



## **Healthcare Compliance Program**

**Effective Date: February 10, 2017**

## **OUR CALLING TO INTEGRITY**

Noden Pharma USA, Inc. ("Noden" or "Company") is a pharmaceutical company committed to providing medicines, in a responsible manner, which enhance the lives of patients.

In today's Healthcare environment, behaving with integrity and honesty is essential to creating a culture which promotes high ethical standards. At Noden, we strive to be a responsible corporate citizen, employing a principled approach throughout all interactions. This Healthcare Compliance Program ("the Program") formalizes some of the basic practices and principles we follow to maintain our high ethical standards.

We are responsible for understanding the important legal and ethical framework in which we operate, the issues that affect our business, and for acting with integrity at all times. Each employee, independent contractor, and consultant who acts on behalf of Noden or a contractor is expected to familiarize themselves with these policies and the resources available when seeking clarification or raising concerns. These policies are to be used as part of ongoing training. They form one part of the ethics guidance for our greater team, together with the policies of our third-party contractors, and our parent company, PDL BioPharma.

As stated herein, we will carry out all of our business affairs honestly and ethically. The Company has decided to institute specific policies to address the more frequent risks posed by these statutes and to ensure that our continued business success is based on the quality of products and service, not improper influence. As always, our goal and our charge is to act ethically and with patients' interests first and these policies memorialize our existing practices. Our commitment to act ethically extends beyond the four corners of these pages.

In addition to supporting our general commitment to conducting our business in an open and honest manner, we intend to ensure that our team is aware of the challenges presented by healthcare laws. As a company operating in the healthcare market, products that we or our contractors may manufacture, market or sell are subject to government regulation and efforts to influence regulatory officials. When we engage third-parties to provide services to us or to our customers and patients, we may need to take appropriate measures to ensure that these business partners have not and will not engage in corrupt activity or other behaviors that violate our ethics principles. It is everyone's responsibility to protect and uphold the good reputation of Noden for honesty, ethics, fair-dealing, and patient care. We only want patients to use our products for the right reasons—not because of any perceived or actual influence on Healthcare Providers.

The Company has designated a Chief Compliance Officer who is responsible for administering the Healthcare Compliance Program. The Chief Compliance Officer may be reached by mail at Noden Pharma USA, Inc., 75 Arlington Street, Suite 500 Boston MA 02116 , Attention: Ronan Donelan, PhD, by telephone at: +353-1-6778350 or by email at: rdonelan@nodenpharma.com. The Chief

Compliance Officer is available to answer any questions or concerns related to Company practices. If you have a question or concern about what is proper conduct for you or anyone else, promptly raise the issue with the Chief Compliance Officer.

You must report any acts that you believe are inconsistent with our high ethical standards to the Chief Compliance Officer or make a report via the Company's confidential reporting procedures, which allow for anonymous reporting. The Company will not retaliate against personnel for reporting in good faith possible ethical violations.

Any employee who violates our ethical standards is subject to discipline up to and including termination and the Company may report the misconduct to law enforcement authorities. Following good ethical behaviors is for your benefit and for the Company's.

Each of us shapes our Company and our world for the better. By working together, we can fulfill our commitment to integrity, which includes complying with the spirit and the letter of the laws that govern our industry. If even one of us acts unethically, however, it can destroy the good work we have done. The Company is in your hands.

Thank you,



Danny Hart  
Chief Executive Officer



Michael McCann  
Head US Sales and Marketing



Ronan Donelan, PhD  
Chief Compliance Officer

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## **HEALTHCARE COMPLIANCE PROGRAM — GENERAL PROVISIONS**

### **HC-01.01**

#### **COMPLIANCE COMMITMENT**

Noden Pharma USA, Inc. ("Noden" or the "Company") is committed to conducting business activities in compliance with applicable laws, rules and regulations, and following the highest ethical standards in its interactions with its customers.

It is the policy of Noden that all interactions with Healthcare Providers that are made on behalf of the Company are consistent with ethical business practices and socially responsible industry conduct. This Healthcare Compliance Program and related policies and procedures are an expression of this core value, and are intended to provide guidelines for complying with the law for all Noden personnel and agents.

#### **PURPOSE**

The Noden Healthcare Compliance Program (the "Program") addresses and contains the policies critical to supporting and maintaining compliance with applicable industry laws and regulations, and thereby facilitates the integrity of the organization. The Program, in conjunction with training and other company practices, standard operating procedures and guidance materials, sets forth the policies and expectation of the Company regarding compliance with the law, regulations, industry guidance, and ethical business practices.

#### **SCOPE**

This Program and related policies apply to Noden Pharma USA, Inc. ("Noden" or the "Company"), its directors, officers and employees located or operating in the United States of America. Adherence to the policies set forth in this Program is a condition of employment and violations will be dealt with promptly and may result in disciplinary measures up to and including the termination of employment.

All independent contractors who engage in sales or marketing activities, or contact or communicate with Healthcare Providers on behalf of Noden (including sales and marketing agents, distributors, third-party sales and marketing intermediaries), shall comply with the provisions set forth in this Program, or shall adopt policies and procedures consistent with, and no less restrictive than, this Program.

Noden shall advise entities that manufacturer products on behalf of Noden of this Program, as applicable, and inform such entities of Noden's expectations of compliance with applicable laws and regulations.

## **DISTRIBUTION OF HEALTHCARE COMPLIANCE PROGRAM & TRAINING**

Noden shall distribute this Program to all officers, directors, employees and independent contractors to ensure their familiarity with the Program, related Company policies and procedures, and application federal and state laws and industry standards.

All Noden officers, directors and employees shall annually certify to having received and reviewed the Program. At the discretion of the Chief Compliance Officer, such individuals may be required to receive general compliance training on the Program and applicable laws and regulations.

All Personnel, including independent contractors, who engage in sales or marketing activities, or contact or communicate with Healthcare Providers on behalf of Noden, shall receive mandatory annual training on this Program or their internal policies and procedures that are consistent with, and no less restrictive than, this Program, and applicable laws and regulations, at a level appropriate to their position and responsibilities. Training on this Program should be provided promptly to newly hired or contracted individuals who engage in sales or marketing activities, or contact or communicate with Healthcare Providers on behalf of Noden.

Noden shall maintain appropriate certification and training records for Noden personnel, as well as copies of training materials and presentations. Independent contractors shall maintain appropriate certification and training records for their employees and subcontractors, as well as copies of training materials and presentations. Independent contractors shall promptly make such materials available to Noden or its agent upon request.

## **CHIEF COMPLIANCE OFFICER**

Noden has designated a Chief Compliance Officer to oversee the implementation and operation of this Program. The Chief Compliance Officer has the authority to report directly to the Noden Board of Directors and CEO.

In exercising such authority, the Chief Compliance Officer's responsibilities shall include:

1. Developing, implementing, administering and overseeing the periodic review of the Program;
2. Preparing reports on the Program to Board of Directors, the CEO, and other Company committees and management on a periodic basis;
3. Overseeing educational and training requirements of the Program;
4. Disseminating informational materials explaining compliance requirements, compliance responsibilities or highlighting the importance of compliance to Personnel;

5. Ensuring that Personnel are aware of the requirements of the Program;
6. Ensuring applicable lists of excluded, debarred and ineligible individuals and entities have been checked with respect to all Personnel;
7. Conducting internal compliance reviews and monitoring adherence to the Program;
8. Reviewing audits and reports prepared by auditors or investigators;
9. Reviewing and, where appropriate, acting in response to reports of noncompliance received through the Anonymous Hotline or otherwise brought to the Chief Compliance Officer's attention;
10. Independently investigating and acting on matters related to compliance, including on matters reported to the Anonymous Hotline;
11. Participating in the investigation of actual or potential compliance concerns, and as appropriate, reporting of any self-discovered violations of federal health care program requirements;
12. Organizing and maintaining all documentation regarding the Program, including records of matters reported to the Anonymous Hotline and any follow-up actions taken regarding such matters;
13. Interpreting and providing guidance on any issue concerning the Program;
14. Monitoring developments relating to compliance with applicable laws, regulations, and standards of conduct;
15. Overseeing and approving any revisions to the Program as needed in response to: (i) an identified weakness in the compliance program or identified systemic patterns of noncompliance; or (ii) changes in the business for Noden or applicable federal, state or local statutes, regulations, or binding case law; and
16. Any other duties as may be assigned by the CEO or as required, ensuring that the Program meets its objectives.

The Chief Compliance Officer shall have the authority to review all documents and information relevant to conducting compliance related activities under the Program.

#### **COMPLIANCE COMMITTEE**

Noden shall designate a Compliance Committee, chaired by the Chief Compliance Officer and comprised of relevant members of Senior Management and representatives of applicable sales



and marketing contractors, to support the Chief Compliance Officer in the performance of the responsibilities set forth above.

### **EXCEPTIONS AND AMENDMENTS**

In circumstances where conduct prohibited by this Program or other Company policy does not implicate underlying legal or ethical concerns, it may be appropriate to grant infrequent, fact-specific exceptions. Exceptions must comply with all legal and regulatory requirements, and require the specific written approval of Noden's CEO and the General Counsel of PDL BioPharma, Inc..

This Program and related policies may be amended or revised from time to time with the approval of the Chief Compliance Officer, to ensure compliance with applicable laws and regulations, and to ensure the Company's practices conform to best practices appropriate for the business.

### **COMPLIANCE PROGRAM CERTIFICATION**

It is the Company's policy to adhere to this Program. The Company shall declare, in writing, that it is the intention of the Company to operate in compliance with both this Program and applicable law (including, for example, the requirements of the State of California Health and Safety Code, Sections 119400 to 119402). The Company shall post this statement, a copy of this Program, and its Anonymous Whistleblower Hotline on its website.

