioners or any other information the Commission deems appropriate to share.

We look forward to the final report of the Commission. Please don't hesitate to contact me if you have questions or would like additional information.

Frederick P. Somers
Associate Executive Director, Professional Affairs
American Occupational Therapy Association, Inc.

STANDARDS FOR AN ACCREDITED EDUCATIONAL PROGRAM FOR THE OCCUPATIONAL THERAPIST

Adopted December 1998; Effective July 1, 2000

ACCREDITATION COUNCIL FOR OCCUPATIONAL THERAPY EDUCATION

of

THE AMERICAN OCCUPATIONAL THERAPY ASSOCIATION, INC.

The Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association (AOTA) accredits educational programs for the occupational therapist. The Standards comply with the United States Department of Education (USDE) criteria for recognition of accrediting agencies.

> *These Standards are the requirements used in accrediting educational programs that prepare individuals to enter the occupational therapy profession. The extent to which a program complies with these Standards determines its accreditation status.*

Sections A and C contain general standards, while Section B delineates standards specific to curriculum. The specific standards in Section B are stated as outcome-based criteria.

PREAMBLE

The rapidly changing and dynamic nature of contemporary health and human service delivery systems requires the entry-level occupational therapist to possess basic skills as a direct care provider, consultant, educator, manager of personnel and resources, researcher, and advocate for the profession and the consumer.

A contemporary entry-level occupational therapist must:

- have acquired, as a foundation for professional study, a breadth and depth of knowledge in the liberal arts and sciences and an understanding of issues related to globalism and diversity;
- be educated as a generalist, with a broad exposure to the delivery models and systems utilized in settings where occupational therapy is currently practiced and where it is emerging as a service;
- have achieved entry-level competence through a combination of academic and fieldwork education;
- be prepared to articulate and apply professional principles, intervention approaches and rationales, and expected outcomes as related to occupation;
- be prepared to supervise and work in cooperation with the occupational therapy assistant;
- be prepared to be a lifelong learner and keep current with best professional practice;
- uphold the ethical standards, values, and attitudes of the occupational therapy profession;
- be prepared to be an effective consumer of the latest research and knowledge bases that undergird practice and contribute to the growth and dissemination of research and knowledge.

SECTION A: GENERAL REQUIREMENTS FOR ACCREDITATION

1.0 SPONSORSHIP

1.1 The sponsoring institution(s) and affiliates, if any, must be accredited by recognized national, regional, or state agencies with accrediting authority. For programs in countries other than the United States, ACOTE will determine an alternative and equivalent external review process.

1.2 Sponsoring institutions must be authorized under applicable law or other acceptable authority to provide a program of postsecondary education and must have degree granting authority.

1.3 For programs in which the academic and fieldwork components of the curriculum are provided by two or more institutions, responsibilities of each sponsoring institution and fieldwork site must be clearly documented in a memorandum of understanding.

1.4 Documentation must be provided that each memorandum of understanding between institutions and fieldwork sites is reviewed at least every five years by both parties.

1.5 Accredited occupational therapy educational programs may only be established in senior colleges, universities, or medical schools.

1.6 The sponsoring institution shall assume primary responsibility for appointment of faculty, admission of students, curriculum planning, including selection of course content, and granting the certificate or degree documenting satisfactory completion of the educational program. The sponsoring institution shall also be responsible for the coordination of classroom teaching and supervised fieldwork practice and for providing assurance that the practice activities assigned to students in a fieldwork setting are appropriate to the program.

2.0 ACADEMIC RESOURCES

2.1 The program must have a director who is assigned to the occupational therapy program on a full-time basis.

2.2 The program director shall be an occupational therapist, initially certified nationally, and credentialed according to state requirements. The director shall have a minimum of five years of professional experience in areas related to clinical practice, administration, and teaching. At least two of these years must be a full-time academic appointment with teaching responsibilities.

2.3 The program director shall have academic qualifications comparable to other administrators who manage similar programs within the institution; senior faculty status; and relevant experience in higher education requisite for providing effective leadership for the program, its faculty, and its students.

2.4 The program director shall be responsible for the management and administration of the program, including planning, evaluation, budgeting, selection of faculty and staff, maintenance of accreditation, and commitment to strategies for professional development.

2.5 The program director and faculty must possess the necessary academic and experiential qualifications and backgrounds, identified in documented descriptions of roles and responsibilities, appropriate to meet program objectives.

2.6 The occupational therapy faculty will assume responsibility for development, implementation, and evaluation of fieldwork education. There will be an individual specifically identified with fieldwork coordination responsibilities.

2.7 The faculty shall include occupational therapy practitioners who have been initially certified nationally and who have documented expertise in their area(s) of teaching responsibility.

2.8 The occupational therapy faculty must be sufficient in number and must possess the expertise necessary to ensure appropriate curriculum design, content delivery, and program evaluation.

2.9 Faculty responsibilities shall be consistent with the mission of the institution.

2.10 Each full-time faculty member shall have a written continuing professional growth and development plan to ensure effectiveness and currency as an academic educator consistent with the structure of the program's strateg ic plan.

2.11 The program shall develop a strategic plan congruent with the mission of the institution and the curriculum design. This plan shall incorporate professional development plans of the faculty and the program objectives.

2.12 The faculty/student ratio shall permit the achievement of the purpose and stated objectives of the program, be compatible with accepted practices of the institution for similar programs, promote quality education in laboratory and fieldwork experiences, and ensure student and/or consumer safety.

2.13 Clerical and support staff shall be provided to the program, consistent with institutional practice, to meet programmatic and administrative requirements.

2.14 The program shall be allocated a budget of regular institutional funds, not including grants, gifts, and other restricted sources, sufficient to implement and maintain the objectives of the program and to fulfill the program's o bligation to matriculated and entering students.

2.15 Classrooms and laboratories shall be provided consistent with the program's educational objectives, teaching methods, number of students, and safety/health standards of the institution, and shall allow for efficient operation of the program.

2.16 Laboratory space shall be assigned to the occupational therapy program on a priority basis.

2.17 Space shall be provided to store and secure equipment and supplies.

2.18 The program director and faculty shall have office space consistent with institutional practice.

2.19 Space shall be provided for the private advising of students.

2.20 Appropriate and sufficient equipment and supplies shall be provided for student use and for the didactic and supervised fieldwork components of the curriculum.

2.21 Students shall be given access to the evaluative and treatment technologies that reflect current practice.

2.22 Students shall have ready access to a supply of current books, journals, periodicals, computers, software, and other reference materials needed to meet the requirements of the curriculum. This may include, but is not limited to, libraries, on-line services, interlibrary loan, and resource centers.

2.23 Instructional aids and technology shall be available in sufficient quantity and quality to be consistent with the program objectives and teaching methods.

3.0 STUDENTS

3.1 Admission of students to the occupational therapy program shall be made in accordance with the practices of the institution. There shall be stated admission criteria that are clearly defined and published, and reflective of the demands of the program.

3.2 Policies pertaining to standards for admission, advanced placement, transfer of credit, credit for experiential learning (if applicable), and prerequisite educational or work experience requirements shall be readily accessible to prospective students and the public.

