CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
EYEPOINT INC.

I. PREAMBLE

EyePoint Inc. and all subsidiaries and any additional affiliated entities owned, controlled, or operated by EyePoint Inc. including those that may be created during the term of this CIA (collectively, "Entity") hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, Entity is entering into a Settlement Agreement with the United States.

II. EFFECTIVE DATE, TERM, AND DEFINITIONS

A. Effective Date. The "Effective Date" of this CIA shall be the signature date of the final signatory to this CIA.

B. Term. The term of this CIA shall be five years from the Effective Date, except that Sections VII and X shall continue for 120 days after OIG's receipt of: (1) Entity's final Annual Report or (2) any additional documentation relating to the final Annual Report requested by OIG, whichever is later. Also, if OIG issues a Stipulated Penalties Demand Letter pursuant to Section X.C.1 or a Notice of Material Breach and Intent to Exclude pursuant to Section X.D.2 prior to the expiration of the 120-day period, then Section X shall remain in effect until the Stipulated Penalties Review described in Section X.E.2 or the Exclusion Review described in Section X.E.3 is completed, and Entity complies with the decision.

C. Definitions.

1. "Certifying Covered Persons" means the following: Chief People Officer and SVP IT, SVP Chief Commercial Officer, EVP Chief Financial Officer, Chief Regulatory Officer, Chief Scientific Officer, Chief Medical Officer, SVP, Global Quality & Device Development, VP Head of Medical Affairs, SVP Marketing & Strategy, SVP Market Access.

2. "Covered Functions" means "Promotional Functions" and "Product Related Functions" collectively.

3. "Covered Persons" means: (a) all owners who are natural persons other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading; (b) all officers, board members, and employees of Entity; (c) all contractors who perform any of the Covered Functions on behalf of Entity. Covered Persons does not include part-time or per diem employees or contractors who are not reasonably expected to work more than 160 hours during a Reporting Period, except that any such individual shall become a "Covered Person" at the point when they work more than 160 hours during a Reporting Period.

4. "Covered Recipient" is defined for purposes of Section III.N of this CIA, as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by the Centers for Medicare and Medicaid Services (CMS).

5. "Disclosure Program" means a program that enables individuals to disclose through one of several independent reporting paths any potential violations of criminal, civil, or administrative law related to the Federal health care programs, FDA requirements, Government Reimbursed Products, or any issues or questions associated with Entity's policies, conduct, practices, or procedures.

6. "Exclusion Lists" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available at http://www.oig.hhs.gov) and state Medicaid program exclusion lists that are publicly available.

7. "Excluded Person" means an individual or entity who is currently excluded from participation in one or more Federal health care programs.

8. "GAI" means Generative Artificial Intelligence.

9. "Government Reimbursed Products" means all Entity products that are: (a) marketed or sold by Entity in the United States (or pursuant to contracts with the United States) and (b) reimbursed by Federal health care programs.

10. "Payments" is defined for purposes of Section III.N of the CIA as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by CMS.

11. "Promotional Functions" means: (a) the selling, detailing, marketing, advertising, promoting, or branding of Government Reimbursed Products and (b) the preparation or external dissemination of promotional materials or information about, or the provision of promotional services relating to, Government Reimbursed Products, including those functions relating to Entity's review and approval processes for promotional materials and any applicable review committee(s).

12. "Product Related Functions" means: (a) the preparation or external dissemination of non-promotional materials about Government Reimbursed Products, including those functions relating to any applicable review committees and medical affairs/medical information services or involved in scientific exchange; (b) contracting with health care professionals (HCPs) licensed in the United States or with health care institutions (HCIs) to conduct post-marketing clinical trials, Investigator-Sponsored Studies (ISSs), and any other types of post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products to Compendia (such as Drugdex or other compendia of information about Government Reimbursed Products) or to any government payor.

13. "Reportable Event" means: (a) a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which criminal penalties or civil monetary penalties under Section 1128A or 1128B of the Social Security Act (the "Act") or exclusion under Section 1128 of the Act may be authorized; (b) a matter that a reasonable person would consider a probable violation of FDA requirements relating to the marketing or sale of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below; (c) the employment of or contracting with a Covered Person who is an Excluded Person; or (d) the filing of a bankruptcy petition by Entity.

14. "Reporting Period" means each one-year period during the term of this CIA, beginning with the one-year period starting on the Effective Date.

15. "Sponsorships" means support for a program, event, or organization in return for the advertisement or promotion of Entity products, including healthcare-related conventions and conference sponsorships, promotional booths, exhibit space, advertisements, memberships, signage rights, naming rights, and subscriptions.

16. "Third Party Educational Activity" means any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by Entity, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

17. "Training Plan" means a plan that meets the requirements of Section III.C.1.

18. "Transition Plan" means a plan to address whether and how Entity's compliance program will continue to include the compliance program requirements set forth in Section III, following the end of the CIA's term.

19. "Timely Written Request" is defined as a request in writing received by OIG at least one day prior to the date on which any act is due to be performed or any notification or report is due to be filed.

III. COMPLIANCE PROGRAM REQUIREMENTS

Entity shall establish and maintain a compliance program that includes the following elements:

A. Compliance Program Structure and Oversight.

1. *Compliance Officer*.

a. Within 90 days after the Effective Date, Entity shall appoint a Compliance Officer who shall be an employee and who shall report directly either to the Chief Executive Officer of Entity or to the Board of Entity. The Compliance Officer shall have direct and independent access to the Board at any time. The Compliance Officer shall have sufficient stature within the Entity to interact as an equal of all other leaders who report to the CEO or directly to the Board.

b. The Compliance Officer shall not lead or report to Entity's legal or financial functions and shall not provide Entity with legal or financial advice. The Compliance Officer also shall not be responsible, either directly or indirectly, for any Covered Functions.

c. The Compliance Officer shall be responsible for:

i. Overseeing and monitoring the implementation and operation of the compliance program,

ii. Advising the CEO, Board, and other executive and senior leaders on compliance risks facing Entity, compliance risks related to strategic and operational decisions of Entity, and the operation of Entity's compliance program,

iii. Chairing the Compliance Committee,

iv. Reporting to the Board at least quarterly on the implementation, operation, and needs of the compliance program, the compliance risks Entity faces, the methods

through which Entity is addressing or can address those risks, and all the reporting requirements of this CIA,

v. Developing and implementing policies, procedures, processes, and programs designed to ensure compliance with the requirements set forth in this CIA,

vi. Revising the compliance program periodically in light of changes in the needs of the organization, applicable law, and policies and procedures of third party payors,

vii. Coordinating with Human Resources to ensure that all directors, owners, employees, contractors, and medical staff, if applicable, are screened before appointment or engagement and annually thereafter against the Exclusion Lists,

viii. Coordinating with other relevant Entity components (e.g., Internal Audit, Risk, Quality) to develop work plans for reviewing, monitoring, and auditing compliance risks,

ix. Monitoring the day-to-day compliance activities engaged in by Entity, and

x. Performing other duties related to the Entity's compliance program.

d. The Compliance Officer shall not have any other noncompliance job responsibilities that OIG decides may interfere or conflict with the Compliance Officer's ability to perform the duties outlined in this CIA.

e. Entity shall report to OIG, in writing, any changes in the identity, duties, or job responsibilities of the Compliance Officer within five days after such a change.

2. *Compliance Committee*.

a. Within 90 days after the Effective Date, Entity shall appoint a Compliance Committee to aid and support the Compliance Officer in implementing, operating, and monitoring the Compliance Program.

b. The Compliance Committee shall be chaired by the Compliance Officer.

c. The Compliance Committee shall include, at minimum, relevant leaders of both operational and supporting departments such as

sales, marketing, market access, field access, patient support, regulatory, medical affairs/medical information, finance, internal audit, information technology, health information management, artificial intelligence, human resources, legal, risk management, research and development, manufacturing, and other operational leaders. All members shall have the authority and ability to speak for the department they represent.

d. The Compliance Committee shall be responsible for, among other things,

i. Analyzing the legal and regulatory requirements applicable to the Entity,

ii. Analyzing, developing, and annually reviewing the policies and procedures required by Section III.B,

iii. Monitoring and recommending internal systems and controls,

iv. Assessing education and training needs and effectiveness, including reviewing the training required by Section III.C at least annually,

v. Implementing and overseeing the risk assessment process required by Section III.E,

vi. Developing the disclosure program required by Section III.F and promoting compliance reporting, and

vii. Developing and implementing the Transition Plan required by Section III.O.

e. The Compliance Committee shall meet at least quarterly.

3. *Board Oversight*.

a. The Compliance Committee of the Board ("Board") shall be responsible for the review and oversight of Entity's compliance with Federal health care program requirements, FDA requirements, and the requirements of this CIA.

b. The Board must include at least one independent (e.g., non-owner, non-employee, and non-executive) member.

c. The Board shall, at minimum, ensure that:

i. the Compliance Officer and the Compliance Committee have sufficient authority, independence, and resources to perform the requirements of Sections III.A.1 and III.A.2,

ii. the Board has sufficient oversight to ensure the effectiveness of Entity's compliance program, including the performance of the Compliance Officer and the Compliance Committee,

iii. the Board periodically evaluates the effectiveness of the Compliance Committee's risk assessment process,

iv. the Board meets at least quarterly to review and oversee the Compliance Program and the performance of the Compliance Officer and the Compliance Committee, (e.g., meeting with the Compliance Officer and meeting in executive session with the Compliance Officer without Entity leaders, counsel, or employees present), and

v. adopt a resolution after the end of each Reporting Period, signed by each member of the Board, regarding its review and oversight of Entity's compliance with Federal health care program requirements, FDA requirements, and the requirements of this CIA.

