Guiding Principles for ONS Policies Related to Corporate Support and Resolving Conflicts of Interest

Introduction

This document states ONS's philosophy and guiding principles with respect to corporate support* from pharmaceutical companies and other for-profit corporations and for avoiding conflicts of interest (COIs) in pursuing its work as a nonprofit professional and scientific association. These principles have evolved over many years, during which ONS developed constructive relationships with for-profit businesses while maintaining a high standard for independence and integrity. Corporate support has permitted ONS to initiate and enhance programs that help it achieve its purposes and fulfill its mission.

One of ONS's most valuable assets is its reputation for independence and integrity in expressing the voice of oncology nurses on matters relating to the nursing profession and quality cancer care. ONS is vigilant in ensuring that its relationships with business entities never compromise this asset and that any COIs are resolved.

* "Corporate support," for purposes of this document, encompasses the full range of relationships between ONS and for-profit corporations, including the purchase of services (such as advertising and exhibit space), grants for educational programs, and sponsorship of activities.

Note. This document reflects the perspective of ONS as a nonprofit professional and scientific association; other considerations apply to the ONS Foundation, ONS:Edge, and the Oncology Nursing Certification Corporation (ONCC), all separate, affiliated corporations.

Guiding Principles

- 1. Corporate support for programs and activities should help advance ONS's mission and vision.
- 2. Any program or activity for which corporate support is accepted must be under ONS's complete control.
- 3. ONS does not permit corporate support to compromise its independence and integrity.
- 4. ONS is transparent in its acceptance of any corporate support; the identity of the corporate supporter is disclosed prominently with the activity that is being supported.
- 5. ONS does not accept corporate support for the development of standards and guidelines or any activity related to governance, strategic planning, policy development, or direct lobbying efforts.
- 6. ONS acceptance of corporate support does not imply ONS endorsement of the supporting entity or any of its products or activities.
- 7. ONS follows standard business practices in facilitating access to its members through advertising, exhibiting, and rental of its mailing lists.
- 8. ONS accepts grants to conduct independent educational programs in compliance with the accreditation standards of the American Nurses Credentialing Centers Commission on Accreditation (ANCC).
- 9. ONS accepts grants to support technical supplements in its journals, in conformance with the ONS Financial Disclosure Policy and standard disclosure practices for scientific and medical publishing.
- 10. ONS accepts grants to conduct activities that foster the advancement of oncology nursing practice.
- 11. ONS accepts sponsorship for social functions and other selected meeting services and activities for conference attendees; ONS retains complete control over such functions, services, and activities.
- 12. ONS has adopted COI policies and procedures to meet the requirements of the Internal Revenue Service (IRS) and to ensure that no individual, while serving ONS or its Affiliated Organizations, engages in a situation that may be construed as an actual, potential, or perceived COI. All COIs or potential COIs must be fully and immediately disclosed and openly resolved. A COI is not determined by the individual, but, rather, by an impartial group reviewing the relationship. Refer to the ONS Financial Conflict of Interest and General Conflict of Interest Disclosure Policy.
- 13. ONS publishes the *Guiding Principles for ONS Policies Related to Corporate Support and Resolving Conflicts of Interest* on its Web site and invites anyone to bring to the attention of the ONS President or the Chief Executive Officer (CEO) any related questions about any ONS activity.

- 14. The CEO is responsible for implementing procedures to ensure compliance with the *Guiding Principles for ONS Policies Related to Corporate Support and Resolving Conflicts of Interest*.
- 15. The ONS Board of Directors reviews the *Guiding Principles for ONS Policies Related to Corporate Support and Resolving Conflicts of Interest* at least every two years.

Background and Interpretation

Contemporary Legal and Public Affairs Context

For more than a decade, there has been growing pressure by federal and state governments, as well as the public, for greater disclosure, transparency, and accountability by corporations and nonprofit organizations about the sources and uses of their funds. This pressure escalated as a result of well-documented inappropriate, unethical, or criminal conduct in for-profit and nonprofit corporations.

