

**CORPORATE INTEGRITY AGREEMENT AND  
CONDITIONAL EXCLUSION RELEASE  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE UNITED STATES  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
INSYS THERAPEUTICS, INC.**

**I. PREAMBLE**

Insys Therapeutics, Inc., and its agents and subsidiaries other than Insys Pharma, Inc. (collectively, “Insys”), hereby enters into this Corporate Integrity Agreement and Conditional Exclusion Release (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 with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements) and to ensure Insys’s cooperation with OIG. Contemporaneously with this CIA, Insys is entering into a Settlement Agreement and Deferred Prosecution Agreement (DPA) with the United States. Insys is also entering into settlement agreements with various states (State Settlement Agreements), and Insys’s agreement to this CIA is a condition precedent to those agreements.

**II. ADMISSION OF FACTS AND ACCEPTANCE OF RESPONSIBILITY,  
WAIVER OF STATUTE OF LIMITATIONS, TERM OF THE CIA,  
EXCLUSION LIABILITY, AND SCOPE OF THE CIA**

A. Admission of Facts and Acceptance of Responsibility. Insys admits, accepts, and acknowledges responsibility for the conduct set forth in the Statement of Facts, attached as Attachment A (Statement of Facts), which is incorporated into this CIA by reference. Insys further admits, accepts, and acknowledges that the conduct described in the Statement of Facts is true and accurate, and that the wrongdoing described in the Statement of Facts occurred.

Insys expressly acknowledges and stipulates that: (1) the conduct and facts set forth in the Statement of Facts provide a basis for a period of exclusion of Insys under the exclusion statute, 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) and constitute acts described in 42 U.S.C. § 1320a-7a; (2) in the event OIG initiates an exclusion under 42 U.S.C. § 1320a-7(b)(7) due to any

Material Breach, as defined below in Section X.D.1, of this CIA, Insys shall not deny or contest the veracity, accuracy, applicability, or admissibility of the Statement of Facts in any such proceeding; (3) in the event OIG initiates an exclusion under 42 U.S.C.

§ 1320a-7(b)(7) due to any Material Breach of this CIA, Insys shall not deny or contest that exclusion under 42 U.S.C. § 1320a-7(b)(7) is an appropriate remedy and supported by the Statement of Facts; and (4) the length of the exclusion shall be in OIG's discretion and Insys shall not contest the length of exclusion determined by OIG.

Insys further expressly acknowledges and stipulates that: (1) in any appeal of an OIG exclusion under 42 U.S.C. § 1320a-7(b)(7), the appeal shall be properly heard before an HHS Administrative Law Judge, and in the event of a subsequent appeal, the HHS Departmental Appeals Board, in a manner consistent with the provisions in 42 C.F.R. §§ 1001, 1005.2-1005.21; and (2) Insys waives any claims of improper venue with respect to any enforcement action brought by OIG relating to the allegations set forth in the Statement of Facts.

B. Waiver of Statute of Limitations. By entry into this CIA, OIG and Insys agree that, as consideration for OIG not filing or asserting claims in an administrative action against Insys under 42 U.S.C. § 1320a-7(b)(7) based on the admissions in the Statement of Facts and for the term of this CIA, Insys expressly waives the statute of limitations, laches, or any other time-related defenses for the conduct described in the Statement of Facts with respect to any administrative action(s) or claim(s) commenced by OIG under 42 U.S.C. § 1320a-7(b)(7) for any act that is described in 42 U.S.C. § 1320a-7a, except to the extent such defenses were available to Insys on or before the Effective Date, as defined below in Section II.C.

C. Term of the CIA. The period of the compliance obligations assumed by Insys under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period." However, any ongoing investigation or proceeding involving OIG related to the Statement of Facts shall require Insys's cooperation pursuant to Section III.Q until such investigation or proceeding is concluded.

Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Insys's final Annual Report; or (2) any additional materials submitted by Insys pursuant to OIG's request, whichever is later. However, with respect to any investigation or proceeding for which OIG has required Insys's cooperation pursuant to Section III.Q, then Sections II.A, B, C, and D; Section III.Q; Section VII; Section X; and Section XI shall not expire until the resolution of such investigation or proceeding, with the

exception that the expiration will not be delayed by post-trial criminal processes, such as sentencing or appeals.

D. Exclusion Liability. In consideration of the obligations of Insys in the Settlement Agreement and this CIA, and conditioned upon Insys's full payment of the Settlement Amount in the Settlement Agreement, OIG has agreed to permit Insys to enter into this CIA with OIG in lieu of OIG permissively excluding Insys under 42 U.S.C. § 1320a-7(b)(7) based on the admissions in the Statement of Facts. OIG reserves the right to exclude Insys under 42 U.S.C. § 1320a-7(b)(7) based on the admissions in the Statement of Facts in the event that OIG determines Insys is in Material Breach of this CIA. OIG expressly reserves all rights to comply with any statutory obligations to exclude Insys from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Statement of Facts.

Upon Insys's satisfaction of the obligations and requirements of this CIA as determined by OIG, OIG will provide a permissive exclusion release to Insys under 42 U.S.C. § 1320a-7(b)(7) for the Covered Conduct stated in Paragraph D of the Settlement Agreement with the United States.

E. Scope of the CIA. The scope of this CIA shall be governed by the following definitions:

1. For purposes of this CIA, the term "Covered Persons" includes: (a) all owners of Insys 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) and all officers, directors, and employees of Insys; and (b) all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions (as defined below in Section II.E.6) on behalf of Insys.

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

3. The term "Promotional Functions" includes: (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 Insys's review and approval processes for promotional materials and any applicable review committee(s).

4. The term “Product Related Functions” includes: (a) the preparation or external dissemination of non-promotional materials that are governed by Federal healthcare program and/or FDA requirements and distributed to health care professionals (HCPs), health care institutions (HCIs), and payers about Government Reimbursed Products, including those functions relating to any applicable review committees and those functions relating to medical affairs/medical information services or involved in scientific exchange; (b) contracting with HCPs licensed in the United States or with 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).

5. The term “Contribution and Assistance Related Functions” includes: all activities, systems, processes, and procedures relating to the following: (a) grants, charitable contributions , or donations (in cash or in kind) to any independent third-party patient assistance program (Independent Charity PAP) by Insys or any entity acting on behalf of Insys; and (b) the operation of, or participation in, any patient assistance program by Insys or any entity acting on behalf of Insys that provides free drugs to patients, including Federal health care program beneficiaries, or programs to provide financial assistance to patients in the form of cost-sharing assistance (i.e., co-pay coupons or co-pay cards) (programs described under Section II.E.5.b shall be collectively referred to as “Insys PAPs”).

6. The term “Covered Functions” refers to “Promotional Functions” “Product Related Functions” and “Contribution and Assistance Related Functions”, collectively.

7. The term “Third Party Educational Activity” shall mean any scientific, educational, or professional program, meeting, or event for HCPs conducted by a third party and supported by Insys, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

### **III. CORPORATE INTEGRITY OBLIGATIONS**

Insys shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee, Board of Directors, and Management Compliance Obligations

1. *Compliance Officer.* Within 90 days after the Effective Date, Insys shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer shall be an employee and a member of senior management of Insys; shall report directly to the Chief Executive Officer of Insys; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Insys. The Compliance Officer shall be responsible for, without limitation:

- a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of Insys (Board) and shall be authorized to report on such matters to the Board at any time. Written documentation of the Compliance Officer's reports to the Board shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by Insys as well as any reporting obligations created under this CIA.

Any noncompliance job responsibilities of the Compliance Officer shall be limited and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

Insys shall report to OIG, in writing, any changes in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Insys shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as sales, marketing, legal, medical affairs/medical information, regulatory affairs, research and development, human resources, audit, finance, manufacturing, and operations). The Compliance Officer shall chair the Compliance

Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Insys's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

Insys shall report to OIG, in writing, any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board Compliance Obligations.* The Board of Insys shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board must include independent (i.e., non-executive) members.

The Board shall, at a minimum, be responsible for the following:

- a. meeting at least quarterly to review and oversee Insys's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period;
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board, summarizing its review and oversight of Insys's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA; and
- d. for each Reporting Period of the CIA, the Board shall retain an independent individual or entity with expertise in compliance with Federal health care program and FDA requirements (Compliance Expert) to perform a review of the effectiveness of Insys's Compliance Program (Compliance Program Review) and to assess whether John N. Kapoor has

been involved, directly or indirectly, in the operation or management of Insys, or in any decision-making relating to the operation of Insys.

- i. Within 90 days after the Effective Date, Insys shall submit to OIG the following information regarding up to three individuals or entities who Insys would propose to engage as the Compliance Expert: (a) identity, address and phone number; (b) a copy of the proposed engagement letter; (c) information to demonstrate that the individual or entity has expertise in compliance with Federal health care program and FDA requirements; and (d) a certification that the individual or entity does not (i) currently represent and is not currently employed or engaged by Insys and (ii) have a current or prior relationship to Insys or John N. Kapoor that would cause a reasonable person to question the proposed Compliance Expert's objectivity in performing the Compliance Program Review.
- ii. Within 30 days of its receipt of the above-required information regarding the proposed Compliance Expert, OIG, in its sole discretion, shall select one of the proposed Compliance Experts or require Insys to propose to OIG up to three additional Compliance Experts. This process shall continue until OIG selects the Compliance Expert.
- iii. The Compliance Expert shall attend all Board meetings held pursuant to Section III.A.3.a above, and attend any report to the Board by the Compliance Officer or Compliance Committee. The Compliance Expert shall have access to all materials necessary to perform the Compliance Program Review and to assess whether John N. Kapoor has been involved, directly or indirectly, in the operation or management of Insys, or in any decision-making relating to the operation of Insys's CIA.
- iv. For each Reporting Period, the Compliance Expert shall create a work plan for the Compliance Program

Review and prepare a written report about the Compliance Program Review. The written report (Compliance Program Review Report) shall include a description of the Compliance Program Review and any recommendations with respect to Insys's compliance program and the Compliance Expert's assessment regarding whether John N. Kapoor has been involved, directly or indirectly, in the operation or management of Insys, or in any decision-making relating to the operation of Insys.

- v. The Board shall review the Compliance Program Review Report as part of its review and oversight of Insys's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each Annual Report submitted by Insys. In addition, 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.

At a minimum, the resolution shall include the following language:

“The Board has made a reasonable inquiry into the operations of Insys'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, Insys has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

If the Board is unable to provide such a conclusion in the resolution, the Board shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Insys.

Insys shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Insys employees (Certifying



Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Insys business unit is in compliance with applicable Federal health care program and FDA requirements and with the obligations of this CIA. These Certifying Employees shall include, at a minimum, the leaders of all business units/divisions that perform Covered Functions, including the following: Vice President (VP) – Corporate Development and Strategy; Senior VP – Research & Development & Regulatory; Executive Director of Commercial; VP, Clinical Development; Executive Director of Sales; and, to the extent that a business unit or division performs Covered Functions and is not covered by the certification of one of the above-listed individuals, other such executives, vice-presidents, and directors of business units or divisions as would be necessary to ensure that there is a Certifying Employee from each such business unit or division.

For each Reporting Period, each Certifying Employee shall sign a certification that states:

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of the department] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Insys policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] of Insys is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

If any Certifying Employee is unable to provide such a certification, the Certifying Employee shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above.

Within 120 days after the Effective Date, Insys shall develop and implement a written process for Certifying Employees to follow for the purpose of completing the certification required by this section (e.g., reports that must be reviewed, assessments that must be completed, sub-certifications that must be obtained, etc. prior to the Certifying Employee making the required certification).