The resolution shall include at minimum the following language:

"The Board has made a reasonable inquiry into the operations of Entity's compliance program, including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Entity has implemented an effective compliance program to meet Federal health care program requirements, FDA requirements, and the requirements of Entity's Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services."

If the Board is unable to adopt such a resolution, the Board shall provide a written explanation why it is unable to adopt the resolution and the steps the Board is taking to implement an effective compliance program at Entity.

Information relied upon by the Board to sign the Resolution shall be made available to OIG upon request.

4. *Board Compliance Expert*.

a. Within 90 days after the Effective Date, the Board shall retain an individual or entity with expertise in compliance with Federal health care program requirements and FDA requirements (Compliance Expert) to perform reviews of the effectiveness of Entity's compliance program. The Compliance Expert shall perform its review and produce a report thereof in the first and fourth Reporting Periods. The OIG, at its discretion, may adjust the occurrence of the compliance program reviews or require an additional review be conducted during the term of the CIA.

b. *Independence.* The Compliance Expert must not be employed or engaged by Entity and must not have a current or prior relationship to Entity that would cause a reasonable person to question the Compliance Expert's objectivity in performing the review.

c. *Written Report*. The Compliance Expert shall prepare a written report (Compliance Expert Report) that includes a description of the review and any recommendations with respect to Entity's compliance program.

d. *Board Response*. The Board shall review the Compliance Expert Report as part of its review and oversight of Entity's compliance program. The Board shall prepare a written response to the Compliance Expert Report, with corrective action plan(s) related to any report recommendations.

e. *Certification of Independence*. Each Compliance Expert Report must be accompanied by a certification from the Compliance Expert that it does not have a prohibited relationship with Entity as described in Section III.A.4.b. The certification must include a summary of any current or prior relationship between the Compliance Expert and Entity.

f. *Records*. Copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request.

5. *Management Certifications.*

a. Certifying Covered Persons shall monitor compliance within the divisions or departments for which they are responsible and annually certify that the applicable Entity division or department is in compliance with applicable Federal health care program requirements, FDA requirements, and the requirements of this

CIA. Certifying Covered Persons shall draw from sources within their area of responsibility (e.g., departmental metrics, interactions with department employees, knowledge gained from exercise of responsibility) to complete their certification.

b. For each Reporting Period, each Certifying Covered Person shall certify as follows:

"I have been trained on and understand the compliance requirements and responsibilities. My job responsibilities include ensuring [insert name of division or department]'s compliance with all applicable Federal health care program requirements, FDA requirements, requirements of the Corporate Integrity Agreement, and Entity's policies and procedures. To the best of my knowledge, the [insert name of division or department] is in compliance with all applicable Federal health care program requirements, FDA requirements, and the requirements of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by Entity and the United States."

Any exceptions that would otherwise prevent the Certifying Covered Person from providing this certification shall be noted in writing below the certification. If, despite this, any Certifying Covered Person is unable to provide this certification, the Certifying Covered Person shall provide a written explanation of the reasons why he or she is unable to provide the certification.

B. Written Standards. Within 90 days after the Effective Date, Entity shall develop and implement written policies and procedures (Policies and Procedures) that address the following:

1. Entity's compliance program,

2. the applicable requirements of any Federal health care program under which Entity's Government Reimbursed Products are reimbursed,

3. appropriate ways to conduct Covered Functions in compliance with all: (i) applicable Federal healthcare program requirements, including, but not limited to the Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements,

4. the materials and information that may be distributed by Entity sales representatives or other field personnel (including any contract sales force) about Government Reimbursed Products and the manner in which Entity sales representatives or other field personnel respond to requests for

information about uses of Government Reimbursed Products that are not FDA approved, cleared, or exempt (non-FDA approved uses),

5. the materials and information that may be distributed by Medical Information and the mechanisms through, and manner in which, Medical Information receives and responds to requests for information from an HCP or another individual or entity about non-FDA approved uses of Government Reimbursed Products; the form and content of information disseminated by Entity in response to such requests; and the internal review process for the information disseminated,

6. the manner and circumstances under which medical personnel interact with or participate in meetings or events with HCPs, HCIs, or payors (either alone or with Entity sales representatives) and the role of the medical personnel at such meetings or events, as well as how they handle responses to requests for information about non-FDA approved uses of Government Reimbursed Products,

7. the manner and circumstances under which Entity personnel interact with HCPs and HCIs (including members of pharmacy and therapeutics committees) regarding formularies, clinical practice guidelines, and protocol-related issues or provide information relevant to such issues,

8. the materials and information that may be distributed or made available by Entity through social media and/or direct-to-consumer advertising and the review and monitoring of such materials and information,

9. the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other Entity field personnel who interact with HCPs and HCIs regarding Government Reimbursed Products,

10. the development, implementation, and review of all plans for the distribution of samples of, or coupons or vouchers for, Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples, coupons, or vouchers from Entity (including, separately, from sales representatives, from Medical Information, or through other channels),

11. the manner and circumstances under which Entity provides patient support programs, the review and approval of related written materials, and the monitoring of patient support program activities,

12. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training

programs, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements,

13. the circumstances and limitations under which Entity personnel are permitted to provide meals or other transfers of value to HCPs or HCIs and the requirement for accurately reporting all such transfers of value in accordance with all applicable disclosure requirements (including the Open Payments Program),

14. programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities,

15. sponsorship or funding of grants (including educational grants) or charitable contributions,

16. funding of, or participation in, any Sponsorships or Third Party Educational Activity as defined in Section II.C.15 and II.C.16 above,

17. review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside Entity by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Entity's review and approval process and are elevated when appropriate,

18. compensation (including through salaries, bonuses, or other means) for Covered Persons engaged in Covered Functions,

19. the submission of information about any Government Reimbursed Product to any compendia such as Drugdex, any government payor, or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter collectively Compendia). This includes any initial submission of information to any Compendia or payor and the submission of any additional, updated, supplemental, or changed information (including any changes based on Entity's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results),

20. sponsorship or other support of post-marketing clinical trials and all other post-marketing studies of Government Reimbursed Products and support of ISSs (collectively, "Research"), including the decision to provide financial or other support for such Research; the manner in which Research support is provided; the publication of information about the Research (including

the publication of information about the Research results and trial outcomes); and uses made of publications relating to Research, and

21. authorship of journal articles or other publications about Government Reimbursed Products or about therapeutic areas or disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and Entity or other potential conflicts of interest that might bias the author's work; the identification of all authors or contributors (including professional writers) associated with a given publication; and the scope and breadth of research results made available to each author or contributor.

Entity shall make available all Policies and Procedures to Covered Persons, shall enforce its Policies and Procedures, and shall make compliance with its Policies and Procedures an element of evaluating the performance of all Covered Persons. All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education.

1. *Training Plan.* Within 90 days after the Effective Date, Entity shall develop a Training Plan that includes the following information: (a) training topics; (b) categories of personnel required to attend each training session; (c) length of the training session(s); (d) schedule for training; and (e) format of the training. The Training Plan shall be a written plan developed based on the needs and risks of Entity. The Training Plan shall outline the steps Entity will take to ensure that Entity's personnel receive training on a periodic basis during the term of the CIA.

2. *Covered Persons Training.* Covered Persons shall be trained regarding (a) Entity's CIA requirements, (b) Entity's compliance program, (c) the requirements of all Federal health care programs under which Entity's Government Reimbursed Products are reimbursed and (d) the requirements of 42 U.S.C. § 1320a-7b(b) (the Anti-Kickback Statute).

3. *Compliance Committee Training.* Within 90 days after the Effective Date, the Compliance Committee shall receive training regarding the Compliance Committee's duties and responsibilities and Entity's expectation of them in their role as a Compliance Committee member. New Compliance Committee members shall receive this training within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

4. *Board Training*. Within 90 days after the Effective Date, Board members shall receive training regarding their responsibilities for corporate governance and review and oversight of the compliance program. The training shall address the specific responsibilities of health care board

members, including the risks, oversight areas, and approaches to conducting effective oversight of a health care entity, and shall include a discussion of the OIG's guidance on board member responsibilities. Each Board member shall also receive the training described in Section III.C.2.

New Board members shall receive the training described in this Section III.C.4 within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later. The Compliance Committee shall review the Board training at least annually and update the Board training as necessary.

5. *Training Records*. Entity shall make available to OIG, upon request, training materials and records verifying that the training described in this Section III.C has been provided.

D. Review Procedures.

1. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, Entity shall engage an entity (the "Independent Review Organization" or "IRO") that meets the qualifications outlined in Appendix A to perform the reviews specified in Appendix B.