Given this environment, there has been close scrutiny of the pharmaceutical and related industries and their spending practices. One specific area that has been investigated is the level of corporate support these companies provide to health professionals and professional associations for a variety of educational activities and other programs, and whether these activities influence health professionals about healthcare decisions. These same issues have been widely discussed by the Senate Finance Committee, the Office of the Inspector General for Health and Human Services, the Food and Drug Administration, and the IRS. Professional and trade groups such as Pharmaceutical Research and Manufacturers of America (PhRMA), American Medical Association, Association of American Medical Colleges, and American College of Chest Physicians have issued reports and recommended changes about these practices.

ONS receives corporate/commercial support from the pharmaceutical, medical device, and other related industries for its activities and programs in the form of educational grants, sponsorships, advertising, and meeting exhibits. This corporate support enables ONS to conduct educational programs and other professional activities on a wide range of professional practice issues for its members. At the same time, this corporate support may raise concerns about potential influence or monetary dependence that may occur for ONS as a result of receiving this type of support. However, ONS takes appropriate measures to ensure that corporate support does not influence its activities, policies, or decisions.

It is against this backdrop that the adoption of guiding principles on acceptance of corporate support for ONS educational, professional, and business activities is a necessary step to protect the integrity and reputation of the organization and of ONS as the professional society of oncology nurses.

Distinctions among Grants, Sponsorship, and Purchase of Association Services*

ONS receives corporate funding from the pharmaceutical and related industries for selected activities and programs. Some of this corporate funding is for support of professional development and educational programs, and some of it consists of the purchase of standard business services that associations like ONS provide.

Professional Practice and Educational Activities

ONS solicits and obtains educational grants from commercial interests and other entities for selected professional and educational activities. These activities include, but are not limited to, professional development (e.g., awards), journal supplements, continuing education programs, and other ONS-initiated professional initiatives. In recent years the healthcare industry has changed its policies and procedures for the distribution and accountability of educational grants. There is now a strict separation between monies used for marketing/promotional activities and funds given for professional/educational programs. This separation is primarily in response to the concerns about corporate influence and bias. These educational grants no longer originate from the promotional/marketing side of the corporation, and all companies that distribute educational grants do so from a separate division of the company. For continuing professional education activities, the use of these grants must comply with the requirements of the ANCC, the Accreditation Council for Pharmacy Education, or the Accreditation Council for Continuing Medical Education. For example, the grantor is not permitted to have a role in program development or delivery or in the selection of speakers and may be recognized only through acknowledgement of the grant support. The recipient of the grant must adhere to the proposed budget for the educational activity and provide a detailed reconciliation of expenditures at the conclusion of the educational program to the grantor. Refer to ONS's Commercial Support Policies for Continuing Nursing Education Activities for specific policies related to CNE.

Sponsorship

ONS receives corporate support as sponsorship of non-educational activities such as bussing expenses during national conferences and selected social events. The sponsoring company pays ONS a fixed dollar amount in exchange for the sponsoring company's name and logo being acknowledged in conjunction with the activity. The promotion of specific drug names or product lines is prohibited in the context of sponsorship.

Standard Business Activities of Associations

Another area of corporate support involves the purchase of exhibit space at the ONS national and regional conferences, and other meetings. The purchase of exhibit space allows the exhibiting company to educate ONS members about the products and services of the specific company. ONS has developed rules and regulations for any company or organization that exhibits at its conferences and meetings in the respective Exhibitor Prospectus. ONS Exhibitor Rules and Regulations encourage pharmaceutical companies to follow the PhRMA code according to their own corporate policies. ONS is in no way responsible for the interpretation of the PhRMA Code or for providing legal advice about the code's interpretation. Exhibiting companies should consult with their legal counsel to determine their actions in relation to the new PhRMA Code. Solicitation of business, order taking, and selling activity are prohibited on the exhibit floor.

Another revenue source for ONS is commercial advertising in a variety of places, including, but not limited to the ONS journals and website. ONS has adopted advertising policies that address the type of advertising content that will be accepted. While this activity can be viewed as educational for ONS members, advertising is considered a "commercial" or business activity by the IRS.

Trends

Regardless of the type of professional or business support received by ONS, more public disclosures about these types of corporate support are occurring from the pharmaceutical industry as well as from ONS as the recipient. It is now common practice among pharmaceutical companies to voluntarily and publicly disclose grants, donations, sponsorships, and other interactions with health professionals. Likewise, tax-exempt organizations such as ONS are being required to increase disclosures on their IRS Form 990 about their activities and programs, how they are funded, and the source of funding. Starting in 2009, the IRS Form 990 has been publicly available on the IRS web site.