<b>Policy Effective Date:</b> February 10, 2017	<b>Version Effective Date:</b>
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## GENERAL DEFINITIONS

### HC-02.01

#### PURPOSE

This document sets forth the general definitions for certain terms applicable to the Healthcare Compliance Program of Noden Pharma USA, Inc. ("Noden" or the "Company").

#### SCOPE

These definitions apply to the Healthcare Compliance Program and related policies.

#### GENERAL DEFINITIONS

*"Federal Health Care Program"* means any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States government or a state health care program, including but not limited to Medicare, Medicaid, Tricare, and Veterans programs.

*"Healthcare Provider"* means individuals (clinical or non-clinical, including but not limited to physicians, pharmacists, registered nurses, physician's assistants, medical students, research coordinators and other medical professionals) or entities (such as hospitals or group purchasing organizations) that directly or indirectly order, prescribe, purchase or arrange for or recommend the purchasing, prescribing or ordering of products manufactured, sold or distributed by the Company or its contractors, together with their Immediate Family Members.

*"Immediate family members"* means husband or wife; natural or adoptive parent; child or sibling; step-parent, stepchild, stepbrother or stepsister; father-, mother-, daughter-, son-, brother- or sister-in-law; grandparent or grandchild; or spouse of a grand-parent or grandchild.

*"Ineligible Person or Entity"* means any person or entity that has been excluded by U.S. Department of Health and Human Services Office of Inspector General pursuant to Section 1128 of the Social Security Act (42 U.S.C. 1320-7), debarred by the U.S. Food and Drug Administration ("FDA") pursuant to section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a), disqualified by the U.S. FDA pursuant to applicable regulations, or otherwise suspended or ineligible to participate in any Federal Health Care Program.

*"Personnel"* means all Company officers, directors, executives and employees, and as applicable, independent contractors.

*"Remuneration"* means the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.



*“Senior Management”* means the Noden Chief Executive Officer, Head US Sales and Marketing, Head of Regulatory Affairs and Pharmacovigilance, Head of Manufacturing and Logistics, Director of Finance, and Board of Directors.

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## **POLICY ON COMPLIANCE WITH LAWS, REGULATIONS & GUIDANCE**

### **HC-03.01**

#### **PURPOSE**

This document sets forth the policy of Noden Pharma USA, Inc. ("Noden" or the "Company") with respect to compliance with applicable federal and state laws and regulations, and industry guidance.

#### **SCOPE**

This policy applies to Noden, its directors, officers, employees, and independent contractors.

#### **DEFINITIONS**

Except as specifically defined herein, capitalized terms in this section have the meaning given in the General Definitions section of the Healthcare Compliance Program.

#### **POLICY**

##### ***Compliance with Laws***

It is the policy of Noden to remain compliant with all applicable legal requirements, including the U.S. Anti-kickback Statute ("AKS"), U.S. False Claims Act ("FCA"), regulations and guidance issued by the U.S. Food and Drug Administration ("FDA"), guidelines issued by the Office of Inspector General of the U.S. Department of Health and Human Services, and applicable international laws and regulations governing the sales and marketing of pharmaceutical and other healthcare products. In addition, it is the policy of Noden to comply with the Pharmaceutical Research and Manufacturers of America ("PhRMA") Code on Interactions with Health Care Professionals (the "PhRMA Code").

##### ***Anti-kickback Laws***

The AKS prohibits the payment or receipt of any remuneration (meaning the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind) intended to induce referrals or the purchasing, leasing or ordering of any item or service that may be reimbursed, in whole or in part, under a Federal Health Care Program. It also prohibits the payment or receipt of any Remuneration intended to induce arranging for, or the recommendation of, the purchasing, leasing or ordering of any such item or service.

A Healthcare Provider's decisions about patient care should be in the best interest of the patient, not potentially tainted by motives of personal gain or enrichment. A Healthcare Provider should recommend or prescribe a pharmaceutical product because the Healthcare Provider has

determined that the product is the best treatment choice for the patient, not because the Healthcare Provider received something of value from a manufacturer.

The Company, directly and through contractors and distributors, provides goods that may be reimbursed in whole or in part by Medicare, Medicaid or other government programs (e.g., pharmaceuticals). A payment or other Remuneration offered by the Company (or its contractors or distributors) to induce referrals, prescribing or the purchase of our goods could violate the AKS.

In compliance with the AKS, Noden shall not offer, pay, solicit or receive remuneration of any kind from anyone to induce or otherwise incentivize:

- a) The purchase, lease, order, recommendation or arrangement for the purchase, lease or order of an item or service; or
- b) The referral for any item or service that is reimbursed under a federal or state health care program.

The U.S. Government created certain "safe harbors" to the AKS, which, if complied with, protect the underlying transaction, relationship or payment from civil or criminal penalty under the statute. The Company shall in all instances seek to structure its relationships with customers and distributors in a manner that satisfies the requirements of applicable safe harbors. Consistent with applicable policies, including the Contract Review Policy, the PDL BioPharma, Inc. Legal Department shall be consulted regarding contracts with Healthcare Providers in a position to purchase or order the Company's products, or recommend or arrange for the purchase or order the Company's products.

A number of safe harbors are relevant to the pharmaceutical industry, but three are especially important:

- a. **Discount safe harbor**: permits a pharmaceutical manufacturer to discount the price of a product, provided that the discount is properly reported to the government and complies with other safe harbor requirements.
- b. **Managed care safe harbor**: permits a pharmaceutical manufacturer to provide a wide array of discounted items or services to certain eligible managed care organizations under specified circumstances.
- c. **Personal services safe harbor**: permits legitimate service arrangements with Healthcare Providers and other customers, such as *bona fide* consulting or speaking agreements.

Because the AKS is an intent-based statute, failure to satisfy all requirements of an applicable safe harbor does not mean the conduct is illegal. Each such arrangement should be evaluated

with the assistance of the Chief Compliance Officer and the PDL BioPharma, Inc. Legal Department to determine whether anything of value is being offered or exchanged to induce referrals, recommendations or the purchase of goods from Noden.

Certain states, including but not limited to, California, Massachusetts and Vermont, have laws similar to the AKS which apply to all items sold by the Company that are reimbursed by any third-party payor, including commercial payors. As such, the Company and all Personnel are prohibited from paying or offering a kickback, bribe, rebate, gift or other inducement in exchange for referrals of business, or in an attempt to induce or reward referrals of business. The Company and all Personnel are also prohibited from soliciting or receiving a kickback, bribe, rebate, gift or other inducement in exchange for referrals of business.

Personnel faced with situations that appear questionable under these laws should consult with the Chief Compliance Officer for guidance.

### ***FDA Laws and Regulations***

The Food and Drug Administration ("FDA") was created to protect the health and safety of the American people by, among other things, approving or not approving new medical products, and if approved, regulating how such products are manufactured, marketed and sold. The business for Noden is regulated by the FDA under the Food, Drug and Cosmetic Act (the "FDCA") and its implementing regulations. Although Noden does not develop new products, the FDA exercises oversight of the product labeling, and promotion and advertisement for Noden.

Product labelling refers to all printed information (text and graphics) included on the exterior packaging or container of a product, as well as the product's prescribing information (also referred to as the package insert ("PI")). The FDA has authority to decide what information is set forth in a product's label.

Promotion and advertising refers to any activity undertaken by Noden or its agents to promote its products after the PI is established. Any materials and statements used to promote a prescription product — including brochures, detail aids, promotional programs and communications, and third-party promotional materials prepared for Noden — must be consistent with the PI. For example, if the approved indication in the PI specifies patients with a particular disease, the applicable FDA regulation does not permit the product to be promoted for use in patients with any other disease state, even if available scientific evidence shows that such use might be beneficial to the patient — such promotion is referred to generally as "Off-Label." In addition to requiring that products only be promoted "on-label," the FDA requires that promotional activities and advertisements be truthful and not misleading, and provide a fair balance of the product's risks and benefits.

Personnel shall refer all questions or inquiries regarding FDA regulations and interactions with the FDA to the Chief Compliance Officer or Company Medical Information line.

### ***Disclosure and Sunshine Act Obligations***

The Company shall require compliance with the laws and regulations of the United States, as well as the laws of applicable states and municipalities, with respect to disclosure or approval requirements associated with payments or transfers of value to physicians (e.g., provision of meals, engagement of physicians as consultants), including but not limited to section 6002 of the Patient Protection and Affordable Care Act, Transparency Reports and Reporting of Physician Ownership or Investment Interests, known as the “Sunshine Act,” as well as similar state and local physician payment disclosure laws in Connecticut, the District of Columbia, Massachusetts, Minnesota, Vermont, and other states and municipalities. Company contractors shall adopt policies to timely and accurately report all payments or other transfers of value to physicians.

Personnel shall refer questions regarding disclosure and Sunshine Act obligations to their immediate supervisor or the Chief Compliance Officer.

### ***Medicare Rebate Statute and Other Government Pricing Laws***

The United States Government is the single largest purchaser and payor of healthcare items and services, including pharmaceuticals in the country. Federal health care programs include Medicare, Medicaid, the Veterans Administration, and the Department of Defense (as well as TRICARE). For these programs to determine appropriate pricing for pharmaceuticals, the government agencies rely on information provided by drug manufacturers.

There are a number of laws and regulations governing drug manufacturer's obligations to report price and reimbursement data, as well as discounts, rebates and other price concessions offered to customers. In accordance with these laws, Noden shall collect, calculate and verify such information, and shall accurately, timely and completely report such information.

Personnel shall refer questions regarding federal and state pricing laws to Government Pricing Specialists, LLC, the Executive Director, Managed Markets & Trade and/or the Head US Sales and Marketing.

### ***Privacy and Data Security Laws***

The Company is committed to protecting the privacy and security of patient data, including protected health information, as required under various laws, including the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology and Clinical Health Act and applicable state privacy and security laws (collectively, “Health Privacy Laws”). The Company may from time to time obtain information about protected health information, as defined under HIPAA, including a patient’s medical condition, history, medication

and family illnesses in order to conduct its operations. This information is to be considered confidential and highly sensitive. Noden and its Personnel shall not release or discussed this information with others without guidance from the Chief Compliance Officer.

In the event of an accidental release of protected health information, Personnel should immediately contact the Chief Compliance Officer.

Personnel shall refer questions regarding privacy and data security laws to the Chief Compliance Officer.

### ***HHS Office Of Inspector General Compliance Program Guidance***

The U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") is responsible for overseeing and maintaining integrity of the federal healthcare programs, including Medicare and Medicaid. The OIG conducts audits, investigations and inspections of healthcare providers to ensure compliance with applicable laws and regulations. Periodically, the OIG issues guidance to healthcare industry participants on compliance with healthcare laws and regulations, such as the AKS.

In 2003, the OIG published the Compliance Program Guidance for Pharmaceutical Manufacturers ("OIG Guidance"). Through this guidance, the OIG sought to "assist companies that develop, manufacture, market and sell pharmaceutical drugs ... in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the federal health care programs and in evaluating and, as necessary, refining existing compliance programs."

Although the OIG Guidance is voluntary, it is widely accepted by the pharmaceutical industry, and Noden has incorporated its principles into this Healthcare Compliance Program.

### ***PhRMA Code***

PhRMA is an industry organization, representing many of the larger pharmaceutical research and biotechnology companies in operating the United States. PhRMA developed a "Code on Interactions with Healthcare Professionals," which sets forth standards regarding interactions and relationships between PhRMA members and physicians, and other healthcare professionals. A basic principle of the PhRMA Code is that companies should act consistent with the highest ethical standards, in addition to complying with the applicable legal requirements. The guidelines in the PhRMA Code are meant to assist companies to ensure interactions with physicians and other healthcare professionals are designed to benefit patients and enhance the practice of medicine, and to minimize the possibility that such interactions are perceived as inappropriate by patients, the public or the government.



The PhRMA Code has been widely-adopted as the "industry code" and has been used as an example of such in various state laws. Noden believes the PhRMA Code sets forth best practices regarding interactions with Healthcare Providers generally and has incorporated its requirements in this Healthcare Compliance Program.

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# **POLICY ON COMPLIANCE PROGRAM POLICY AND PROCEDURE WRITING**

## **HC-04.01**

### **PURPOSE**

This document sets out the policy of Noden Pharma USA, Inc. ("Noden" or the "Company") with respect to establishing parameters for the development and documentation of the Healthcare Compliance Program policies and procedures for Noden.

### **SCOPE**

This policy applies to Noden, its directors, officers, employees, and independent contractors.

### **DEFINITIONS**

Except as specifically defined herein, capitalized terms in this section have the meaning given in the General Definitions section of the Healthcare Compliance Program.

### **POLICY**

Noden believes in communicating clearly about Healthcare Compliance Program Policies and Procedures (P&Ps). P&Ps for Noden will be approved according to an established process. These documents will be available to all Personnel.

**Format.** A standard electronic format will be used for all P&Ps. This form will be available internally. Policy text font is Calibri 12.

In addition to electronic copies, hard copies of the current P&Ps will be maintained by the Chief Compliance Officer.

**P&Ps Numbering.** P&Ps will be numbered sequentially as they are approved. The numbering code will be as follows: DD-AA.BB, where:

- "DD" refers to the department and/or subject (e.g., HC for Healthcare Compliance);
- "AA" refers to the sequential policy number
- "BB" refers to the sequential version for the policy.

For example, HC-04.01 refers to the original version of this policy, and the third version will be HC-04.03.

**P&Ps Review Schedule.** All P&Ps must be reviewed by the Chief Compliance Officer or his or her designee on an annual basis, which may or may not lead to P&Ps revisions. Revision(s) stemming from annual review must go through an approval process.

If revisions are not needed, the P&P reviewer will sign the bottom of the P&Ps document to indicate review completion or maintain a separate log identifying dates and name(s) of reviewer/approver.

The Chief Compliance Officer or his designee, and the Compliance Committee, must approve all P&Ps revisions. The Compliance Committee's approval of any P&P revisions shall be reflected in the minutes of the meeting in which such approval was given. The Chief Compliance Officer or his designee must complete the "Revision Approved by" box in a separate log maintained to document such revisions. The log must include the approver's name, title and date of approval, and the date of approval by the Compliance Committee.

**Approval of New P&Ps.** The Chief Compliance Officer or Compliance Committee, acting at the direction of the Chief Compliance Officer, must perform the following tasks to obtain approval of proposed P&Ps:

- Complete Policy header information (Policy Subject and Policy Number);
- Obtain appropriate departmental approval (if the Chief Compliance Officer (or his/her designee) determines that the approval is necessary); and
- Submit the proposed P&Ps to the Chief Compliance Officer and Compliance Committee for final approval.

**Department Reviewer Responsibilities.** Upon receipt of proposed P&Ps for departmental approval, the Department Reviewer, or his/her designee, shall read and review, make comments, suggestions and/or revisions, and sign and return the proposed P&Ps to the sender within 10 business days.

**Chief Compliance Officer and Compliance Committee Responsibilities.** The Chief Compliance Officer or Compliance Committee, acting at the direction of the Chief Compliance Officer, has overall responsibility for P&Ps through the final Chief Compliance Officer and Compliance Committee approval. Duties include:

- Maintain a hard-copy master file and P&Ps database on a shared drive;
- Facilitate the conversion of all P&Ps maintained by the Company into the standard format;
- Monitor the P&Ps review and approval process and make changes, as needed, to streamline process and enhance communication;
- Coordinate training/education on P&Ps;
- File a numbered final copy of approved P&Ps;
- Disseminate approved P&Ps to affected departments;

- Coordinate Chief Compliance Officer and Compliance Committee’s review and approval meetings and/or sign-off processes for new P&Ps; and
- Send reminders for policy and/or procedure reviews, as needed.

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## **POLICY ON WHISTLEBLOWERS**

**HC-05.01**

### **PURPOSE**

Noden Pharma USA, Inc., is committed to providing a workplace conducive to open discussion of its business practices. It is Company policy to comply with all applicable laws that protect employees against unlawful discrimination or retaliation by their employer as a result of their lawfully reporting information regarding, or their participating in, investigations involving accounting and auditing matters, healthcare compliance matters, corporate fraud or other violations by the Company or its agents of federal, state, local or international laws or regulations.

### **SCOPE**

This policy applies to Noden, its directors, officers, employees, and independent contractors.

### **DEFINITIONS**

Except as specifically defined herein, capitalized terms in this section have the meaning given in the General Definitions section of the Healthcare Compliance Program.

### **POLICY**

#### ***Reporting Violations of Law***

Personnel are encouraged to discuss issues and concerns regarding corporate fraud or other violations of law with their supervisors, who are in turn responsible for informing the Chief Compliance Officer of any concerns raised in order to assess severity and materiality of the issue or concern. If an individual prefers not to discuss certain sensitive matters with the direct supervisor, the individual may instead discuss such matters with the Chief Compliance Officer or submit the complaint anonymously through the procedures as set forth under "Reporting Confidential Complaints" below. In any event, employees and consultants are encouraged to discuss issues and concerns with appropriate persons within the Company to allow the Company to take appropriate action before reporting such matters directly to government or law enforcement agencies.

The Chief Compliance Officer shall refer complaints submitted, as he or she determines to be appropriate or as required under the directives of the Board of Directors of the Company (the "Board") (or a designated Committee of the Board), to appropriate members of Senior Management, the Board or an appropriate Committee of the Board.

### ***Reporting Confidential Complaints***

The Company has established a procedure by which complaints may be reported confidentially and anonymously. This includes reporting complaints regarding the Company's accounting, auditing, internal accounting controls and disclosure practices (and reporting any concerns generally involving questionable accounting or auditing matters), as well as reporting complaints regarding compliance with healthcare laws and regulations.

Personnel may anonymously report complaints by (i) summarizing the complaint or concern in writing and submitting it to the Compliance contact either by U.S. mail, interoffice mail or email; (ii) leaving an anonymous voicemail in the Compliance contact's voicemail box; (iii) calling the Anonymous Hotline at (877) 874-8416; or (iv) logging a concern online at <https://pdl.alertline.com>. Messages involving accounting and auditing matters, healthcare compliance matters or noncompliance with this Policy shall be directed to the Chief Compliance Officer. The Chief Compliance Officer shall present all such complaints to the Compliance Committee. An individual may utilize this confidential process either to raise new complaints or if he or she feels that a complaint previously raised with a supervisor or the Chief Compliance Officer has not been appropriately handled.

### ***Reporting Retaliation***

Company policy prevents any reporting party from being subject to disciplinary or retaliatory action by the Company or any of its employees or agents as a result of the individual:

- reporting a compliance concern in good faith, including in accordance with this Policy, or for good faith participation in any investigation or other proceeding related to such a report;
- disclosing information to a government or law enforcement agency, where the employee has reasonable cause to believe that the information discloses a violation or possible violation of federal or state law or regulation; or
- providing information, causing information to be provided, filing, causing to be filed, testifying, participating in a proceeding filed or about to be filed or otherwise assisting in an investigation or proceeding regarding any conduct that the employee reasonably believes involves a violation of federal or state law or regulation, where, with respect to investigations, such information or assistance is provided to or the investigation is being conducted by a federal or state regulatory agency, a member of Congress or a person at the Company with supervisory or similar authority over the employee.