2. *OIG Review of IRO*. Entity must submit the following information regarding the IRO(s):

   a. identity, address, and phone number,

   b. a copy of the engagement letter,

   c. information to demonstrate that the IRO has the qualifications outlined in Appendix A,

   d. proof of current licensure of health care professionals, if applicable, and

   e. a certification from the IRO regarding its professional independence and objectivity with respect to Entity that includes a summary of all current and prior engagements between Entity and the IRO.

   Within 30 days of OIG receiving the information required by this section, or any additional information submitted by Entity in response to a request by OIG, whichever is later, OIG will notify Entity if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Entity may continue to engage the IRO.

3. *Access to Records and Personnel.* Entity shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in Appendix B and that all records furnished to the IRO are accurate and complete.

4. *Retention of Records*. Entity shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports exchanged between the IRO and Entity related to the reviews described in Appendix B.

5. *Responsibilities and Limitations.* Nothing in this Section III.D affects Entity's responsibilities or liabilities under any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the False Claims Act, or the Anti-Kickback Statute.

6. *IRO Removal or Termination*.

   a. *By Entity or IRO*. If Entity terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Entity must submit a notice to OIG explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal, no later than 30 days after termination or withdrawal. Within 60 days of termination or withdrawal of the IRO, Entity must engage a new IRO that meets the requirements of Appendix A and must seek OIG approval of the new IRO in accordance with Section III.D.2.

   b. *By OIG*. If OIG believes the IRO does not possess the qualifications specified in Appendix A, is not independent or objective as described in Appendix A, or has failed to carry out the responsibilities enumerated in Appendix A, OIG shall notify Entity in writing regarding OIG's basis for determining that the IRO has not met the requirements of Appendix A. Entity shall have 30 days from the date of OIG's written notice to provide information regarding the IRO's qualifications, independence, or performance of its responsibilities to resolve the concerns identified. If, following OIG's review of information provided by Entity, OIG determines that the IRO has not met the requirements of Appendix A, OIG shall notify Entity in writing that Entity shall be required to engage a new IRO. Entity must engage a new IRO within 60 days of its receipt of OIG's written notice and follow the procedures in Section III.D.2. The final determination as to whether Entity must engage a new IRO shall be decided by OIG.

E. Risk Assessment Process. Within 90 days after the Effective Date, Entity shall develop and implement a centralized annual risk assessment process to identify and address risks

associated with each Government Reimbursed Product, including risks associated with the Covered Functions. The risk assessment process shall be conducted at least annually and shall require Entity to:

1. identify potential risks,

2. assess the severity of the identified risks,

3. evaluate and prioritize the risks,

4. develop and implement work plans or audit plans (as appropriate) related to the identified risk areas, and

5. monitor the effectiveness of the work plans or audit plans in mitigating the risks.

The Compliance Committee shall be responsible for implementation and oversight of the risk assessment process.

F. Disclosure Program. Within 90 days after the Effective Date, Entity shall establish a Disclosure Program.

1. *Reporting Options*. The Disclosure Program's independent reporting paths shall include, at minimum, the option to disclose at any time (a) directly to the Compliance Officer or (b) through a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained, and which shall be operated under the direction and control of the Compliance Officer. Entity shall not require Covered Persons to communicate with a manager or other person before using the Disclosure Program.

2. *Nonretaliation*. The Disclosure Program shall prohibit retaliation against individuals for use of the Disclosure Program and Entity shall not retaliate against individuals for use of the Disclosure Program.

3. *Publication*. Entity shall publicize the existence of the Disclosure Program (e.g., via periodic e-mails, by posting the information on a website or in prominent common areas).

4. *Disclosure Log*. The Compliance Officer (or designee) shall record all disclosures (whether or not related to a potential violation of criminal, civil, or administrative law related to the Federal health care programs and regardless of the independent reporting path used) in a Disclosure Log within three days of receipt by the Compliance Program. The Disclosure Log shall include the following information: (a) a factual summary of each disclosure received (whether anonymous or not), (b) the date the disclosure was received, (c) the individual or department responsible for reviewing the

disclosure, (d) the status of the review, (e) a description of the investigation's findings, (f) any corrective action taken in response to the review, (g) any policy, process, or other remedial changes made as a result of the investigation, (h) the date the disclosure was resolved, and (i) any resulting referral or disclosure to Federal or State authorities.

5. *Review of Disclosures*. The Compliance Officer (or designee) shall conduct a review of each disclosure received through the Disclosure Program, including gathering relevant information from the disclosing individual, and shall ensure that appropriate follow-up is conducted.

6. *Disclosure Oversight*. The Compliance Officer shall regularly share information about reports received through the Disclosure Program and investigations conducted with the Compliance Committee, the CEO, and the Board.

G. Excluded Persons.

1. *Screening Requirements*. Entity shall:

a. Screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Excluded Persons; and

b. Screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

2. *Removal Requirement*. If Entity has actual notice that a Covered Person has become an Excluded Person, Entity shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid for in whole or part, directly or indirectly, by any Federal health care program(s) from which the Covered Person has been excluded, at least until such time as the Covered Person is reinstated into participation in such Federal health care program(s). Items or services furnished, ordered, or prescribed by Excluded Persons are not payable by Federal health care programs and Entity may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an Excluded Person regardless of whether Entity meets the requirements of Section III.G.

H. Notification of Government Investigation or Legal Proceeding. Entity shall notify OIG, in writing, of any ongoing investigation or legal proceeding by a governmental entity or its agents involving an allegation that Entity has committed a crime or has engaged in fraudulent activities, within 30 days of Entity receiving notice of such investigation or legal proceeding. This notification shall include a description of the allegation(s), the

identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Within 30 days after resolution of the matter, Entity shall notify OIG, in writing, of the resolution of the investigation or legal proceeding.

I. Reportable Events. Entity shall notify OIG, in writing, within 30 days after determining that a Reportable Event exists, as follows:

1. *Probable Violation of Law.* The report to OIG shall include:

a. a complete description of all details relevant to the Reportable Event, including, at minimum:

i. the types of claims, transactions, or other conduct giving rise to the Reportable Event,

ii. the period during which the conduct occurred,

iii. the Entity's investigation of the conduct,

iv. the root cause or causes of the conduct, and

v. the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event,

b. a statement of the Federal criminal, civil, or administrative laws that are probably violated by the Reportable Event,

c. the Federal health care programs affected by the Reportable Event, and

d. a description of Entity's actions taken to correct the Reportable Event, address the root cause(s) to prevent it from recurring, and strengthen any identified areas of vulnerability.

2. *Probable Violation of FDA Requirements.* The report to OIG shall include:

a. a complete description of all details relevant to the Reportable Event, including, at a minimum:

i. the types of claims, transactions or other conduct giving rise to the Reportable Event,

ii. the period during which the conduct occurred,

iii. the Entity's investigation of the conduct,

iv. the root cause of the conduct, and

v. the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event;

b. a statement of the FDA requirements probably violated by the Reportable Event; and

c. a description of Entity's actions taken to correct the Reportable Event, address the root cause(s) to prevent it from recurring, and strengthen any identified areas of vulnerability.

3. *Excluded Person.* The report to OIG shall include:

a. the identity of the Excluded Person and the job duties performed by the Excluded Person,

b. the dates of the Excluded Person's employment or contractual relationship,

c. a description of the Exclusion Lists screening that Entity completed before and/or during the Excluded Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Excluded Person,

d. a description of how the Excluded Person was identified, and

e. a description of any corrective action implemented to prevent future employment or contracting with an Excluded Person.

4. *Bankruptcy.* The report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program requirements implicated.

J. Notification of Communications with FDA. Within 30 days after the date of any written report, correspondence, or communication between Entity and the FDA that materially discusses Entity's or a Covered Person's actual or potential unlawful or improper promotion of Entity's products (including any improper dissemination of information about non-FDA approved uses), Entity shall provide a copy of the report, correspondence, or communication to OIG. Within 30 days after resolution of the matter, Entity shall notify OIG, in writing, of the resolution.

K. Requirements Relating to Speaker Programs.[1] Within 90 days following the Effective Date, or at least 90 days prior to the implementation of Speaker Program(s), Entity shall establish and implement the following requirements relating to arrangements with HCPs

[1] *Entity represents that as of the Effective Date it does not have any Speaker Programs.*

to serve as presenters on behalf of Entity or participate in training programs related to such presentations (Speaker Programs).

1. An annual budget and needs assessment process that identifies the business needs for, and the estimated numbers of, Speaker Programs for the following year. As part of the process, Entity shall identify the business need for the planned Speaker Programs and the basis for such need (e.g., recent FDA approval of a new product or indication or the recent publication of clinical data from independent clinical studies). Entity shall collect specific details about the Speaker Programs (e.g., the expected number of programs, the topics of the programs, and the identity and qualifications of the proposed speakers.) The annual Speaker Programs budget shall identify the total budgeted amounts to be spent on Speaker Programs. Entity compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of approved plans. The purpose of this review shall be to ensure that Speaker Programs are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and Entity Policies and Procedures.

2. A process to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance requirements for the speakers (including requirements regarding the use of Entity approved materials and requirements that speakers may not directly or indirectly promote the product for non-FDA approved uses.)