^{*} These categories of support can be further distinguished by their varied tax treatment under the IRS code. Educational grants are exempt from taxation as long as they are directly related to the exempt purpose of the organization. Sponsorship activities are exempt from taxation as long as they comply with IRS criteria for sponsored activity. Advertising and career placement services are taxable revenue. Exhibit income is non-taxable if held in conjunction with an annual convention.

Principles in Seeking and Accepting Educational Grants and Sponsorship

Educational Grants

ONS seeks and accepts educational grants from corporations. In doing so, ONS strictly adheres to all applicable policies, regulations, and standards, including ONS policies, the ANCC, the Accreditation Council for Continuing Medical Education (ACCME) Essential Areas and Standards, FDA Guidelines for Industry-Supported Scientific and Educational Activities, and the PhRMA Code on Interactions with Healthcare Professionals. Interactions are guided by the following principles.

- 1. ONS maintains written policies governing its acceptance and administration of commercial support for continuing nursing educational activities.
- 2. All interactions with commercial supporters are transparent.
- 3. All interactions are conducted in an open and honest manner and within the applicable laws and regulations.
- 4. ONS maintains control over all aspects of its educational activities, including content, subject matter, faculty selection, and delivery. For grants received toward non-CNE activities and depending on the nature of the activity, the grantor may be able to participate in an advisory capacity and within parameters set forth within the grant agreement.
- 5. ONS maintains ownership of all rights associated with its educational materials, including copyright.
- 6. Activities supported through educational grants must benefit ONS members or the delivery of health care.
- 7. Activities supported through educational grants must preserve ONS's independence and integrity.
- 8. Educational grants are used for scientific and educational purposes only and not for the purpose of promoting a product or service. Funding of a program with an educational grant does not imply endorsement of the grantor or its policies.
- 9. An educational grant must not include any type of influence by the grantor over ONS.
- 10. Multiple commercial supporters for a specific project will be sought whenever feasible.
- 11. ONS does not accept commercial support for any activity related to the development of standards and guidelines, governance, strategic planning, policy development, or advocacy.

- 12. ONS discloses to faculty and participants any external funding received for an educational activity or product.
- 13. ONS requires a signed letter of agreement for all educational grants stipulating the independence of the educational activity, ONS's control over all aspects of the educational content, and the commercial supporter's agreement to comply with all applicable standards and regulations.
- 14. ONS maintains an internal separation or "firewall" to ensure that staff members involved in developing educational content do not engage in discussions regarding a company's marketing or promotional strategies.

Sponsorship

ONS seeks and accepts commercial sponsorship for selected activities. In doing so, ONS strictly adheres to all applicable policies, regulations, and standards, including ONS policies, the PhRMA Code on Interactions with Healthcare Professionals, and governmental regulations. Commercial support from industry makes possible added member services. Interactions with sponsors are guided by the following principles.

- 1. ONS maintains written policies governing its acceptance and administration of commercial sponsorship.
- 2. All interactions with industry sponsors are transparent.
- 3. All interactions are conducted in an open and honest manner and within the applicable laws and regulations.
- 4. ONS maintains control over content, copyright, and the use of the ONS logo related to any sponsored activity.
- 5. ONS maintains ownership of all rights associated with the sponsored activity.
- 6. Sponsorship of an ONS activity does not imply ONS endorsement of the sponsor or its products or policies.
- 7. The sponsor must not exert any type of influence over ONS. However, depending on the nature of the activity (e.g., non-CNE activities), the sponsor may be able to participate in an advisory capacity and

within parameters set forth within the sponsorship agreement.

- 8. The sponsorship must maintain ONS's independence and integrity.
- 9. Multiple sponsors for a specific activity will be sought whenever feasible.
- 10. ONS does not accept sponsorship for the development of standards and guidelines, or any activity related to governance, strategic planning, policy development, or advocacy.
- 11. ONS discloses any external sponsorship of its activities.
- 12. ONS requires a signed letter of agreement with sponsors stipulating ONS control over all aspects of the activity, including content, publicity, venue, and the sponsor's promise to comply with all applicable standards and regulations.
- 13. ONS maintains an internal separation or "firewall" to ensure that staff members involved in developing the sponsored activity do not engage in discussions regarding a company's marketing or promotional strategies.