However, Personnel who file reports or provide evidence that they know to be false or without a reasonable belief in the truth and accuracy of such information shall not be protected by the above Policy statement and may be subject to disciplinary action, including termination. In addition, except to the extent required by law, the Company does not intend this Policy to protect

reporting parties who violate the confidentiality of any applicable lawyer-client privilege to which the Company or its agents may be entitled under statute or common law principles, or to protect any individuals who violate their confidentiality obligations with regard to the Company's trade secret information. Personnel considering providing information that may violate these privileges or reveal the Company's trade secrets are advised to consult an attorney before doing so.

If any Personnel believes he or she has been subjected to any action that violates this Policy, he or she may file a complaint with his or her own supervisor or the Chief Compliance Officer using the below contact information. If it is determined that an employee has experienced any improper retaliatory action in violation of this Policy, such individual shall be entitled to appropriate corrective action.

### ***Notice of Immunity under the Defend Trade Secrets Act of 2016***

An individual shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made in confidence to a federal, state or local government official or to an attorney solely for the purpose of reporting or investigating a suspected violation of law. An individual shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual files any document containing the trade secret under seal and does not disclose the trade secret, except pursuant to court order.

### ***Chief Compliance Officer***

The Company has designated a Chief Compliance Officer who is responsible for administering this Policy. The Compliance contact may be reached by mail at: 75 Arlington Street, Suite 500 Boston MA 02116, Attention: Ronan Donelan Ph. D., by telephone at +353 1 6778350 or by email at [rdonelan@nodenpharma.com](mailto:rdonelan@nodenpharma.com). In addition, compliance questions and concerns can be sent to the compliance inbox for Noden at: [compliance@nodenpharma.com](mailto:compliance@nodenpharma.com). The Chief Compliance Officer is responsible for receiving, collecting, reviewing, processing and resolving concerns and reports by employees and others on the matters described above and other similar matters. The Chief Compliance Officer's responsibilities may be expanded or reduced at the discretion of the Board, but specific responsibilities under this Policy include:

- administering, implementing and overseeing ongoing compliance under this Policy;
- establishing and administering procedures to assure that employee complaints shall be collected, reviewed promptly, resolved in an appropriate manner and retained;

- making himself or herself available to discuss with employees any complaints raised or reports filed;
- with respect to complaints received by the Company relating to accounting and auditing matters, establishing and administering procedures, to assure that such complaints shall be collected, reviewed promptly, resolved in an appropriate manner and retained. For employee complaints regarding accounting and auditing matters, such complaints should be directed to the Chief Compliance Officer; and
- administering and overseeing the Company’s training and educational programs designed to ensure that Company employees with supervisory authority with respect to other employees, or who are otherwise involved in the administration of Company policies, are aware of this Policy, know to involve the Compliance contact in any matters involving this Policy that arise (including informing the Compliance contact of every complaint that arises) and are trained in the proper handling of employee complaints covered by this Policy.

<b>Policy Effective Date:</b> February 10, 2017	<b>Version Effective Date:</b>
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## **POLICY ON RESPONSE TO SUSPECTED VIOLATIONS AND NONCOMPLIANCE**

**HC-06.01**

### **PURPOSE**

This document describes the policy of Noden Pharma USA, Inc. ("Noden" or the "Company") with respect to reporting, investigating and enforcement of suspected noncompliance with Noden policies and applicable federal and state laws and regulations.

### **SCOPE**

This policy applies to Noden, its directors, officers, employees, and independent contractors.

This policy shall be read in tandem with the Policy on Whistleblowers.

### **DEFINITIONS**

Except as specifically defined herein, capitalized terms in this section have the meaning given in the General Definitions section of this Healthcare Compliance Program.

### **POLICY**

It is the policy of the Company that, if a violation of any applicable law, regulation, or standard of conduct relating to the business of the Company is detected, the Company shall take all reasonable steps to respond to the violation, including appropriate investigation and remedial and disciplinary action, and take steps to prevent further similar violations, including any necessary modifications to this Compliance Program.

#### ***Reporting***

Violations of the policies described in the Healthcare Compliance Program could expose Noden, its employees, and agents to civil and criminal liability. As set forth in the Policy on Whistleblowers, Noden Personnel, including independent contractors, are responsible for promptly reporting actual or potential wrongdoing, including non-compliance with these Policies and any applicable laws to their supervisor or the Chief Compliance Officer. Further, Personnel who receive information from another employee or agent regarding potential violations of the Healthcare Compliance Program, the law or regulations, and/or compliance-related problems or concerns, must immediately bring the matter to the attention of their supervisor or the Chief Compliance Officer.

The Company has provided a mechanism for anonymous reporting of actual or potential compliance concerns through the Anonymous Hotline for Noden by calling the Anonymous Hotline at (877) 874-8416, or logging a concern online at <https://pdl.alertline.com>. The Company shall maintain confidentiality regarding reported concerns, insofar as such confidentiality is legal and practical.

### ***Investigating***

Whenever the Chief Compliance Officer receives information regarding a suspected or possible violation of the policies described in the Healthcare Compliance Program or of applicable laws and regulations, the Chief Compliance Officer shall take appropriate steps to examine the information and verify the factual basis of a violation or suspected violation. The Company shall through appropriate Personnel, and in consultation with relevant subject matter experts, determine the appropriate scope of any investigation and the necessary response. Appropriate responses to a violation or suspected violation may include, without limitation:

- (1) Investigating all aspects of the alleged violation;
- (2) Preparing recommendations for corrective action;
- (3) Considering the advisability of disclosing the incident to government entities;
- (4) Formally notifying the Compliance Committee and Noden's Board of Directors, as appropriate, of the incident and the planned response.

During any stage of the investigation, the Chief Compliance Officer may seek the advice and guidance of independent legal counsel.

Results of each investigation, including any corrective action taken, shall be documented and maintained by the Chief Compliance Officer. Any matter that is communicated to the Chief Compliance Officer but which, after investigation, is determined not to be appropriate for processing through the Healthcare Compliance Program shall be referred to the appropriate department for resolution.

Personnel, including independent contractors, are expected to cooperate fully with any audit or investigation by Noden into any compliance-related matter or a suspected violation. Failure to cooperate with any such audit or investigation may result in disciplinary action, up to and including immediate termination.

### ***Enforcement And Discipline***

It is the policy of the Company that the Healthcare Compliance Program shall be consistently enforced through appropriate disciplinary mechanisms. Disciplinary actions may be up to and including dismissal, and may extend, as appropriate, to individuals responsible for the failure to

prevent, detect, or report an offense. The Company shall enforce the Healthcare Compliance Program consistently—regardless of the seniority of the employee or importance of the agent, business partner, or customer involved. Moreover, the Company shall take all reasonable and necessary steps to stop any ongoing misconduct.

A record of any discipline of Personnel resulting from noncompliance with the Healthcare Compliance Program shall be maintained in the Chief Compliance Officer's file and in the applicable personnel record. Further, the immediate supervisors shall receive notice of the discipline.

The annual employment or contract review of all Personnel and other contract renewals shall include an assessment of adherence to the Healthcare Compliance Program.

### **CORRECTIVE ACTION**

Corrective actions aim to remedy the underlying problem that resulted in noncompliance, in addition to resolving any additional problems stemming from noncompliance. As mentioned above, the Chief Compliance Officer (and/or Compliance Committee) will recommend appropriate corrective action(s) consistent with the results of a compliance investigation. Each corrective action plan will be tailored to the particular noncompliance identified and will include mechanisms to prevent continued or further noncompliance. The Chief Compliance Officer and/or Compliance Committee will document all elements of the corrective action plan and will engage in ongoing monitoring to ensure that the plan is carried out.

Corrective action may include, but shall not be limited to:

1. New or modified standards of conduct, policies and procedures;
2. Additional employee education and training;
3. Changes to auditing and monitoring; and
4. Appropriate employee disciplinary action.

In addition, where appropriate, and in accordance with the relevant provisions of law or as applicable reporting obligations dictate, the Chief Compliance Officer, in consultation with legal counsel and with the prior approval of Senior Management, is responsible for ensuring that required or appropriate reporting to governmental authorities occurs.

### **NON-RETALIATION, NON-RETRIBUTION**

As set forth in the Policy on Whistleblowers, Noden employees reporting in good faith a suspected violation of the Healthcare Compliance Program, any other Company policy, or any



applicable law or regulation shall not be subject to retaliation or any adverse action for taking action in furtherance of the enforcement of such policies or compliance with the law.

Noden and its officers, directors and employees are not permitted to engage in retaliation, retribution, or any form of harassment against another employee for reporting a compliance-related concern. Any retaliation, retribution or harassment shall be subject to appropriate personnel action, up to and including termination. Independent contractors for Noden are expected to establish a similar non-retaliation, non-retribution policy.

<b>Policy Effective Date:</b> February 10, 2017	<b>Version Effective Date:</b>
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## **POLICY ON COMPLIANCE PROGRAM MONITORING & AUDITING**

### **HC-07.01**

#### **PURPOSE**

This document sets forth the policy of Noden Pharma USA, Inc. ("Noden" or the "Company") with respect to monitoring and auditing compliance with the policies set forth in the Healthcare Compliance Program and applicable laws and regulations.

#### **SCOPE**

This policy applies to Noden, its directors, officers, employees, and independent contractors.

#### **DEFINITIONS**

Except as specifically defined herein, capitalized terms in this section have the meaning given in the General Definitions section of this Healthcare Compliance Program.

#### **POLICY**

It is the policy of Noden that it shall conduct ongoing Compliance Monitoring and periodic Compliance Auditing of compliance with Company policies, and the law and regulations.

Compliance Monitoring refers to the ongoing collection and evaluation of data to verify whether practices or procedures meet the applicable requirements set forth by Noden policy and/or government laws and regulations. Compliance Monitoring often focuses on the process (or function) rather than the outcome alone.

Compliance Auditing refers to the comprehensive review of an organization's adherence to regulatory guidelines or company policies, or a subset of such guidelines or policies.

Annual Compliance Audits shall also be conducted to assess the effectiveness of the Healthcare Compliance Program and its related obligations, such as whether: (1) there has been appropriate dissemination of the Healthcare Compliance Program, (2) annual compliance training has occurred, (3) the anonymous reporting system has been implemented and is properly functioning, (4) reports and complaints have been tracked and addressed, and appropriate audits have been conducted, and (5) any identified actual or suspected violation of the law has been appropriately investigated, rectified and the wrongdoer disciplined.

Compliance Monitoring and Compliance Audits shall be conducted under the direction of the Chief Compliance Officer, or at the direction of the Board of Directors. Audits may also be performed with external or internal audit resources under the direction of legal counsel. Upon discovery of compliance-related issues during an audit or monitoring activity, the person(s)

performing the audit or monitoring activity shall notify the Chief Compliance Officer immediately, who will address the issue in accordance with the Policy on Response to Suspected Violations and Noncompliance. The Chief Compliance Officer shall report the results of any audits, and information relating to any necessary corrective or remedial action taken in light of such audits, to the Board of Directors no less than annually, or more frequently as appropriate.

The Company shall establish monitoring and auditing priorities based on factors that may include: identified risk factor and trends; government enforcement actions; changes in statutes, regulations, or case law; changes in Noden operations; or other relevant factors as determined by the Chief Compliance Officer.

The Chief Compliance Officer or his or her designee will consult with operational departments to evaluate the need for and design of monitoring programs that can be incorporated into day-to-day activities and enhance compliance efforts. Any such monitoring programs will be documented, reviewed from time to time, revised if necessary, and terminated if appropriate.

Similarly, audit tools will be maintained in the Chief Compliance Officer's files, along with documentation of all audit results.

<b>Policy Effective Date:</b> February 10, 2017	<b>Version Effective Date:</b>
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## **POLICY ON INTERACTIONS WITH HEALTHCARE PROVIDERS**

**HC-08.01**

### **PURPOSE**

This document sets forth the policy of Noden Pharma USA, Inc. ("Noden" or the "Company") with respect to interaction of its Personnel with Healthcare Providers.

### **SCOPE**

This policy applies to Noden, its directors, officers, employees, and independent contractors.

### **DEFINITIONS**

Except as specifically defined herein, capitalized terms in this section have the meaning given in the General Definitions section of the Healthcare Compliance Program.

### **POLICY**

#### ***General Rule***

It is the policy of Noden that all interactions with Healthcare Providers shall comply with applicable federal, state and local laws and regulations, including the federal Anti-kickback Statute. All actions taken by Noden shall be intended to inform the potential treating medical community and patients about the Company's products and provide relevant scientific and educational information to support patient care and the practice of medicine.

When interacting with Healthcare Providers, Noden is prohibited from offering, giving or providing Healthcare Providers with any item or service intended, directly or indirectly, to encourage the Healthcare Provider to purchase, use, prescribe or recommend Noden products.

Personnel are prohibited from engaging in any act or conduct that Noden is prohibited from undertaking.

#### ***Prohibited Gifts***

Noden may not offer or provide gifts to Healthcare Providers or their staff, even if such items are of minimal value, primarily associated with a Healthcare Provider's practice, and/or accompanied by patient or physician educational materials. Examples of prohibited gifts include luggage, laptop bags, recreational electronic devices, mugs, pens, notepads, so-called "reminder items" that display the company name or product logo, cash and cash equivalents, gift certificates and coupons.

Payments in cash or “cash equivalents” (e.g., gift certificates) are permitted only as compensation for bona fide services provided under a written agreement that complies with applicable Noden policies.

The following items are not considered to be prohibited gifts provided the distribution of such items complies with applicable policies.

1. Prescription drug samples
2. Patient assistance program drugs
3. Coupons or other similar discounts offered to consumers for Noden products or drug vouchers
4. Approved written material of minimal value (e.g., reprints and patient educational materials and brochures)

### ***Permitted Educational Items***

Noden may provide to Healthcare Providers educational items of modest value based on regional standards provided that the items are:

- designed for the education of patients or Healthcare Providers;
- offered to Healthcare Providers only on an occasional basis;
- not otherwise useful to the Healthcare Provider outside of the context of healthcare education; and
- otherwise in compliance with this policy, the PhRMA Code or other applicable country-specific industry guidance.
- The total value provided to any customer not to exceed \$100 per calendar year/per recipient.

The value of a permitted educational item is based on what it would otherwise cost the Healthcare Provider to obtain the item (i.e., retail value) and not on what it costs the Company to procure the item. Examples of permitted educational items include textbooks, anatomical models, medical diagrams/visual material, and medical journals.

### ***Meals and Refreshments***

Noden may provide occasional in-office meals or refreshments to Healthcare Professionals only in conjunction with a bona fide business meeting or informational presentation. Such interactions must include discussion of Noden, Noden products, or other scientific or educational information. The provision of meals or refreshments without a Noden representative present are

prohibited, as are meals and refreshments offered as “take-out” after a presentation (such as “dine & dash” programs).

All meals offered or provided by sales Personnel or immediate supervisors must occur in the Healthcare Provider's office or in a hospital setting. All meals must be of modest value according to Noden standards. **Noden defines a modest in-office meal as \$25 per person**, including tax, gratuities and deliver charge.

Personnel other than sales representatives (i.e., senior managers and executives) are permitted to provide meals or refreshments at out-of-office locations if the meal is: (1) modest (as defined by Noden standards below for out-of-office meals); (2) not part of an entertainment or recreational event, or occurring at an entertainment or recreational venue; and (3) provided in a manner conducive to informational communication.

Noden defines a modest out-of-office meal depending on the meal type (i.e., breakfast, lunch or dinner) and geographic location of the meal (i.e., less-expensive Tier 1 city or more-expensive Tier 2 city). The Tier 2 Cities List is included as **Attachment A** to this policy. Accordingly, Noden defines “modest” to be a per person amount no more than: \$25 for breakfast/snack, \$50 for lunch, and \$125 for dinner, including tax and gratuities for Tier 1 cities; and \$35 for breakfast/snack, \$60 for lunch, and \$175 for dinner, including tax and gratuity for Tier 2 cities. This information is produced in graphical form below:

Meal Type	City Tier	Per Person Amount
Breakfast / Snack	Tier 1	\$25
	Tier 2	\$35
Lunch	Tier 1	\$50
	Tier 2	\$60
Dinner	Tier 1	\$125
	Tier 2	\$175

Meals may be provided to a Healthcare Provider's office staff (i.e., non-physician staff or non-clinical staff) only where the topic being discussed at the session is of relevance to such staff and must follow all provisions of this Policy.

A physician's or other Healthcare Provider's spouse or guest may not be included at any meal covered under this Policy unless the guest or spouse is a qualified Healthcare Provider whose attendance would otherwise be appropriate.

### ***Entertainment***

Entertainment and recreational events are strictly prohibited and may not be provided to Healthcare Providers. Examples of "entertainment" include sporting events; artistic performances or events (e.g., ballet, comedy club, art gallery); music performances; and tickets or coupons to any other event, regardless of whether Personnel accompany the Healthcare Provider.

### ***Transportation & Lodging***

Noden may not pay for transportation and/or lodging for Healthcare Providers to attend programs such as promotional speaker programs, medical or professional conferences, or continuing medical education programs *unless* the Healthcare Provider's attendance at the program is in connection with bona fide consulting, speaking or investigator services via a signed agreement with the Company. (See Policy on Consulting Arrangements with Healthcare Providers.) This prohibition applies to Noden-sponsored and third-party scientific or educational conferences or professional meetings. Similarly, Noden may not provide travel or lodging for a spouse or guest of a Healthcare Provider to attend such programs, conferences or meetings.

### ***Document Retention & Expense Reporting***

All expense-related information, including information related to expenditures to Healthcare Providers, must be accurately and completely documented when submitting expense reports for approval and reimbursement, including at a minimum: (1) amount spent on each Healthcare Provider in attendance, (2) the identity and state licensure of each Healthcare Provider in attendance, (3) date and place where expense was incurred, and (4) inclusion of related receipts.

Expenditures to Healthcare Providers shall be tracked and reported to various government agencies according to applicable federal and state transparency laws. For example, several states require pharmaceutical companies to report gifts, compensation or other transfers of value to healthcare practitioners and entities; while others impose gift or meal bans. The U.S. Physician Payments Sunshine Act requires Noden to track expenditures for all prescribers and teaching institutions and report such information on an annual basis. All Sales Representatives are required to enter this information into Expense Reporting software. All non-Sales Representatives (e.g., Noden senior managers and executives) will communicate detailed information about each event/meeting and email that to the QuintilesIMS contact that manages transparency reporting on behalf of Noden. All transfers of value will be aggregated into a single software program used for transparency reporting. For questions regarding applicable tracking



and reporting requirements for a specific state, please contact the QuintilesIMS contact for Noden: Marc Adler, Esq., at [marc.adler@quintilesims.com](mailto:marc.adler@quintilesims.com) or 609-216-6407. Company contractors shall adopt appropriate policies and procedures to assist the Company with its reporting.

<b>Policy Effective Date:</b> February 10, 2017	<b>Version Effective Date:</b>
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## POLICY ON INTERACTIONS WITH HEALTHCARE PROVIDERS

### HC-08.01 — Attachment A: Tier 2 Cities List

TIER 2 CITIES	
1.	Atlanta
2.	Boston
3.	Chicago
4.	Dallas
5.	District of Columbia (DC)
6.	Denver
7.	Houston
8.	Las Vegas
9.	Los Angeles
10.	Miami
11.	New York
12.	New Orleans
13.	Palo Alto
14.	Philadelphia
15.	San Diego
16.	San Francisco
17.	Seattle

<p><b>Attachment Effective Date:</b> February 10, 2017</p>	<p><b>Attachment Version:</b> 1</p> <p><b>Date Revised:</b> N/A</p>
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## **POLICY ON CONSULTING ARRANGEMENTS WITH HEALTHCARE PROVIDERS**

**HC-09.01**

### **PURPOSE**

This document sets forth the policy of Noden Pharma USA, Inc. ("Noden" or the "Company") with respect to the retention by Noden of Healthcare Providers as consultants, and similar arrangements.

### **SCOPE**

This policy applies to Noden, its directors, officers, employees, and independent contractors.

### **DEFINITIONS**

Except as specifically defined herein, capitalized terms in this section have the meaning given in the General Definitions section of the Healthcare Compliance Program.

“Consulting arrangement” as used in this policy is to be interpreted broadly and is intended to apply to all situations in which Noden obtains the services of a Healthcare Provider to provide advice, feedback, or any other service in an area of interest to Noden relating to the Healthcare Provider’s professional background. Examples of the consulting arrangements covered by this policy include consulting agreements, promotional speaker programs, and advisory board panels. This policy does not address or pertain to bona fide market research conducted by a third-party in which Noden is blind to the identity of the participants and which blinds the participants to the identity of Noden as the sponsor.

Neither the activities of investigators pursuant to a protocol for a Company-sponsored clinical trial nor investigator-initiated research projects are covered by this policy. However, investigators must still follow applicable regulations and Company policy when engaged in a product-related activity on behalf of Noden.

### **POLICY**

#### ***General Rule***

Noden may fulfill legitimate business needs by entering into consulting arrangements with Healthcare Providers for bona fide services provided to the Company. When retaining Healthcare Providers to perform consulting services, Noden should never select a Healthcare Provider in order to encourage that individual or entity to purchase, use, prescribe or recommend Noden

products; nor should Noden suggest that the engagement is intended, directly or indirectly, for that purpose.

### ***Requirement for a Business Needs Assessment***

The decision for Noden to enter a consulting arrangement with a Healthcare Provider must be for the purpose of satisfying a legitimate business need, such as to speak, write or provide training and education on Noden products, provide technical expertise and conduct clinical research. Prior to engaging in a consulting arrangement with any Healthcare Provider, the Company shall identify and document the business need for the information, services or advice from a Healthcare Provider and the amount of Healthcare Provider consulting services required to meet such business need (the "Business Needs Assessment"). The Chief Compliance Officer (and other business head(s), as appropriate) shall be a designated approver for each Business Needs Assessment.

A consulting arrangement may be entered into with a Healthcare Provider only if the services to be provided by the Healthcare Provider comport with the applicable Business Needs Assessment, do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the arrangement, and do not involve the counseling or promotion of any business arrangement or activity that violates any State or Federal law. Any changes or revisions to a consulting arrangement with a Healthcare Provider must be reflected in an updated or revised Business Needs Assessment.

### ***Selection of Healthcare Provider Consultants***

Noden shall select a Healthcare Provider as a consultant based on defined criteria as determined by the Business Needs Assessment, as well as: (1) competence to perform the required tasks as evidenced by education, experience, licensure and other relevant factors; (2) evaluation of the Healthcare Provider's prior performance of services to Noden, if any; and (3) willingness of the Healthcare Provider to comply with the terms and conditions of the consulting agreement and policies and procedures for Noden. In no event shall the selection of a Healthcare Provider as a consultant be based on: (1) the actual or potential volume or value of business generated or influenced by, or anticipated from, Healthcare Provider; (2) the desire to influence the Healthcare Provider's use or opinion of Noden products; or (3) the desire to influence any customer or potential customer's purchase or use of Noden products.

### ***Contract Requirements for Healthcare Provider Consultants***

Noden shall enter into a signed, written agreement with each Healthcare Provider retained as a consultant that describes the nature and scope of services to be performed by the consultant prior to the commencement of such services and prior to any payment by the Company for such services (the "Agreement"). In addition to fee for hire arrangements, a written agreement is

required for “expense only” and “in kind” service arrangements. All Agreements must be signed by the CEO of Noden Pharma USA Inc. and the Healthcare Provider.

All Agreements shall be in writing and must:

- (1) clearly define the terms of the requested consulting services;
- (2) clearly document the amount and form of payment (i.e., flat rate, hourly rate, milestone payments, royalty, expense reimbursement);
- (3) specify a mechanism to verify that the requested services are performed;
- (4) have a limited term with a minimum of one year and a maximum of 2 years, subject to any exceptions approved by the CEO of Noden Pharma USA Inc., such as for time limited projects; and
- (5) have standard covenants related to compliance with anti-corruption laws and relevant industry and Healthcare Compliance Program and policies and procedures for Noden.

All Agreements must include a statement that the Healthcare Provider's engagement as a consultant is not intended as an inducement to or reward for, and is in no way contingent upon, the Healthcare Provider's future purchase, use or recommendation of any Noden product; and that if the Healthcare Provider uses, recommends or comments upon the attributes of any Noden product in connection with the treatment of a patient, a scientific or educational presentation or publication, a media interview or any other third-party communication or interaction, the Healthcare Provider shall disclose that they are or have been a paid consultant of Noden and shall disclose any and all other financial relationships with the Company.

### ***Compensation of Healthcare Provider Consultants***

Compensation paid by Noden to a Healthcare Provider consultant must, when taken as a whole, be commercially reasonable and consistent with Fair Market Value for the services rendered by the consultant in an arm's length transaction.

Compensation paid to Healthcare Provider consultants must be supported with a Fair Market Value analysis that takes into consideration: (1) nationally-recognized standards for compensation within the consultant's area of specialty; (2) the consultant's standard rate for services, if any; (3) rates charged by similarly situated professionals or entities for comparable services; and (4) the time spent on the services. The Fair Market Value analysis may be performed by the Company or an independent third-party.

Compensation to be paid to a Healthcare Provider consultant must be set forth in the Agreement and structured on a measureable basis (i.e., hourly fee, milestone payments, flat fee). Compensation may not vary during the term of the Agreement in any manner that takes into

consideration the volume or value of referrals or other business generated for Noden by the Healthcare Provider consultant, or any individual or entity affiliated with the Healthcare Provider consultant (e.g., employer, partner, spouse).

Compensation shall be paid only through Noden check or wire-transfer payable to the Healthcare Provider consultant (or to an entity designated in writing by the Healthcare Provider consultant). Reimbursement for Healthcare Provider consultant services through expense reports is prohibited and sales personnel may not deliver payment to a Healthcare Provider consultant.

All payments must comply with applicable tax and other legal requirements.

### ***Travel Expense Reimbursement***

Noden may reimburse reasonable and modest travel, lodging and meal expenses incurred by Healthcare Provider consultants while providing services to the Company in conjunction with an executed written consulting agreement. Such expenses should be reviewed and paid separately from compensation for the consultant services.

Noden shall not pay travel or lodging expenses for a guest (e.g., spouse, significant other) of a Healthcare Provider consultant travelling on behalf of Noden. Guests may attend meetings or business meals with the Healthcare Provider consultant only if the guest pays for the costs of their own travel, lodging and meals.

### **DOCUMENT RETENTION**

The Chief Compliance Officer shall maintain all documentation related to each Healthcare Provider consultant arrangement including, without limitation, (1) an executed Agreement, including any addenda; and (2) documentation of all services and payments under the Agreement, including invoices, time records, services records and expense reimbursement requests. The documentation shall be retained consistent with the document and record retention policies of Noden.

### **MONITORING & AUDITING HEALTHCARE PROVIDER CONSULTING ARRANGEMENTS**

Noden shall monitor the work performed by each Healthcare Provider consultant to ensure that the services being provided are consistent with the applicable Business Needs Assessment and the terms of the Agreement. If there is no longer a legitimate business need for the Healthcare Professional consultant's services as described in the Agreement, Noden shall terminate the consulting arrangement.

Noden shall, as directed by the Chief Compliance Officer, periodically audit and review Healthcare Provider consulting arrangements, including the Business Needs Assessment, written agreement, materials relating to services provided by Healthcare Providers, and expense reimbursement

materials, in order to assess whether the activities and payments were consistent with this policy and applicable laws and regulations.

<b>Policy Effective Date:</b> February 10, 2017	<b>Version Effective Date:</b>
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## **POLICY ON PRODUCT ADVERTISING & PROMOTION**

### **HC-10.01**

#### **PURPOSE**

This document sets forth the policy of Noden Pharma USA, Inc. ("Noden" or the "Company") with respect to advertising, promotion, marketing and sale of its products.

#### **SCOPE**

This policy applies to all the Personnel, including independent contractors, who have been engaged by the Company to promote the prescription, sale or use of the Company's approved pharmaceutical products. The policy is not limited to commercial departments but applies to Personnel in any department.

This policy does not address or apply to non-promotional distribution of scientific information or clinical trial information.

#### **DEFINITIONS**

Except as specifically defined herein, capitalized terms in this section have the meaning given in the General Definitions section the Healthcare Compliance Program.

#### **POLICY**

##### ***General Rule***

Noden and its contractors are subject to a variety of federal and state laws and regulations that govern promotional activities. These laws include the federal AKS and FCA, regulations issued by the FDA, and guidelines issued by the US Department of Health and Human Services Office of Inspector General ("OIG"). The Company's activities are also governed by the PhRMA Code and various state laws.

The Company's promotional, educational, and scientific activities are intended to facilitate the safe, effective, and knowledgeable use of the Company's products in a manner consistent with the approved prescribing Information and appropriate patient care. Personnel should never engage in marketing or promotional activities that encourage the use of a Company product for a purpose that is inconsistent with the product's FDA-approved labeling. The Company shall provide truthful, non-misleading information to Healthcare Providers in accordance with applicable laws, regulations, and the Company policies.

All promotional programs and materials must conform to the Company's compliance policies, all FDA rules and regulations on marketing and promotion of prescription drug products, the PhRMA

Code, and other applicable laws and regulations. These obligations extend not only to written materials (including electronic written communications, such as emails), but also to all communications by Personnel that promote the prescription, use or sale of the Company's pharmaceutical products. Verbal communications by Personnel are expected to meet the same standards as written (or printed) materials.

### ***Good Promotional Practices***

All presentations, statements, and information disseminated by Personnel for the purpose of promoting a Company product or that occur in a promotional context must meet certain standards. Noden shall provide training to Personnel on these standards, including:

- **On-label Promotion.** Promoting on-label means that claims must be consistent with the relevant product's FDA-approved label. Personnel may not directly or indirectly solicit, encourage or promote a Company product for an unapproved indication, for use in populations that are not included in the approved labeling, for a dosing or administration regimen that is not included in the approved labeling, or for any other use that is inconsistent with the approved labeling.
- **Prescribing Information.** Personnel must always distribute the current approved prescribing Information for every Company product mentioned during promotion. Written communications to Healthcare Providers, including faxes or e-mails, that constitute promotion must also include the prescribing Information.
- **Fair Balance.** Promotional presentations and materials must balance information about a product's efficacy with information about the product's contraindications, warnings and precautions, adverse reactions, and product limitations. In addition, the materials should contain clear references to the sources of information that support the claims made. In promoting the Company's products, Personnel may not:
  - Dismiss, limit, diminish or minimize the importance of the products' safety information.
  - Highlight or emphasize positive data points only.
  - Take statements from their original context in a manner that distorts their meaning or renders them misleading.
  - Present a side effect as if it were a clinical benefit.

Fair balance is not only a matter of specific points made during a single discussion; it is also a matter of the overall impression provided to a Healthcare Provider about a product over an extended period of time. The total effect of product discussions must be accurate and balanced.

- **Truthful and Not Misleading.** Personnel may not make any false or misleading claims regarding Company products. A false or misleading claim is, among other things, a statement that is not supported by adequate and well controlled clinical studies or that fails to present all relevant data or context. For example, false or misleading claims can include exaggerations or overstatements (i.e., the “best” of a class or “benign” side effects) or conclusory statements that over-interpret data.
- **Appropriately Targeted.** Promotional communications should be directed only at Healthcare Providers who are reasonably likely to prescribe the Company product for a use that is consistent with the FDA-approved labeling. Similarly, product advertisements and other promotional activities must be directed at medical specialties that can reasonably be expected to utilize the Company product for its approved use.
- **Substantial Evidence.** All claims regarding a product must be adequately substantiated, as determined by the Promotional Review Committee (“PRC”). Superiority or comparative claims are generally not permissible unless they are supported by adequate and well-controlled head-to-head clinical trials against reference products.
- **Product Comparisons.** Clinical comparisons of safety or efficacy between Company products and other products must be based on appropriate comparative data, such as data from a head-to-head study. Other comparisons must relate to intrinsic product features (e.g., how a product is administered) or FDA approval status (e.g., the product’s approved indication).

Personnel engaged in promotional activities may not engage in discussions regarding non-Company products unless they have received approved promotional materials making that comparison and have received training on how such materials may be used. Notwithstanding this general rule, Personnel may provide other limited information regarding competitive products when (1) they are asked by a Healthcare Provider, or (2) they observe a misunderstanding regarding the similarities or differences between two products and there is a need to dispel the confusion. In such circumstances, the comparisons with the products of other companies must strictly comply with the following guidelines:

- **Nature of Comparison.** Sales and marketing Personnel may present factual information found in the competitor’s Product Information (“PI”) regarding indications, contraindications, and dosage and administration and may make factual comparisons of information from these sections of the PI for a competitor product to the same information for the Company product. They may not make judgments or offer interpretations. They may not make any clinical comparisons concerning safety or efficacy, unless such comparisons are based on materials approved by the PRC.

- **Source of Information.** Sales and marketing Personnel must base their discussions only on the PIs for the products being compared and materials approved by the PRC as appropriate for discussion with Healthcare Providers. No other materials may be used, and approved materials may not be altered or modified. When referring to another company's PI, sales and marketing Personnel must use the current PI. PIs for relevant competitor products shall be made available to sales and marketing Personnel by corporate headquarters as appropriate.
- **Balance.** As with all product discussions, product comparisons may be made only in the form of a balanced presentation. Sales and marketing Personnel may not single out the benefits of one product and the shortcomings of another. Instead, all the information required to answer the Healthcare Provider's questions fairly and accurately should be provided. If further information is required, questions should be referred to the Medical Affairs contact at QuintilesIMS.

### ***Use of Approved Promotional Materials***

Personnel engaged in promotional activities may use and distribute only materials that have been approved by their respective PRC. Internal training materials, educational background pieces, or any other materials intended for internal educational purposes may not be discussed or presented in promotional activities. When promotional materials are replaced or become outdated, sales Personnel should destroy them.

Personnel may not distribute home-made promotional materials. Approved promotional materials may not be altered or modified. Impermissible alterations include (but are not limited to) highlighting, marking or underlining points in the promotional materials.

E-mails or other written communications to Healthcare Providers generated by Personnel may not mention or make any claims about Company products unless the communication has been reviewed and approved by the PRC committee.

Communications from the Company to or with field Personnel that alter the content, emphasis, or intended audience of an approved communication are considered to be inconsistent with PRC-approved materials and must be separately approved prior to their use or dissemination.

### ***Requests for Off-Label Information***

Healthcare Providers and others may, from time to time ask questions about off-label uses of Company products (e.g., unapproved indications, unapproved doses, unapproved patient populations). Personnel may not prompt, encourage, solicit, or initiate these discussions.

Unsolicited requests for off-label information concerning Company products must be referred to the appropriate Personnel who are responsible for the compliance function and signed by the

requesting physician. Personnel must also inform the Healthcare Provider that the use is not consistent with the PI.

If Personnel are unsure whether certain information is considered off-label, then they should consult their managers for guidance before providing any information in response.

### ***Electronic Communications***

Electronic communications, such as email, voice mail, and fax, should be considered the same as written communications. Accordingly, the policies set forth above apply to electronic forms of communication as well. It is particularly important with electronic communications such as email to keep in mind the potential legal implications of casual or inappropriate language.

### ***FDA Oversight***

FDA's oversight of the approval and promotion of products are central to our healthcare system. Under the Food, Drug and Cosmetic Act and related regulations and FDA guidance, we are held to the FDA's standards when we make safety and efficacy claims about our products.

A violation of the Food, Drug and Cosmetic Act, implementing regulations or its guidance documents on advertising and promotion can have serious consequences for the Noden and its Personnel, including receipt of enforcement letters from the FDA, or significant civil or criminal penalties. Improper marketing activities can also result in prosecution under the FCA, with the potential for enormous financial penalties.

The Company strictly forbids the promotion of any Company product in any manner that violates applicable rules, regulations, or guidance materials.

<b>Policy Effective Date:</b> February 10, 2017	<b>Version Effective Date:</b>
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## **POLICY ON EDUCATIONAL GRANTS & CHARITABLE DONATIONS**

### **HC-11.01**

#### **PURPOSE**

This document sets forth the policy of Noden Pharma USA, Inc. ("Noden" or the "Company") with respect to financial support for charitable organizations and independent medical or scientific educational programs.

#### **SCOPE**

This policy applies to Noden, its directors, officers, employees, and independent contractors.

This policy does not cover research grants.

#### **DEFINITIONS**

Except as specifically defined herein, capitalized terms in this section have the meaning given in the General Definitions section of the Healthcare Compliance Program.

#### **POLICY**

Noden supports activities through educational grants and charitable contributions that are consistent with its corporate objectives, therapeutic areas of focus and that educate Healthcare Providers, improve or benefit patient care, and promote disease awareness. Such grants and contributions shall not be intended to influence the prescribing, purchasing, or recommending (including formulary recommendations) of any Noden product.

#### ***Educational Grants***

Noden may provide education grants to third-parties in support of bona fide scientific and medical educational programs developed for Healthcare Providers, patients, or other appropriate healthcare audiences, such as continuing medical education programs, provided that the program is primarily dedicated, in both time and effort, to promoting objective scientific and medical education activities and discourse.

Grants issued pursuant to this policy may be made only to established and reputable organizations, institutions, societies or associations. Such organizations may include, but are not limited to, nonprofit organizations focused on an appropriate disease state, medical societies, medical institutions and regional/local professional associations. Grants may not be made to an individual or made on behalf of a specific individual. Grants may not be tied in any way to the past, present, or future purchase, use, prescription, or recommendation of Company products.

Financial support provided by Noden may not be provided to reduce or support the costs of travel, lodging, or other personal expenses of non-faculty Healthcare Providers attending scientific or medical education programs, either directly to the individuals attending the program, or indirectly through the third-party sponsor of the program. Noden may not provide or sponsor meals directly at scientific and medical educational programs, except that a third-party sponsor of the program at its own discretion may apply all or a portion of the financial support provided by Noden to provide meals for all participants. Financial support may not be offered to compensate for the time spent by Healthcare Providers participating in the program, or to reduce or support the third-party sponsor's normal operating expenses.

The third-party sponsor must retain independent control of the program content, faculty, educational methods, materials and venue. Noden may not in any way control or seek to influence the content of the program or materials, such as by suggesting content or topics, recommending potential speakers, preparing scripts, drafts, or talking points for speakers, or determining the list of attendees.

Where applicable, the programs that Noden supports will be designed and implemented in accordance with relevant U.S. Food and Drug Administration's Guidance Documents, including without limitation Guidance on Industry-Supported Scientific and Educational Activities, the AACME Standards for Commercial Support of Continuing Medical Education ("ACCME Standards"), and the PhRMA Code.

#### ***Charitable Contributions.***

Noden may provide charitable contributions, without expectation of favor or return, only to registered, tax-exempt 501(c)(3) organizations and only for bona fide charitable or philanthropic purposes. Charitable contributions provided by Noden to support the general activities of a charitable organization or the general fund raising drives for projects undertaken by such an organization, including: (1) genuine independent medical research for the advancement of medical science; (2) genuine medical education (e.g., through scholarships and similar financial support); (3) certified continuing medical education; (4) patient and public education; (5) indigent care; and (6) other charitable purposes. Charitable donations may also be made for the general use of a non-profit organization, consistent with its mission and charter.

Noden may make charitable contributions to fund healthcare-related charitable fundraising events such as balls, galas, awards dinners, charity golf or tennis tournaments, or other events where the primary purpose is to raise funds to benefit the charitable non-profit organization. It is also acceptable for Noden to participate in such events by, for example, purchasing a table at a fund-raising gala or a foursome for a golf tournament. It is not appropriate, however, to invite Healthcare Providers to join Noden at such events (e.g., by joining Noden at a table or participating in a foursome purchased by Noden). Seats may be used only for Noden employees or donated back to the sponsoring organization or other charitable organization to use.



Noden may not make charitable contributions for promotional purposes or to enhance sales and marketing relationships. Noden may not make charitable contributions to individuals or on behalf of individuals; nor shall Noden make charitable donations in response to requests made by Healthcare Provider, unless the Healthcare Provider is an employee or officer of the charitable organization and submits a written request on behalf of the organization. Noden may not make charitable contributions in the form of multi-year commitments; nor may Noden guarantee renewal of any charitable contribution.

#### **DOCUMENT RETENTION**

Noden shall maintain all documentation related to each educational grant and charitable contribution, such as a copy of the request for the contribution, a copy of the budget/breakdown of how the funds will be used by the recipient, any applicable Company approvals, and any signed agreement regarding such funds and any attachments thereto.

<b>Policy Effective Date:</b> February 10, 2017	<b>Version Effective Date:</b>
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## **POLICY ON USE OF PRESCRIBING DATA**

### **HC-12.01**

#### **PURPOSE**

This document sets forth the policy of Noden Pharma USA, Inc. ("Noden" or the "Company") with respect to the appropriate and legal collection, maintenance and utilization of Healthcare Provider prescribing data.

#### **SCOPE**

This policy applies to Noden and Personnel to the extent they are involved, directly or indirectly, in tracking, accumulating, or managing the prescribing data of Healthcare Providers.

#### **DEFINITIONS**

Except as specifically defined herein, capitalized terms in this section have the meaning given in the General Definitions section of the Healthcare Compliance Program.

#### **POLICY**

##### ***General Rule***

Prescriber data, which does not identify individual patients, may serve many purposes, including enabling companies to: (a) impart important safety and risk information to prescribers of a particular drug; (b) conduct research; (c) comply with FDA mandated risk management plans that require drug companies to identify and interact with physicians who prescribe certain drugs; (d) track adverse events of marketed prescriptions drugs; (e) better structure clinical trials and (f) focus marketing activities on those Healthcare Providers who would most likely benefit from information about a particular drug.

Noden may use non-patient identified prescriber data to facilitate communications with Healthcare Providers and shall use this data responsibly. Importantly, the Company shall respect the confidential nature of prescriber data and shall, by proper education and training for Personnel, further the proper use of this information. Any improper use of this data shall not be tolerated and shall result in appropriate disciplinary actions.

However, in respect of the confidential nature of this data and a Healthcare Provider's personal desire to keep this information from company sales representatives, the Company fully supports the use of the AMA Physician Data Restriction Plan. In addition, for those Healthcare Providers that request it directly from the company, the Company shall require that prescriber data obtained from the AMA and outside sources shall not be made available to Company sales representatives.

***Privacy and Data Protection Laws***

Noden is committed to complying with the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology and Clinical Health Act, and its accompanying regulations, as well as with various state privacy and data protection laws that govern health or other personal information about individuals (collectively, the “Health Privacy Laws”), as such laws are applicable to the Company.

Although the Company is not a covered entity under these laws, the Health Privacy Laws apply to many of the Company’s customers and Company Personnel must respect patient privacy, minimize access to patient information, and safeguard any patient information that they receive. The Company and its Personnel shall take precautions to prevent the Company and its Personnel from receiving information protected under these federal laws from customers, absent the appropriate required consents and authorizations.

In addition, the majority of states have enacted a variety of privacy and data protection laws that govern “personal information” about individuals. The definition of “personal information” varies from state to state but generally includes an individual’s name and social security number, financial information or driver’s license number. In order to comply with these state data protection laws, Noden and its Personnel must protect patient information and any known or suspected violations or security breaches must be reported to a supervisor or the Chief Compliance Officer in accordance with this policy.

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## **POLICY ON SAFETY AND MONITORING**

### **HC-13.01**

#### **PURPOSE**

This document sets forth the policy of Noden Pharma USA, Inc. ("Noden" or the "Company") with respect to its commitment to ensuring patient safety and complying with Food and Drug Administration ("FDA") requirements regarding the tracking and monitoring of patient safety information.

#### **SCOPE**

This policy applies to Noden, its directors, officers, employees, and independent contractors.

#### **DEFINITIONS**

Except as specifically defined herein, capitalized terms in this section have the meaning given in the General Definitions section of the Healthcare Compliance Program.

#### **POLICY**

##### ***Commitment To Safety***

Patient health and safety are of paramount importance to Noden. The Company also recognizes that some risks associated with pharmaceutical products may not become apparent until after a product has been approved for commercial use. As a result, the Company works with Healthcare Providers and patients to confirm that potential safety concerns continue to be examined and reported after approval of a product. In addition, FDA regulations require the Company to monitor and report patient safety information obtained after approval. It is important that all Personnel understand and follow the steps described below if they become aware of a potential safety issue.

##### ***Reporting Adverse Events, Product Complaints***

If a consumer or Healthcare Provider shares with Noden or any Personnel information about an adverse event or product complaint, such information must be reported within one (1) business day, where possible, of learning of the event or complaint using the [Noden\\_Medinfo@quintiles.com](mailto:Noden_Medinfo@quintiles.com) email address.

An Adverse Event is an unwanted or harmful reaction experienced following the administration of a drug or combination of drugs. Product complaints include any oral, written or verbal communication that alleges deficiencies related to the identity, strength, quality or purity of a distributed product.

Adverse Events and product complaints should be reported even in circumstances where they are mentioned only in passing, or when Personnel hear them outside of their role as a Company employee or independent contractor (e.g. from a family member or friend who is taking a Company product).

When reporting an Adverse Event or product complaint, Personnel should provide all available information, including, where possible, the name and contact information of the Healthcare Provider or consumer who disclosed the Adverse Event, the product used, patient initials, gender and age, and a general description of the event.

***Reporting Other Potential Safety Issues***

Personnel concerned about a safety issue associated with a Company product, whether related to the product as a whole or a particular batch or shipment of the product, should report the concern to [Safety\\_Noden@quintiles.com](mailto:Safety_Noden@quintiles.com) email address, within one (1) business day, where possible, but in no event greater than three (3) days, after becoming aware of the issue. The report receiver shall pass this information on to the relevant Company department(s) so that appropriate action can be taken.

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## **POLICY ON INELIGIBLE PERSONS AND ENTITIES**

### **HC-14.01**

#### **PURPOSE**

This document sets out the policy of Noden Pharma USA, Inc. ("Noden" or the "Company") with respect to employing and contracting with individuals and entities excluded by the U.S. Department of Health and Human Services Office of Inspector General ("HHS OIG"), or debarred or disqualified by the U.S. Food and Drug Administration ("FDA") or other government agencies.

#### **SCOPE**

This policy applies to Noden, its directors, officers, employees, and independent contractors.

#### **DEFINITIONS**

Except as specifically defined herein, capitalized terms in this section have the meaning given in the General Definitions section of the Healthcare Compliance Program.

#### **POLICY**

All Personnel, manufacturers, investigators, and all other vendors of Noden shall be screened against HHS OIG's List of Excluded Individuals and Entities, the U.S. Government Services Administration's System for Award Management, and, as appropriate, the U.S. FDA's Debarment List and Clinical Investigator—Disqualification Proceedings Database. Such screening shall occur prior to employment or contracting, and annually thereafter.

Noden requires all employees, agents, vendors, contractors and investigators to promptly report to the Chief Compliance Officer their status as an Ineligible Person or Entity, and any change in status.

Noden shall terminate the employment of any Company director, officer, or employee determined to be an Ineligible Person shall be terminated, unless such person can demonstrate that he or she is no longer ineligible (e.g., reinstated or non-longer disqualified). Notwithstanding whether the person is no longer ineligible, if the person is found to have misrepresented his or her status as an Ineligible Person, the person may be subject to appropriate discipline, up to and including termination.

If any agent, contractor, vendor, manufacturer, or investigator is determined to be an Ineligible Person or Entity, the financial arrangement between the Company and the person or entity shall be terminated. All contractual arrangements between the Company and the individual or entity shall require that the individuals and entities, and the employees of such individuals and entities working on Company matters, not be Ineligible Persons or Entities.

**Regarding Restricted Clinical Investigators.** If an individual is listed in U.S. FDA’s Clinical Investigator—Disqualification Proceedings Database as a Restricted Clinical Investigator, the Company may at its sole discretion continue or terminate the arrangement with the individual.

**DOCUMENT RETENTION**

The Company shall maintain a record of its screening for Ineligible Persons and Entities to permit auditing and monitoring of compliance with this policy, as well as applicable laws and regulations. All such documentation shall be retained by the Company consistent with its document and record retention policies.

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