3. A centralized, electronic system to initiate and track all Speaker Programs that includes controls designed to ensure that Speaker Programs are used for legitimate and lawful purposes in accordance with all applicable Federal health care program and FDA requirements.

4. A process to ensure that speakers are paid according to a centrally managed, pre-set rate structure determined based on an independent fair-market value analysis.

5. A comprehensive list of Speaker Program attendees through its centralized system. In addition, Entity shall use its centralized system to handle all logistics and spending associated with Speaker Programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with Speaker Programs.

6. A requirement for certifications by sales representatives or other Entity personnel that Speaker Programs comply with Entity requirements, or in the event of non-compliance, Entity shall require the identification of the

policy violation and ensure appropriate follow up activity to address the violation.

7. A Speaker Monitoring Program under which Entity compliance or other appropriately trained Entity personnel who are independent from the functional area being monitored (Monitoring Personnel) shall attend 20% of Speaker Programs during each Reporting Period and conduct live audits of the Speaker Programs (Speaker Program Audits). The Speaker Programs subject to Speaker Program Audits shall be selected using either a risk-based targeting approach or a random sampling approach. For each Speaker Program reviewed, Monitoring Personnel shall review slide materials and other materials used as part of the Speaker Program, speaker statements made during the program, and Entity sales representative activities during the Speaker Program to assess whether the Speaker Programs were conducted in a manner consistent with Entity's Policies and Procedures. Results from the Speaker Monitoring Program shall be compiled and reported to the Compliance Officer for review and remediation as appropriate.

L. Field Force Monitoring and Review Efforts.[2] Within 90 days after the Effective Date, or at least 90 days prior to the Entity establishing a Field Force, Entity shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its field personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of field personnel's interactions with HCPs and HCIs and to identify potential inappropriate promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: (1) direct field observations (Observations) of field personnel; and (2) the monitoring and review of other records relating to field personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Observations*. As a component of the FFMP, Monitoring Personnel shall conduct observations of field personnel (including any contract sales personnel) to assess whether the messages delivered and materials distributed to HCPs and HCIs are consistent with applicable legal requirements and with Entity's Policies and Procedures. These observations shall be full day ride-alongs with field personnel (Observations), and each Observation shall consist of directly observing all meetings between a field representative and HCPs and HCIs during the workday. The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, and be conducted across the United States.

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes: (a) the identity of the field personnel; (b) the identity of the Monitoring Personnel who conducted the Observation; (c) the date and duration of the Observation; (d) the product(s) promoted during the Observation; (e) an overall assessment of compliance with Entity Policies and Procedures; and (f) the identification

[2] *Entity represents that as of the Effective Date it does not have a Field Force.*

of any potential inappropriate promotional activity or other improper conduct by the field personnel.

Monitoring Personnel shall conduct at least 20% of Observations during each Reporting Period. Monitoring Personnel shall have access to all relevant records and information necessary to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

2. *Records Reviews.* As a component of the FFMP, Entity shall also review various types of records to assess field personnel's interactions with HCPs and HCIs and to identify potential or actual compliance violations.

a. For each Reporting Period, Entity shall develop and implement a plan for conducting Records Reviews associated with at least 3 Government Reimbursed Products. The Records Reviews shall include a review of records relating to the activities of field personnel in every separate district and/or region (as applicable) who promoted the products under review.

The Records Reviews shall include the monitoring and review of:

(i) records and systems associated with field personnel's interactions with HCPs and HCIs (including records relating to consulting and other fee-for-service arrangements, speaker program activities, samples, travel, meals, expense reports, any payments to HCPs or HCIs, and sales communications from managers);

(ii) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of the representatives' interactions with HCPs and HCIs;

(iii) records relating to requests for medical information about or inquiries relating to the Government Reimbursed Products under review;

(iv) field personnel call notes;

(v) e-mails, texts, and records of other electronic communications of the field personnel; and

(vi) recorded results of the Observations of field personnel, coaching guides, and district manager notes.

3. *Reporting and Follow-up.* Results from the FFMP shall be compiled and reported to the Compliance Officer for review and remediation as appropriate.

M. Requirements Relating to Certain Non-Promotional Activities. To the extent that Entity engages HCPs for services other than for speaker programs, Research-related activities, or publication activities (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs shall be referred to herein as Consultants. To the extent that Entity engages or supports U.S.-based HCPs or HCIs to conduct Research (as defined above in Section III.B.20), such HCPs and HCIs shall be referred to collectively as "Researchers." To the extent that Entity engages HCPs or HCIs to produce articles or other publications relating to Government Reimbursed Products (collectively, "Publication Activities") such HCPs or HCIs shall be referred to as Authors. Within 90 days after the Effective Date, Entity shall implement the requirements outlined below relating to the following types of activities: (1) consultant arrangement activities; (2) Research-related activities; (3) publication activities; and (4) medical education grants.

1. *Consulting Arrangement Activities*. Entity shall:

a. Require all Consultants to enter written agreements describing the scope of work to be performed, the consultant fees to be paid, and compliance requirements for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on an independent fair-market value analysis.

b. Establish a process to develop an annual budgeting plan that specifies (i) the business needs for, and the estimated numbers of, the various Consultant engagements and activities to occur during the following year and (ii) the budgeted amounts to be spent on Consultant-related activities. Entity compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan, for the purpose of ensuring that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and Entity Policies and Procedures.

c. Establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs and HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and the type of work product to be generated). Any deviations from the Consultant budgeting plans

shall be documented in the needs assessment form and shall be subject to review and approval by Entity compliance personnel.

d. Amend its policies and procedures in a manner designed to ensure that each Consultant performs the work for which the Consultant is engaged and that, as applicable, Entity receives the work product generated by the Consultant.

e. Establish a Consultant Monitoring Program through which it shall conduct audits of at least 20% of EyePoint's Consultant arrangements during each Reporting Period. The Consultant Monitoring Program shall select Consultant arrangements for review using either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review needs assessment documents, Consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), in order to assess whether the programs and arrangements were conducted in a manner consistent with Entity's Policies and Procedures. Results from the Consultant Monitoring Program, including the identification of potential violations of Entity policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow up as appropriate.

2. *Research-Related Activities.* Entity shall:

a. Require all Researchers to enter written agreements describing the scope of the clinical research or other work to be performed, the fees to be paid or support to be given, and compliance requirements for the Researchers. Researchers retained to conduct Research shall be paid according to a centrally managed, pre-set rate structure that is determined based on an independent fair-market value analysis.

b. Establish a process to develop an annual budgeting plan for Researchers that specifies (i) the business or scientific need or scientific opportunity for, and the estimated numbers of, the various Researcher engagements and activities to occur during the year; and (ii) the budgeted amounts to be spent on Researcher-related activities during the year. Entity compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan, for the purpose of ensuring that Research arrangements and related events are used for legitimate purposes in accordance with Entity Policies and Procedures and with Federal health care program and FDA requirements.

c. Establish a process to ensure that a needs assessment has been completed to justify the retention of the Researcher prior to the retention of the Researcher. The needs assessment shall identify the business or scientific need for the information to be provided by the Researcher and provide specific details about the Research arrangement (including, for example, information about the numbers and qualifications of the HCPs or HCIs to be engaged, a description of the proposed research to be done (including the research protocol) and type of work product to be generated). Any deviations from the Researcher budgeting plans shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Entity compliance personnel.

d. Amend its policies and procedures in a manner designed to ensure that each Researcher performs the work for which the Researcher was engaged.

e. Establish a Researcher Monitoring Program through which it shall conduct audits for each Reporting Period. Entity shall review 20% of Researcher arrangements with HCPs or HCIs for each Reporting Period. The Researcher Monitoring Program shall select Researcher arrangements for review using either a risk-based targeting approach or a random sampling approach. Monitoring Personnel conducting the Researcher Monitoring Program shall review needs assessment documents, proposal and/or protocol documents, approval documents, contracts, and payments in order to assess whether the programs and arrangements were supported by Entity and performed by the Researchers in a manner consistent with Entity's Policies and Procedures. Results from the Researcher Monitoring Program, including identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

3. *Publication Activities.* Entity shall:

a. Require all Authors to enter written agreements describing the scope of work to be performed, the fees to be paid in connection with the Publication Activities, and compliance requirements of the Authors. Authors shall be paid according to a centrally managed, pre-set rate structure that is determined based on an independent fair-market value analysis.

b. Establish a process to develop annual plans that specify: (i) the business needs for and the estimated number of various Publication Activities (Publication Plans), and (ii) the budgeted amounts to be

spent on Publication Activities. Entity's compliance personnel shall be involved in the review and approval of such annual Publication Plans, including any modification of an approved plan, for the purpose of ensuring that Publication Activities and related events are used for legitimate purposes in accordance with Entity Policies and Procedures and with Federal health care program and FDA requirements.

c. Establish a needs assessment process for Publication Activities. This process shall ensure that a needs assessment has been completed prior to the retention of an Author to undertake a Publication Activity. The needs assessment shall provide specific details about Publication Activities to be performed (including a description of the proposed work to be done, type of work product to be generated, and the purpose for the work.) Any deviations from the Publications Plan shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Entity compliance personnel.