3.3 Criteria for successful completion of each segment of the educational program and for graduation shall be given in advance to each student.

3.4 Evaluation content and methods shall be consistent with the objectives and competencies of the didactic and fieldwork components of the program.

3.5 Evaluation shall be employed on a regular basis to provide students and program officials with timely indications of the students' progress and academic standing.

3.6 Students must be informed of and have access to the health services provided to other students in the institution.

3.7 Advising related to professional coursework and fieldwork education shall be the responsibility of the occupational therapy faculty.

3.8 A mechanism shall be in place to ensure collaboration between the fieldwork educator and representatives of the academic program during fieldwork experiences.

3.9 The program faculty shall have access to institutional and community resources and make them available to students in situations that could interfere with student progress through the program.

4.0 OPERATIONAL POLICIES

4.1 All program publications and advertising (including academic calendars, announcements, catalogs, handbooks, and internet descriptions) must accurately reflect the program offered.

4.2 The program's accreditation status and the name, address, and telephone number of ACOTE shall be published in the catalog, program brochures for prospective students, and, if available, internet sites.

4.3 Faculty recruitment and employment practices as well as student recruitment and admission procedures shall be non-discriminatory.

4.4 Graduation requirements, tuition, and fees shall be accurately stated, published, and made known to all applicants.

4.5 The program or sponsoring institution shall have a defined and published policy and procedure for processing student and faculty grievances.

4.6 Policies and processes for student withdrawal and for refunds of tuition and fees shall be published and made known to all applicants.

4.7 Policies and procedures for student probation, suspension, and dismissal shall be published and made known.

4.8 Policies and procedures shall be published and made known for human subject research protocol; appropriate use of equipment and supplies; and for all educational activities that have implications for the health and safety of clients, students, and faculty (including infection control and evacuation procedures).

4.9 A program admitting students on the basis of ability to benefit must publicize its objectives, assessment measures, and means of evaluating ability to benefit.

4.10 Documentation of all progression and retention, graduation and credentialing requirements, including certification/licensure, shall be published and made known to applicants.

4.11 The program shall have a documented and published policy to ensure students complete all graduation and fieldwork requirements in a timely manner.

4.12 Records regarding student admission, enrollment, and achievement shall be maintained and kept in a secure setting. Grades and credits for courses shall be recorded on students' transcripts and permanently maintained by the sponsoring institution.

5.0 CURRICULUM FRAMEWORK

This is a description of the program that includes the mission, philosophy, and curriculum design.

5.1 The statement of the mission of the occupational therapy program shall be consistent with that of the sponsoring institution.

5.2 The statement of philosophy of the occupational therapy program shall reflect the current published philosophy of the profession and shall include a statement of the program's fundamental beliefs about human beings and how they learn.

5.3 The curriculum design shall reflect the mission and philosophy of both the occupational therapy program and the institution and shall provide the basis for program planning, implementation, and evaluation. The design shall identify educational goals and describe the selection of the content, scope and sequencing of coursework.

5.4 Didactic instruction and supervised practice shall follow a plan documenting learning experiences appropriate for the development of the competencies required for graduation; the plan shall also delineate the instructional methods (e.g., presentations, demonstrations, discussions) and materials that shall be used to develop these competencies.

5.5 Instruction must follow a plan that documents clearly written course syllabi that are consistent with the curriculum design and describe learning objectives and competencies to be achieved for both didactic and fieldwork education components.

5.6 Instruction must follow a plan that documents evaluation of students on a regular basis to assess their acquisition of knowledge, skills, and attitudes, and their ability to apply them to occupational therapy practice.

6.0 PROGRAM EVALUATION

The program must have a continuing system for reviewing the effectiveness of the educational program, especially as measured by student achievement, faculty performance, and the ability to meet program goals. Timely self-study reports must be prepared to aid the faculty and staff, the sponsoring institution, and the accrediting agencies in assessing program qualities and needs.

6.1 Programs shall routinely secure and systematically analyze sufficient qualitative and quantitative information about the extent to which the program is meeting its stated goals and objectives. This must include, but need not be limited to:

- faculty effectiveness in their assigned teaching responsibilities;
- students' progression through the program;
- graduates' performance on the National Board for Certification in Occupational Therapy (NBCOT) exam; and
- graduate job placement and performance based on employer satisfaction.

The manner in which programs seek to comply with this criterion may vary; however, timely efforts should be made to document the data and analysis provided. These sources of data may include, but should not be limited to, surveys covering type and scope of practice, salary, job satisfaction, and adequacy of the educational program in addressing education and skills, and interviews or surveys with program graduates and employers of graduates.

6.2 The results of ongoing evaluation must be appropriately reflected in the program's strategic plan, curriculum design, and other dimensions of the program.

Program evaluation should be a continuing systematic process with internal and external curriculum validation in consultation with employers, faculty, preceptors, fieldwork educators, students, and

graduates, with follow-up studies of their employment and national examination performance. Other dimensions of the program merit consideration as well, such as the mission and philosophy of the program, admission criteria and process, and the purpose and productivity of all advisory bodies.

SECTION B: SPECIFIC REQUIREMENTS FOR ACCREDITATION

1.0 FOUNDATIONAL CONTENT REQUIREMENTS

Program content shall be based on a broad foundation in the liberal arts and sciences. A strong foundation in the biological, physical, social and behavioral sciences supports an understanding of occupation across the life span. Coursework in these areas may be prerequisite to or concurrent with professional education and shall facilitate development of the performance criteria listed below. The student will:

1.1 Demonstrate oral and written communication skills.

1.2 Employ logical thinking, critical analysis, problem solving, and creativity.

1.3 Demonstrate competence in basic computer use.

1.4 Demonstrate knowledge and understanding of the structure and function of the human body to include the biological and physical sciences.

1.5 Demonstrate knowledge and understanding of human development throughout the life span.

1.6 Demonstrate knowledge and understanding of the concepts of human behavior to include the behavioral and social sciences.

1.7 Demonstrate knowledge and appreciation of the role of sociocultural, socioeconomic, diversity factors, and lifestyle choices in contemporary society.

1.8 Appreciate the influence of social conditions and the ethical context in which humans choose and engage in occupations.

1.9 Demonstrate the ability to use statistics, tests, and measurements.

2.0 BASIC TENETS OF OCCUPATIONAL THERAPY

These shall facilitate development of the performance criteria listed below. The student will:

2.1 Acknowledge and understand the importance of the history and philosophical base of the profession of occupational therapy.

2.2 Be able to differentiate among occupation, activity, and purposeful activity.

2.3 Understand the meaning and dynamics of occupation and purposeful activity including the interaction of performance areas, performance components, and performance contexts.

2.4 Be able to articulate to the consumer, potential employers, and the general public both the unique nature of occupation as viewed by the profession of occupational therapy and the value of occupation for the client.

2.5 Acknowledge and understand the importance of the balance of performance areas to the achievement of health and wellness.

2.6 Understand and appreciate the role of occupation in the promotion of health and the prevention of disease and disability for the individual, family, and society.

2.7 Understand the effects of health, disability, disease processes, and traumatic injury to the individual within the context of family and society.

2.8 Exhibit the ability to analyze tasks relative to performance areas, performance components, and performance contexts.