5. *Additional Certification by Chief Executive Officer and Chair of the Board.* The Chief Executive Officer and the Chair of the Board annually shall each certify to the following:

*Insys Therapeutics, Inc.  
Corporate Integrity Agreement and Conditional Exclusion Release*

“I have taken steps and exercised due diligence to ensure that John N. Kapoor: (i) was not an employee, manager, executive, officer, or Board member of Insys, (ii) did not participate in the operation, management, decision-making, or oversight of Insys in such capacities, and (iii) other than in his capacity as an owner of Insys operating under an Independent Voting Trust Agreement, John N. Kapoor did not exert affirmative control of Insys and did not participate in an advisory, management, or decision-making role with Insys, during the Reporting Period. I understand that this certification is being provided to and relied upon by the United States.”

If the Chief Executive Officer or Chair of the Board is unable to provide such a certification the Chief Executive Officer or Chair of the Board (as applicable) shall provide a written explanation of the reasons why he/she is unable to provide the certification outlined above.

B. Written Standards

Within 120 days after the Effective Date, Insys shall develop and implement written policies and procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Insys’s compliance with Federal health care program and FDA requirements (Policies and Procedures). Throughout the term of this CIA, Insys shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all employees. The Policies and Procedures shall be made available to all Covered Persons. At a minimum, the Policies and Procedures shall address the following:

- a. appropriate ways to conduct Promotional Functions in compliance with all: (i) applicable Federal healthcare program requirements, including, but not limited to the Federal 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;
- b. appropriate ways to conduct Product Related Functions in compliance with: (i) all applicable Federal healthcare program requirements, including, but not limited to the Federal 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;

- c. appropriate ways to conduct Contribution and Assistance Related Functions in compliance with all applicable Federal health care program requirements, including but not limited to, the Federal 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);
- d. the materials and information that may be distributed by Insys sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which Insys sales representatives respond to requests for information about non-FDA approved (or “off-label”) uses of Government Reimbursed Products;
- e. the materials and information that may be distributed by Medical Affairs and the mechanisms through, and manner in which, Medical Affairs receives and responds to requests for information from an HCP or another individual or entity about off-label uses of Government Reimbursed Products; the form and content of information disseminated by Insys in response to such requests; and the internal review process for the information disseminated;
- f. the manner and circumstances under which medical personnel interact with or participate in meetings or events with HCPs, HCIs, or payers (either alone or with Insys 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 off-label uses of Government Reimbursed Products;
- g. the manner and circumstances under which Insys employees may interact with payers (including insurance companies and their agents). These Policies and Procedures shall preclude Insys employees from interacting with insurance companies and their agents in connection with any prior authorization activities, except insofar as those activities relate to formulary placement;

- h. the materials and information that may be distributed or made available by Insys through social media and/or direct-to-consumer advertising;
- i. the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other Insys representatives who promote and sell Government Reimbursed Products;
- j. 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 Insys (including, separately, from sales representatives, from Medical Information, or through other channels);
- k. arrangements with HCPs to participate in speaker programs and related activities (including speaker training programs). The Policies and Procedures shall specify that Insys may not provide direct or indirect remuneration to any HCP who is not an employee of Insys and who serves as a speaker for Insys;
- l. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to arrangements for the following types of activities: 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;
- m. 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;
- n. sponsorship or funding of grants (including educational grants) or charitable contributions;

- o. funding of, or participation in, any Third Party Educational Activity as defined in Section II.E.7 above;
- p. review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside Insys 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 Insys's review and approval process and are elevated when appropriate;
- q. arrangements and interactions with (including donations to and sponsorship of) Independent Charity PAPs. These Policies and Procedures shall be designed to ensure that Insys's arrangements and interactions comply with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that Insys's arrangements and interactions (including donations and sponsorship) comply with all guidance issued by OIG relating to the support and funding of patient assistance programs, including but not limited to, the OIG's Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005) and OIG's Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014);
- r. the operation of, or participation in, any Insys PAP. These Policies and Procedures shall be designed to ensure that Insys's operation of or in participation in such programs complies with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that Insys's operation of or participation in any such Insys PAP complies with all guidance issued by OIG relating to assistance provided to patients by pharmaceutical manufacturers to reduce or eliminate the cost of copayments for drugs, including but not limited to, the OIG's Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014);

- s. the materials and information that may be distributed by appropriate Insys personnel about Independent Charity PAPs or Contribution and Assistance Related Functions and the manner in, and circumstances under, which appropriate Insys personnel may respond to requests for information about Independent Charity PAPs or Contribution and Assistance Related Functions;
- t. compensation (including through salaries, bonuses, or other means) for Covered Persons engaged in Promotional Functions;
- u. the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter “Compendia”). This includes any initial submission of information to any Compendia and the submission of any additional, updated, supplemental, or changed information (including any changes based on Insys’s discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results);
- v. 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;
- w. 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 Insys 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; and

- x. disciplinary policies and procedures for violations of Insys's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

At least annually (and more frequently, if appropriate), Insys shall assess and update, as necessary, the Policies and Procedures. Any new or revised Policies and Procedures shall be made available to all Covered Persons.

All Policies and Procedures shall be made available to OIG upon request.

C. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, Insys shall develop a written plan (Training Plan) that outlines the steps Insys will take to ensure that: (a) all Covered Persons receive at least annual training regarding Insys's CIA requirements and compliance program, and (b) all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions and (ii) all Insys Policies and Procedures and other requirements applicable to Covered Functions. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons and required to attend each training session, length of the training session(s), schedule for training, and format of the training. Insys shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period. This training may be conducted by an outside compliance expert.

2. *Board Member Training.* Within 90 days after the Effective Date, each member of the Board shall receive at least two hours of training. This training shall address the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of OIG's guidance on Board member responsibilities.

New members of the Board shall receive the Board Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

3. *Training Records.* Insys shall make available to OIG, upon request, training materials and records verifying that Covered Persons and Board members have timely received the training required under this section.

D. Risk Assessment and Internal Review Process

Within 120 days after the Effective Date, Insys shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each Government Reimbursed Product, including risks associated with the sales, marketing, and promotion of such products and risks associated with Insys's operation of any Insys PAP and the company's arrangements and interactions with any Independent Charity PAPs. The risk assessment and internal review process shall require compliance, legal, and department leaders, at least annually, to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Insys shall maintain the risk assessment and internal review process for the term of the CIA.

E. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Insys shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and Insys shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Insys) related to the reviews.



- c. *Access to Records and Personnel.* Insys shall ensure the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E., and that all records furnished to the IRO are accurate and complete.

2. *Systems, Transactions, and Additional Items Reviews.* As set forth more fully in Appendix B, the IRO reviews shall consist of three components: Systems Reviews and Transactions Reviews relating to the Covered Functions and an Additional Items Review.

- a. *Systems Review.* The Systems Reviews shall assess Insys's systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in Insys's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the first and fourth Reporting Periods. If Insys materially changes its relevant systems, processes, policies, and procedures, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods, as set forth more fully in Appendix B.
- b. *Transactions Review.* The Transactions Reviews shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components.
- c. *Additional Items Review.* Each IRO review shall also include a review of up to three additional areas or practices of Insys identified by OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the IRO review for a particular Reporting Period, OIG will consult with Insys and may consider internal audit and monitoring work conducted by Insys, the Government Reimbursed Product portfolio, the nature and scope of Insys's promotional practices and arrangements with HCPs and HCIs, and other information known to it.

3. *IRO Review Reports.* The IRO shall prepare a report based upon each IRO review performed (IRO Review Report). Information to be included in the IRO Review Report is described in Appendices A-B.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Insys a certification that the IRO has: (a) evaluated its professional independence and objectivity with respect to the reviews required under this Section III.E; and (b) concluded that it is, in fact, independent and objective in accordance with the requirements specified in Appendix A to this CIA. The IRO's certification shall include a summary of current and prior engagements between Insys and IRO.

F. Disclosure Program

Within 90 days after the Effective Date, Insys shall establish a Disclosure Program that includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Insys's policies, conduct, practices, or procedures with respect to a Federal health care program or an FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Insys shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of Insys's Covered Persons shall be expected to report suspected violations of any Federal health care program or FDA requirements to the Compliance Officer or other appropriate individual designated by Insys. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Insys shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the

disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons

1. *Definitions.* For purposes of this CIA:

- a. an “Ineligible Person” shall include an individual or entity who:
  - i. is currently excluded from participation in the Federal health care programs; or
  - ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.
- b. “Exclusion List” means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at <http://www.oig.hhs.gov>).

2. *Screening Requirements.* Insys shall ensure that all prospective and current Covered Persons are not Ineligible Persons by implementing the following screening requirements.

- a. Insys shall screen all prospective Covered Persons against the Exclusion List prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.
- b. Insys shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on a quarterly basis thereafter.
- c. Insys shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects Insys’s responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by an excluded person. Insys understands that items or services furnished,

ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Insys may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Insys meets the requirements of Section III.G.

3. *Removal Requirement.* If Insys has actual notice that a Covered Person has become an Ineligible Person, Insys shall remove such Covered Person from responsibility for, or involvement with, Insys's business operations related to the Federal health care program(s) from which such Covered Person has been excluded and shall remove such Covered Person from any position for which the Covered Person's compensation is paid 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).

4. *Pending Charges and Proposed Exclusions.* If Insys has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term, Insys shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, or the accuracy of any claims submitted to any Federal health care program.

#### H. Incentive Compensation Restriction and Financial Recoupment Programs

1. *Employee and Executive Incentive Compensation Restriction Program.* Insys agrees to develop and maintain throughout the term of the CIA policies and procedures that shall: (1) be designed to ensure that financial incentives do not improperly motivate sales representatives or their direct managers to engage in improper promotion, sales and marketing of Insys's products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation any sales that may indicate off-label promotion of Insys's products (Employee and Executive Incentive Compensation Program). The specific terms and conditions of the Employee and Executive Incentive Compensation Program are described in Appendix C to this CIA.

2. *Financial Recoupment Program.* Insys agrees to establish and maintain throughout the term of this CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay for any employee, including any executive, who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program, as identified in Appendix C to this CIA). The specific terms and conditions of the Executive Financial Recoupment Program are described in Appendix C to this CIA.

I. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, Insys shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Insys conducted or brought by a governmental entity or its agents involving an allegation that Insys has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Insys also shall provide written notice to OIG within 30 days after the resolution of the matter and describe the findings and/or results of the investigation or proceeding, if any.

J. Reportable Events

1. *Definition of Reportable Event.* For purposes of this CIA, a “Reportable Event” means anything that involves:

- 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 penalties or exclusion may be authorized;
- b. a matter that a reasonable person would consider a probable violation of FDA requirements relating to the promotion of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.K below;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by Insys.

A Reportable Event may be the result of an isolated event or a series of occurrences.

2. *Reporting of Reportable Events.* If Insys determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Insys shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. Insys shall not be required to report as a Reportable Event a matter that is the subject of an ongoing investigation or legal proceeding by a government entity or its agents if disclosed under Section III.I above.

3. *Reportable Events under Sections III.J.1.a and III.J.1.b.* For Reportable Events under Sections III.J.1.a and b, the report to OIG shall include:

- a. a complete description of all details relevant to the Reportable Event, including, at a minimum, the types of claims, transactions or other conduct giving rise to the Reportable Event, the period during which the conduct occurred, and 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, if any;
- c. the Federal health care programs affected by the Reportable Event, if any;
- d. a statement of the FDA requirements probably violated by the Reportable Event, if any; and
- e. a description of Insys's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.J.1.c.* For Reportable Events under Section III.J.1.c, the report to OIG shall include:

- a. the identity of the Ineligible Person and the job duties performed by that individual;
- b. the dates of the Ineligible Person's employment or contractual relationship;
- c. a description of the Exclusion List screening that Insys completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and

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

5. *Reportable Events under Section III.J.1.d.* For Reportable Events under Section III.J.1.d, the report to OIG shall include documentation of the bankruptcy filing and a description of any Federal health care program and/or FDA requirements implicated.

K. Notification of Communications with FDA

Within 30 days after the date of any written report, correspondence, or communication between Insys and the FDA that materially discusses Insys's or a Covered Person's actual or potential unlawful or improper promotion of Insys's products (including any improper dissemination of information about non-approved uses), Insys shall provide a copy of the report, correspondence, or communication to OIG. Insys shall also provide written notice to OIG within 30 days after the resolution of any such disclosed improper promotional matter, and shall provide OIG with a description of the findings and/or results of the matter, if any.

