

NHIA STANDARDS FOR ETHICAL PRACTICE INFORMATION KIT



National Home Infusion Association



National Home Infusion Association

Content

INTRODUCTION

VALUE TO MEMBERS

ETHICS STANDARDS

FAQs

ATTESTATION

CERTIFICATE/SEAL



National Home Infusion Association

INTRODUCTION

In 1991, a group of leaders representing the alternate-site infusion community came together to form the National Home Infusion Association, a shared effort to allow the industry and its members to work collaboratively toward the improvement of care to patients, and the growth and success of the industry.

Since the founding of NHIA, the association has been dedicated to representing and advancing the interests of organizations that provide infusion and specialized pharmacy products and services to the entire spectrum of home-based patients. For the past 20 years, NHIA members have maintained a steadfast commitment to providing patients with safe, high-quality care and distinguished themselves by operating with the highest standards of ethical behavior.

Yet, America's health care system is at a crossroads. Providers must face the challenges of a changing health care landscape. At a time when sensational headlines on fraud and abuse abound, the alternate site infusion industry must differentiate itself from those that seek to abuse the system. Greater complexity in regulatory requirements and the Obama administration's zero tolerance for unethical behavior are all solid reasons to set the definitive bar for ethical business standards among NHIA members.

The newly created *NHIA Standards for Ethical Practice* serve as the industry's proclamation of the virtue of its principles and actions and reaffirm its commitment to operating with integrity and the highest regard for the quality of patient care.

The following pages offer more information about the *NHIA Standards for Ethical Practice* and its value to patients and the industry overall. Complete materials including the contents of this binder can be found at the following NHIA web page: www.nhia.org/about/ethics.



National Home Infusion Association

VALUE TO MEMBERS

Importance of Standards for Ethical Practice to Members and Industry

The *NHIA Standards for Ethical Practice* reflect the industry's commitment to providing high-quality care to patients and reaffirm our Members' pledge to operate their businesses with integrity. As responsible health care providers and business leaders, these NHIA Standards can also serve as an effective tool in making decisions and taking appropriate actions that are ethical and in compliance with applicable legal requirements.

In today's changing regulatory environment, the Standards position NHIA and its members as leaders in compliance. By self-regulating rather than waiting for legislation, the industry is promoting its high standards of care to patients and its commitment to sound business practices. At the same time, the *NHIA Standards for Ethical Practice* provide members the ability to distinguish themselves as trusted provider partners outside of the alternate-site infusion industry.

Overall, the benefits of formalizing the industry's moral principles include:

- Reaffirming our industry's pledge to operate our businesses with integrity.
- Serving our members as an effective tool for ethical and legal decision making.
- Enhancing the reputation of NHIA and its members in the eyes of legislators, regulators, the media, and the public.
- Providing NHIA members with a clear, easy way to demonstrate their commitment to high ethical practices among patients and referral sources.
- Communicating to all parties NHIA's expectation that our members place the highest priority on compliance with all legal and regulatory requirements and execute their operations in a highly principled manner.
- Giving the NHIA Board of Directors a definitive set of criteria for evaluating cases where a member's conformance to expectations for ethical behavior comes into question.



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.



National Home Infusion Association

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.



National Home Infusion Association

- 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}



National Home Infusion Association

- 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}



National Home Infusion Association

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}



National Home Infusion Association

- 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.



National Home Infusion Association

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.



National Home Infusion Association

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.



National Home Infusion Association

- 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.



National Home Infusion Association

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.



National Home Infusion Association

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.



National Home Infusion Association

FREQUENTLY ASKED QUESTIONS

NHIA Standards for Ethical Practice

Who is subject to the Standards for Ethical Practice?

The Standards apply to all National Home Infusion Association (NHIA) Members. The primary emphasis of the Standards is on provider Members who directly serve patients, interact with referral sources and bill payers.

Why did the National Home Infusion Association (NHIA) create this document?

The U.S. Congress and Department of Health and Human Services (HHS) are committed to enhancing the government's efforts to identify and eliminate waste, fraud, abuse and errors associated with government payers such as Medicare, Medicaid and TRICARE. In recent years, health care legislation has included increasingly more stringent requirements to ensure that services are provided legally, ethically and in compliance with all applicable laws, rules and regulations. For example, the health reform package which was passed into law in March 2010 includes several new reforms and government investments designed to further identify and eradicate fraud, waste and abuse. In addition, an increasing number of states have passed "payer-blind" legislation which adopts the same kinds of provisions as federal legislation and which applies to services provided to patients covered by non-government payers.