2.9 Demonstrate appreciation for the individual's perception of quality of life, well being, and occupation to promote health and prevention of injury and disease.

2.10 Understand the need for and use of compensatory strategies when desired life tasks cannot be performed.

3.0 OCCUPATIONAL THERAPY THEORETICAL PERSPECTIVES

The theoretical basis for the practice of occupational therapy shall facilitate development of the performance criteria listed below. The student will:

3.1 Understand the theories that underlie the practice of occupational therapy.

3.2 Understand the models of practice and frames of reference that are used in occupational therapy.

3.3 Understand how theories, models of practice, and frames of reference are used in occupational therapy evaluation and intervention.

3.4 Understand how history, theory, and sociopolitical climate influence practice.

3.5 Be able to apply theoretical constructs to evaluation and intervention with clients to analyze and effect meaningful occupation.

3.6 Develop a basic understanding of theory development and its importance to occupational therapy.

4.0 SCREENING AND EVALUATION

The process of screening and evaluation shall be based on theoretical perspectives, models of practice, and frames of reference that facilitate development of the performance criteria listed below. The student will:

4.1 Use standardized and non-standardized screening tools to determine the need for occupational therapy intervention. These include, but are not limited to, specified screening assessments, skilled observation, checklists, histories, interviews with the client/family/significant others, and consultations with other professionals.

4.2 Select appropriate assessment tools based on client need, contextual factors, and psychometric properties of tests.

4.3 Use appropriate procedures and protocols, including standardized formats, when administering assessments.

4.4 Understand and appreciate the importance of cooperation with the occupational therapy assistant as a data gatherer and contributor to the screening and evaluation process.

4.5 Exhibit the ability to interpret criterion referenced and norm referenced standardized test scores based on an understanding of sampling, normative data, standard and criterion scores, reliability, and validity.

4.6 Consider factors that might bias assessment results, such as culture, disability status, and situational variables related to the individual and context.

4.7 Interpret the evaluation data in relation to uniform terminology of the profession and relevant theoretical frameworks.

4.8 Demonstrate the ability to use safety precautions with clients during the screening and evaluation process, such as standards for infection control that include, but are not limited to, universal precautions.

4.9 Identify when it is appropriate for referral to specialists, internal and external to the profession, for additional evaluation.

4.10 Document occupational therapy services to ensure accountability of service provision and to meet standards for reimbursement of services. Documentation shall effectively communicate the need and rationale for occupational therapy services.

5.0 INTERVENTION PLAN: FORMULATION AND IMPLEMENTATION

The process of formulation and implementation of the therapeutic intervention plan shall be based on theoretical perspectives, models of practice, and frames of reference and shall facilitate development of the performance criteria listed below. The student will:

5.1 Interpret evaluation findings based on appropriate theoretical approaches, models of practice, and frames of reference.

5.2 Develop occupationally based intervention plans and strategies, including goals and methods to achieve them, based on the stated needs of the client as well as data gathered during the evaluation process.

5.3 Provide evidence-based effective therapeutic intervention related to performance areas, performance components, and performance contexts directly and in collaboration with the client and others.

5.4 Employ relevant occupations and purposeful activities that support the intervention goals and are meaningful to the client.

5.5 Use individual and group interaction and therapeutic use of self as a means of achieving therapeutic goals.

5.6 Develop and promote the use of appropriate home and community programming to support performance in the client's natural environment.

5.7 Demonstrate the ability to educate and train client/family/significant others to facilitate skills in performance areas as well as prevention, health maintenance, and safety.

5.8 Exhibit the ability to use the teaching-learning process with client/family/significant others, colleagues, other health providers, and the public. This includes assisting learners to identify their needs and objectives and using educational methods that will support these needs and objectives.

5.9 Demonstrate the ability to interact through written, oral, and nonverbal communication with client/family/significant others, colleagues, other health providers, and the public.

5.10 Use therapeutic adaptation with occupations pertinent to the need of the client. This shall include, but not be limited to, family/careprovider training, behavioral modifications, orthotics, prosthetics, assistive devices, equipment, and other technologies.

5.11 Demonstrate the ability to grade and adapt tasks related to performance areas and performance components for therapeutic intervention.

5.12 Demonstrate the ability to teach compensatory strategies such as use of technology, adaptations to the environment, and involvement of humans and nonhumans in the completion of tasks.

5.13 Demonstrate the ability to use safety precautions with the client during therapeutic intervention, such as contraindications and use of infection control standards that include, but are not limited to, universal precautions.

5.14 Develop skills in supervising and collaborating with occupational therapy assistants on therapeutic interventions.

5.15 Demonstrate the ability to refer to specialists both internal and external to the profession for consultation and intervention.

5.16 Monitor and reassess, in collaboration with the client, the effect of occupational therapy intervention and the need for continued and/or modified intervention.

5.17 Plan for discharge, in collaboration with the client, by reviewing the needs of client/family/significant others, resources, and discharge environment. This includes, but is not limited to, the identification of community, human, and fiscal resources, recommendations for environmental adaptations, and home programming.

5.18 Organize, collect, and analyze data in a systematic manner for evaluation of practice outcomes.

5.19 Terminate occupational therapy services when stated outcomes have been achieved or determined that they cannot be achieved. This includes a summary of occupational therapy outcomes, appropriate recommendations and referrals, and discussion with the client of post-discharge needs.

5.20 Document occupational therapy services to ensure accountability of service provision and to meet standards for reimbursement of services. Documentation shall effectively communicate the need and rationale for occupational therapy services and must be appropriate to the system in which the service is delivered.

6.0 CONTEXT OF SERVICE DELIVERY

The knowledge and understanding of the various contexts in which occupational therapy services are provided shall facilitate development of the performance criteria listed below. The student will:

6.1 Understand the models of health care, education, community, and social systems as they relate to the practice of occupational therapy.

6.2 Understand the current policy issues in the above mentioned systems that influence the practice of occupational therapy.

6.3 Understand the current social, economic, political, geographic, and demographic factors that promote policy development and the provision of occupational therapy services.

6.4 Understand the role and responsibility of the practitioner to address changes in service delivery policies and to effect changes in the system.

6.5 Understand the trends in models of service delivery and their effect on the practice of occupational therapy, including, but not limited to, medical, educational, community, and social models.

6.6 Appreciate the influence of international occupational therapy contributions to education, research, and practice.

7.0 MANAGEMENT OF OCCUPATIONAL THERAPY SERVICES

Application of principles of management and systems in the provision of occupational therapy services to individuals and organizations shall facilitate development of the performance criteria listed below. The student will:

7.1 Understand a variety of systems and service models, including, but not limited to, health care, education, community, and social models, and how these models may effect service provision.

7.2 Demonstrate knowledge of the social, economic, political, and demographic factors that influence the delivery of health care in the United States.

7.3 Understand the implications and effects of federal and state regulatory and legislative bodies on practice.

7.4 Understand governmental and policy issues, including knowledge and implications of current statutes and regulations that affect the provision of occupational therapy services.

7.5 Demonstrate knowledge of applicable national and state requirements for credentialing.

7.6 Demonstrate knowledge of and ability to comply with the various reimbursement mechanisms that affect the practice of occupational therapy, including, but not limited to, federal and state reimbursement practices and third party and private payers.