L. Field Force Monitoring and Review Efforts

Within 120 days after the Effective Date, Insys shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential promotion of products for non-approved uses or other improper conduct. As described in more detail below, the FFMP shall include: (1) a Speaker Monitoring Program; (2) direct field observations (Observations) of sales personnel; and (3) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.*

- a. Insys shall implement a process to require all speakers to complete training concerning compliance obligations for the speakers (including requirements regarding the use of Insys approved materials and requirements that speakers may not directly or indirectly promote the product for off-label uses). These requirements must be specified in a written agreement between Insys and the speaker for any speakers who are not employed by Insys.

- b. Insys shall establish 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.
- c. Insys shall maintain a comprehensive list of speaker program attendees through its centralized system.
- d. Insys shall require certifications by sales representatives or other Insys personnel that a speaker program complied with Insys requirements, or in the event of non-compliance, Insys shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.
- e. Insys shall institute a Speaker Monitoring Program under which Insys compliance or other appropriately trained Insys personnel or non-employee personnel who are independent from the functional area being monitored (Monitoring Personnel) shall attend ten speaker programs during each Reporting Period and conduct live audits of the programs (Speaker Program Audits). The programs subject to Speaker Program Audits shall be selected using either a risk-based targeting approach or a random sampling approach. For each 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 Insys sales representative activities during the program to assess whether the programs were conducted in a manner consistent with Insys's Policies and Procedures.

Insys shall maintain the controls around speaker programs as described above and shall conduct its Speaker Program Audits as described above throughout the term of the CIA.

2. *Observations.* As a component of the FFMP, Monitoring Personnel shall conduct observations of field sales representatives (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 Insys's Policies and Procedures. These observations shall be full day ride-alongs with field sales representatives (Observations), and each Observation shall consist of directly observing



all meetings between a sales representative and HCPs and HCIs during the workday. The Observations shall be scheduled throughout the year, judgmentally selected by Monitoring Personnel, include a review of each therapeutic area and actively promoted Government Reimbursed Product, and be conducted across the United States.

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Monitoring Personnel who conducted the Observation;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Insys Policies and Procedures; and
- 6) the identification of any potential off-label promotional activity or other improper conduct by the field sales representative.

Monitoring Personnel shall conduct at least five 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.

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

- a. For each Reporting Period, Insys shall develop and implement a plan for conducting Records Reviews associated with at least two Government Reimbursed Products. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate district and/or region (as applicable) who promoted the Government Reimbursed Products under review.
- b. The Records Reviews shall include the monitoring and review of:
  - (i) records and systems associated with field sales representatives' interactions with HCPs and HCIs (including records relating to speaker program

- activities, samples, travel and entertainment, 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 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 sales representative call notes;
  - (v) field sales representatives' e-mails and other electronic records; and
  - (vi) recorded results of the Observations of field sales force representatives, coaching guides, and district manager notes.

4. *Reporting and Follow-up.* Results from the FFMP shall be compiled and reported to the Compliance Officer for review and remediation as appropriate. Potential violations related to improper promotion of a Government Reimbursed Product or potential violations of Federal health care program or FDA requirements shall be reported to the Compliance Officer for appropriate follow-up activity. In the event that a compliance issue, including but not limited to any potential improper promotion or noncompliance with Insys's Policies and Procedures or legal or compliance requirements, is identified during any portion of the FFMP, Insys shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the investigative procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken, including the disclosure of Reportable Events pursuant to Section III.J above, as applicable. Any compliance issues identified during the FFMP and any corrective action shall be recorded in the files of the Compliance Officer.

M. Monitoring of Non-Promotional Activities

Within 120 days after the Effective Date, Insys shall develop and implement a monitoring program for the following types of activities: (1) consultant arrangement activities; (2) Research-related activities; (3) publication activities; and (4) medical

education grants. This program shall be referred to as the Non-Promotional Monitoring Program (NPMP).

1. *Consulting Arrangement Activities.* To the extent that Insys 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.

- a. Insys shall require all Consultants to enter written agreements describing the scope of work to be performed, the consultant fees to be paid, and compliance obligations for the Consultants. Consultants shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Insys.
- b. Within 120 days after the Effective Date, Insys shall establish a process to develop an annual budgeting plan that identifies the business needs for, and the estimated numbers of, the various Consultant engagements and activities to occur during the following year. The annual Consultant budgeting plan shall also identify the budgeted amounts to be spent on Consultant-related activities. Insys compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure 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 Insys Policies and Procedures.
- c. Within 120 days after the Effective Date, Insys shall 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 Insys compliance personnel.

- d. Within 120 days after the Effective Date, Insys shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, Insys received the work product generated by the Consultant.
- e. Within 120 days after the Effective Date, Insys shall establish a Consultant Monitoring Program through which it shall conduct audits (Consultant Program Audits) of at least 15 consultant programs with HCPs 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 Insys's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of Insys 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.* To the extent that Insys engages or supports U.S.-based HCPs or HCIs to conduct Research (as defined above in Section III.B.v), such HCPs and HCIs shall be referred to collectively as "Researchers."

- a. Insys shall 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 obligations for the Researchers.
- b. Researchers retained to conduct Research shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Insys.

- c. Within 120 days after the Effective Date, Insys shall establish a process to develop an annual budgeting plan for Researchers that identifies 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. The annual Researcher budgeting plan shall also identify the budgeted amounts to be spent on Researcher-related activities during the year. Insys compliance personnel shall be involved in the review and approval of such budgeting plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Research arrangements and related events are used for legitimate purposes in accordance with Insys Policies and Procedures and with Federal health care program and FDA requirements.
- d. Within 120 days after the Effective Date, Insys shall 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 Insys compliance personnel.
- e. Within 120 days after the Effective Date, Insys shall amend its policies and procedures in a manner designed to ensure that each Researcher performed the work for which the Researcher was engaged.
- f. Within 120 days after the Effective Date, Insys shall establish a Researcher Monitoring Program through which it shall conduct audits for each Reporting Period (Researcher Program Audits). Insys shall review five 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 Program Audits 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 Insys and performed by the Researchers in a manner consistent with Insys's Policies and Procedures. Results from the Researcher Program Audits, 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.* To the extent that Insys 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.

- a. Insys shall 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 obligations of the Authors. Authors shall be paid according to a centrally managed, pre-set rate structure that is determined based on a fair-market value analysis conducted by Insys.
- b. Within 120 days after the Effective Date, Insys shall establish a process to develop annual plans that identify the business needs for and the estimated number of various Publication Activities (Publication Plans). The annual Publication Plan shall also identify the budgeted amounts to be spent on Publication Activities. Insys's compliance personnel shall be involved in the review and approval of such annual Publication Plans, including any modification of an approved plan. The purpose of this review shall be to ensure that Publication Activities and related events are used for legitimate purposes in accordance with Insys Policies and

Procedures and with Federal health care program and FDA requirements.

- c. Within 120 days after the Effective Date, Insys shall 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 Insys compliance personnel.
- d. Within 120 days after the Effective Date, Insys shall establish a Publication Monitoring Program through which it shall conduct audits for each Reporting Period of Publication Activities associated with at least two manuscripts and two abstracts/posters. The Publication Monitoring Program shall select publications for review both on 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 Insys's Policies and Procedures. Results from the Publication 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.

4. *Grant Activities.*

- a. Within 120 days after the Effective Date, Insys shall establish a grants management system which shall be the exclusive mechanism through which requestors may request or be awarded grants for independent medical education grants,

other grant activities, and non-patient assistance program charitable contributions supported by Insys.

- b. Grant and charitable contribution requests shall be processed in accordance with standardized, objective criteria developed by Insys (such as based upon the qualifications of the requestor, or the quality of the program funded by the grant.) In addition, the grants or charitable contributions shall be provided only pursuant to a written agreement with the funding recipient, and if payments to the funding recipient are consistent with the written agreement. Insys's sales and marketing personnel shall have no involvement in, or influence over, the review and approval of medical education grants or charitable contribution requests.
- c. Within 120 days after the Effective Date, Insys shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least five medical education grants. The Grants Monitoring Program shall select grants for review both on either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the grant management system's review of the requests, and documents and materials relating to the grants and any events or activities funded through the grants to assess whether the activities were conducted in a manner consistent with Insys's Policies and Procedures. Results from the Grants 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.

Insys shall continue the grant and charitable contribution process described above (or an equivalent process) throughout the term of the CIA and shall notify OIG in writing at least 60 days prior to the implementation of any new system after the Effective Date.

5. *Follow Up Reviews and Reporting.* In the event that a potential violation of Insys's Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, are identified during any



aspect of the NPMP, Insys shall investigate the incident consistent with established policies and procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.J above, if applicable.

N. Independent Charity Patient Assistance Program Activities

To the extent that Insys makes monetary donations to Independent Charity PAPs, it shall implement the policies, procedures, and practices set forth in this Section III.N within 120 days after the Effective Date or prior to making any donation to any Independent Charity PAP, whichever is later. Insys shall continue the Independent Charity PAP policies, procedures, and practices described below (or equivalent processes) throughout the term of the CIA, and shall notify OIG in writing at least 60 days prior to the implementation of any modifications to such policies, procedures, and practices.

1. *Independent Charity Group.* Insys shall vest sole responsibility and authority for budgeting and all other activities relating to Independent Charity PAPs in a department or group within Insys known as the “Independent Charity Group” that has the following roles and responsibilities:

- a. The Independent Charity Group shall be separate and independent from Insys’s commercial organization.
- b. The Independent Charity Group shall operate independently from Insys’s commercial organization and Insys’s commercial organization shall have no involvement in, or influence over, the review, approval, or implementation of any budget or other decisions or activities relating to Independent Charity PAPs.
- c. Insys shall vest in the Independent Charity Group sole responsibility and authority for communicating with Independent Charity PAPs regarding Insys’s donations to such PAPs and Insys’s commercial organization shall not communicate with, influence, or be involved in any communications with, or receive information from the Independent Charity PAPs.

- d. Insys's Independent Charity Group shall gather information about Independent Charity PAPs and their disease funds in a manner that does not exert or attempt to exert any direct or indirect control over the entity operating the PAP or over its assistance program.
- e. For purposes of this CIA, the "commercial organization" shall be defined to include the sales, marketing, and similar commercial business units of Insys.

2. *Budgeting Process.* Insys's Independent Charity Group shall establish a budget process to be followed for Insys's donations to Independent Charity PAPs that meets the following requirements:

- a. The Independent Charity Group shall develop an annual budget for donations to Independent Charity PAPs based on objective criteria in accordance with general guidelines approved by the legal department with input from the compliance department.
- b. Insys shall approve the annual budget for donations to Independent Charity PAPs at a level within the organization above the commercial organization (e.g., at the executive level).
- c. The Independent Charity Group shall have sole responsibility for allocating the approved budget across donations to Independent Charity PAPs and to any disease state fund established by the Independent Charity PAP.
- d. The Independent Charity Group shall have sole responsibility for assessing requests for additional or supplemental funding from Independent Charity PAPs outside of the annual budget using standardized, objective criteria established by the Independent Charity Group. Any such requests also shall be subject to legal and compliance personnel review and approval, to ensure that any supplemental funding to the Independent Charity PAP is provided in accordance with applicable Federal health care program requirements, OIG guidance, and Insys Policies and Procedures.

- e. The commercial organization shall have no involvement in the budget process, and the budget to be used for donations to Independent Charity PAPs shall not be based on monies allocated to the Independent Charity Group from the commercial organization.