d. Establish a Publication Monitoring Program through which it shall conduct audits for each Reporting Period of at least 20% of EyePoint's Publication Activities. The Publication Monitoring Program shall select publications for review using either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review needs assessment documents, proposal documents, approval documents, contracts, payments and materials relating to the Publication Activities (including work product resulting from the Activities), in order to assess whether the activities were conducted in a manner consistent with Entity's Policies and Procedures. Results from the Publication Monitoring Program, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

4. *Grant and Charitable Contribution Activities.* Entity shall:

a. Establish a centralized system which shall be the exclusive mechanism through which requestors may request or be awarded amounts for independent medical education, amounts for other educational activities, and other grant activities involving HCPs and HCIs (referred to below as "Grants"), and health care related charitable contributions supported by Entity (referred to below as "Contributions").

b. Establish a process to review requests for Grants and Contributions according to standardized, objective criteria developed by Entity (such as based upon the qualifications of the requestor, or the quality of the program funded by the Grant or Contribution) and to ensure that Grants and Contributions are provided only pursuant to a written agreement with the funding recipient and that payments to the funding recipient are consistent with the written agreement. Entity's sales and marketing personnel shall have no involvement in, or influence over, the review and approval of requests for Grants or Contributions.

c. Establish a Grants and Contributions Monitoring Program through which it shall conduct audits for each Reporting Period of at least 20% of EyePoint's Grants and Contributions. The Grants and Contributions Monitoring Program shall select Grants and Contributions for review using either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review proposal documents (including requests), approval documents, contracts, payments and materials relating to the review of the requests, and documents and materials relating to the Grants or Contributions and any events or activities funded through the Grants or Contributions to assess whether the activities were conducted in a manner consistent with Entity's Policies and Procedures. Results from the Grants and Contributions Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

N. Reporting of Physician Payments.[3] Within 90 days after the Effective Date, or at the time Entity submits its first annual report to CMS as an Applicable Manufacturer (as that term is defined under the CMS Open Payments Program), Entity shall post on its website a description of the types of Payments it makes to Covered Recipients and include a link to CMS's Open Payments Program website (www.cms.gov/priorities/key-initiatives/open-payments). Entity also shall include on its website instructions regarding how to utilize the CMS Open Payments Data search tool to search for information regarding Payments provided to Covered Recipients from Entity.

O. Transition Plan. Prior to the end of the fourth Reporting Period, Entity shall develop a Transition Plan that is reviewed and approved by the Board. The Transition Plan shall be

[3] *Entity represents that as of the Effective Date it is not an Applicable Manufacturer.*

implemented following the end of the CIA's term. A copy of Entity's approved Transition Plan shall be included in Entity's fourth Annual Report.

IV. SUCCESSOR LIABILITY

A. Sales and Purchases.

1. *Sales*. If, after the Effective Date, Entity proposes to sell any or all of its business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) that will engage in any of the Covered Functions or that relate to the furnishing of items or services that may be reimbursed by a Federal health care program, then the CIA shall be binding on the purchaser.

2. *Purchases*. If, after the Effective Date, Entity proposes to purchase or establish a new business, business unit, or location that will engage in any of the Covered Functions or relate to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the new business, business unit, or location (and all Covered Persons at each new business, business unit, or location).

B. Notification Requirements. Entity shall notify OIG in writing of any such sale, purchase, or establishment within 30 days following the closing of the transaction.

C. Exemptions. If Entity wishes to obtain a determination by OIG that a proposed sale or purchase will not be subject to the CIA, Entity must notify OIG in writing at least 30 days in advance of the proposed sale or purchase. This notification shall include a description of the business, business unit, or location to be sold or purchased, a description of the terms of the transaction, and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION REPORT AND ANNUAL REPORTS

A. Implementation Report. Within 120 days after the Effective Date, Entity shall submit a written report (Implementation Report) to OIG that includes, at minimum, the following information:

1. the name, business email, business phone number, and position description of the Compliance Officer required by Section III.A.1, and a detailed description of any noncompliance job responsibilities,

2. the names and positions of the members of the Compliance Committee required by Section III.A.2,

3. the names of the Board members who are responsible for satisfying the Board compliance requirements described in Section III.A.3, and identities of the Board member(s) who are independent,

4. for the Compliance Expert required by Section III.A.4: (a) identity, address, and phone number; (b) information to demonstrate the individual's or entity's expertise in compliance with Federal health care program requirements and FDA requirements, and (c) a certification from the Compliance Expert that they do not have a current or prior relationship to Entity that would cause a reasonable person to question the Compliance Expert's objectivity in performing the review,

5. the names and positions of the Certifying Covered Persons required by Section III.A.5,

6. a list of the Policies and Procedures required by Section III.B,

7. the Training Plan required by Section III.C.1 and descriptions of the Covered Persons training required by Section III.C.2, Compliance Committee training required by Section III.C.3, and the Board training required by Section III.C.4 (including a summary of the topics covered, the length of the training, and when the training was provided),

8. the IRO information required by Section III.D.2,

9. a description of the risk assessment process required by Section III.E,

10. a description of the Disclosure Program required by Section III.F,

11. a description of the Excluded Persons screening and removal process required by Section III.G,

12. a description of policies, procedures, and systems implemented pursuant to the Speaker Program Requirements outlined in Section III.K,[4]

13. a description of the FFMP required by Section III.L,[5]

14. a description of the policies, procedures and systems implemented pursuant to the Requirements Relating to Certain Non-Promotional Activities outlined in Section III.M,

15. a certification from the Compliance Officer that information regarding Payments has been posted on Entity's website as required by Section III.N,

16. a description of Entity's corporate structure, including identification of any parent and sister companies, and their respective lines of business, and any individual owners,

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[4] Entity represents that as of the Effective Date it does not have any Speaker Programs, so this requirement is suspended until 90 days prior to the implementation of any Speaker Program.

[5] Entity represents that as of the Effective Date it does not have a Field Force, so this requirement is suspended until 90 days prior to the establishment of a Field Force.

17. a list of all of Entity's locations and the corresponding name under which each location is doing business, and

18. certifications by the Compliance Officer and Chief Executive Officer that:

    a. to the best of his or her knowledge, except as otherwise described in the report, Entity has implemented and is in compliance with all of the requirements of this CIA,

    b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful, and

    c. he or she understands that the certification is being provided to and relied upon by the United States.

B. Annual Reports. Entity shall submit to OIG a written report (Annual Report) for each of the five Reporting Periods. Annual Reports must be received by OIG no later than 60 days after the end of the applicable Reporting Period. Each Annual Report shall include, at minimum, the following information:

1. any change in the identity, position description, or noncompliance job responsibilities of the Compliance Officer required by Section III.A.1,

2. a current list of the Certifying Covered Persons required by Section III.A.5 and any changes made during the Reporting Period to the Certifying Covered Persons,

3. a current list of the members of the Compliance Committee required by Section III.A.2 and any changes made during the Reporting Period to the Compliance Committee members,

4. the dates of each meeting of the Compliance Committee required by Section III.A.2 (copies of the meeting minutes shall be made available to OIG upon request),

5. a current list of the Board members who are responsible for satisfying the Board compliance requirements required by Section III.A.3 and any changes made during the Reporting Period to the Board members,

6. the dates of each report made by the Compliance Officer to the Board required by Section III.A.1 (written documentation of such reports shall be made available to OIG upon request),

7. the Board resolution required by Section III.A.3,

8. a copy of the Compliance Expert's Report required by Section IIIA.4.c and the certification from the Compliance Expert required by Section III.A.4.e,

9. the Board's response to the Compliance Expert Report required by Section III.A.4.d, with corrective action plan(s) related to any report recommendations (copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request),

10. the certifications of Certifying Covered Persons required by Section III.A.5,

11. a list of any new or revised Policies and Procedures required by Section III.B developed during the Reporting Period,

12. a description of any changes to the Training Plan required by Section III.C, and a summary of all training furnished to Covered Persons, the Compliance Committee, and Board members during the Reporting Period, including the details required by Section III.C.1,

13. a complete copy of all reports prepared pursuant to Section III.D and a certification of independence from the IRO as specified in Appendix B,

14. Entity's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports, and confirmation of Entity's commitment to timely provide information required by Section IV of Appendix B,

15. a description of any changes to the risk assessment process required by Section III.E, including the reason(s) for such changes,

16. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) risk areas identified, (b) work plans and internal audit plans developed, (c) internal audits performed, (d) corrective action plans developed in response to internal audits, and (e) steps taken to track the implementation of the work plans and corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request,

17. a summary of the disclosures in the Disclosure Log required by Section III.F that relate to Federal health care programs, FDA Requirements, or Government Reimbursed Products including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved. The complete disclosure log shall be made available to OIG upon request,

18. a description of any changes to the Excluded Persons screening and removal process required by Section III.G, including the reason(s) for such changes,

19. a summary of any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H that includes a description of the allegation(s), the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding,

20. a summary of all Reportable Events required to have been reported pursuant to Section III.I during the Reporting Period,

21. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.J that includes a description of each matter and the status of each matter,