Multiple-Company Support of Educational Activities

The traditional model for commercial support of educational activities involves a single commercial supporter providing grant support for a single educational activity. While this model continues to be appropriate, support from multiple sources for a single educational activity ("multi-supported" education) is sometimes a preferred model.

A number of benefits to multi-supported education have been suggested, including a reduction of cost to the individual commercial supporter, allowing broader funding of educational projects; added assurance of independence of the educational activity; elevated perception of the quality and integrity of the educational activity among participants and faculty; and preference among commercial supporters associated with a potential reduction in their legal risk.

ONS considers the appropriateness and feasibility of seeking support from more than one source, particularly when the project for which support is being sought will include discussion of healthcare treatments, products, or services used by patients; when more than one potential source of funding can be identified; and when there is potential for participants to perceive bias or commercial influence.

Avoidance of Conflicts of Interest by the ONS Board of Directors

The ONS Board of Directors adopted a financial COI policy to meet the requirements of the IRS Form 990, addressing a component of their fiduciary duties (Duty of Care and Loyalty). One aspect of the Duty of Loyalty which is relevant to a discussion concerning external corporate support at ONS involves disclosure of outside activities by Board members. As part of the Duty of Loyalty, a Board member has a continuing and annual obligation to provide written disclosure to ONS of outside interests, because these outside activities may give rise to serious concerns or perceptions that the outside activity will

- 1. Bias or influence the individual's decision making regarding a program, policy, or activity under consideration by ONS, or
- 2. Create an unfair competitive advantage for any individual person or outside organization.

It is not unusual for a nurse elected to the ONS Board to have other concurrent professional and business interests. Many of these other interests involve the pharmaceutical/medical device industry or other related corporations. Some of these other professional interests may involve actual or perceived COIs. ONS and the Board are proactive in managing these potential COIs. In certain instances, a Board member may stop completely an activity for the duration of his or her term on the ONS Board. In other situations, a Board member may decide not to participate in discussions and votes on actions before the Board where a potential COI or bias exists.

Consistent with current trends for more transparency and accountability by corporations and their Board of Directors during their terms of office, the protective measures taken by the ONS Board Executive Committee and the CEO have become more specific. Members of the ONS Board cannot be employed by the pharmaceutical or medical device industry while serving on the ONS Board Executive Committee. For purposes of this policy, employed means primary employment. The Executive Committee is comprised of the President, President-elect, Secretary and Treasurer.

The following parameters must be met by ONS Board Executive Committee and CEO.

- Avoid acceptance of honoraria or other remunerations (e.g., speaker bureaus and consulting arrangements) directly from related industries, and when offered, an honorarium is directed to the ONS Foundation.
- Avoid direct participation in external business or educational programs in order to avoid concerns or perceptions that these outside activities are competing with or influencing ONS products, services, or other membership activities.
- 3. Postpone professional consulting arrangements and participation on advisory panels with related industries while a member of the ONS Board Executive Committee and CEO unless they are

unrelated to ONS activities, programs, or professional policies.

Avoidance of Conflicts of Interest by Volunteers and Staff

ONS has a general COI disclosure policy that no individual, while serving ONS, will allow a situation to exist that may be construed as an actual, potential, or perceived conflict of interest. All COIs or potential COIs must be fully and immediately disclosed and openly resolved. A conflict of interest is not determined by the individual, but, rather, by an impartial group reviewing the relationship. A conflict of interest is defined as a situation in which personal or professional concerns or connections of an individual affect his or her ability to place the welfare of ONS before personal benefits.

This policy applies to ONS employees, members of project teams, advisory panels, task forces, and think tanks; special interest group and chapter leaders; faculty and speakers; authors, editors, and editorial reviewers; award and research grant reviewers; consultants; and liaisons.

This document was adapted with permission from the American Society of Health System Pharmacists (ASHP) Policy on Accepting Corporate Support and Avoiding Conflicts of Interest.

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