3. *Criteria Relating to Donations to Independent Charity PAPs.* The Independent Charity Group (with input from the legal department and compliance departments) shall establish standardized, objective written criteria that govern donations to Independent Charity PAPs and any specific disease state funds of such PAPs, designed to ensure that the Independent Charity PAP does not function as a conduit for payments or other benefits from Insys to patients and does not impermissibly influence patients' drug choices. In addition, Insys agrees that it will donate to an Independent Charity PAP only if the following criteria are satisfied:

- a. Insys does not and shall not exert (directly or through any affiliate) any influence or control over the identification, delineation, establishment, or modification of any specific disease funds operated by the Independent Charity PAP. Among other things, Insys has not made and shall not make (directly or through any affiliate) suggestions or requests to the Independent Charity PAP about the identification, delineation, establishment, or modification of disease state funds.
- b. Insys does not and shall not exert (directly or through any affiliate) any direct or indirect influence or control over the Independent Charity PAP's process or criteria for determining eligibility of patients who qualify for its assistance program.
- c. Insys does not and shall not solicit or receive (directly or indirectly through third parties) any data or information from the Independent Charity PAP that would enable it to correlate the amount or frequency of its donations with support for Insys's products or services.
- d. Insys does not and shall not provide donations for a disease state fund that covers only a single product or that covers only Insys's products.

- e. Personnel from Insys's legal and compliance departments shall review all proposed donations and arrangements between Insys and any Independent Charity PAP prior to such donations being made or arrangements being entered into by Insys.

O. Notice to Health Care Providers and Entities

Within 30 days after the Effective Date, Insys shall post in a prominent place on the main page of the health care professional section of its company website (or other placement agreed to in advance by OIG), a copy of a letter signed by Insys's Chief Executive Officer containing the language set forth below:

As you may be aware, Insys recently entered into a civil, criminal, and administrative settlement with the United States and individual states in connection with Insys's promotion of Subsys. This letter provides you with additional information about the global settlement, explains Insys's commitments going forward, and provides you with access to information about those commitments.

The Government alleges that Insys engaged in several types of unlawful and improper conduct relating to the promotion of Subsys. To address criminal liability, Insys agreed to enter a Deferred Prosecution Agreement and pay \$30 million in criminal fines and forfeiture. A subsidiary of Insys agreed to plead guilty to criminal charges. In addition, to resolve liability under the Federal False Claims Act (including the alleged payment of kickbacks), Insys agreed to enter a civil settlement and pay \$195 million. More information about the criminal and civil resolutions may be found at the following: **[Insys shall include a link to the USAO, OCL, and Insys websites in the letter.]**

As part of the global settlement, Insys also entered into a corporate integrity agreement and conditional exclusion release with the Office of Inspector General of the U.S. Department of Health and Human Services. That agreement is available at <http://oig.hhs.gov/fraud/CIA/index.html>. Under the agreement, Insys agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by Insys's representatives to Insys's Compliance organization or the FDA using the information set out below.

Please call Insys at [insert toll free number] or visit us at [insert web link] if you have questions about the settlement referenced above. Please call Insys at [insert toll free number] or visit us at [insert web address] to report any instances in which you believe that an Insys representative inappropriately promoted a product or engaged in other questionable conduct.

Alternatively, you may report any improper conduct associated with prescription drug marketing committed by an Insys Representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about Insys products to [insert toll free number].

The notice shall remain posted for a period of at least 180 days. The Compliance Officer (or a designee) shall maintain a log of all calls and messages received in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The log of all calls and messages received in response to the notice shall be made available to OIG upon request.

P. Reporting of Physician Payments

1. *Reporting of Payment Information.* Within 90 days after the Effective Date, Insys 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 Data website ([www.openpaymentsdata.cms.gov](http://www.openpaymentsdata.cms.gov)). Insys 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 Insys.

2. *Definitions.* For purposes of this Section III.P, the terms "Payments" and "Covered Recipient" are defined as specified in 42 U.S.C. § 1320a-7h and the related regulations and guidance (including FAQs) published by CMS.

Q. Cooperation with OIG

Insys shall cooperate fully and truthfully with OIG in any and all matters as directed by OIG. Insys agrees and understands that full and truthful cooperation includes, but is not limited to: (1) prompt and truthful disclosure to OIG of all matters relating to any Federal or state health care law investigation, prosecution, or other enforcement action, related to the conduct of the nature described in the Statement of Facts, including violations of the Federal health care program requirements or state health care law by medical practitioners and prescribers; and (2) truthful testimony in any administrative hearing and/or judicial proceeding. Insys also agrees to fully and

truthfully cooperate in U.S. v. Babich, *et al.*, Case No. 1:16-cr-10343, in the U.S. District Court for the District of Massachusetts. Insys, upon reasonable notice, shall make reasonable efforts to facilitate access to, and encourage the cooperation of, its officers, directors, owners, managers, members, and employees for interviews and testimony, and will furnish to OIG, upon reasonable request, all non-privileged documents and records in its possession, custody, or control relating to any investigation of the Statement of Facts that it has undertaken, or that has been performed by another on its behalf.

#### **IV. SUCCESSOR LIABILITY**

In the event that, after the Effective Date, Insys proposes to (a) 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 are subject to this CIA; or (b) purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any such new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. Insys shall give notice of such sale or purchase to OIG within 30 days following the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, Insys wishes to obtain a determination by OIG that the proposed purchaser or the proposed acquisition will not be subject to the requirements of the CIA, Insys must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief 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 AND ANNUAL REPORTS**

##### **A. Implementation Report**

Within 120 days after the Effective Date, Insys shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

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 obligations described in Section III.A.3;
4. the names and positions of the Certifying Employees required by Section III.A.4 and a description of the process to be followed in connection with the certifications required under that Section;
5. a list of the Policies and Procedures required by Section III.B;
6. the Training Plan required by Section III.C.1 and a description of the Board training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);
7. a description of the risk assessment and internal review process required by Section III.D;
8. 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 to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Insys;
9. a description of the Disclosure Program required by Section III.F;
10. a description of the Ineligible Persons screening and removal process required by Section III.G;
11. a description of the Independent Charity PAP policies, procedures, and practices required by Section III.N;
12. a certification by the Compliance Officer that the notice required by Section III.O was posted in the manner required by Section III.O and a summary of the calls or messages received in response to the notice;
13. a certification from the Compliance Officer that information regarding Payments has been posted on Insys's website as required by Section III.P;

14. a list of all of Insys's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; and the locations' Medicare and state Medicaid provider number and/or supplier number(s) if any;

15. a description of Insys's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business; and

16. the certifications required by Section V.C.

B. Annual Reports

Insys shall submit a written report to OIG on its compliance with the CIA requirements for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum, the following information:

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board compliance obligations; and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, and Certifying Employees or any changes to the process to be followed in connection with the certifications required by Section III.A.4;

2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);

3. the Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the Board, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;

4. a copy of the Compliance Program Review Report required by Section III.A.3;

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



6. a description of any changes to Insys's Training Plan developed pursuant to Section III.C and a summary of any Board of Directors training provided during the Reporting Period;
7. a description of any changes to the risk assessment and internal review process required by Section III.D, including the reasons for such changes;
8. a summary of the following components of the risk assessment and internal review process during the Reporting Period: (a) work plans developed; (b) internal audits performed; (c) corrective action plans developed in response to internal audits; and (d) steps taken to track the implementation of the corrective action plans. Copies of any work plans, internal audit reports, and corrective action plans shall be made available to OIG upon request;
9. a complete copy of all reports prepared pursuant to Section III.E and Insys's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;
10. a certification from the IRO regarding its professional independence and objectivity with respect to Insys;
11. 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 (if applicable). The complete disclosure log shall be made available to OIG upon request;
12. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;
13. a description of the Incentive Compensation Restriction and Financial Recoupment Programs required by Section III.H;
14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
15. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period;

16. a summary describing any written communication with the FDA required to have been reported pursuant to Section III.K. This summary shall include a description of each matter and the status of each matter;

17. a summary of the FFMP and 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 occurred and a description of the action (s) that Insys took as a result of such determinations;

18. a summary of the NPMP and the results of the program described in Section III.M, including detailed description of any identified instances in which it was determined that the activities violated Insys's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) Insys took as a result of such determinations;

19. a description of any changes to the Independent Charity PAP policies, procedures, and practices outlined in Section III.N including the reasons for such changes;

20. a summary of the calls and messages received in response to the notice required by Section III.O and the disposition of those calls and messages;

21. a certification from the Compliance Officer that information regarding Payments has been posted on Insys's website as required by Section III.P;

22. a description of all changes to the most recently provided list of Insys's locations (including addresses) as required by Section V.A.14;

23. a description of any changes to Insys's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and

24. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications

1. *Certifying Employees.* In each Annual Report, Insys shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Compliance Officer and Chief Executive Officer.* The Implementation Report and each Annual Report shall include a certification 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, Insys has implemented and is in compliance with all 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;
- c. he or she understands that the certification is being provided to and relied upon by the United States;
- d. for each disease fund of an Independent Charity PAP to which Insys made a donation during the Reporting Period, the facts and circumstances relating to the donation were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and Insys policies and procedures (including those outlined in Section III.N); and
- e. for each patient assistance program that Insys or any entity acting on behalf of Insys operates or participates in (e.g., through cash or in-kind donations), the facts and circumstances relating to the program were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and Insys policies and procedures.

3. *Chief Executive Officer and Board Chair.* In each Annual Report, Insys shall include the certifications by the Chief Executive Officer and Chair of the Board required by Section III.A.5.

D. Designation of Information

Insys 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. Insys shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

**VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

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  
Cohen Building, Room 5527  
330 Independence Avenue, S.W.  
Washington, DC 20201  
Telephone: 202.619.2078  
Facsimile: 202.205.0604

Insys:

Insys Therapeutics, Inc.  
Attention: General Counsel  
1333 South Spectrum Blvd.  
Suite 100  
Chandler, AZ 85286  
Telephone: 602.910.2617  
Facsimile: 602.910.2627

Unless otherwise specified, all notifications and reports required by this CIA may be made by electronic mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. Upon request by OIG, Insys may be required to provide OIG with an additional copy of each notification or report required by this CIA in OIG's requested format (electronic or paper).

*Insys Therapeutics, Inc.  
Corporate Integrity Agreement and Conditional Exclusion Release*

## **VII. OIG INSPECTION, AUDIT, AND REVIEW 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 Insys's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Insys's locations for the purpose of verifying and evaluating: (a) Insys's compliance with the terms of this CIA and (b) Insys's compliance with Federal health care program requirements and with all applicable FDA requirements. The documentation described above shall be made available by Insys to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, and/or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Insys's owners, employees, contractors and directors 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. Insys shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Insys's owners, employees, contractors and directors may elect to be interviewed with or without a representative of Insys present.

## **VIII. DOCUMENT AND RECORD RETENTION**

Insys 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.

## **IX. DISCLOSURES**

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

## **X. BREACH AND DEFAULT PROVISIONS**

Insys is expected to fully and timely comply with all of its CIA obligations.

### **A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, Insys and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as “Stipulated Penalties”) in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Insys fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board of Directors compliance obligations and the engagement of a Compliance Expert, the performance of a Compliance Program Review, and the preparation of a Compliance Program Review Report, as required by Section III.A.3;
- d. the management certification obligations;
- e. written Policies and Procedures;
- f. the development of a written training plan and the training and education of Covered Persons and Board Members;
- g. a risk assessment and internal review process;
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements;
- j. the Incentive Compensation Restriction and Financial Recoupment Programs;

- k. notification of Government investigations or legal proceedings;
- l. reporting of Reportable Events;
- m. notification of written communications with FDA;
- n. the FFMP;
- o. the NPMP;
- p. the Independent Charity PAP policies, procedures, and practices required by Section III.N;
- q. notification to HCPs and HCIs; and
- r. posting of any Payment-related information.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Insys fails to engage and use an IRO as required by Section III.E and Appendices A-B.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Insys fails to submit a complete Implementation Report, Annual Report or any certification to OIG in accordance with the requirements of Section V by the deadlines for submission.

4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Insys fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendices A-B.

5. A Stipulated Penalty of \$1,500 for each day Insys fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Insys fails to grant access.)