7.7 Advocate for the profession and the consumer and demonstrate an understanding of the due process and appeals systems when reimbursement is not approved for occupational therapy services.

7.8 Demonstrate an understanding of the resources a practitioner can use to respond to changes in the marketplace.

7.9 Use principles of time management, including being able to schedule and prioritize workloads.

7.10 Maintain and organize treatment areas, equipment, and supply inventory.

7.11 Maintain records as required in practice setting, third party payers, and regulatory agencies.

7.12 Demonstrate the ability to design program improvement measures and ongoing service delivery assessment using predetermined criteria.

7.13 Plan, develop, and organize the delivery of services to include the determination of programmatic needs such as staffing and service delivery options.

7.14 Understand the supervisory process of occupational therapy and non-occupational therapy personnel.

7.15 Develop strategies for effective use of professional and non-professional staff.

7.16 Understand the ongoing professional responsibility for providing fieldwork education and supervision.

7.17 Develop skills to formulate and manage teams for effective service provision.

7.18 Understand the use of outcome studies analysis to direct administrative changes.

7.19 Develop fundamental marketing skills to advance the profession.

8.0 USE OF RESEARCH

The ability to read and understand current research that affects practice and the provision of occupational therapy services shall facilitate development of the performance criteria listed below. The student will:

8.1 Articulate the importance of research for practice and the continued development of the profession.

8.2 Be able to use professional literature to make informed practice decisions.

8.3 Know when and how to find and use national and international informational resources, including appropriate literature within and outside of occupational therapy.

8.4 Understand and interpret basic descriptive, correlational, and inferential statistics.

8.5 Understand and critique research studies, including various methodologies using both quantitative and qualitative designs.

8.6 Understand the importance of scholarly activities that will contribute to the development of a body of knowledge relevant to the profession of occupational therapy.

8.7 Design and implement beginning-level research studies.

8.8 Develop basic skills necessary for the publication and presentation of research projects.

8.9 Develop a basic understanding of the process of securing grants.

9.0 PROFESSIONAL ETHICS, VALUES, AND RESPONSIBILITIES

An understanding and appreciation of ethics and values of the profession of occupational therapy shall facilitate development of the performance criteria listed below. The student will:

9.1 Demonstrate a knowledge and understanding of the AOTA Code of Ethics, Core Values and Attitudes of Occupational Therapy, and AOTA Standards of Practice as a guide for professional interactions and in client treatment and employment settings.

9.2 Understand the functions and influence of national, state, and local occupational therapy associations and other related professional associations.

9.3 Promote occupational therapy by educating other professionals, consumers, third-party payers, and the public.

9.4 Acknowledge the personal responsibility for planning ongoing professional development to ensure a level of practice consistent with current and accepted standards.

9.5 Demonstrate an understanding of professional responsibilities related to liability concerns under current models of service provision.

9.6 Develop an understanding of personal and professional abilities and competencies as they relate to job responsibilities.

9.7 Understand and appreciate the varied roles of the occupational therapist as a practitioner, educator, researcher, and entrepreneur.

9.8 Articulate the importance of professional relationships between the occupational therapist and the occupational therapy assistant.

9.9 Understand professional responsibilities when service provision is on a contractual basis in the current system.

9.10 Demonstrate an understanding of approaches to use in resolving personal and organizational ethical conflicts.

9.11 Demonstrate an understanding of the variety of informal and formal ethical dispute resolution systems that have jurisdiction over occupational therapy practice.

9.12 Be able to assist the consumer in gaining access to occupational therapy services.

9.13 Demonstrate knowledge of advocacy for the benefit of the consumer and the profession.

10.0 FIELDWORK EDUCATION

Fieldwork education is a crucial part of professional preparation and is best integrated as a component of the curriculum design. Fieldwork experiences should be implemented and evaluated for their

effectiveness by the educational institution. The experience should provide the student with the opportunity to carry out professional responsibilities under supervision and for professional role modeling. The program will:

10.1 Document a plan to assure collaboration between academic and fieldwork representatives. The plan shall include agreed upon fieldwork objectives that are documented and made known to the student.

10.2 Ensure that the ratio of fieldwork educators to student(s) enables proper supervision and frequent assessment of the progress in achieving stated fieldwork objectives.

10.3 Ensure that fieldwork agreements shall be sufficient in scope and number to allow completion of graduation requirements in a timely manner in accordance with the policy adopted by the program.

10.4 Conduct fieldwork in settings equipped to provide application of principles learned in the academic program and appropriate to the learning needs of the student.

10.5 Require that all aspects of the fieldwork program be consistent with the curriculum design of the program.

The goal of Level I Fieldwork is to introduce students to the fieldwork experience, and develop a basic comfort level with and understanding of the needs of clients. Level I fieldwork shall be integral to the program's curriculum design and include experiences designed to enrich didactic coursework through directed observation and participation in selected aspects of the occupational therapy process. The focus of these experiences is not intended to be independent performance. Qualified personnel for supervised Level I fieldwork include, but are not limited to, occupational therapy practitioners initially certified nationally, psychologists, physician assistants, teachers, social workers, nurses, and physical therapists. The program will:

10.6 Ensure that Level I fieldwork shall not be substituted for any part of Level II fieldwork.

10.7 Document all Level I fieldwork experiences that are provided to students.

10.8 Document mechanisms for formal evaluation of student performance on Level I fieldwork.

The goal of Level II fieldwork is to develop competent, entry-level, generalist occupational therapists. Level II fieldwork shall be integral to the program's curriculum design and shall include an in-depth experience in delivering occupational therapy services to clients, focusing on the application of purposeful and meaningful occupation and/or research, administration and management of occupational therapy services. It is recommended that the student be exposed to a variety of clients across the life span and to a variety of settings. The fieldwork experience shall be designed to promote clinical reasoning and reflective practice; to transmit the values and beliefs that enable ethical practice; and to develop professionalism and competence as career responsibilities. The program will:

10.9 Recognize that Level II fieldwork can take place in a variety of traditional settings and emerging areas of practice. The student can complete Level II fieldwork in a minimum of one setting and maximum of four different settings.

10.10 Require a minimum of the equivalent of 24 weeks full-time Level II fieldwork. This may be completed on a full-time or part-time basis, but may not be less than half-time as defined by the fieldwork site.

10.11 Ensure that the student shall be supervised by an occupational therapist who meets state regulations and has a minimum of one year of practice experience, subsequent to the requisite initial certification. The supervising therapist may be engaged by the fieldwork site or by the educational program.

10.12 Ensure that supervision provides protection of consumers and opportunities for appropriate role modeling of occupational therapy practice. Initially, supervision should be direct, then decrease to less direct supervision as is appropriate for the setting, the severity of client's condition, and the ability of the student.

10.13 In a setting where there is no occupational therapist on site, the program must document that there is a plan for the provision of occupational therapy services. On-site supervision must be provided in accordance with the plan and state credentialing requirements. The student must receive a minimum of six hours of occupational therapy supervision per week, including direct observation of client interaction. Additionally, the occupational therapy supervisor must be readily available for communication and consultation during work hours. Such fieldwork shall not exceed 12 weeks.