NHIA and its Members are committed to promoting compliance with applicable rules, laws and regulations. The publication of this document serves multiple roles. It provides guidance to NHIA Members although they should consult with their own legal counsel on specific details and their application to the Member's business operations. It also demonstrates that the Association and its Members will commitment to Congress and regulatory agencies operate in an ethical, legal, patient-centric manner. Adoption of these standards by NHIA and its members will promote trust in the Association and in its Members' services.



National Home Infusion Association

Does NHIA expect me and my organization to adopt these provisions verbatim?

The Standards are intended to serve as umbrella guidance to Members and affiliates to enable you to develop your own internal policies and procedures which are customized to your organization. They are, however, grounded in existing laws, rules, regulations or public guidance pertaining to our industry. The government expects providers of all sizes, legal structures, numbers of employees, locations in the country, etc. to comply. NHIA expects you to embrace the direction we are taking to further clarify our position regarding a zero tolerance for fraud and abuse.

Will I or my Chief Executive Officer (CEO) have to sign a certification document stating that we adopt the *NHIA Standards for Ethical Practice*?

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* and attest to accepting the general tenets of the document.

Will we be audited by NHIA to determine our adherence to the Standards document?

No. Participation and adoption is important. However, auditing its Members is well beyond the scope of activities for the Association.

Do the Standards impact the way that we comply with antitrust laws and regulations?

No. NHIA and its Members must continue to adhere to all applicable federal and state antitrust laws and regulations. This includes large group meetings, advisory boards and other situations involving several competitors. No provision in the Standards document shall be interpreted as a recommendation or suggestion that it is permissible for a group of competitors to participate in any antitrust activities of any kind, including price fixing, refusing to negotiate, etc.

How do the Standards address unlawful inducements of referrals or patients?

NHIA is committed to promoting Members' compliance with all state and/or federal laws and regulations that prohibit the offer or solicit unlawful inducements of referrals for patients whose insurance is funded by government health care programs. Included in this prohibition are physician self-referrals.



National Home Infusion Association

Do the Standards apply to subcontracted nursing agencies, first-dose pharmacies, per diem clinicians, distributors and manufacturers/suppliers?

Members who incorporate the Standards into their business operations have a responsibility to communicate the principles to their employees, subcontractors and manufacturers/suppliers with the expectation that they will embrace the tenets of the document. This does not mean that NHIA members need to distribute a copy or conduct training on this document or their own compliance policies and procedures. Rather, via various communication methods, the Association recommends that you educate your constituents about your own – and our industry’s – commitment to compliance on a frequent basis.

Why does the Standards document address various constituents with whom we might interact, such as referral sources and patients?

The nature of the home infusion and specialty infusion pharmacy business is such that our Members interact with a number of different constituents who are the subject of general and specific laws, rules and/or regulations. For example, physicians and hospital discharge planners may make the referral to a home infusion provider, but a patient/caregiver is the recipient of our services and a separate, third-party payer typically pays the claim we submit. There are existing laws, rules and regulations which govern how infusion/specialty providers must operate when interacting with these audiences. Interactions with referral sources, patients, vendors and other parties should be free of the bias that results from unlawful inducements, conflicts of interest and the like.

My company provides key chains and pens at local health fairs. Is it acceptable to offer patients gifts or free services that promote wellness?

Laws, rules and regulations exist to prevent individuals whose care is paid by a federally funded health care program from receiving or being offered gifts, including free services, if such a gift constitutes an unlawful inducement for the patient to choose or continue using a certain provider. Gifts of modest value (see Standards) are acceptable. The cumulative value of all items given in any one-year period to any one patient should not exceed \$50. The value limits apply to services such as health screenings, clinical questionnaires to screen for certain conditions, or blood pressure checks.

For example, it would be acceptable for Members to give specialty advertising items to patients, such as key chains, pens and the like, as long as the \$10 per item and \$50 cumulative value is not exceeded in any one-year period. It is not acceptable for Members to offer discount coupons, incentives for switching from one provider to another or routine waivers of co-pays in an effort to convince the patient to choose or switch providers. Consult with your legal counsel to develop an in-house policy if you don't have one already.