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of Insys as part of its Implementation Report, any Annual Report, additional documentation to a report (as requested by OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$2,500 for each day Insys fails to grant the IRO access to all records and personnel necessary to complete the reviews required by Section III.E and for each day Insys fails to furnish accurate and complete records to the IRO, as required by Section III.E and Appendix A; and

8. A Stipulated Penalty of \$1,000 for each day Insys fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Insys stating the specific grounds for its determination that Insys has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Insys shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date Insys receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-7 of this Section.

B. Timely Written Requests for Extensions

Insys may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the 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 Insys fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such 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 Insys receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter.* Upon a finding that Insys has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Insys of: (a) Insys's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Insys shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed



upon provisions set forth below in Section X.E. In the event Insys elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Insys cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a Material Breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.d, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Insys has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA

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

- a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- b. a failure by Insys to report a Reportable Event and take corrective action as required in Section III.J;
- c. a failure to engage and use an IRO in accordance with Section III.E and Appendices A-B;
- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
- e. a failure by Insys to cease all marketing and promotion of Subsys at the time it is sold or licensed to a bona fide independent third party in an arms' length transaction or within 90 days of the Effective Date of the CIA, whichever occurs first;

- f. a failure by Insys to cease all payments to prescribers and non-Insys employee physicians for participating in any speaker programs and related activities in connection with any Insys product;
- g. a failure by Insys to divest Subsys and its buprenorphine candidate product in an arms' length transaction to a bona fide independent third party, which does not include anyone who is associated with or an immediate family member of John N. Kapoor, and to cease all business activities related to opioids within 12 months of the Effective Date of the CIA;
- h. a failure by Insys to cooperate with OIG in accordance with Section III.Q;
- i. a breach by Insys of the DPA entered into between Insys and the United States as determined by the United States Attorney's Office for the District of Massachusetts; or
- j. a failure by Insys to remove John N. Kapoor from any involvement in the daily activities, business decisions, operations, Board of Directors duties, management, or control of Insys.

2. *Material Breach and Intent to Exclude Arising from Sections X.D.1.a-d.* In the event that OIG determines Insys has materially breached this CIA pursuant to Sections X.D.1.a-d and that exclusion is the appropriate remedy, OIG will initiate an exclusion of Insys under 42 U.S.C. § 1320a-7(b)(7) based on the Statement of Facts. The length of the exclusion shall be in OIG's discretion.

- a. *Notice of Material Breach.* Upon a determination by OIG that Insys has materially breached this CIA under Sections X.D.1.a-d and that exclusion is the appropriate remedy, OIG will notify Insys of: (a) Insys's Material Breach; and (b) OIG's intent to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").
- b. *Opportunity to Cure.* For any Material Breach arising from Sections X.D.1.a-d, Insys shall have 30 days from the date of

receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- i. the alleged Material Breach has been cured; or
  - ii. the alleged Material Breach cannot be cured within the 30 day period, but that: (i) Insys has begun to take action to cure the Material Breach; (ii) Insys is pursuing such action with due diligence; and (iii) Insys has provided to OIG a reasonable timetable for curing the Material Breach.
- c. *Exclusion Letter.* If, at the conclusion of the 30 day opportunity to cure period for any Material Breach arising from Sections X.D.1.a-d, Insys fails to satisfy the requirements of Section X.D.2.b, OIG may exclude Insys from participation in the Federal health care programs. OIG will notify Insys in writing of its determination to exclude Insys for any Material Breach arising from Section X.D.1.a-d (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Insys's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Insys may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

3. *Material Breach Arising from Sections X.D.1.e-g.* In the event that OIG determines Insys has materially breached this CIA pursuant to Sections X.D.1.e-g and that exclusion is the appropriate remedy, OIG will initiate an exclusion of Insys under 42 U.S.C. § 1320a-7(b)(7) based on the Statement of Facts. The length of the exclusion shall be in OIG's discretion.

- a. *Exclusion Letter.* OIG will notify Insys in a written Exclusion Letter of its determination to exclude Insys for any Material Breach arising from Section X.D.1.e-g. Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Insys's receipt of the Exclusion Letter. The exclusion shall have

national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Insys may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

- b. *No Opportunity to Cure.* Insys shall have no opportunity or right to cure any Material Breach arising from Sections X.D.1.e-g.

4. *Material Breach Arising from Sections X.D.1.h-j.* In the event that OIG determines Insys has materially breached this CIA pursuant to Sections X.D.1.h-j and that exclusion is the appropriate remedy, OIG will initiate an exclusion of Insys under 42 U.S.C. § 1320a-7(b)(7) based on the Statement of Facts. The length of the exclusion shall be in OIG's discretion. CIA

- a. *Immediate Exclusion Letter.* OIG will notify Insys in writing of its determination to exclude Insys for any Material Breach arising from Section X.D.1.h-j (this letter shall be referred to hereinafter as the "Immediate Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, Insys agrees that the exclusion shall go into effect 5 days after the date of Insys's receipt of the Immediate Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, Insys may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.
- b. *No Opportunity to Cure.* Insys shall have no opportunity or right to cure any Material Breach arising from Sections X.D.1.h-j.

#### E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to Insys of its Demand Letter, its Exclusion Letter, or its Immediate Exclusion Letter, for the resolution of disputes arising under this CIA, Insys 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 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. 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 HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter or the Immediate Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at <http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html>.

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 Insys was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Insys shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Insys to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Insys requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review for Any Material Breach Arising from Sections X.D.1.a-d.* 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 any Material Breach arising from Sections X.D.1.a-d of this CIA shall be whether Insys was in Material Breach as defined in Sections X.D.1.a-d and, if so, whether:

- a. Insys cured such breach within 30 days of its receipt of the Notice of Material Breach; or
- b. the alleged Material Breach could not have been cured within the 30 day period, but that, during the 30 day period following Insys's receipt of the Notice of Material Breach:
  - (i) Insys had begun to take action to cure the Material Breach within that period; (ii) Insys pursued such action with due diligence; and (iii) Insys provided to OIG within that period a reasonable timetable for curing the Material Breach.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Insys, only after a DAB decision in favor of OIG. Insys's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Insys upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Insys may request review of the ALJ decision by the DAB. 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. Insys 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 Insys, Insys shall be reinstated effective on the date of the original exclusion.

4. *Exclusion Review for Any Material Breach Arising from Sections X.D.1.e-g.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issue in a proceeding for exclusion based on any Material Breach arising from Sections X.D.1.e-g of this CIA shall be whether Insys is in Material Breach as defined in Sections X.D.1.e-g.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Insys, only after a DAB decision in favor of OIG. Insys's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Insys upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Insys may request review of the ALJ decision by the DAB. 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. Insys 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 Insys, Insys shall be reinstated effective on the date of the original exclusion.

5. *Exclusion Review for Any Material Breach Arising from Sections X.D.1.h-j.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issue in a proceeding for exclusion based on any Material Breach arising from Sections X.D.1.h-j of this CIA shall be whether Insys is in Material Breach as defined in Sections X.D.1.h-j.

For purposes of the exclusion herein, the exclusion shall take effect 5 days after the date of Insys's receipt of the Immediate Exclusion Letter and prior to any ALJ appeal, hearing, or decision. If the ALJ finds in favor of Insys, Insys shall be reinstated effective

the date of the original exclusion. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, Insys may request review of the ALJ decision by the DAB. If the DAB finds in favor of Insys, Insys shall be reinstated effective on the date of the original exclusion. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 5 days after the DAB decision. Insys shall waive its right to any further notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB.

6. *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. Consequently, 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.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

Insys and OIG agree as follows:

A. This CIA shall become final and binding on the date the final signature is obtained on the CIA.

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

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

D. The undersigned Insys 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 capacity and that they are authorized to execute this CIA.

E. 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 signatures shall constitute acceptable, binding signatures for purposes of this CIA.

**ON BEHALF OF INSYS THERAPEUTICS, INC.**

/Andrece Housley/  
ANDRECE HOUSLEY  
Chief Financial Officer  
Insys Therapeutics, Inc.

6/5/19  
DATE

/Matthew Dunn/  
GEOFFREY E. HOBART, ESQ.  
MATTHEW DUNN, ESQ  
Covington & Burling LLP  
Counsel for Insys Therapeutics, Inc.

6/5/2019  
DATE



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

/Lisa M. Re/  
LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U.S. Department of Health and Human Services

06/05/2019  
DATE

/Sandra Jean Sands/  
SANDRA JEAN SANDS  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

06/05/2019  
DATE

/Mary E. Riordan/  
MARY RIORDAN  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

06/05/2019  
DATE

/Katie R. Fink/  
KATIE R. FINK  
Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services

6/5/2019  
DATE

## **APPENDIX A INDEPENDENT REVIEW ORGANIZATION**

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.E of the CIA.

### **A. IRO Engagement**

1. Insys shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by Insys in response to a request by OIG, whichever is later, OIG will notify Insys if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Insys may continue to engage the IRO.

2. If Insys engages a new IRO during the term of the CIA, that IRO must also meet the requirements of this Appendix. If a new IRO is engaged, Insys shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Insys at the request of OIG, whichever is later, OIG will notify Insys if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Insys may continue to engage the IRO.

### **B. IRO Qualifications**

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and in all applicable Federal health care program and FDA requirements relating to the Covered Functions, 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.

2. assign individuals to design and select the samples for the IRO Transactions Reviews who are knowledgeable about the appropriate statistical sampling techniques; and

3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities

The IRO shall:

1. perform each component of the IRO Reviews in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in the IRO Reviews;
3. request clarification from the appropriate authority (e.g., CMS), if in doubt of the application of a particular Federal health care program requirement;
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. Insys Responsibilities

Insys shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in III.E of this CIA and that all records furnished to the IRO are accurate and complete.

E. IRO Independence and Objectivity

The IRO must perform each component of the IRO Reviews in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

1. **Insys and IRO.** If Insys terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Insys must submit a notice explaining (a) its reasons for termination of the IRO or (b) the IRO's reasons for its withdrawal to OIG, no later than 30 days after termination or withdrawal. Insys must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. **OIG Removal of IRO.** In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph E, or has failed to carry out its responsibilities as described in Paragraph C, OIG shall notify Insys in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Insys 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 in order to resolve the concerns identified by OIG. If, following OIG's review of any information provided by Insys regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Insys in writing that Insys shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Insys must engage a new IRO within 60 days of its receipt of OIG's written notice. The final determination as to whether or not to require Insys to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### COVERED FUNCTIONS REVIEW

#### I. Covered Functions Review, General Description

As specified more fully below, Insys shall retain an Independent Review Organization (IRO) (or IROs) to perform reviews (IRO Reviews) to assist Insys in assessing and evaluating systems, processes, policies, procedures, and practices related to certain of the Covered Functions. The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Insys may engage, at its discretion, a single IRO to perform both components of the IRO Reviews provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in the applicable systems, processes, policies, and procedures of Insys relating to the Covered Functions, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Insys materially changes its systems, processes, policies, and procedures relating to the Covered Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Transactions Review for each Reporting Period of the CIA.

#### II. Systems Review

##### A. Promotional and Product Related Functions Systems Review

The Promotional and Product Related Functions Systems Review shall be a review of systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) of Insys relating to Promotional Functions and Product Related Functions. Where practical, Insys personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Insys in accordance with the preceding sentence.