10.14 For programs wishing to pursue fieldwork outside of the United States. Ensure that the student completing Level II fieldwork outside the United States is supervised by an occupational therapist who has graduated from a program approved by the World Federation of Occupational Therapists (WFOT) and has one year of experience in practice. Such fieldwork shall not exceed 12 weeks.

SECTION C: MAINTAINING AND ADMINISTERING ACCREDITATION

1.0 PROGRAM AND SPONSORING INSTITUTION RESPONSIBILITIES

1.1 The accreditation review process conducted by ACOTE can be initiated only at the written request of the chief executive officer or an officially designated representative of the sponsoring institution and the occupational therapy program director or dean overseeing the proposed program.

1.2 This process is initiated by submitting a letter of intent to seek accreditation to the:

Accreditation Department
American Occupational Therapy Association, Inc.
4720 Montgomery Lane
P.O. Box 31220
Bethesda, MD 20824-1220

1.3 At any time before the final accreditation action is made by ACOTE, a program or sponsoring institution may withdraw its request for initial or continuing accreditation.

1.4 To maintain accreditation, the following actions are required: The program must submit a Report of Self-Study and other required reports within a period of time determined by ACOTE. The program must agree to a site visit date before the end of the period for which accreditation was previously awarded. In accordance with stated policy, the program must inform ACOTE within 90 days of a change in program director. The sponsoring institution must inform ACOTE of the transfer of program sponsorship.

1.5 The program and the sponsoring institution must pay accreditation fees within a time period specified in the ACOTE Accreditation Manual.

Failure to meet these administrative requirements for maintaining accreditation may lead to being placed on Administrative Probation and ultimately to having accreditation withdrawn.

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2.1 All policies and procedures relating to the accreditation process are found in the AOTA Accreditation Council for Occupational Therapy Education (ACOTE) Accreditation Manual.

2.2 ACOTE will follow fair practice procedures when complaints are received by ACOTE indicating that accredited programs or programs seeking accreditation may not be in substantial compliance with the Standards for an Accredited Educational Program for the Occupational Therapist or may not be following established accreditation policies. A record of complaints is maintained by the AOTA Accreditation Department. The policy and procedure for complaints are found in the AOTA Accreditation Council for Occupational Therapy Education (ACOTE) Accreditation Manual.

STANDARDS FOR AN ACCREDITED EDUCATIONAL PROGRAM FOR THE OCCUPATIONAL THERAPY ASSISTANT

Adopted December 1998; Effective July 1, 2000

ACCREDITATION COUNCIL FOR OCCUPATIONAL THERAPY EDUCATION

of

THE AMERICAN OCCUPATIONAL THERAPY ASSOCIATION, INC.

The Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association (AOTA) accredits educational programs for the occupational therapy assistant. The Standards comply with the United States Department of Education (USDE) criteria for recognition of accrediting agencies.

> *These Standards are the requirements used in accrediting educational programs that prepare individuals to become occupational therapy assistants. The extent to which a program complies with these Standards determines its accreditation status.*

Sections A and C contain general standards, while Section B delineates standards specific to curriculum. The specific standards in Section B are stated as outcome-based criteria.

PREAMBLE

The rapidly changing and dynamic nature of contemporary health and human service delivery systems requires the entry-level occupational therapy assistant to possess basic skills as a direct care provider, educator, and advocate for the profession and the consumer.

A contemporary entry-level occupational therapy assistant must:

- have acquired an educational foundation in the liberal arts and sciences, including a focus on issues related to diversity;
- be educated as a generalist, with a broad exposure to the delivery models and systems utilized in settings where occupational therapy is currently practiced and where it is emerging as a service;
- have achieved entry-level competence through a combination of academic and fieldwork education;
- be prepared to work under the supervision of and in cooperation with the occupational therapist;
- be prepared to articulate and apply occupational therapy principles, intervention approaches and rationales, and expected outcomes as these relate to occupation;
- be prepared to be a lifelong learner and keep current with best practice;
- uphold the ethical standards, values, and attitudes of the occupational therapy profession.

SECTION A: GENERAL REQUIREMENTS FOR ACCREDITATION

1.0 SPONSORSHIP

1.1 The sponsoring institution(s) and affiliates, if any, must be accredited by recognized national, regional, or state agencies with accrediting authority.

1.2 Sponsoring institutions must be authorized under applicable law or other acceptable authority to provide a program of postsecondary education, must have degree granting authority, or be a program offered within the military services.

1.3 For programs in which the academic and fieldwork components of the curriculum are provided by two or more institutions, responsibilities of each sponsoring institution and fieldwork site must be clearly documented in a memorandum of understanding.

1.4 Documentation must be provided that each memorandum of understanding between institutions and fieldwork sites is reviewed at least every five years by both parties.

1.5 Accredited occupational therapy assistant educational programs may only be established in community, technical, junior and senior colleges, universities, medical schools, vocational schools/institutions, or military services.

1.6 The sponsoring institution shall assume primary responsibility for appointment of faculty, admission of students, curriculum planning, including selection of course content, and granting the certificate or degree documenting satisfactory completion of the educational program. The sponsoring institution shall also be responsible for the coordination of classroom teaching and supervised fieldwork practice and for providing assurance that the practice activities assigned to students in a fieldwork setting are appropriate to the program.

2.0 ACADEMIC RESOURCES

2.1 The program must have a director who is assigned to the occupational therapy assistant program on a full-time basis.

2.2 The program director shall be an occupational therapist, initially certified nationally, and credentialed according to state requirements. The director shall have a minimum of five years of professional experience in areas related to clinical practice, administration, and teaching. At least one of these years must be a full-time academic appointment with teaching responsibilities.

2.3 The program director shall have academic qualifications comparable to other administrators who manage similar programs within the institution and relevant experience in higher education requisite for providing effective leadership for the program, its faculty, and its students.

2.4 The program director must have an understanding of and experience with occupational therapy assistants, which includes clinical supervision.

2.5 The program director shall be responsible for the management and administration of the program, including planning, evaluation, budgeting, selection of faculty and staff, maintenance of accreditation, and commitment to strategies for professional development.

2.6 The program must have at least one additional full-time equivalent faculty member.

2.7 The program director and faculty must possess the necessary academic and experiential qualifications and backgrounds, identified in documented descriptions of roles and responsibilities, appropriate to meet program objectives.

2.8 The occupational therapy assistant faculty will assume responsibility for development, implementation, and evaluation of fieldwork education. There will be an individual specifically identified with fieldwork coordination responsibilities.

2.9 The faculty shall include occupational therapy practitioners who have been initially certified nationally and who have documented expertise in their area(s) of teaching responsibility.

2.10 The occupational therapy assistant faculty must be sufficient in number and must possess the expertise necessary to ensure appropriate curriculum design, content delivery, and program evaluation.

2.11 Faculty responsibilities shall be consistent with the mission of the institution.

2.12 Each full-time faculty member shall have a written continuing professional growth and development plan to ensure effectiveness and currency as an academic educator consistent with the structure of the program' s strategic plan.

2.13 The program shall develop a strategic plan congruent with the mission of the institution and the curriculum design. This plan shall incorporate professional development plans of the faculty and the program objectives.

2.14 The faculty/student ratio shall permit the achievement of the purpose and stated objectives of the program, be compatible with accepted practices of the institution for similar programs, promote quality education in laboratory and fieldwork experiences, and ensure student and/or consumer safety.

2.15 Clerical and support staff shall be provided to the program, consistent with institutional practice, to meet programmatic and administrative requirements.

2.16 The program shall be allocated a budget of regular institutional funds, not including grants, gifts, and other restricted sources, sufficient to implement and maintain the objectives of the program and to fulfill the program' s obligation to matriculated and entering students.

2.17 Classrooms and laboratories shall be provided consistent with the program's educational objectives, teaching methods, number of students, and safety/health standards of the institution, and shall allow for efficient operation of the program.

2.18 Laboratory space shall be assigned to the occupational therapy assistant program on a priority basis.

2.19 Space shall be provided to store and secure equipment and supplies.

2.20 The program director and faculty shall have office space consistent with institutional practice.

2.21 Space shall be provided for the private advising of students.

2.22 Appropriate and sufficient equipment and supplies shall be provided for student use and for the didactic and supervised fieldwork components of the curriculum.

2.23 Students shall be given access to the evaluative and treatment technologies that reflect current practice.

2.24 Students shall have ready access to a supply of current books, journals, periodicals, computers, software, and other reference materials needed to meet the requirements of the curriculum. This may include, but is not limited to, libraries, on-line services, interlibrary loan, and resource centers.

2.25 Instructional aids and technology shall be available in sufficient quantity and quality to be consistent with the program objectives and teaching methods.

3.0 STUDENTS

3.1 Admission of students to the occupational therapy assistant program shall be made in accordance with the practices of the institution. There shall be stated admission criteria that are clearly defined and published, and reflective of the demands of the program.

3.2 Policies pertaining to standards for admission, advanced placement, transfer of credit, credit for experiential learning (if applicable), and prerequisite educational or work experience requirements shall be readily accessible to prospective students and the public.

3.3 Criteria for successful completion of each segment of the educational program and for graduation shall be given in advance to each student.

3.4 Evaluation content and methods shall be consistent with the objectives and competencies of the didactic and supervised fieldwork components of the program.

3.5 Evaluation shall be employed on a regular basis to provide students and program officials with timely indications of the students' progress and academic standing.

3.6 Students must be informed of and have access to the health services provided to other students in the institution.

3.7 Advising related to coursework in the occupational therapy assistant program and fieldwork education shall be the responsibility of the occupational therapy assistant faculty.

3.8 A mechanism shall be in place to ensure collaboration between the fieldwork educator and representatives of the academic program during fieldwork experiences.

3.9 The program faculty shall have access to institutional and community resources and make them available to students in situations that could interfere with student progress through the program.

4.0 OPERATIONAL POLICIES

4.1 All program publications and advertising (including academic calendars, announcements, catalogs, handbooks, and internet descriptions) must accurately reflect the program offered.

4.2 The program's accreditation status and the name, address, and telephone number of ACOTE shall be published in the catalog, program brochures for prospective students and, if available, internet sites.

4.3 Faculty recruitment and employment practices as well as student recruitment and admission procedures shall be non-discriminatory.

4.4 Graduation requirements, tuition, and fees shall be accurately stated, published, and made known to all applicants.

4.5 The program or sponsoring institution shall have a defined and published policy and procedure for processing student and faculty grievances.

4.6 Policies and processes for student withdrawal and for refunds of tuition and fees shall be published and made known to all applicants.

4.7 Policies and procedures for student probation, suspension, and dismissal shall be published and made known.

4.8 Policies and procedures shall be published and made known for human subject research protocol; appropriate use of equipment and supplies; and for all educational activities that have implications for the health and safety of clients, students, and faculty (including infection control and evacuation procedures).

4.9 A program admitting students on the basis of ability to benefit must publicize its objectives, assessment measures, and means of evaluating ability to benefit.

4.10 Documentation of all progression and retention, graduation and credentialing requirements, including certification/licensure, shall be published and made known to applicants.

4.11 The program shall have a documented and published policy to ensure students complete all graduation and fieldwork requirements in a timely manner.

4.12 Records regarding student admission, enrollment, and achievement shall be maintained and kept in a secure setting. Grades and credits for courses shall be recorded on students' transcripts and permanently maintained by the sponsoring institution.

5.0 CURRICULUM FRAMEWORK

This is a description of the program that includes the mission, philosophy, and curriculum design.

5.1 The statement of the mission of the occupational therapy assistant program shall be consistent with that of the sponsoring institution.

5.2 The statement of philosophy of the occupational therapy assistant program shall reflect the current published philosophy of the profession and shall include a statement of the program's fundamental beliefs about human beings and how they learn.

5.3 The curriculum design shall reflect the mission and philosophy of both the occupational therapy assistant program and the institution and shall provide the basis for program planning, implementation, and evaluation. The design shall identify educational goals and describe the selection of the content, scope, and sequencing of coursework.

5.4 Didactic instruction and supervised practice shall follow a plan documenting learning experiences appropriate for the development of the competencies required for graduation; the plan shall also delineate the instructional methods (e.g., presentations, demonstrations, discussions) and materials that shall be used to develop these competencies.

5.5 Instruction must follow a plan that documents clearly written course syllabi that are consistent with the curriculum design and describe learning objectives and competencies to be achieved for both didactic and fieldwork education components.

5.6 Instruction must follow a plan that documents evaluation of students on a regular basis to assess their acquisition of knowledge, skills, and attitudes, and their ability to apply them to occupational therapy practice.

6.0 PROGRAM EVALUATION

The program must have a continuing system for reviewing the effectiveness of the educational program, especially as measured by student achievement, faculty performance, and the ability to meet program goals. Timely self-study reports must be prepared to aid the faculty and staff, the sponsoring institution, and the accrediting agencies in assessing program qualities and needs.

6.1 Programs shall routinely secure and systematically analyze sufficient qualitative and quantitative information about the extent to which the program is meeting its stated goals and objectives. This must include, but need not be limited to:

- faculty effectiveness in their assigned teaching responsibilities;
- students' progression through the program;
- graduates' performance on the National Board for Certification in Occupational Therapy (NBCOT) exam; and
- graduate job placement and performance based on employer satisfaction.

The manner in which programs seek to comply with this criterion may vary; however, timely efforts should be made to document the data and analysis provided. These sources of data may include, but should not be limited to, surveys covering type and scope of practice, salary, job satisfaction, and

adequacy of the educational program in addressing education and skills, and interviews or surveys with program graduates and employers of graduates.

6.2 The results of ongoing evaluation must be appropriately reflected in the program' s strategic plan, curriculum design, and other dimensions of the program.

Program evaluation should be a continuing systematic process with internal and external curriculum validation in consultation with employers, faculty, preceptors, fieldwork educators, students, and graduates, with follow-up studies of their employment and national examination performance. Other dimensions of the program merit consideration as well, such as the mission and philosophy of the program, admission criteria and process, and the purpose and productivity of all advisory bodies.