22. a summary of any changes to the policies, procedures, and systems relating to Speaker Programs required by Section III.K, including the reason(s) for such changes, and a summary of the results of the Speaker Monitoring Program described in Section III.K,[6]

23. the results of the FFMP required by Section III.L, including copies of the Observations for any instances in which it was determined that improper promotion or other improper activity occurred and a description of the action(s) that Entity took as a result of such determinations,[7]

24. a summary of any changes to the policies, procedures, and systems relating to Certain Non-Promotional Activities required by Section III.M, including the reason(s) for such changes, and a summary of results of the Consultant Monitoring Program, Researcher Monitoring Program, Publication Monitoring Program, and Grants and Contributions Monitoring Program described in Section III.M,

25. in the fourth Annual Report, a copy of the Transition Plan required by Section III.O,

26. a description of all changes to the most recently provided list of Entity's locations (including addresses) as required by Section V.A.17,

27. a description of any changes to Entity's corporate structure, any parent and sister companies, and their respective lines of business,

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[6] *Entity represents that as of the Effective Date it does not have any Speaker Programs, so this requirement is suspended until the Reporting Period in which Entity implements any Speaker Program.*

[7] *Entity represents that as of the Effective Date it does not have a Field Force, so this requirement is suspended until the Reporting Period in which Entity establishes a Field Force.*

28. A statement indicating whether the Entity used (or did not use) GAI in connection with its compliance program or the preparation of the Annual Report. If the Entity used GAI, the Entity should explain how GAI was used and verify that it checked the accuracy of any portion of the Annual Report drafted or assisted by GAI, and

29. certifications by the Compliance Officer, Chief Executive Officer and individual owners that:

    a. to the best of his or her knowledge, except as otherwise described in the report, Entity has implemented and is in compliance with all of the requirements of this CIA,

    b. to the best of his or her knowledge, Entity provided complete and accurate documentation to the IRO,

    c. he or she has reviewed the report, has made reasonable inquiry regarding its content, and believes that the information in the report is accurate and truthful, and

    d. he or she understands that the certification is being provided to and relied upon by the United States.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

All notifications and reports required under this CIA shall be submitted using the following contact information:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Telephone: 202.619.2078
Email Address: officeofcounsel@oig.hhs.gov

Entity:

Paul Curtin
Chief Compliance Officer
EyePoint Inc.
pcurtin@eyepoint.bio
P: 857 299 1099
C: 203 247 3109

Unless otherwise requested by OIG, all notifications and reports required by this

CIA shall be submitted electronically. OIG shall notify Entity in writing of any changes to the OIG contact information listed above. Entity shall notify OIG in writing within three days of any changes to the Entity contact information listed above.

VII. OIG RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may conduct interviews, examine and/or request copies of or copy Entity's books, records, and other documents and supporting materials, and conduct announced or unannounced on-site reviews of any of Entity's locations, for the purpose of evaluating: (a) Entity's compliance with the requirements of this CIA and (b) Entity's compliance with the requirements of the Federal health care programs and with all applicable FDA requirements. The documentation described above shall be made available by Entity to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction.

For purposes of this provision, OIG or its duly authorized representative(s) may interview any of Entity's Covered Persons who consent to be interviewed at the individual's place of business during normal business hours, or at such other place and time as may be mutually agreed upon between the individual and OIG. Entity shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Entity's Covered Persons may elect to be interviewed with or without a representative of Entity present.

VIII. DOCUMENT RETENTION AND DISCLOSURES

A. Document and Record Retention. Entity shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs and to compliance with this CIA for six years (or longer if otherwise required by law) from the Effective Date.

B. Disclosures. Entity shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Entity shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Entity prior to any release by OIG of information submitted by Entity pursuant to this CIA and identified upon submission by Entity as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Entity shall have the rights set forth at 45 C.F.R. § 5.42(a).

IX. EXTENSIONS

Entity may submit a Timely Written Request for an extension of time to perform any act or file any notification or report required by this CIA.

X. BREACH PROVISIONS

A. Stipulated Penalties. OIG may assess:

1. A Stipulated Penalty of up to $2,500 for each day Entity fails to comply with any of the following CIA Sections:

III.A Compliance Program Structure and Oversight,

III.B Written Standards,

III.C Training and Education,

III.D Review Procedures,

III.E Risk Assessment Process,

III.F Disclosure Program,

III.G Excluded Persons,

III.H Notification of Government Investigation or Legal Proceeding,

III.I Reportable Events,

III.J Notification of Communications with FDA,

III.K Requirements Relating to Speaker Programs,

III.L Field Force Monitoring and Review Efforts,

III.M Requirements Relating to Certain Non-Promotional Activities,

III.N Reporting of Physician Payments,

III.O Transition Plan,

IV Successor Liability,

V Implementation Report and Annual Reports,

VII OIG Rights,

VIII Document Retention and Disclosures,

2. A Stipulated Penalty of up to $50,000 for each false certification, false statement, or false representation made to OIG by or on behalf of Entity under this CIA.

B. Stipulated Penalties and Timely Extension Requests. If OIG grants a Timely Written Request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Entity fails to meet the revised deadline set by OIG. If OIG denies a Timely Written Request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after Entity receives OIG's written denial of such request or the original due date, whichever is later.

C. Payment of Stipulated Penalties.

1. *Demand Letter*. If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify Entity of: (a) Entity's failure to comply and (b) OIG's demand for payment of Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Payment*. Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter within 20 days after the date of the Demand Letter.

3. *Disputing Stipulated Penalties.* Entity may request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance within 20 days of the Demand Letter, pursuant to the agreed upon provisions set forth below in Section X.E.

D. Exclusion for Material Breach.

1. *Definition of Material Breach*. A material breach of this CIA means:

a. failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under Section X.C, unless such Stipulated Penalty was overturned by an ALJ on appeal pursuant to the procedures described in Section X.E below;

b. failure to comply with Section III.A.1,

c. failure to comply with Section III.D,

d. failure to comply with Section III.I,

e. failure to comply with Section V,

f. failure to respond to a Demand Letter in accordance with Section X.C,

g. a false statement, false representation, or false certification made to OIG by or on behalf of Entity in or under this CIA,

h. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering Entity to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG, or

i. failure to come into compliance with a requirement of this CIA for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

2. *Notice of Material Breach and Intent to Exclude*. The parties agree that a Material Breach of this CIA by Entity constitutes an independent basis for Entity's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years for each material breach. Upon a preliminary determination by OIG that Entity has materially breached this CIA, OIG shall notify Entity of: (a) Entity's material breach and (b) OIG's intent to exclude Entity. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

3. *Response to Notice*. Entity shall have 20 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter*. If OIG determines that exclusion is warranted, OIG shall notify Entity in writing of its determination to exclude Entity. (This letter shall be referred to as the "Exclusion Letter.") Subject to the Dispute Resolution provisions in Section X.E, the exclusion shall go into effect 20 days after the date of the Exclusion Letter. The effect of the exclusion shall be that no Federal health care program payment may be made for any items or services furnished, ordered, or prescribed by Entity, including administrative and management services, except as stated in regulations found at 42 C.F.R. § 1001.1901(c). The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Entity may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution.

1. *Review Rights*. Upon OIG's issuing a Demand Letter or Exclusion Letter to Entity, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, Entity shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part

1005. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing shall be made within 20 days after the date of the Demand Letter or Exclusion Letter and (b) no discovery shall be available to the parties. The standard of proof will be judged by a preponderance of the evidence, as provided in 42 C.F.R. § 1005.15(d). Subject to the burdens allocated below in Section X.E.2 and X.E.3, Entity shall bear the burden of proof with respect to any affirmative defenses and OIG shall bear the burden of proof with respect to all other issues.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Entity was in full and timely compliance with the requirements of this CIA for which OIG demands payment and (b) the period of noncompliance. Entity shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that Entity has breached this CIA and orders Entity to pay Stipulated Penalties, Entity must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless Entity properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, Entity must (a) come into compliance with the requirement(s) that resulted in the OIG imposing Stipulated Penalties and (b) pay the Stipulated Penalties within 20 days after the DAB issues its decision.

3. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Entity was in material breach of this CIA. Entity shall have the burden of proving its full and timely compliance. If the ALJ sustains the OIG's determination of material breach, the exclusion shall take effect 20 days after the ALJ issues the decision. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Entity shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Entity, Entity shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. The parties to this CIA agree that the DAB's decision (or the

ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and Entity agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

XI. GENERAL TERMS AND CONDITIONS

A. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

B. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Entity's responsibility to follow all applicable Federal health care program requirements or (2) the government's right to impose appropriate remedies for failure to follow applicable Federal health care program requirements.

C. The undersigned Entity signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatories represent that they are signing this CIA in their official capacities and that they are authorized to execute this CIA.

D. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Electronically transmitted copies of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF ENTITY

/Ron Honig/
Ron I. Honig
Chief Legal Officer

July 13 2026
DATE

/Douglas A. Fellman/
Douglas A. Fellman
Partner, Hogan Lovells Cadwalader US LLP

July 13, 2026
DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

DATE

NANCY W. BROWN
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

DATE

ON BEHALF OF ENTITY

Douglas A. Fellman
Partner, Hogan Lovells US LLP

DATE

ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

/Susan E. Gillin/
SUSAN E. GILLIN
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

2026.07.10
DATE

/Nancy W. Brown/
NANCY W. BROWN
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

7/13/2026
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION REQUIREMENTS

I. Independence and Objectivity. The Independent Review Organization (IRO) must be able to perform the reviews specified in Appendix B in a professionally independent and objective fashion as defined in the most recent Generally Accepted Government Auditing Standards (Yellow Book) issued by the U.S. Government Accountability Office.

II. Qualifications. The IRO shall assign:

A. personnel to conduct the Systems Review and Transactions Review who have expertise in the pharmaceutical industry and in all appliable Federal health care program and FDA requirements relating to the Covered Functions (as defined in Section II.C of the CIA), including but not limited to expertise relating to marketing and promotional activities associated with pharmaceutical products and the Federal Anti-Kickback Statute and False Claims Act, and

B. sufficient staff and resources to conduct the reviews required by the CIA in a timely manner.

III. Responsibilities. The IRO shall:

A. perform each component of the Systems Review and Transactions Review in accordance with the requirements of the CIA and Appendix B,

B. follow all applicable Federal health care program rules and reimbursement guidelines and all applicable FDA requirements in making assessments in the Systems Review and Transaction Review,

C. request clarification from the applicable Federal health care program if in doubt regarding the application of a particular program policy or regulation,

D. respond to all OIG inquires in a prompt, objective, and factual manner,

E. prepare timely, clear, well-written reports that include all the information required by Appendix B, and

F. retain and make available to OIG, upon request, all Work Papers (as defined in Appendix B), supporting documents, correspondence, and draft reports exchanged between the IRO and Entity.

APPENDIX B

INDEPENDENT REVIEW ORGANIZATION REVIEWS

The IRO shall perform a Systems Review and a Transactions Review relating to the Covered Functions (as defined in Section II.C of the CIA). If there are no material changes in the applicable systems, processes, policies, and procedures of Entity relating to reviewed Policies and Procedures described below, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Entity materially changes applicable systems, processes, policies, and procedures, the IRO shall perform an additional Systems Review for the Reporting Period(s) that identifies the material changes and reviews the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

A. Systems Review. For the Systems Review, the IRO shall review systems, processes, policies, and procedures of Entity associated with the following (hereafter "Reviewed Policies and Procedures"):

1. Entity's systems, policies, and procedures applicable to the materials and information that may be distributed or made available by Entity sales representatives or other field personnel (including any contract sales force) about Government Reimbursed Products and the methods by which the materials and information are distributed or made available;

2. Entity's systems, policies, and procedures relating to the manner in which field personnel and personnel from Medical Information handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved uses of Government Reimbursed Products) and the dissemination of materials relating to the uses of these products. This review shall include: (a) the manner in which Entity field personnel handle requests for information about non-FDA approved uses of Government Reimbursed Products, (b) the manner in which Medical Information personnel, including those at Entity's headquarters, handle and respond to requests for information about non-FDA approved uses of Government Reimbursed Products; (c) the form and content of information and materials related to Government Reimbursed Products disseminated to HCPs, HCIs, payors, and formulary decision-makers by Entity; (d) the systems, processes, policies, and procedures to track requests to Medical Information for information about non-FDA approved uses of products and responses to those requests; (e) the manner in which Entity collects and supports information reported in any systems used to track and respond to requests to Medical Information for Government Reimbursed Product information; (f) the processes and procedures by which Medical Information or other appropriate individuals within Entity identify situations in which it appears that inappropriate or improper promotion may have occurred; and (g) Entity's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;

3. Entity's systems, policies, and procedures applicable to the manner and circumstances under which Entity's medical personnel (including those from Medical

Information) participate in meetings or events with HCPs, HCIs, or payors (either alone or with sales representatives) regarding Government Reimbursed Products, and the role of the medical personnel at such meetings or events;

4. Entity's systems, policies, and procedures applicable to the manner and circumstances under which Entity personnel interact with HCPs and HCIs (including members of pharmacy and therapeutics committees) regarding formularies, clinical practice guidelines, and protocol-related issues or provide information relevant to such issues;

5. Entity's systems, policies, and procedures applicable to the materials and information that may be distributed or made available by Entity through social media and/or direct-to-consumer advertising including the review and monitoring of such materials and information;

6. Entity's systems, policies, and procedures relating to the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other Entity field personnel who interact with HCPs and HCIs regarding Government Reimbursed Products;

7. Entity's systems, policies, and procedures relating to the development, implementation, and review of all plans for the distribution of samples (and/or coupons or vouchers for such samples) of Government Reimbursed Products (Sample Distribution Plans). This shall include a review of the bases upon, and circumstances under which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples, coupons or vouchers from Entity (including, separately, from sales representatives, from Medical Information, or through other channels);

8. Entity's systems, policies, and procedures applicable to any patient support programs including the review and approval of related written materials and the monitoring of patient support programs;

9. Entity's systems (including any centralized systems), policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;

10. Entity's systems, policies, and procedures relating to the engagement of non-speaker related consultants or other fee-for-service arrangements (including, but not limited to, presentations, advisory boards, preceptorships, mentorships, and ad hoc advisory activities, and any other financial engagement) that Entity entered with HCPs or HCIs and all events and expenses associated with such activities;

11. Entity's systems, policies, and procedures relating to any situation in which meals or other transfers of value are provided to HCPs or HCIs, including any systems for tracking and accurately reporting all such transfers of value in accordance with all applicable disclosure requirements (including the Open Payments Program);

12. Entity's systems, policies, and procedures applicable to programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;

13. Entity's systems, policies, and procedures relating to the sponsorship or funding of grants (including educational grants) or charitable contributions;

14. Entity's systems, policies, and procedures applicable to the funding of, or participation in, any Sponsorships or Third-Party Educational Activity as defined in Sections II.C.15 and II.C.16 of the CIA;

15. Entity's systems, policies, and procedures applicable to the review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside Entity by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel) in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Entity's review and approval process and are elevated when appropriate;

16. Entity's systems, policies, and procedures relating to compensation (including through salaries, bonuses, or other means) for Covered Persons engaged in Promotional Functions with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in or tolerate the improper promotion, sales, and marketing of Government Reimbursed Products. To the extent that Entity establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;

17. Entity's systems, policies, and procedures relating to the submission of information about any Government Reimbursed Product to any compendia such as Drugdex, any government payor, or any published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia"), including any initial submission of information and the submission of any additional, updated, supplemental, or changed information (including any changes based on Entity's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results);

18. Entity's systems, policies, and procedures applicable to sponsorship or other support of post-marketing clinical trials and all other post-marketing studies of Government Reimbursed Products and support of ISSs (collectively, "Research"), including the decision to provide financial or other support for such Research; the manner in which Research support is provided; the publication of information about the Research (including the publication of information about the Research results and trial outcomes); and uses made of publications relating to Research; and

19. Entity's systems, policies, and procedures relating to authorship of journal articles or other publications about Government Reimbursed Products or about therapeutic areas or

disease states that may be treated with Government Reimbursed Products, including, but not limited to, the disclosure of any and all financial relationships between the author and Entity or other potential conflicts of interest that might bias the author's work; the identification of all authors or contributors (including professional writers) associated with a given publication; and the scope and breadth of research results made available to each author or contributor.

B. Systems Review Report. The IRO shall prepare a Systems Review Report based on each Systems Review that includes the following information:

1. a description of the documentation (including policies) reviewed and any personnel interviewed;

2. a detailed description of systems, policies, processes, and procedures relating to the items identified in Section A above, including a general description of the control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Section A above are made known or disseminated within Entity;

4. a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products;

5. a detailed description of the incentive compensation system for Covered Persons who are field representatives and their direct managers, including a description of the bases upon which compensation is determined. To the extent that Entity may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;

6. findings and supporting rationale regarding any weaknesses in the systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures identified in Section A above, if any; and

7. recommendations to improve any of the systems, policies, processes, or procedures relating to any of the Reviewed Policies and Procedures identified in Section A above, if any.

C. Transactions Review. The Transactions Review shall include:

1. *Review of Call Plans and Call Plan Review Process*. The IRO shall conduct a review and assessment of Entity's review of its call plans for Government Reimbursed Products.

a. Entity shall provide the IRO with: (a) a list of Government Reimbursed Products promoted by Entity during the Reporting Period; (b) information about the FDA-approved uses for each such product; and (c) the call plans for each such product. Entity shall also provide the IRO with information

about the reviews of call plans that Entity conducted during the relevant Reporting Period (if any) and any modifications to the call plans made as a result of Entity's reviews.

b. For each call plan, the IRO shall select a sample of 20% of the HCPs and HCIs included on the call plan. For each call plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by Entity in conducting its review and/or modifying the call plan. The IRO shall seek to determine whether Entity followed its criteria and Policies and Procedures in reviewing and modifying the call plan.

c. The IRO shall note any instances in which it appears that the sampled HCPs or HCIs on a call plan are inconsistent with Entity's criteria relating to the call plan and/or Entity's Policies and Procedures. The IRO shall also note any instances in which it appears that Entity failed to follow its criteria or Policies and Procedures.