Specifically, the IRO shall review systems, processes, policies, and procedures of Insys associated with the following (hereafter “Reviewed Policies and Procedures”):

1. Insys’s systems, policies, processes and procedures applicable to the manner in which sales representatives and personnel from Medical Affairs handle requests or inquiries relating to information about the uses of Government Reimbursed Products (including non-FDA-approved (i.e., off-label) 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 Insys sales representatives handle requests for information about off-label uses of Government Reimbursed Products, (b) the manner in which Medical Affairs personnel, including those at Insys’s headquarters, handle and respond to requests for information about off-label uses of Government Reimbursed Products; (c) the form and content of information and materials related to Government Reimbursed Products disseminated to HCPs, HCIs, payers, and formulary decision-makers by Insys; (d) the systems, processes, policies, and procedures of Insys to track requests to Medical Affairs for information about off-label uses of products and responses to those requests; (e) the manner in which Insys collect and supports information reported in any systems used to track and respond to requests to Medical Affairs for Government Reimbursed Product information; (f) the processes and procedures by which Medical Affairs or other appropriate individuals within Insys identify situations in which it appears that off-label or other improper promotion may have occurred; and (g) the processes and procedures of Insys for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;

2. Insys’s systems, policies, processes, and procedures applicable to the manner and circumstances under which Insys’s personnel from Medical Affairs (e.g., medical science liaisons or other medical or scientific personnel) participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) regarding Government Reimbursed Products and the role of Medical Affairs personnel at such meetings or events;

3. Insys’s systems, policies, processes, and procedures applicable to Insys’s internal review of promotional materials related to Government Reimbursed Products disseminated to HCPs, HCIs and payers and individuals or entities (e.g., PBMs) acting on behalf of HCPs, HCIs or payers;

4. Insys’s systems, policies, processes, and procedures applicable to the development and review of Insys processes relating to incentive compensation for Covered Persons who are prescriber-facing sales representatives and their direct managers, 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 the improper promotion, sales, and marketing of Government Reimbursed Products. To the extent that Insys establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;

5. Insys's systems, policies, processes, and procedures applicable to the development and review of Insys's call plans for Government Reimbursed Products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the call plans based on all relevant factors including expected utilization of Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;

6. Insys's systems, policies, processes, and procedures applicable to the development and review of Sample Distribution Plans (as defined in Section III.B.j of the CIA). 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 from Insys (including, separately, from Insys sales representatives and other Insys personnel or components). It shall also include a review of whether samples of Government Reimbursed Products are distributed by Insys through sales representatives or are distributed from a central location and the rationale for the manner of distribution;

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

8. Insys's systems, processes, policies, and procedures relating to 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 Insys entered with HCPs or HCIs and all events and expenses associated with such activities;

9. Insys's systems, processes, policies, and procedures relating to the funding, directly or indirectly, of Third Party Educational Activities (as defined in Section II.E.7 of the CIA) and all events and expenses relating to such activities;

10. Insys's systems, processes, policies, and procedures applicable to the submission of information about any Government Reimbursed Product to any Compendia (as defined in Section III.B.u of the CIA) such as Drugdex or other published

source of information used in connection with the determination of coverage by a Federal health care program for the product;

11. Insys's systems, processes, policies, and procedures applicable to Research (as defined in Section III.B.v of the CIA), including the decision to provide financial or other support for 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 such Research;

12. Insys's systems, processes, policies, and procedures relating to authorship-related practices (as defined in Section III.B.w of the CIA), including, but not limited to, the disclosure of all financial relationships between the author and Insys, the identification of all authors or contributors (including professional writers, if any) associated with a given publication, and the scope and breadth of research results made available to each author or contributor;

13. Insys's systems, processes, policies, and procedures relating to the provision of any reimbursement and/or coding support, advice or assistance (including relating to prior authorization issues) to any HCPs, HCIs or payers and the internal review and approval of any materials used in connection with such activities; and

14. Insys's systems, processes, policies, and procedures relating to its risk assessment and internal review process. This review shall assess whether the risk assessment and internal review process identifies and addresses relevant and appropriate risks relevant to the Covered Functions

B. Contribution and Assistance Related Functions Systems Review

The Contribution and Assistance Related Functions Systems Review shall be a review of the systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) of Insys relating to Contribution and Assistance Related Functions. Where practical, Insys personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by Insys in accordance with the preceding sentence.

Specifically, the IRO shall review systems, processes, policies, and procedures of Insys associated with the following (hereafter "Reviewed Policies and Procedures"):



1. Insys's systems, policies, processes, and procedures relating to arrangements and interactions with (including donations to and sponsorship of) independent third-party patient assistance programs (Independent Charity PAPs). This review shall include an assessment of the following:

- a. Insys's organizational structure as it relates to arrangements and interactions with Independent Charity PAPs, including:
  - i. the identification of those individuals, departments, or groups within Insys that have responsibility for, or involvement with, such arrangements and interactions;
  - ii. the respective scope and nature of the responsibilities of each individual, department, or group with responsibility for, or involvement with, arrangements and interactions with Independent Charity PAPs;
  - iii. the identification of those individuals, departments, or groups within Insys (e.g., the commercial organization) that are precluded from involvement with arrangements and interactions with Independent Charity PAPs; and
  - iv. the manner by which the separation of Independent Charity PAP-related responsibilities from the commercial organization is enforced.
- b. Insys's written policies and procedures as they relate to arrangements and interactions with Independent Charity PAPs, including:
  - i. the criteria governing whether and under what circumstances Insys would donate to an Independent Charity PAP or any specific disease state fund of such a PAP;
  - ii. communications (including any limitations on such communications) between any representatives of Insys and any Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such

- communications, and the subject matter of such communications including the exchange of any data);
- iii. communications (including any limitations on such communications) between those individuals, departments, or groups within Insys with responsibility for Independent Charity PAPs and the commercial organization of Insys (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications); and
  - iv. communications (including any limitations on such communications) between representatives of Insys and health care providers or patients regarding assistance available through any Independent Charity PAP.
- c. Insys policies and practices as they relate to the budgeting process applicable to donations to Independent Charity PAPs as outlined in Section III.N.2 of the CIA, including as it relates to initial or annual donation amounts and any supplemental amounts;
  - d. Insys policies and practices as they relate to the process by which decisions about the following are made and approved: i) whether to donate (or continue to donate) to an Independent Charity PAP; and ii) the amount of the donation (including any initial or annual amount and any supplemental amount);
  - e. Insys's criteria, policies, and practices as they relate to donations made by Insys to any Independent Charity PAPs as referenced in Section III.N.3, including the internal review process followed in connection with any donations to Independent Charity PAPs; and
  - f. Insys's policies and practices as they relate to information provided, directly or indirectly, to the public about the availability of patient assistance for Insys's products.

2. Insys's systems, policies, processes, and procedures relating to any Insys PAP (as defined in Section II.E.5 of the CIA). This review shall include an assessment of the following:

- a. Insys's organizational structure as it relates to Insys PAPs, including:
  - i. the identification of those individuals, departments, or groups within Insys that have responsibility for, or involvement with Insys PAPs; and
  - ii. the respective scope and nature of the responsibilities of each individual, department, or group with responsibility for, or involvement with, Insys PAPs.
- b. Insys's written policies and procedures as they relate to Insys PAPs, including:
  - i. the nature and amounts (or value) of the assistance provided to patients under each of the Insys PAPs;
  - ii. the eligibility criteria governing whether and under what circumstances Insys provides assistance to patients under each of the Insys PAPs;
  - iii. Insys's external communications about the Insys PAPs;
  - iv. the maintenance of records regarding free product and other assistance provided to or through Insys PAPs;
  - v. ensuring effective communication between Insys, Insys PAPs, or both, and Medicare Part D plans; and
  - vi. billing for free product provided to or through Insys PAPs.
- c. Insys's policies and practices as they relate to the budgeting process for financial or in-kind assistance provided under any Insys PAPs, including as they relate to initial or annual donation amounts and any supplemental amounts;

- d. Insys's policies and practices as they relate to the process by which decisions about the following are made and approved: (i) whether to provide (or continue to provide) assistance through any Insys PAP; and (ii) the amount (or value) of the assistance to be provided through each program (including any initial or annual amount and any supplemental amount); and
- e. Insys's policies and practices as they relate to any contracts or arrangements entered between Insys and outside entities relating to any Insys PAPs or the distribution of free product, including the individuals, groups, or departments involved in the negotiation process, the requirements and terms of the contracts or arrangements, and the review and approval of such contracts or arrangements.

C. IRO Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Sections II.A and II.B above, the report shall include the following items:

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 Sections II.A and II.B 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 Sections II.A and II.B above are made known or disseminated within the Insys;
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 prescriber-facing sales representatives or their direct managers, including a description of the bases upon which compensation is determined. To the extent that Insys may establish compensation differently for individual products, the IRO

shall report separately on each such type of compensation arrangement;

6. findings relating to whether Insys's risk assessment and internal review process identifies and addresses relevant and appropriate risks relating to Covered Functions;

7. findings relating to whether the risk assessment and internal review processes result in the implementation of appropriate corrective action plans and appropriate tracking and monitoring of such corrective action plans;

8. a detailed description of any system(s) used to track requests for donations or other assistance from any Independent Charity PAP;

9. a detailed description of any system(s) used to track donations or other assistance provided in response to requests from Independent Charity PAPs;

10. a detailed description of any system(s) used to track requests for donations or other assistance from or through any Insys PAP;

11. a detailed description of any system(s) used to track donations or other assistance provided in response to requests from or through any Insys PAP;

12. findings and supporting rationale regarding any weaknesses in the systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and

13. recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

### III. Transactions Review

As described more fully below, the Transactions Review shall include: (1) a review of Insys' call plans and the call plan review process; (2) a review of Sampling Events as defined below in Section III.B; (3) a review of records relating to a sample of the Payments that are reported by Insys pursuant to Section III.P of the CIA; (4) a review of Consulting Activities; (5) a review of Insys's arrangements with selected Independent Charity PAPs; and (6) a review of up to three additional items identified by the OIG in accordance with Section III.E.2.c of the CIA (hereafter "Additional Items"). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

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

1. Insys shall provide the IRO with: i) a list of Government Reimbursed Products promoted by Insys during the Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) the call plans for each such product. Insys shall also provide the IRO with information about the reviews of call plans that Insys conducted during the relevant Reporting Period (if any) and any modifications to the call plans made as a result of Insys's reviews.

2. For each call plan, the IRO shall select a sample of 50 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 Insys in conducting their review and/or modifying the call plan. The IRO shall seek to determine whether Insys followed their criteria and Policies and Procedures in reviewing and modifying the call plan.

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

B. Review of the Distribution of Samples of Insys 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. Insys shall provide the IRO with: i) a list of Government Reimbursed Products for which Insys distributed samples during the Reporting Period; ii) information about the FDA-approved uses for each such product; and iii) information about Insys's Sample Distribution Plans.

2. For each Government Reimbursed Product for which Insys distributed samples during the Reporting Period, the IRO shall randomly select a sample of 50 separate instances in which Insys provided samples of the product to HCPs or HCIs. Each such instance shall be known as a "Sampling Event."

3. 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: i) the quantity, dosage, and form of the Government Reimbursed Product samples provided to the HCP or HCI; ii) the

identity and type of medical specialty or clinical practice of the HCP or HCI; iii) which individual Insys sales representatives or other Insys personnel provided the sample to the HCP or HCI; and iv) the manner and mechanism through which the sample was requested (e.g., sample request form, letter, or call to the Insys).

4. For each Sampling Event, the IRO shall 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 and whether the sample was distributed by an Insys representative in a manner consistent with the Sample Distribution Plan for the product(s) provided during the Sampling Event.

5. For each Sampling Event, the IRO shall 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 Insys 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 Insys failed to follow its Sample Distribution Plan for the Government Reimbursed Product(s) provided during the Sampling Event.

### C. Review of Physician Payment Listings

1. *Information to be Reviewed.* As set forth in Section III.P of the CIA, Insys reports Payments to Covered Recipients to CMS that are listed on the Open Payments Data website. For purposes of the review described in in this Section III.C, the term “Control Documents” shall include all documents or electronic records associated with each Payment reflected on the Open Payments Data website for the applicable calendar year. For example, the term “Control Documents” includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments; contracts relating to the Payment(s); documents relating to the occurrence of Payment(s); documents reflecting any work product generated in connection with the Payment(s); documents submitted by sales representatives or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

2. *Selection of Sample for Review.* For each Reporting Period, the OIG shall have the discretion to identify up to 50 Covered Recipients who received Payments from Insys during the prior calendar year who will be subject to the review described

below. If the OIG elects to exercise this discretion, it shall notify the IRO at least 90 days prior to the end of the Reporting Period of the Covered Recipients subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 Covered Recipients to be included in the review. For each selected Covered Recipient, the IRO shall review Control Documents relating to Payments to the Covered Recipient for all categories reflected on the Open Payments Data website, except for Food/Beverage and Travel/Lodging categories of Payments.

3. *IRO Review of Control Documents for Selected Covered Recipients.*

For each Covered Recipient selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reported to CMS to evaluate the following:

- a. Whether Control Documents are available relating to each Payment for each selected Covered Recipient;
- b. Whether the Control Documents were completed and archived in accordance with the requirements set forth in Insys's policies;
- c. Whether the aggregate value of the Payment(s) as reflected in the information reported to CMS for the selected Covered Recipient is consistent with the value of the Payments(s) reflected in the Control Documents; and
- d. Whether the Control Documents reflect that Insys policies were followed in connection with Payment(s) reflected in the report to CMS (e.g., all required written approvals for the activity were obtained in accordance with all applicable policies).

4. *Identification of Material Errors and Additional Review.* A Material Error is defined as any of the following:

- a. A situation in which all required Control Documents relating to Payments for the selected Covered Recipient do not exist and (i) no corrective action was initiated prior to the selection of the selected Covered Recipient; or (ii) the IRO cannot confirm that Insys otherwise followed applicable policies and procedures relating to the Payment for the selected Covered



Recipient, including its policies and procedures relating to any Payment(s); or

- b. Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Insys's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Insys has initiated corrective action prior to the selection of the Covered Recipient, or if a Control Document does not exist but the IRO can determine that Insys otherwise followed their policies and procedures with regard to each Payment, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

#### D. IRO Review of Consulting Activities

1. *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 including but not limited to speaker programs, advisory boards, research and development meetings, product training and education sessions, presentations, ad hoc advisory activities, research and any other financial engagement or arrangement and all related expenses.

2. *Selection of Sample.* For the first Reporting Period, the IRO shall select and review a sample of the greater of 10 or 20% of the Consulting Activities that Insys entered into with 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, in order to facilitate the OIG's determination of the number of each type of Consulting Activities to be reviewed by the IRO, Insys shall provide the following information to the 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 to be spent in connection with each type of Consulting Activity during the Reporting Period. For the second and subsequent Reporting Periods, the IRO shall review a total of at least 10 Consulting Activities or 20% of the Consulting Activities (whichever is greater) which shall include a review of specified numbers of each type of Consulting Activities as determined by the OIG.

3. *Scope of Review.* For each Consulting Activity reviewed the IRO shall determine whether:

- a. 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;
- b. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure established by Insys;
- c. the rate structure was established based on a FMV analysis conducted by Insys;
- d. the Consulting Activity was identified in the annual Consultant budgeting plan developed by Insys;
- e. 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;
- f. the Consulting Activity was reviewed and approved in accordance with Insys Policies and Procedures;
- g. Insys 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
- h. the activity undertaken by the Consultant and/or the work product generated by the HCP or HCI was used by Insys in a

manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity.

E. Review of Arrangements with Independent Charity PAPs. The IRO shall conduct a review and assessment of Insys’s compliance with the Independent Charity PAP processes, policies, and procedures outlined in Section III.N of the CIA. More specifically, the IRO shall review the arrangements and interactions with all Independent Charity PAPs or disease state funds with which Insys entered charitable donation arrangements during the Reporting Period for which the IRO is conducting the review.

1. For purposes of this IRO review, the term “Reviewed Materials” shall include the following for each Independent Charity PAP reviewed: (a) all budget-related documents; (b) all documents relating to any decision to provide donations to the Independent Charity PAP; (c) any agreements between Insys and the Independent Charity PAP; (d) all email, correspondence and other documents reflecting communications and interactions between Insys and the Independent Charity PAP; (e) all email, correspondence and other documents reflecting communications and interactions within Insys (or between Insys and any entity acting on its behalf) relating to the arrangement with the Independent Charity PAP; and (f) other available information relating to the arrangements and interactions between Insys and the selected Independent Charity PAP. In addition to reviewing documents and written materials, the IRO may also interview individuals at Insys who have responsibility for arrangements and interactions with Independent Charity PAPs.

2. For each Independent Charity PAP selected as part of the IRO review, the IRO shall assess the Reviewed Materials and any interviews conducted by the IRO to evaluate whether the Independent Charity PAP-related activities were conducted in a manner consistent with Insys’s policies and procedures including those described in Section III.N and with OIG guidance. More specifically, the IRO Review shall evaluate and identify:

- a. Whether activities relating to arrangements and interactions with the Independent Charity PAP were undertaken by the appropriate individuals, departments, or groups within Insys in accordance with the company’s policies and procedures including those outlined in Section III.N;
- b. Whether Insys’s commercial organization (as defined in Section III.N) played a role in any arrangement or interaction with the Independent Charity PAP in violation of Insys’s policies and procedures or OIG guidance;

- c. Whether Insys followed the budgeting policies and practices outlined in Section III.N.2 regarding any initial or annual donation amounts to the Independent Charity PAP and any supplemental amounts;
- d. Whether Insys followed the decision-making and approval process outlined in Section III.N of the CIA with regard to any decisions: i) whether to donate (or continue to donate) to the Independent Charity PAP; ii) the amount of the donation (including any initial or annual amount and any supplemental amount); and iii) the criteria governing whether Insys would donate to the Independent Charity PAP or any specific disease state fund of such a PAP;
- e. Whether Insys followed the criteria, policies, and practices outlined in Section III.N.3 of the CIA in connection with all donations made by Insys to any Independent Charity PAP, including as they pertain to the internal review of potential donations and the adherence to the criteria specified in Section III.N.3;
- f. Any communications that occurred between any representatives of Insys and the Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications (including the exchange of any data)) and whether any such communications complied with Insys's policies and procedures and OIG guidance;
- g. Any communications that occurred between the groups or departments within Insys responsible for Independent Charity PAP functions and the commercial organization and whether any such communications complied with Insys's policies and procedures;
- h. Any communications that occurred between any representatives of Insys and health care providers or patients relating to assistance available through the Independent Charity PAP and whether any such communications complied with Insys's policies and procedures;

- i. Whether, for each donation from Insys to any Independent Charity PAP, Insys complied with the requirements outlined in Section III.N.3; and
- j. Whether, based on its review, the IRO found that Insys exerted influence or control over any Independent Charity PAP in violation of Insys's policies and procedures, including those outlined in Section III.N.3.

F. IRO Review of Additional Items. As set forth in Section III.E of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items").

1. No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify Insys 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 Insys 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 Insys's systems, processes, policies, and procedures based on its review of each Additional Item).

2. Insys may propose to the OIG that its internal audit(s) and/or reviews conducted as part of the Field Force Monitoring Program described in Section III.L or the Non-Promotional Activities described in Section III.M of the CIA 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 Insys's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

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

4. If the OIG agrees to permit certain of Insys's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal 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.

G. Transactions Review Report. For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

1. *General Elements to Be Included in Report*

- a. Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
- b. Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit and universe utilized in performing the procedures for each sample reviewed; and
- c. Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

2. *Results to be Included in Report*. The following results shall be included in each Transaction Review Report:

- a. Relating to the Call Plan Reviews.
  - i. a list of the Government Reimbursed Products promoted by Insys 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: i) a description of the criteria used by Insys in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans; ii) 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 Insys's criteria relating to

the call plan and/or Insys's policies and procedures; and iv) a description of all instances in which it appears that Insys failed to follow its criteria or policies and procedures relating to call plans;

- iii. the findings and supporting rationale regarding any weaknesses in Insys's systems, processes, policies, procedures, and practices relating to call plans, if any; and
- iv. recommendations, if any, for changes in Insys'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 Sampling Event Reviews

- i. for each Government Reimbursed Product distributed during the Reporting Period: i) 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); ii) 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 Insys in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iii) a detailed description of any instances in which it appears that Insys 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 Insys'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 Insys'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.

c. Relating to the Physician Payment Listing Reviews

- i. a description of the entries on the Open Payments Data website for each selected Covered Recipient and a description of the Control Documents reviewed in connection with each selected Covered Recipient;
- ii. for each selected Covered Recipient, findings and supporting rationale as to whether: (a) all required Control Documents exist; (b) each Control Document was completed in accordance with all of the requirements set forth in the applicable Insys policy; (c) the aggregate value of the Payment(s) as reflected in the report to CMS for the sampled Covered Recipient is consistent with the value of the Payment(s) reflected in the Control Documents; (d) each Control Document reflects that Insys's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (e) any corrective action or disciplinary action was undertaken in those instances in which Insys's policies were not followed;
- iii. for each selected Covered Recipient reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the Covered Recipient, including a description of the circumstances requiring corrective action and the nature of the corrective action; and



- iv. if any Material Errors are discovered, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error.

d. Relating to the Review of Consulting Activities. In connection with 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. 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 Insys;
  - c. the rate structure was established based on a FMV analysis conducted by Insys;
  - d. the Consulting Activity was identified in the annual Consulting budgeting plan developed by Insys;
  - e. a needs assessment that identifies the business need for the Consulting Activity and provides detail about the activity was prepared prior to the initiation of the Consulting Activity;

- f. the Consulting Activity was reviewed and approved in accordance with Insys Policies and Procedures;
  - g. Insys collected and retained a record of the specific activity performed by the HCP and, if applicable, a copy of the work product generated in connection with the Consulting Activity;
  - h. the activity undertaken by the Consultant and/or the work product generated was used by Insys in a manner consistent with the needs assessment that was completed prior to the initiation of the Consulting Activity;
  - i. the IRO identified any weaknesses in Insys's systems, processes, policies, procedures and/or practices relating to Consulting Activities; and
  - j. the IRO has recommendations for improvements to Insys's systems, processes, policies, procedures and/or practices relating to Consulting Activities.
- e. Relating to the Review of Independent Charity PAP Arrangements
- i. a list of the Independent Charity PAPs with which Insys entered charitable donation arrangements during the Reporting Period;
  - ii. for each Independent Charity PAP for which the IRO reviewed arrangements or interactions during the Reporting Period: (a) a description of the review conducted by IRO; and (b) a summary of all instances in which it appears that Insys failed to follow its policies and procedures and/or OIG guidance regarding its arrangements or interactions with an Independent Charity PAP;

- iii. for each Independent Charity PAP reviewed by the IRO, findings regarding each element specified in Section III.E above;
  - iv. the findings and supporting rationale regarding any overall weaknesses in Insys's systems, processes, policies, procedures, and practices relating to its arrangements and interactions with Independent Charity PAPs; and
  - v. recommendations, if any, for changes in Insys's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to its arrangements and interactions with Independent Charity PAPs.
- f. 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 Insys'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 Insys's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

## APPENDIX C

### INCENTIVE COMPENSATION RESTRICTION and FINANCIAL RECOUPMENT PROGRAM

To the extent not already accomplished, Insys shall establish and maintain throughout the term of the CIA a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual incentive compensation (including Cash Awards and Equity Awards) for any Eligible Individual (defined below in Paragraph B) who is the subject of an Affirmative Recoupment Determination (as defined below in Paragraph D). This program shall be known as the “Financial Recoupment Program”. This recoupment program shall apply to Eligible Individuals who are either current Insys employees or who are former Insys employees at the time of a Recoupment Determination.

**(A) Annual Incentive Plan.** Any annual cash incentive award described under any Insys incentive plan for employees for each Insys employee in the U.S. is at risk of a downward adjustment if the employee fails to comply with all applicable laws, regulations and rules. If Insys discovers any employee noncompliance that would implicate a downward adjustment of an annual (or other) incentive award as described in this paragraph, it shall evaluate the situation and make a determination about whether any downward adjustment should be made and the degree of adjustment. Insys shall maintain these downward adjustment portions of the Annual Incentive Plan throughout the term of the CIA.