National Home Infusion Association

In the Standards document, who are the specific “referral sources” being described?

The government defines “referral sources” as individuals and entities who may prescribe, purchase, recommend, use, or arrange for the use, purchase or rental of Members’ products and services. The term applies to both clinical and non-clinical personnel. In other words, a referral source can be a physician, nurse practitioner, another clinician, a provider or supplier, as well as clinic or physician office staff, discharge planners or hospital administrators among other entities.

Can I provide support services to assist referral sources in understanding our products and services?

Referral sources benefit from certain information and/or training on Member services when the goal is to help patients gain access to services and products which the referral source believes they need and therefore prescribe or recommend. It is to be expected that information about coverage and payment for Members’ products and services, payer documentation and billing requirements, advocacy activities and similar information will be shared with referral sources. However, laws and regulations are clear about which activities a provider may perform and which must be performed by a referral source. For example, Members may not provide “expense relief” to a hospital by performing its discharge planning functions that would otherwise be absorbed as a cost that the hospital would incur. Fax machines and other office equipment may not be provided for free to referral sources. And it goes without saying that Members may not complete paperwork or forms that the government requires the referral source to complete, such as certificates of need or justification of medical necessity.

In the past, I provided funds or a meal at my referral source’s holiday party. Does the Standards document allow me to do that?

No. Such support would be inappropriate under current rules and laws. Consult with your legal counsel.

May a Member conduct a sales meeting at a resort location and pay for a referral source’s travel to the meeting for purposes of providing product information and negotiating sales terms?

Occasional hospitality in the form of “modest meals and receptions” which are “conducive to the exchange of information” is generally permitted. However, a resort location would not meet this standard. Consult with your legal counsel, because such a meeting may not meet the guidance issued by the Office of Inspector General (OIG).



National Home Infusion Association

May a Member pay for guests or spouses of a referral source to attend a conference or sales meeting?

Members may provide "occasional" hospitality only in the form of modest meals and receptions for referral source attendees as long as these are conducive to the exchange of information. Meals and hospitality should be incidental and conducive to the underlying business purpose. It is inappropriate to extend benefits to relatives of referral sources or others who do not have a legitimate professional interest in the meeting.

What do the terms "modest," "occasional," and "hospitality" mean?

In the eyes of the government and experts who interpret its regulations, "modest" means moderate or low value and "occasional" means infrequent. Meals and hospitality should be secondary to a legitimate purpose which can be documented. Members should consult with their legal counsel to develop policies that set limits on the frequency and amount of spending on hospitality provided to referral sources. Also, there are federal and/or state self referral or conflict of interest laws related to referral sources which should be incorporated into Members' policies and procedures on the advice of legal counsel.

Can a Member provide an educational grant to support the attendance of a referral source at a third-party educational conference?

This is an area of increasing scrutiny by the government and also by organizations representing pharmaceutical companies, physicians and other referral sources. Grants should be made to the conference sponsor, and that group should select and interface with the attendee about his/her program/speech. It is inappropriate for a Member to designate grant funds to be earmarked for specific referral sources. Members should not pay the registration fees or fees associated with continuing education (CE) credits of individual referral sources or other health care professionals, especially physicians in the case of Continuing Medical Education (CME) credits.

May a Member designate attendees or faculty who will speak at third-party educational conferences?

No. The ultimate selection should be made by the conference sponsor, who is entitled to incorporate input from various constituents, including Members' recommendations.

Is the value of a gift to a referral source determined by the Member's cost to acquire it or by the fair market value of the item or service?

An unlawful inducement is determined by the retail fair market value of the gift or item. Members should consider the fair market value of the gift in determining whether a gift to a referral source is within the meaning of the Standards document and related regulations.



National Home Infusion Association

I sometimes provide a small gift such as flowers or a fruit basket to a referral source or to a referral source's family upon significant life events such as a birth or death. Can I continue to do so?

Each Member should consult with legal counsel to determine whether such gifts to a referral source, or to a referral source's family, are consistent with the spirit of the laws and regulations on the books, and the Standards document. In general, gifts should be related to business interactions between Members and referral sources.

Should I consider the Standards document to constitute legal advice?

