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1 PURPOSE AND SCOPE

The purpose of this policy is to describe the process for the reporting and investigation of complaints regarding the conduct of Hyperion Therapeutics Inc. (Hyperion) business, including but not limited to financial (accounting standards, internal controls, and audit practices), healthcare, and research and development matters (product promotion, interaction with healthcare professionals and other customers, and other healthcare compliance matters, research and development)

2 POLICY STATEMENT

2.1 General

- 2.1.1 It is the policy of Hyperion to comply with all applicable legal and regulatory requirements applicable to its business. Compliance includes all applicable healthcare compliance laws such as applicable provisions of the Federal Food, Drug, and Cosmetic Act and FDA regulations, the federal anti-kickback statute and Department of Health and Human Services Office of the Inspector General (OIG) regulations, the Medicaid rebate and other price reporting provisions of the Social Security Act and Centers for Medicare and Medicaid Services (CMS) regulations, the False Claims Act, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and comparable state laws. Hyperion is also committed to compliance with the principles set forth in the PhRMA Code on Interaction with Healthcare Professionals as well as the OIG's 2003 Compliance Program Guidance for Pharmaceutical Manufacturers.
- 2.1.2 All employees (employees, officers, directors, and others acting on behalf of the company) are responsible for reporting perceived misconduct, including actual or potential violations of law, regulation, policy, and procedures to his/her immediate supervisor, the Hyperion Compliance Officer and/or the hotline.
- 2.1.3 An "open door policy" will be maintained at all levels of management to encourage employees to report problems and concerns.
- 2.1.4 To promote a culture of legal and regulatory compliance and to facilitate the reporting of complaints related to financial and compliance matters, Hyperion has established and will maintain a telephone hotline that employees may use to report problems and concerns either anonymously or in confidence. The telephone number will be made readily available to all employees by conspicuously posting the telephone number in common work areas and in other ways.
- 2.1.5 Employees who report problems and concerns via the hotline in good faith will be protected from any form of retaliation or retribution. Any form of retaliation against any employee who reports a perceived problem or concern in good faith is strictly prohibited, and any employee who commits or condones any form of retaliation will be subject to discipline up to, and including, termination.

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2.1.6 The Hyperion Board of Directors, or its authorized committees, will oversee all compliance matters, and investigations of concerns in these areas. The Audit Committee is responsible for the oversight of financial matters, and the Nominating, Corporate Governance and Compliance Committee is responsible for the oversight of all non-financial compliance matters.

2.1.7 Management must take appropriate measures to ensure support for this policy and encourage the reporting of problems and concerns. At a minimum, the following actions should be taken and become an ongoing aspect of the management process:

- Meet with subordinates to discuss the main points of this policy.
- Provide all subordinates with a copy of this policy.
- Post a copy of this policy on employee bulletin boards and/or in a newsletter or online.

3 POLICY REQUIREMENTS

3.1.1 Reporting Complaints


3.1.2 Anyone with knowledge of a potential violation of law, regulation, code of conduct, policy or procedure has an affirmative duty to report that information to the Hyperion Compliance Officer. Failure to report a potential violation may result in appropriate disciplinary action. Anonymous or confidential submissions of concerns can be made directly to the compliance hotline.

The hotline is available 24 hours a day, 365 days a year.

To file a complaint through the National Hotline Services (an independent vendor under contract with Hyperion), individuals can dial the **toll-free number 1-800-601-2168**. A National Hotline Services agent will take the call. A caller filing a concern or complaint has the option to remain anonymous or provide the National hotline Services agent with his/her contact information in the event additional information is needed. When reporting a complaint, the conversation should include a discussion of the following items:

- a description of the matter, and any persons involved, with whatever details are available in order to permit the matter to be investigated,
- the period of time during which the employee observed the matter, and
- any steps the individual has taken to investigate the matter, including reporting it to a manager or the manager’s reaction.

The hotline will be staffed with qualified and properly trained personnel. All callers will be given the opportunity to speak with a live operator.

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- All callers to the hotline will hear the same pre-recorded message explaining their rights, any limitations, the non-retaliation policy and other pertinent information.
- No attempt will be made to identify a caller who requests anonymity. Whenever callers disclose their identity, it will be held in confidence to the fullest extent allowed by law.
- To file a complaint utilizing Silent Whistle, an employee should go to this website: <http://www.silentwhistle.com>. This confidential website allows Hyperion personnel the option to file an anonymous written complaint over the Internet through a site maintained by Allegiance, Inc.

Examples of reportable financial matters include but are not limited to the following:


- Fraud or deliberate error in the preparation, evaluation, review or audit of any financial statements of the Company;
- Fraud or deliberate error in the recording and maintaining of financial records of the Company;
- Deficiencies in or noncompliance with the company’s internal accounting controls;
- Misrepresentation or false statement to or by a senior officer or accountant regarding a matter contained in the financial records, financial reports or audit reports of the Company; or
- Deviation from full and fair reporting of the Company’s financial condition.

Examples of reportable compliance matters include but are not limited to the following:

- Failure to promote or otherwise discuss the Company’s prescription drug products in a manner that is truthful, non-misleading, and balanced;
- Promotion of the Company’s prescription drug products in a manner that is inconsistent with the FDA approval for the products (“off-label” promotions);
- The misuse or prohibited disclosure of protected patient health information
- False or improper company reporting to government or other entities of pricing, reimbursement, or other information concerning company products, other fraud or deliberate error in Company interactions with government or private payors regarding reimbursement for Company products; or
- Offering or paying something of material value to a healthcare professional, or other person or entity in a position to influence prescribing, in order to induce that person to purchase, prescribe, use, recommend, provide favorable formulary status for, or dispense a Company product.

3.2 Processing Complaints from National Hot Line Service and Silent Whistle

- 3.2.1 All calls to the hotline will be documented on the confidential hotline intake form (Confidential Hotline Report), and will include the nature of the complaint or violation


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reported, the date and time reported, and the department or facility affected. All call records will be logged and sequentially numbered.

- 3.2.2 Upon receipt of a compliant, National Hotline Service/Allegiance will provide the Confidential Hotline Report, via email, of the compliant to the Hyperion Compliance Officer, Chair of the Board of Directors, and (i) in the case of financial matters, to the Chair of the Audit Committee or (ii) in the case of non-financial compliance matters to the Chair of the Nominating, Corporate Governance and Compliance Committee.
- 3.2.3 Upon receipt of a complaint, the Hyperion Compliance Officer, the Chair of the appropriate Committee (Nominating, Corporate Governance and Compliance Committee or Audit Committee), and General Counsel will promptly meet in person or by telephone and make a determination, in their reasonable judgment, whether such complaint is potentially material to the Company or whether it raises plausible concerns.
- 3.2.4 Depending upon the allegations, it may be appropriate for the Hyperion Compliance Officer to address an issue with: (a) immediate supervisor, (b) department manager, (c) department head/director, or (d) senior administrative officer of the organization.

3.3 Complaint Investigations


- 3.3.1 The Hyperion Compliance Officer is responsible for developing an action plan and conducting investigations with Committee oversight. The Audit Committee is responsible for the oversight of investigation of complaints relating to financial matters and the Nominating, Corporate Governance and Compliance Committee is responsible for investigation complaints relating to other compliance matters.
- 3.3.2 In the case where the allegation is a criminal violation of law, the Hyperion Compliance Officer, senior management or the Board of Directors, consulting legal counsel as appropriate, must determine whether there is sufficient evidence to support referral to a duly authorized law enforcement agency.
- 3.3.3 With respect to investigation of complaints, investigative responsibilities of the Hyperion Compliance Officer and Committee include:
 - Assuring that appropriate investigative channels are used and that the plan to address the reported violations is appropriate for the circumstances in its judgment;
 - Assuring that the appropriate executive officers, Committees, and the Board of Directors are apprised of the allegations, as necessary and appropriate;
 - Ensuring that appropriate resources and expertise are brought into the investigation so that reports of allegations may be reviewed in a timely and thorough manner;
 - Ensuring that there are not conflicts of interest on the part of any party involved in conducting a particular investigation;