SECTION B: SPECIFIC REQUIREMENTS FOR ACCREDITATION

1.0 FOUNDATIONAL CONTENT REQUIREMENTS

Program content shall be based on a broad foundation of the liberal arts and sciences. A foundation in the biological, physical, social, and behavioral sciences supports an understanding of occupation across the life span. Coursework in these areas may be prerequisite to or concurrent with occupational therapy assistant education and shall facilitate development of the performance criteria listed below. The student will:

1.1 Demonstrate oral and written communication skills.

1.2 Employ logical thinking, critical analysis, problem solving, and creativity.

1.3 Demonstrate competence in basic computer use.

1.4 Demonstrate knowledge and understanding of the structure and function of the human body to include the biological and physical sciences.

1.5 Demonstrate knowledge and understanding of human development throughout the life span.

1.6 Demonstrate knowledge and understanding of the concepts of human behavior to include the behavioral and social sciences.

1.7 Demonstrate knowledge and appreciation of the role of sociocultural, socioeconomic, diversity factors, and lifestyle choices in contemporary society.

1.8 Appreciate the influence of social conditions and the ethical context in which humans choose and engage in occupations.

2.0 BASIC TENETS OF OCCUPATIONAL THERAPY

These shall facilitate development of the performance criteria listed below. The student will:

2.1 Acknowledge and understand the importance of the history and philosophical base of the profession of occupational therapy.

2.2 Be able to differentiate among occupation, activity, and purposeful activity.

2.3 Understand the meaning and dynamics of occupation and purposeful activity including the interaction of performance areas, performance components, and performance contexts.

2.4 Be able to articulate to the consumer, potential employers, and the general public the unique nature of occupation as viewed by the profession of occupational therapy.

2.5 Acknowledge and understand the importance of the balance of performance areas to the achievement of health and wellness.

2.6 Understand and appreciate the role of occupation in the promotion of health and the prevention of disease and disability for the individual, family, and society.

2.7 Understand the effects of health, disability, disease processes, and traumatic injury to the individual within the context of family and society.

2.8 Exhibit the ability to analyze tasks relative to performance areas, performance components, and performance contexts.

2.9 Demonstrate appreciation for the individual's perception of quality of life, well being, and occupation to promote health and prevention of injury and disease.

2.10 Understand the need for and use of compensatory strategies when desired life tasks cannot be performed.

2.11 Be familiar with the theories, models of practice, and frames of reference that underlie the practice of occupational therapy.

3.0 SCREENING AND EVALUATION

The process of screening and evaluation shall be done under the supervision of and in cooperation with the occupational therapist and shall be based on theoretical perspectives, models of practice, and frames of reference that facilitate development of the performance criteria listed below. The student will:

3.1 Gather and share data for the purpose of screening and evaluation including, but not limited to, specified screening assessments, skilled observation, checklists, histories, interviews with the client/family/significant others, and consultations with other professionals.

3.2 Administer selected assessments and use occupation for the purpose of assessment.

3.3 Demonstrate the ability to use safety precautions with clients during the screening and evaluation process, such as standards for infection control that include, but are not limited to, universal precautions.

3.4 Document occupational therapy services to ensure accountability of service provision and to meet standards for reimbursement of services. Documentation shall effectively communicate the need and rationale for occupational therapy services.

4.0 INTERVENTION AND IMPLEMENTATION

The process of intervention shall be done under the supervision of and in cooperation with the occupational therapist and shall facilitate development of the performance criteria listed below. The student will:

4.1 Select, adapt, and sequence relevant occupations and purposeful activities that support the intervention goals and plan as written by the occupational therapist. These occupations and purposeful activities shall be directly related to performance areas, performance components, and performance contexts. They shall be meaningful to the client, maximizing participation and independence.

4.2 Use individual and group interaction and therapeutic use of self as a means of achieving therapeutic goals.

4.3 Adapt the environment, tools, materials, and occupations to the needs of clients and their sociocultural context.

4.4 Develop and promote the use of appropriate home and community programming to support performance in the client's natural environment.

4.5 Demonstrate the ability to educate and train client/family/significant others to facilitate skills in performance areas as well as prevention, health maintenance, and safety.

4.6 Demonstrate the ability to interact through written, oral and nonverbal communication with client/family/significant others, colleagues, other health providers, and the public.

4.7 Use therapeutic adaptation with occupations pertinent to the needs of the client. This shall include, but not be limited to, family/care provider training, environmental and behavioral modifications, orthotics, prosthetics, assistive devices, equipment, and other technologies.

4.8 Exhibit the ability to use the teaching-learning process with client/family/significant others, colleagues, other health providers, and the public. This includes assisting learners to identify their needs and objectives and using educational methods that will support those needs and objectives.

4.9 Demonstrate the ability to use safety precautions with the client during therapeutic intervention, such as contraindications and use of infection control standards that include, but are not limited to, universal precautions.

4.10 Modify intervention approaches to reflect the changing needs of the client.

4.11 Demonstrate the ability to refer to specialists, internal and external to the profession, for consultation and intervention.

4.12 Monitor and reassess the effect of occupational therapy intervention and the need for continued and/or modified intervention.

4.13 Facilitate discharge planning by reviewing the needs of client/family/significant others, resources, and discharge environment. This includes, but is not limited to, identification of community, human, and fiscal resources, recommendations for environmental adaptations, and home programming.

4.14 Recommend the need for termination of occupational therapy services when stated outcomes have been achieved. This includes a summary of occupational therapy outcomes, appropriate recommendations and referrals, and discussion with the client of post-discharge needs.

4.15 Document occupational therapy services to ensure accountability of service provision and to meet standards for reimbursement of services. Documentation shall effectively communicate the need and rationale for occupational therapy services and must be appropriate to the system in which the service is delivered.

5.0 CONTEXT OF SERVICE DELIVERY

The knowledge and understanding of the various contexts in which occupational therapy services are provided shall facilitate development of the performance criteria listed below. The student will:

5.1 Understand the models of health care, education, community, and social systems as they relate to the practice of occupational therapy.

5.2 Understand the role and responsibility of the practitioner to address changes in service delivery policies and to effect changes in the system.

6.0 ASSIST IN MANAGEMENT OF OCCUPATIONAL THERAPY SERVICES

Application of principles of management and systems in the provision of occupational therapy services to individuals and organizations shall facilitate development of the performance criteria listed below. The student will:

6.1 Understand a variety of systems and service models, including, but not limited to, health care, education, community, and social models, and how these models may effect service provision.

6.2 Understand the implications and effects of federal and state regulatory and legislative bodies on practice.

6.3 Demonstrate knowledge of applicable national and state requirements for credentialing.

6.4 Demonstrate knowledge of and ability to comply with the various reimbursement mechanisms that affect the practice of occupational therapy, including, but not limited to, federal and state reimbursement practices and third party and private payers.

6.5 Advocate for the profession and the consumer and demonstrate an understanding of the due process and appeals systems when reimbursement is not approved for occupational therapy services.

6.6 Use principles of time management, including being able to schedule and prioritize workloads.

6.7 Maintain and organize treatment areas, equipment, and supply inventory.

6.8 Maintain records as required by practice setting, third-party payers, and regulatory agencies.

6.9 Demonstrate program evaluation using predetermined criteria.

6.10 Understand the ongoing professional responsibility for providing fieldwork education and supervision.

7.0 USE OF PROFESSIONAL LITERATURE

The ability to read and understand professional literature and recognize its implications for practice and the provision of occupational therapy services shall facilitate development of the performance criteria listed below. The student will:

7.1 Articulate the importance of professional literature for practice and the continued development of the profession.

7.2 Be able to use professional literature to make informed practice decisions, in cooperation with the occupational therapist.

7.3 Know when and how to find and use informational resources, including appropriate literature within and outside of occupational therapy.

8.0 PROFESSIONAL ETHICS, VALUES, AND RESPONSIBILITIES

An understanding and appreciation of ethics and values of the profession of occupational therapy shall facilitate development of the performance criteria listed below. The student will:

8.1 Demonstrate a knowledge and understanding of the AOTA Code of Ethics, Core Values and Attitudes of Occupational Therapy, and AOTA Standards of Practice as a guide for professional interactions and in client treatment and employment settings.

8.2 Understand the functions and influence of national, state, and local occupational therapy associations and other related professional associations.

8.3 Promote occupational therapy by educating other professionals, consumers, third-party payers, and the public.

8.4 Acknowledge the personal responsibility for planning ongoing professional development to ensure a level of practice consistent with current and accepted standards.

8.5 Demonstrate an understanding of professional responsibilities related to liability concerns under current models of service provision.

8.6 Develop an understanding of personal and professional abilities and competencies as they relate to job responsibilities.

8.7 Understand and appreciate the varied roles of the occupational therapy assistant as a practitioner and educator.

8.8 Articulate the importance of professional relationships between the occupational therapist and the occupational therapy assistant.

8.9 Understand professional responsibilities when service provision is on a contractual basis in the current system.

8.10 Demonstrate an understanding of approaches to use in resolving personal and organizational ethical conflicts.

8.11 Demonstrate an understanding of the variety of informal and formal ethical dispute resolution systems that have jurisdiction over occupational therapy practice.

8.12 Be able to assist the consumer in gaining access to occupational therapy services.

8.13 Demonstrate knowledge of advocacy for the benefit of the consumer and the profession.

9.0 FIELDWORK EDUCATION

Fieldwork education is a crucial part of the preparation of the occupational therapy assistant and is best integrated as a component of the curriculum design. Fieldwork experiences should be implemented and evaluated for their effectiveness by the educational institution. The experience should provide the student with the opportunity to carry out professional responsibilities under supervision and for role modeling. The program will:

9.1 Document a plan to ensure collaboration between academic and fieldwork representatives. The plan shall include agreed upon fieldwork objectives that are documented and made known to the student.

9.2 Ensure that the ratio of fieldwork educators to student(s) enables proper supervision and frequent assessment of the progress in achieving stated fieldwork objectives.

9.3 Ensure that fieldwork agreements shall be sufficient in scope and number to allow completion of graduation requirements in a timely manner in accordance with the policy adopted by the program.

9.4 Conduct fieldwork in settings equipped to provide application of principles learned in the academic program and appropriate to the learning needs of the student.

9.5 Require that all aspects of the fieldwork program be consistent with the curriculum design of the program.

The goal of Level I fieldwork is to introduce students to the fieldwork experience, and develop a basic comfort level with and understanding of the needs of clients. Level I fieldwork shall be integral to the program's curriculum design and include experiences designed to enrich didactic coursework through directed observation and participation in selected aspects of the occupational therapy process. The focus of these experiences is not intended to be independent performance. Qualified personnel for supervised Level I fieldwork include, but are not limited to, occupational therapy practitioners initially certified nationally, psychologists, physician assistants, teachers, social workers, nurses, and physical therapists. The program will:

9.6 Ensure that Level I fieldwork shall not be substituted for any part of Level II fieldwork.

9.7 Document all Level I fieldwork experiences that are provided to students.

9.8 Document mechanisms for formal evaluation of student performance on Level I fieldwork.

SECTION B: SPECIFIC REQUIREMENTS FOR ACCREDITATION

The goal of Level II fieldwork is to develop competent, entry-level, generalist occupational therapy assistants. Level II fieldwork shall be integral to the program's curriculum design and shall include an in-depth experience in delivering occupational therapy services to clients, focusing on the application of purposeful and meaningful occupation. It is recommended that the student be exposed to a variety of clients across the life span and to a variety of settings. The fieldwork experience shall be designed to promote clinical reasoning, appropriate to the occupational therapy assistant role; to transmit the values and beliefs that enable ethical practice; and to develop professionalism and competence as career responsibilities. The program will:

9.9 Recognize that Level II fieldwork can take place in a variety of traditional settings and emerging areas of practice. The student can complete Level II fieldwork in a minimum of one setting and maximum of three different settings.

9.10 Require a minimum of the equivalent of 16 weeks full-time Level II fieldwork. This may be completed on a full-time or part-time basis, but may not be less than half-time as defined by the fieldwork site.

9.11 Ensure that the student shall be supervised by an occupational therapy practitioner, who meets state regulations and has a minimum of one year of practice experience, subsequent to the requisite initial certification. The supervisor may be engaged by the fieldwork site or by the educational program.

9.12 Ensure that supervision provides protection of consumers and opportunities for appropriate role modeling of occupational therapy practice. Initially, supervision should be direct, then decrease to less direct supervision as is appropriate for the setting, the severity of the client' s condition, and the ability of the student.

9.13 In a setting where there is no occupational therapy practitioner on site, the program must document that there is a plan for the provision of occupational therapy services. On-site supervision must be provided in accordance with the plan and state credentialing requirements. The student must receive a minimum of six hours of occupational therapy supervision per week, including direct observation of client interaction. Additionally, the occupational therapy supervisor must be readily available for communication and consultation during work hours. Such fieldwork shall not exceed 8 weeks.

SECTION C: MAINTAINING AND ADMINISTERING ACCREDITATION

1.0 PROGRAM AND SPONSORING INSTITUTION RESPONSIBILITIES

1.1 The accreditation review process conducted by ACOTE can be initiated only at the written request of the chief executive officer or an officially designated representative of the sponsoring institution and the occupational therapy assistant program director or dean overseeing the proposed program.

1.2 This process is initiated by submitting a letter of intent to seek accreditation to the:

Accreditation Department
American Occupational Therapy Association, Inc.
4720 Montgomery Lane
P.O. Box 31220
Bethesda, MD 20824-1220

1.3 At any time before the final accreditation action is made by ACOTE, a program or sponsoring institution may withdraw its request for initial or continuing accreditation.

1.4 To maintain accreditation, the following actions are required: The program must submit a Report of Self-Study and other required reports within a period of time determined by ACOTE. The program must agree to a site visit date before the end of the period for which accreditation was previously awarded. In accordance with stated policy, the program must inform ACOTE within 90 days of a change in program director. The sponsoring institution must inform ACOTE of the transfer of program sponsorship.

1.5 The program and the sponsoring institution must pay accreditation fees within a time period specified in the ACOTE Accreditation Manual.

Failure to meet these administrative requirements for maintaining accreditation may lead to being placed on Administrative Probation and ultimately to having accreditation withdrawn.

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