No. The Standards are intended to provide a framework for ethical business decision making within the context of our Members' daily operations and typical interactions with various constituents. They are not intended to be, nor should they be, construed as legal advice. All Members are urged to consult with personal counsel to ensure that their policies, procedures and interactions with referral sources, patients and other constituents comply with all current laws and regulations. Aside from consulting with their own attorneys, Members are urged to monitor guidance issued by the HHS Office of Inspector General and other regulatory bodies.

Will the NHIA staff provide interpretations of the Standards so that Members can contemplate the implications of specific practices or changes in their policies and procedures?

No. The NHIA staff is not in a legal advisory role to Members. Members should address any questions about specific practices to their own attorneys and in-house compliance officers or regulatory compliance experts.



National Home Infusion Association

ACCEPTANCE OF THE NHIA STANDARDS FOR ETHICAL PRACTICE

On behalf of _____¹ ("The Organization"), I have read the *NHIA Standards for Ethical Practice* ("the Standards") and the Frequently Asked Questions as adopted by the NHIA Board of directors on September 22, 2010.

I attest that The Organization accepts the general tenets of the Standards in guiding its clinical practices and business operations. The Organization commits to using the Standards as a framework for ethical business decision making in its daily operations and interactions with patients and other stakeholders. This attestation is effective upon my signature for the duration of time The Organization maintains its NHIA membership.

I acknowledge that The Standards are not intended to be, nor should they be, construed as legal advice; that the NHIA staff is not in a legal advisory role to The Organization, and that NHIA recommends that its members should address questions about specific practices to their own attorneys, in-house compliance officers or regulatory compliance experts.

Signature by
Senior Manager²: _____

Date: _____

Name: _____

Telephone: _____

Title: _____

Email: _____

Mailing Address: _____

Attachment (1)

¹ Enter NHIA member organization; enter alternate-site infusion business unit if applicable for multi-business organizations.

² Senior manager authorized by The Organization to attest to acceptance of the NHIA Standards for Ethical Practice.



National Home Infusion Association

ATTACHMENT TO NHIA ATTESTATION

- Upon receiving your attestation, NHIA will provide The Organization with a Certificate of its commitment to the Standards of which copies may be displayed in its offices and facilities. NHIA will grant The Organization the right to display NHIA Seals which represent The Organization's commitment to the Standards for use in The Organization's electronic or other published materials per stipulations of a Seal licensing agreement that NHIA will provide. Rights granted by NHIA to exhibit the Certificate and display the Seals will cease if The Organization's membership in NHIA should cease.
- The Standards' Appendix B (Association and Board Guidelines for Addressing Documented Violations of the NHIA Standards for Ethical Practice) includes provisions on termination of NHIA membership. A violation by The Organization may result in the actions described in Appendix B.
- Should NHIA make a material update the Standards in the future, NHIA will require a new attestation.

Standards for Ethical Practice

National Home Infusion Association

The National Home Infusion Association (NHIA) is committed to extending association membership privileges to entities that provide health care services and products in a legal and ethical manner, including compliance with all applicable laws, rules and regulations. NHIA certifies that

<Quality Home Infusion Company>

has received and attested to accepting the general tenets of the NHIA Standards for Ethical Practice in guiding the member's clinical practices and business operations.

Date of Issue: April 2, 2011

Russell Bodoff
NHIA President & Chief Executive Officer

Lynn Giglione, RN, BSN
NHIA Board Chair

NHIA is a trade association that represents and advances the interests of organizations that provide infusion and specialized pharmacy products and services to the entire spectrum of home-based patients. Contact this NHIA member or the National Home Infusion Association to obtain a copy of the NHIA Standards for Ethical Practice.

National Home Infusion Association • 100 Daingerfield Road • Alexandria, VA 22314 • Phone: 703-549-3740 • www.nhia.org

National Home Infusion Association

The logo is circular with a blue and white color scheme. It features the letters "NHIA" in a bold, black, sans-serif font at the bottom. Above "NHIA" is a stylized graphic element consisting of three blue dots connected by a line, with a small swoosh underneath. The words "Standards for Ethical Practice" are written in a black, serif font along the bottom edge of the circle. The top half of the circle contains the words "Commitment to Integrity" in a black, cursive font, with "Integrity" partially cut off on the right. The entire logo is set against a light blue background with a white decorative border.