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- Coordinating and facilitating communications across investigative channels as necessary to ensure comprehensive attention to all aspects of the complaint and the investigation; and
- Monitoring the significant elements and the progress of investigation to ensure that allegations are addressed in a timely and thorough manner

3.3.4 Conduct of investigations will comply with the following principles:

- All investigations of wrongdoing should be conducted promptly and include a review of all pertinent documents and, in some cases, interviews with employees.
- Employees who are interviewed should be treated respectfully and with dignity.
- Those charged with investigation of wrongdoing, acting in some cases at the direction of legal counsel, must ensure protection of the confidentiality of the sources of information.
- In some cases, the entire matter should be discussed only with legal counsel. In each case, the facts of the situation will dictate the appropriate manner in which the issue will be handled.
- Interviews should be conducted in person and in private, with one interviewee at a time. Normally, in other than very routine circumstances, sensitive interviews should be conducted by two people. This is to ensure that the circumstance and content of the interview can be verified by a witness. The person being interviewed should be told that the purpose of the inquiry is to gather facts in connection with suspected wrongdoing. Interviewees should be informed that the communication is privileged, but that the privilege rests with the organization, and that the organization can waive the privilege as it deems appropriate to resolve the issue in question.
- The interviewers should obtain the interviewee’s full name, title, employment history, and his/her supervisor’s name.
- The interviewers should state that the interview will remain in confidence to the extent compatible with the proper resolution of all issues, correction of any improprieties, and the commitment to disclose certain types of wrongdoing to appropriate enforcement and regulatory authorities.
- The interviewers should not threaten the interviewee, offer opinions on whether the interviewee has acted appropriately, or speculate how the matter under review will be resolved.
- If the interview is to be conducted with an employee who is suspected of serious misconduct, legal counsel should be present for the interview. Counsel should advise the employee of the seriousness of the matter and of the commitment to disclose the result of its investigation to the government.

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- The individual should be reminded that he or she is free to retain independent counsel if he or she so chooses. If he or she is already represented by counsel or is a member of a union, the ramifications must be thoroughly discussed with legal counsel before proceeding. If, at any time during an interview, the employee requests that his or her lawyer be present, suspend the interview immediately and contact legal counsel.
- In most cases, the interviewer should organize the facts into a written report, assuming that it may eventually be read by an outside party.
- If the investigation and report has been requested or directed by legal counsel, the report should be marked “Confidential—Attorney-Client Privileged” and must be furnished only to counsel. Under those circumstances, it will be the responsibility of legal counsel to report and advise management regarding the facts, circumstances, and alternative courses of action.

3.3.5 The Hyperion Compliance Officer will ensure coordination of each investigation and will have overall responsibility for implementation of the procedures set forth above. Each committee will have the responsibility of reviewing and approving/authorizing prompt and appropriate corrective and preventive action when warranted in the judgment of the committee.

3.3.6 Each Committee will have the authority to retain independent counsel and other advisors in any investigation as it deems necessary or advisable to conduct the investigation in accordance with its charter.

3.4 Resolution, Reporting and Retention of Complaints and Investigations


3.4.1 The following actions are to be accomplished when resolving complaints and investigations. The Hyperion Compliance Officer will:

- Fully debrief complainant;
- Notify appropriate internal parties;
- Identify cause of problem, desired outcome, affected parties, applicable guidelines, and the possible regulatory or financial impact;
- Provide a complete list of findings and recommendations;
- Determine the necessary corrective measures; and
- Document the inquiry.

3.4.2 The Hyperion Compliance Officer, will maintain a log of all complaints, tracking their receipt, investigation and resolution, and shall prepare a periodic summary report for full Audit Committee in the case of financial matters and the full Nominating, Corporate Governance and Compliance Committee in the case of other compliance matters.

3.4.3 All complaints received and reports of investigations are reviewed by legal counsel and considered privileged. Investigations will be maintained indefinitely.

ORIGINAL

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4 REFERENCES

Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufactures, April 2003.