2. *Review of Consulting Activities*. For purposes of this Appendix B, the term "Consulting Activities" shall include all consulting and other fee-for-service arrangements entered with HCPs or HCIs. This shall include, but not be limited to, speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, research and development meetings, product training and education sessions, ad hoc advisory activities, research and any other financial engagements or arrangements with an HCP or HCI and all expenses relating to the engagements or arrangements.

a. For the first Reporting Period, the IRO shall select and review a sample of 20% of the Consulting Activities for which Entity retained HCPs or HCIs and all related expenses. For the second and subsequent Reporting Periods, at least 60 days prior to the end of the applicable Reporting Period, Entity shall provide the following information to OIG: (a) a description of each type of Consulting Activity undertaken during the Reporting Period and a description of the services to be provided under each Consulting Activity; (b) the number of each type of Consulting Activity undertaken during the Reporting Period; and (c) the overall budgeted amount spent in connection with each type of Consulting Activity during the Reporting Period. At least 30 days prior to the end of the applicable Reporting Periods, the OIG shall select the number of each type of Consulting Activity to be reviewed by the IRO during the second and subsequent Reporting Periods, up to a total sample size of 20%.

b. For each Consulting Activity reviewed the IRO shall determine whether:

i. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and related

expenses to be paid for the Consulting Activity, and the compliance obligations for the Consultant;

ii. the compensation paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure established by Entity based on an independent fair market value analysis;

iii. the Consulting Activity was identified in the annual Consultant budgeting plan developed by Entity;

iv. a needs assessment that identifies the business need for the Consulting Activity and provides details about the Consulting Activity was completed prior to the initiation of the Consulting Activity;

v. the Consulting Activity was reviewed and approved in accordance with Entity Policies and Procedures;

vi. Entity collected and retained a record of the specific activity performed by the HCP or HCI and, if applicable, a copy of the work product generated by the HCP or HCI in connection with the Consulting Activity; and

vii. the activity undertaken by the Consultant and/or the work product generated by the HCP or HCI was used by Entity in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity.

In addition, for each Consulting Activity selected for review, Entity shall provide the IRO with information about the total aggregate annual amount paid by Entity to the associated HCP or HCI for all purposes (including, e.g., payments in connection with Speaker Programs.) The IRO shall assess whether Entity paid the HCP or HCI an amount that exceeded the annual cap on compensation established in accordance with Entity's Policies and Procedures.

3. *Review of Additional Items*. For each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items").

a. No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify Entity of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Entity shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the

review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Entity's systems, policies, and procedures based on its review of each Additional Item).

b. Entity may propose to the OIG that its internal audit(s), reviews, or monitoring activities, be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Entity's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

c. In making its decision about whether to permit internal auditing to be substituted for an IRO review of Additional Items, the OIG agrees to consider, among other factors, the nature and scope of Entity's planned internal audit work or compliance monitoring, the results of the Transactions Review(s) during prior Reporting Periods, and Entity's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Entity's request to permit its internal audit work or compliance monitoring or audit activities to be substituted for a portion of the IRO's review of Additional Items for a Reporting Period, Entity shall engage the IRO to perform the review as outlined in this Section C.3.

d. If the OIG agrees to permit certain of Entity's internal audit work or compliance monitoring or audit activities for a given Reporting Period to be substituted for a portion of the Additional Items review, such internal audit work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO.

D. Transactions Review Report. The IRO shall prepare a Transactions Review Report for each Transactions Review that includes the following information:

1. *Transactions Review Methodology.*

a. Review Objective: A statement of the objective intended to be achieved by each part of the review;

b. Review Protocol: A detailed narrative description of how the Transactions Review was performed and what was evaluated; and

c. Sources of Data: A description of documentation and other information relied on by the IRO in performing the Transactions Review.

2. *Transactions Review Findings*.

a. Relating to the Call Plan Review

i. a list of the Government Reimbursed Products promoted by Entity during the Reporting Period and a summary of the FDA-approved uses for such products;

ii. for each Government Reimbursed Product which was promoted during the Reporting Period: (a) a description of the criteria used by Entity in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans; (b) a description of all instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are inconsistent with Entity's criteria relating to the call plan and/or Entity's Policies and Procedures; and (c) a description of all instances in which it appears that Entity failed to follow its criteria or Policies and Procedures relating to call plans;

iii. the findings and supporting rationale regarding any weaknesses in Entity's systems, policies, procedures, and practices relating to call plans, if any; and

iv. recommendations, if any, for changes in Entity's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to call plans.

b. Relating to the Review of Consulting Activities.

i. A description of each type of Consulting Activity reviewed, including the number of each type of Consulting Activity reviewed and an identification of the types of documents and information reviewed for each Consulting Activity;

ii. For each Consulting Activity, the aggregate annual amount paid by Entity to the associated HCP or HCI for all purposes;

iii. For each Consulting Activity reviewed, the IRO's findings and supporting rationale as to whether:

a. a written agreement was in place for each Consulting Activity that describes the scope of work to be performed, the fees and expenses to be paid for each Consulting Activity, and the compliance obligations for the Consultant;

b. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure set by Entity that was established based on an independent fair market value analysis;

c. the Consulting Activity was identified in the annual Consulting budgeting plan developed by Entity;

d. a needs assessment that identifies the business need for the Consulting Activity and provides detail about the activity that was prepared prior to the initiation of the Consulting Activity;

e. the Consulting Activity was reviewed and approved in accordance with Entity Policies and Procedures, including Policies and Procedures relating to the identification, selection and approval of a given HCP or HCI;

f. Entity collected and retained a record of the specific activity performed by the HCP or HCI and, if applicable, a copy of the work product generated in connection with the Consulting Activity;

g. the activity undertaken by the Consultant and/or the work product generated was used by Entity in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity;

h. the aggregate amount paid by Entity to the HCP or HCI exceeded the applicable cap established under Entity's Policies and Procedures;

iv. any weaknesses in Entity's systems, processes, policies, procedures and/or practices relating to Consulting Activities identified by the IRO; and

v. any recommendations for improvements to Entity's systems, processes, policies, procedures and/or practices relating to Consulting Activities.

c. Relating to the Review of Additional Items

i. for each Additional Item reviewed, a description of the review conducted;

ii. for each Additional Item reviewed, the IRO's findings based on its review;

iii. for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Entity's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and

iv. for each Additional Item reviewed, recommendations, if any, for changes in Entity's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

Review of the Distribution of Samples of Government Reimbursed Products.

The IRO shall conduct a review and assessment of the distribution of samples of Government Reimbursed Products to HCPs and HCIs.

1. *Provision of Materials to the IRO.* Entity shall provide the IRO with: (a) a list of Government Reimbursed Products for which Entity distributed samples during the Reporting Period; (b) information about the FDA-approved uses for each such product; and (c) information about Entity's Sample Distribution Plans.

2. *Selection of Sample*. For each Government Reimbursed Product for which Entity distributed samples during the Reporting Period, the IRO shall randomly select a sample of 20% of instances in which Entity provided samples of the product to HCPs or HCIs. Each such instance shall be known as a "Sampling Event."

3. *Materials to Be Reviewed*. For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP or HCI. The reviewed materials shall include materials about the following: (a) the quantity, dosage, and form of the Government Reimbursed Product samples provided to the HCP or HCI; (b) the identity and type of medical specialty or clinical practice of the HCP or HCI; (c) which individual Entity sales representatives or other Entity personnel provided the sample to the HCP

or HCI; and (d) the manner and mechanism through which the sample was requested (e.g., sample request form, letter, or call to Entity).

4. *Scope of Review for Sampling Events*. For each Sampling Event, the IRO shall:

a. evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the Government Reimbursed Product approved by the FDA;

b. evaluate whether the sample was distributed by an Entity representative in a manner consistent with the Sample Distribution Plan for the product(s) provided during the Sampling Event;

c. compare the medical specialty and type of clinical practice of the HCPs and HCIs that received the sample with uses of the Government Reimbursed Product approved by the FDA. The IRO shall note any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event were not consistent with the uses of the Government Reimbursed Product approved by the FDA. For each such situation, the IRO shall note the process followed by Entity in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination. The IRO shall also note any instances in which it appears that Entity failed to follow its Sample Distribution Plan for the Government Reimbursed Product(s) provided during the Sampling Event.

Relating to Sampling Event Review

i. for each Government Reimbursed Product distributed during the Reporting Period: (a) a description of Sample Distribution Plans (including whether sales representatives may provide samples for the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice a sales representative may provide samples); (b) a detailed description of any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event was not consistent with the uses of the Government Reimbursed Product approved by the FDA. This description shall include a description of the process followed by Entity in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and

(c) a detailed description of any instances in which it appears that Entity failed to follow its Sample Distribution Policies and Procedures for the Government Reimbursed Product(s) provided during the Sampling Event;

ii. the findings and supporting rationale regarding any weaknesses in Entity's systems, processes, policies, procedures, and practices relating to the distribution of samples of Government Reimbursed Products, if any; and

iii. recommendations, if any, for changes in Entity's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples.