National Home Infusion Association

NHIA Standards for Ethical Practice
The National Home Infusion Association
Alexandria, Virginia

I. Preamble and Scope

The National Home Infusion Association (NHIA) membership ("Members") consists of companies (and their employees) that fall into the following categories: Provider Members ("Providers"); Business Firm Affiliate Members ("Business Firm Affiliates"); and Other Member category types. All of these categories involve the provision of infusion therapy in patients' homes and in other alternate sites for infusion care. In all aspects of patient care and business operations, Members shall act in good faith and with high integrity, implement sound and consistent business practices and generally uphold the standards of the profession.

All Members recognize that compliance with clinical and ethical standards and laws governing the practice and operational practices of home infusion therapy is paramount to ensuring that quality, safe and cost-effective health care services and medications are provided to patients nationwide. Providers work closely with physicians and their staffs, hospital-based health care professionals, government and non-government health plans, and payers to coordinate home infusion therapy services for their patients. Providers also interface with manufacturers and distributors of medications, medical devices and supplies to identify and enhance the technology needed to support patients who need home infusion therapy services at home and in similar alternate-site settings.

To facilitate Members' interactions with individuals who prescribe, recommend, use, arrange for or purchase home infusion services, NHIA voluntarily adopts these Standards for Ethical Practice, effective January 1, 2011. In adopting these Standards, NHIA sets out its principles for ethical patient care and business practices for all Members. Nothing in this document shall be construed to replace or supersede similar standards of practice or codes of ethics currently implemented by regulatory agencies, accrediting bodies or by the Member organization in its own operation.

This document is not intended to contain or provide legal advice. Members should consult with their own legal counsel on specific questions or interpretations of federal or state laws, rules, regulations and requirements.

Adoped by the National Home Infusion Association Board of Directors on September 22, 2010

II. Patient Care and Caregiver Support

The Association recognizes that certain standards of care and service are needed to safely and effectively provide home infusion services at home or in an alternate-site setting.[1,2,3] Such standards may be outlined by various independent accreditation organizations, professional organizations, and state or federal regulators.[4] When interacting with patients entrusted to their care and with their caregivers, Providers:

1 Shall provide patients and their caregivers with a "Rights and Responsibilities" document that conforms to the Provider's independent accrediting organization's requirements (if applicable) and any federal and state laws and regulations.[4]

2 Shall maintain patient confidentiality and the security of information in accordance with prevailing federal and state laws and regulations, such as the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH).[5]

3 Shall encourage patients and/or their caregivers as appropriate to actively participate in their home infusion therapy care plans.

4 Shall implement an orientation, assessment, training and ongoing professional education program that provides employees and independent contractors (if applicable) with the level of information, training and support that is appropriate to their specific functions.[6]

5 Shall provide an appropriate level of oversight to home health agencies, pharmacies, nutrition experts and other professionals who may provide direct or indirect patient care. When care is provided by a third party on behalf of the Provider, generally the Provider shall enter into a written contract with these other parties and each Provider shall provide orientation/training to such groups regarding the Provider's policies and procedures and other state and federal laws and regulations and/or accrediting organizations' standards, as applicable.[4,7]

6 Shall voluntarily report documentable violations by employees of state professional practice acts, other professional standards and laws pertinent to the provision of home infusion therapy.[8]

7 Shall comply with applicable state and federal requirements for self-disclosure of any self-detected, non-compliant billing practices, remuneration and financial arrangements as required by laws, regulations or contractual agreements.[9]

8 Shall ensure that pharmaceutical and inventory management practices meet state and federal regulations[1,6] and conform to standards of care.

9 Shall support patients' right to choose the option of home infusion therapy services as an alternative to institutional care.

10 Shall support patients' right to choose among qualified providers in their community.

11 Shall not discriminate against patients on the basis of age, sex, race, nationality, religion, sexual preference or other social criteria that are irrelevant to their ability to participate in their home infusion therapy care plan.[10]

12 May adopt formularies that include specific manufacturers' products that meet patient needs, but shall not recommend such products if based solely on economic considerations or do not meet patients' needs. Insurance coverage limits may be considered in product recommendations if such recommendations meet patients' care needs. Any product substitution practices shall conform to applicable state and federal regulations.[11]

13 Shall honor patients' Advance Directives in accordance with state regulations and/or accrediting organizations' standards, as applicable.[3,10]

14 Shall make a good-faith effort to collect out-of-pocket amounts due (deductibles, cost-shares, etc.) while following all state and federal laws and regulations regarding collections activities. Shall not routinely waive co-insurance amounts when prohibited.[12,13,14]

III. Interactions with Referral Sources

Most NHIA Members interface daily with physicians, case managers, discharge planners, health system, hospital and skilled nursing facility managers, managed care contracting departments and other health care professionals involved in the coordination of care for patients who require infusion therapy services. Members also attend conferences, educational programs and health fairs hosted by referral sources. When interacting with referral sources, Members:

1 Shall comply with federal and state laws and regulations such as anti-kickback laws and self-referral statutes, during interactions with physicians and/or other referral sources.[15,16]

2 May offer bona fide education and information about their clinical and patient care services, services of the profession or publicly-available reimbursement information during meetings with referral sources or conferences which referral sources attend to enhance their professional and industry knowledge.[14] Referral sources may lease booth space to display at a conference or purchase advertisements to promote their services, and the Members may offer hospitality services in the form of modest refreshments in conjunction with the in-service/meeting. However, it is not appropriate for Providers or Business Firm Affiliates to pay for expensive meals or special events for referral sources or their relatives. Payment to referral sources for travel expense is generally inappropriate but allowed under circumstances permitted by law. [13,17,18]

3 Shall not pay for the registration or other fees of referring physicians or other referring health care professionals who attend conferences or other events. Members may reimburse their own employed professional staff for costs associated with attending such events.[13,14,15]

4 May provide unrestricted or restricted grants to conference sponsors (such as non-profit foundations, trade associations and meeting planning companies), but not to individual referring physicians or other referring health care professionals who may speak at the conference. Grants shall be bona fide and made consistent with any guidelines published by the sponsoring trade association, professional organization, society or health care organization. Providers may not pay conference speakers directly.[13,14,15,16]

5 May provide occasional charitable donations to support bona fide organizations' goals for advancing medical research, public health education, providing indigent care and/or supportive services to patients. Such charitable contributions shall be appropriately documented and shall not be offered to or solicited by referral sources for the purpose of unlawfully inducing referrals. The charitable contribution also should not be directed toward a specific patient or individual.[10,11,12,13,14,15,19]

6 May provide occasional, modest gifts to referring health care professionals in accordance with guidelines published by federal or state authorities and Member company policies. However, under no circumstances should gifts be provided in exchange for a referral or solicited directly by the referring individual. This principle applies to family members of referring physicians and other referring health care professionals as well.[13,14,15,20]

7 May also give health care professionals branded promotional items of minimal value, but gifts should not be in the form of cash or cash equivalents such as gift cards.[13,14,15,16,18]

8 May participate in community health fairs at which display booths or other venues are offered for organizations to share information about their services. Such participation should be at fair market value and any applicable payment should be made directly to the conference sponsor.[9,10,11,12,13,17]

9 Shall conform to federal and state laws and regulations with respect to relationships with physicians who serve as medical directors or advisors.[13,15]

IV. Interactions with Manufacturers and Business Affiliates

Manufacturers, distributors and other vendors contribute to the advancement of the home infusion profession. Suppliers of medications, medical devices, supplies and ancillary support services, such as in-home delivery, telemedicine and billing/collection, provide necessary expertise to enable home infusion therapy providers to effectively manage their business and patient care functions. The principles set out in Appendix A of this document specifically apply to Provider and Business Firm Affiliate Member interactions and those with other non-member entities.[9,21,22]

V. Compliance Oversight (and Accreditation, if applicable)

All NHIA Members fully support federal/state authorities' and private payers' objectives to prevent and eradicate waste, fraud and abuse in the United States health care system. The Association also recognizes that the administrative requirements of individual health plans are complex and subject to honest, inadvertent billing errors that may result in voluntary refunds or minor penalties/sanctions. Through their expression of support for the following provisions, Members acknowledge the Association's general expectations based on publicly available guidelines and information, and they:

1 Shall act in good faith and with high integrity, implement sound and consistent business practices and generally uphold the standards of the profession in all aspects of patient care and business operations.[1,2,3]

2 Shall comply with all federal, state and local laws, rules, regulations and requirements concerning facility and clinician licensure, billing/collection, pharmaceutical management, product recall management and reporting.

3 Are committed, in conjunction with their legal counsel, to responding to audits, investigations or other probes in a timely manner when associated with the identification or study of potential fraud and abuse.

4 Shall implement a voluntary compliance program which meets the guidelines and expectations issued by the Department of Health and Human Services' (DHHS) Office of Inspector General (OIG), the Food and Drug Administration (FDA), the Drug Enforcement Agency (DEA), individual states' investigative agencies, attorneys general and consumer protection agencies, and other regulatory bodies.[23]

5 Shall, if Members are Medicare suppliers or providers, meet the applicable accreditation requirements, quality standards or other requirements established by statute or regulation or otherwise issued by the Centers for Medicare & Medicaid Services (CMS).[4]

6 Shall ensure that a Provider's executive leadership teams and Board of Directors will provide appropriate oversight over the Provider's operating and clinical practices to ensure appropriate quality of care as well as any compliance activities.[6]

7 Support the Association's goal to work cooperatively with government officials on education and awareness of current or potential changes in reimbursement policies, administrative requirements, compliance requirements and the penalties/sanctions associated with non-compliance.

8 Shall implement quality management practices that conform to state/federal requirements and, as applicable, those of their independent accrediting organization. Examples include but are not limited to measuring and reporting clinical outcomes and patient satisfaction.[6]

9 Shall not provide information to referral sources for the purpose of unlawfully inducing them to prescribe, purchase, rent, recommend, use or arrange for the procurement of Members' products and services. [7,11,15,16,20]

10 Shall not interact with other Members or entities in ways that could directly or inadvertently violate antitrust laws, especially during any and all activities arranged by the Association as well as in other forums.[24]

11. Are encouraged to report documentable unethical and/or illegal practices in the industry to the appropriate authorities through existing channels.

VI. Association Policies Regarding Member Sanctions

The Association is committed to ensuring the highest level of standards of ethical practice among its Members and recognizes that compliance expectations of the government, private health plans, accrediting organizations and other regulators are ever-changing and, at times, open to multiple interpretations. The Association believes that all Members should conform to the expectations of such organizations and sets forth procedures in Appendix B to guide the Association and its Board of Directors in addressing documented violations of these voluntary Standards for Ethical Practice.

VII. Conclusion

The Association and its Members are committed to enhancing the overall access to and provision of ethical, quality home infusion therapy services in the communities we serve. The Association believes that all Members have an independent obligation to ensure that their policies, procedures, and operational practices conform to federal and state laws, regulations, rules, and clinical standards of care. Members also are expected to communicate the principles of this document to their employees and constituents, and to seek legal advice.

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APPENDIX A

Principles for Interactions between Providers, Business Firm Affiliates, and Other Non-member Entities (e.g.: non-member business firms)

1 Manufacturers, distributors, service providers and other business firms may provide bona fide educational programs about their products or services to Providers, which may include clinical training. Such programs may also include modest hospitality, provided that such programs should not include separate entertainment or other similar unrelated events. All such programs must not be offered to unlawfully induce the purchase or lease of such products and services and must otherwise comply with applicable laws and regulations.

2 Providers should not participate in sales contests sponsored by business firms if individual employees receive an award directly from a business firm for reaching certain goals related to a business firm's product or service.

3 Manufacturers, distributors, service providers and other business firms may sponsor professional association events or sales conferences provided the fees to participate represent fair market value of the events.

4 Manufacturers, distributors, service providers and other business firms generally may not provide free advertising or pay for public relations and marketing expenses that Providers would otherwise incur in the course of managing their business. In certain circumstances, joint advertising may be conducted, but both parties must pay fair market value and receive equitable marketing exposure from such advertisements.

5 It is not appropriate for business firms to pay for the cost of a Provider's social or holiday events at which no product or service training takes place.

6 Providers shall treat business firms equitably and respectfully and provide a fair contract management process to those parties who are interested in providing services and products to a Provider's patients and referring customers.

7 To ensure access to safe, quality medical devices and pharmaceuticals, Providers and business firms will adhere to processes issued by the Food and Drug Administration (FDA) and other regulatory bodies in the event of a medical device or pharmaceutical product recall or shortage.

8 Business Firm Affiliates shall support patients' and their caregivers' right to choose home infusion therapy services as an alternative to institutional care and to access a qualified provider in their community.

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APPENDIX B

Association and Board Guidelines for Addressing Documented Violations of the *NHIA Standards for Ethical Practice*

1 Beginning in 2011, NHIA shall release to, educate on and welcome feedback from Members on the *NHIA Standards for Ethical Practice*. It is NHIA's expectation that Members will use the standards as a framework for ethical business decision making within the context of their daily operations and typical interactions with various constituents. Beginning with membership renewals for 2012, NHIA expects to ask Members to acknowledge receipt of the *NHIA Standards for Ethical Practice*, attest to accepting the general tenets of the document and, as applicable, list the name of the organization's independent accrediting organization(s).

2 If any Member or Member employee becomes aware of conduct or practices that may violate applicable and relevant laws, rules or regulations, the Member or individual is encouraged to contact the compliance officer, in-house legal counsel or other senior management contact in the organization where the alleged violation occurred and to request follow-up communication on the matter. If no follow-up occurs, Members are encouraged to report concrete examples of violations of existing laws, rules and regulations to applicable authorities through existing channels. Reports of such violations should not be made directly to NHIA staff or Board members.

3 Members who enter into formal Corporate Compliance Agreements (CCAs) or Corporate Integrity Agreements (CIAs) with federal or state governments in the absence of *a conviction on criminal or civil charges* shall voluntarily report the agreement to the Association's President within 60 days of formalization. No copy of the agreement is required. This policy also applies to fines (but not to voluntary refunds issued during the normal course of business) of $500,000 or more. If Association leaders become aware of such an agreement without notice to the Association, the Board authorizes Association leaders to send a letter to the Member requesting clarification/information about the agreement, sanction or fine, with a request for the Member to reply within 30 business days. The Board shall determine if the clarification is adequate and whether to authorize or terminate such Member's ongoing membership in the Association.

4 Member companies that are criminally convicted of violating laws, regulations or other rules pertaining to false claims, kickback prohibitions and related provisions shall be excluded from membership in the Association for one 12-month period, and subsequent readmission to membership in the Association requires approval of the NHIA Board.

5 Member companies in which one or more principals are criminally convicted of charges of non-compliance with the above-mentioned laws, regulations and rules shall be terminated as Members in the Association for one 12-month period, and subsequent readmission to membership in the Association requires approval of the NHIA Board. A "principal" is defined as an owner, director or board member, officer or senior manager.

6 In the case of a Member company being excluded from participating in government programs, the company shall not be eligible for membership until such time as the company is removed from the list, if ever. The only exception is if a formal, legal appeal process has been initiated.

7 NHIA recognizes that employees from a company terminated from or ineligible for NHIA membership due to the provisions cited above may not have been involved with problematic infractions and desire to continue professional development through NHIA membership. Hence, such employees may apply for Individual Affiliate Membership in NHIA and their applications will require approval (two-thirds) by the NHIA Board prior to acceptance. The NHIA Board reserves the right to reconsider granting ongoing membership to such employees at any time.

8 Dues payments shall not be returned, even on a pro rated basis, to Members whose membership is terminated for the above reasons.

9 Communications by the Association on such matters of membership shall be communicated to the Member via certified mail.

10 The NHIA Board has sole and complete discretion over all membership decisions, and such decisions are final and are not subject to review except by the NHIA Board itself.

1. American Society of Health-System Pharmacists (ASHP): Code of Ethics for Pharmacists, 2004.
2. Infusion Nurses Society (INS): Infusion Nursing Standards of Practice, 2006.
3. Oncology Nursing Society (ONS): Core Values. Available July 2010 at www.ons.org/about/CoreValues.
4. HHS Centers for Medicare & Medicaid Services (CMS): Medicare Supplier Standards for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) and various accrediting organizations.
5. HIPAA and HITECH Acts. (Pub. L. 104-191; Pub. L. 111-5.)
6. Applicable accreditation standards and state-specific/federal requirements.
7. 42 C.F.R. § 411.350 – 411.389), which addresses the Stark anti-kickback law.
8. Per applicable state practice acts and self-disclosure requirements.
9. Section 6409 of the Patient Protection and Affordable Care Act (Pub. L. 111-148)
10. Various state and federal anti-discrimination laws, rules and regulations.
11. HHS OIG Advisory Opinion 06-16, regarding marketing programs between manufacturers and Medicare suppliers of Part B services/products and a description of when kickbacks may apply regarding the same.
12. HHS OIG Special Advisory Opinions 97-01 and 02-01, which address patient inducements, specifically the role that independent patient advocacy organizations may play to pay for benefits for needy beneficiaries.
13. HHS OIG Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries, August 2002.
14. 42 U.S.C. § 1320a-7a (5), which prohibits offering remuneration to influence a Medicare beneficiary's choice of supplier. Included in this statute is the prohibition of the routine waiver of copayment and deductible amounts owed by the patient.
15. Various state laws and regulations and 42 U.S.C. § 1320a-7a (5), which prohibits offering remuneration to influence a Medicare beneficiary's choice of supplier. Among other topics, this law and its regulations describe permissible consulting arrangements between physicians the providers/suppliers that bill Medicare/Medicaid.
16. 42 C.F.R. § 411.357 (o), which addresses interactions with physicians under the Stark anti-kickback law and defines the provision of Continuing Medical Education (CME) credits to physicians as remuneration subject to the same law.
17. American Medical Association (AMA) Code of Medical Ethics, Opinions 8-061, Gifts to Physicians from Industry; and Opinions E-6.12 and E-6.13, available at www.ama-assn.org.
18. Pharmaceutical Research and Manufacturers Association (PhRMA): Code on Interactions with Healthcare Professionals, 2009, available at www.phrma.org. 31 U.S.C. 3729, regarding false claims and civil monetary penalties (CMPs) and administrative sanctions which may be imposed on providers for the submission of false claims.

19. HHS OIG Advisory Opinions Nos. 06-01; 06-20 and 07-08, which address the provision of free goods and services to Medicare beneficiaries.

20. HHS OIG Advisory Opinion 98-16, regarding the role of mail order pharmacies, provider liaisons to hospitals, expense relief for referral sources and kickbacks.

21. AdvaMed Code of Ethics on Interactions with Health Care Professionals, 2003 and 2005, available at www.advamed.org.

22. HHS OIG Compliance Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003).

23. Section 6401 of the Patient Protection and Affordable Care Act (Pub. L. 111-148); 42 U.S.C. 1395cc(j)(8); 42 U.S.C. 1396a(a)(77); 42 U.S.C. 1396a(ii)(5)

24. 15 U.S.C. 1-7.