**(B) Description of the Financial Recoupment Program.** To the extent not already accomplished, within 120 days after the Effective Date of the CIA, Insys shall establish policies and procedures (and modify employment and other contracts as necessary) to provide that annual incentive compensation for each Eligible Individual (as defined below) is at risk of forfeiture in the event of Significant Misconduct (*i.e.*, any violation of any law, regulation or Insys policy) that is discovered by Insys before the incentive compensation is paid. In the event of Significant Misconduct by any Eligible Individual, Insys shall also reserve the right and full discretion to void and forfeit any unvested stock options, unvested stock appreciation rights, unvested stock awards, unvested restricted stock unit awards, unvested performance share awards, and any other unvested right to receive company common stock (collectively, “Equity Awards”), and cash incentive awards, bonus awards, and other similar awards (collectively, “Cash Awards”) (Equity Awards and Cash Awards shall be referred to collectively as “Awards”). If Insys discovers any Significant Misconduct that would implicate the forfeitures described in this Paragraph by an Eligible Individual, it shall evaluate the

situation and make a determination about whether any forfeiture shall be implemented and, if so, the terms of such forfeiture in accordance with the process for a Recoupment Determination (as defined below).

**(i) Definition of Eligible Individuals.** In addition, to the extent not already accomplished, within 120 days after the Effective Date of the CIA, Insys shall modify and supplement their annual bonus plans applicable to an Eligible Individual (and any employment agreements, as appropriate) by imposing the following eligibility and repayment conditions on future Cash Awards and Equity Awards made beginning on January 1, 2020 and making the additional remedies discussed below applicable to all eligible individuals who are officers, executives, or employees of Insys (collectively, “Eligible Individuals”) Insys shall implement policies and procedures and, as necessary, shall modify contracts with Eligible Individuals so that beginning no later than January 1, 2020 the Cash Awards and Equity Awards may be recouped if an Affirmative Recoupment Determination is made. The forfeiture and recoupment rights described in this Paragraph shall apply prospectively to Eligible Individuals beginning no later than the incentive plan applicable beginning on January 1, 2020.

**(ii) Cash Award Eligibility and Repayment Conditions.** Insys shall implement an eligibility and repayment condition on annual Cash Awards that shall be designed to survive both the payment of the Cash Award and the separation of an Eligible Individual’s employment. This will allow Insys, as a consequence of a Triggering Event, to pursue repayment from the Eligible Individual of all or a portion of the Cash Award paid to the Eligible Individual. To the extent permitted by controlling law, these Cash Award eligibility and repayment conditions shall survive the payment of the Eligible Individual’s Cash Award and the separation of the Eligible Individual’s employment for a period of 3 years from the payment of the Cash Award for the applicable plan year. If payment of any portion of a Cash Award is deferred on a mandatory or voluntary basis, the 3-year period shall be measured from the date the Cash Award would have been paid in the absence of deferral.

If an Affirmative Recoupment Determination is made, Insys shall endeavor to collect repayment of any Cash Award from the Eligible Individual through reasonable and appropriate means according to the terms of the incentive plan (or executive contract if applicable), and to the extent permitted by controlling law of the relevant jurisdiction. If necessary and appropriate to collect the repayment, Insys shall file suit against the Eligible Individual unless good cause exists not to do so. For purposes of the Financial Recoupment Program, good cause shall include, but not be limited to, a financial inability on the part of the Eligible Individual to repay any recoupment

amount or Insys's inability to bring such a suit under the controlling law of the relevant jurisdiction.

**(iii) Equity Award Eligibility and Repayment Conditions.** Insys shall implement an eligibility and repayment condition on annual Equity Awards that shall be designed to survive the vesting or distribution of the Equity Award and the separation of an Eligible Individual's employment. This will allow Insys, as a consequence of a Triggering Event, to pursue repayment from the Eligible Individual of all or a portion of the Equity Award. To the extent permitted by controlling law, these Equity Award eligibility and repayment conditions will survive the vesting or distribution of the Eligible Individual's Equity Award and the separation of the Eligible Individual's employment for a period of 3 years from the vesting or distribution of the Equity Award. If payment of any portion of an Equity Award is deferred on a mandatory or voluntary basis, the 3-year period shall be measured from the date the Equity Award would have been vested or distributed in the absence of deferral.

If an Affirmative Recoupment Determination is made, Insys shall endeavor to collect repayment of any Equity Awards from the Eligible Individual through reasonable and appropriate means according to the terms of the incentive plan (or executive contract if applicable), and to the extent permitted by controlling law of the relevant jurisdiction. If necessary and appropriate to collect the repayment, Insys shall file suit against the Eligible Individual unless good cause exists not to do so. For purposes of the Financial Recoupment Program, good cause shall include, but not be limited to, a financial inability on the part of the Eligible Individual to repay any recoupment amount or Insys's inability to bring such a suit under the controlling law of the relevant jurisdiction.

**(iv) Additional Remedies.** If, after expiration of the time period specified in Paragraphs B(ii)-(iii) above, the Recoupment Committee in its sole discretion determines that a Triggering Event has occurred, Insys shall make a determination as to whether to pursue available remedies (e.g., filing suit against the Eligible Individual) existing under statute or common law to the extent available.

**(C) Definition of Triggering Events.** The forfeiture and repayment conditions described above shall be triggered upon a Recoupment Determination that finds:

**(i)** Significant Misconduct relating to the Covered Functions (as defined in Section II.E.6 of the CIA) by the Eligible Individual that, if discovered prior to payment, would have made the Eligible Individual ineligible for a Cash or Equity Award in that plan year or subsequent plan years; or

(ii) Significant Misconduct (as defined above) relating to the Covered Functions (as defined in Section II.E.6 of the CIA) by subordinate employees in the business unit for which the Eligible Individual had responsibility that does not constitute an isolated occurrence and which the Eligible Individual knew or should have known was occurring that, if discovered prior to payment, would have made the Eligible Individual ineligible for a Cash or Equity Award in that plan year or subsequent plan years.

**(D) Administration of Recoupment Programs.** Insys shall engage in a standardized, formal process to determine, in their sole discretion, whether a Triggering Event has occurred, and, if so, the extent of Cash Awards and/or Equity Awards that will be subject to repayment or forfeiture by the Eligible Individual, and the most appropriate method for securing recoupment of the relevant Awards. The findings and conclusions resulting from this process shall be referred to as the “Recoupment Determination.” A determination that Cash Award and/or Equity Award amounts shall be forfeited by or recouped from an Eligible Individual shall be referred to as an “Affirmative Recoupment Determination.”

**(i) Initiation.** Insys shall initiate the Recoupment Determination process upon: (1) discovery of potential Significant Misconduct that may rise to the level of a Triggering Event, or (2) written notification by a United States federal government agency to Insys’s compliance officer of a situation that may rise to the level of a Triggering Event and either occurred in the United States or gives rise to liability relating to Federal health care programs. This written notification shall either identify the Eligible Individual(s) potentially at issue or provide information (e.g., a description of the alleged misconduct and the applicable time period) to allow Insys to identify the Eligible Individual.

**(ii) Recoupment Committee.** The Recoupment Determination shall be made by a committee of senior executives representing the business units engaged in Covered Functions (as defined in Section II.E.6 of the CIA), Legal, and Compliance (Recoupment Committee). The Recoupment Committee may also include members of other functional areas or business groups, as it deems necessary. An Eligible Individual shall not participate in the Recoupment Committee while that individual is subject to a Recoupment Determination. If a Recoupment Determination involves an Executive Officer of Insys, a Recoupment Determination for such individual shall be subject to approval by the Board of Directors (or appropriate committee thereof) of Insys. If an Executive Officer or other Eligible Individual is subject to a Recoupment Determination and is a member of the Board of Directors, that individual shall not participate in the Board’s approval process. For purposes of this Section, “Executive Officer” means any Executive Officer of the Registrant, as described in Insys’s Annual Report to the SEC,

the Corporate Controller, and such other executives of Insys subject to the reporting requirements of Section 16 of the Securities Exchange Act of 1934, as amended, as may be determined by the Company's Board of Directors.

**(iii) Recoupment Determination Process.** Insys shall initiate the Recoupment Determination process within 30 days after discovery by Insys, or notification pursuant to Paragraph D(i), of a potential Triggering Event. Absent extraordinary reasons, the Recoupment Committee shall reach a Recoupment Determination within 90 days after initiation of the determination process.

As part of the Recoupment Determination process, the Recoupment Committee or appropriate Delegate (as defined below) shall: i) undertake an appropriate and substantive review or investigation of the facts and circumstances associated with the Triggering Event or any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; ii) make written findings regarding the facts and circumstances associated with the Triggering Event and any written notifications about potential Triggering Events received pursuant to Paragraph D(i) above; and iii) set forth in writing its determinations (and the rationale for such determinations) about: 1) whether a Triggering Event occurred; 2) the extent of Cash Awards or Equity Awards (collectively "Awards") that will be subject to forfeiture and/or repayment by the Eligible Individual, if any; 3) the means that will be followed to implement the forfeiture and/or secure the recoupment of Awards from the Eligible Individual; and 4) the timetables under which Insys will implement the forfeiture and/or attempt to recoup the Awards.

For purposes of this Paragraph, a "Delegate" shall refer to the Insys personnel to whom the Recoupment Committee has delegated one or more of its required tasks in furtherance of the Financial Recoupment Program.

**(E) Reporting.** The Recoupment Committee shall provide annual reports to the Board of Directors (or an appropriate committee thereof) of Insys about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i)(2) above; ii) a description of any Recoupment Determinations where a Triggering Event occurred during the preceding year (including any decision to require or not require forfeiture/recoupment from any Eligible Individuals, the amount and type of any forfeiture/recoupment, the means for collecting any recoupment and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Affirmative Recoupment Determinations that were not fully completed in prior years. In addition, the Recoupment Committee shall provide



similar annual reports to the Board(s) of Directors of Insys that employs/employed an Eligible Individual that is the subject of a Triggering Event.

The Recoupment Committee shall also provide annual reports to the OIG about: i) the number and circumstances of any Triggering Events that occurred during the preceding year and any written notifications about potential Triggering Events received pursuant to Paragraph D(i)(2) above; ii) a summary description of any Recoupment Determinations where a Triggering Event occurred during the preceding year (including any decision to require or not require forfeiture/recoupment from any Eligible Individuals, the amount and type of any forfeiture/recoupment, the method for collecting any recoupment, and the rationale for such decisions); and iii) a description of the status of any forfeitures and/or recoupments required under prior Affirmative Recoupment Determinations that were not fully completed in prior years. Upon request by OIG, Insys shall provide OIG with additional information regarding any Recoupment Determination for which a Triggering Event has occurred.

Insys commits, to the extent permitted by controlling law, to maintaining all of the forfeiture and recoupment commitments set forth in Paragraphs A-E above for at least the duration of the CIA, absent agreement otherwise with the OIG.

**ATTACHMENT A**  
**STATEMENT OF FACTS**

The following Statement of Facts is incorporated by reference as part of the Corporate Integrity Agreement and Conditional Exclusion Release (“CIA”) between the Office of Inspector General of the United States Department of Health and Human Services and Insys Therapeutics, Inc., and its agents and subsidiaries other than Insys Pharma, Inc. (collectively, “Insys”). Defendant Insys hereby agrees and stipulates that at all times relevant to the Information pending against it in the United States District Court for the District of Massachusetts, in *United States v. Insys Therapeutics, Inc.*, Criminal No. **[Insert number]**, the following is true and accurate:

**Summary**

1. Insys admits, accepts, and acknowledges responsibility for conduct occurring from August 2012 until June 2015, involving the agreement to pay and payment of remuneration to certain licensed, medical practitioners, including physicians and physician assistants, with the intent to bribe and improperly influence the medical practitioners to improperly increase their prescriptions and dosages of SUBSYS® (hereafter “Subsys”), which is fentanyl-based pain medication intended to treat cancer patients suffering intense breakthrough pain. In exchange for the remuneration, the medical practitioners improperly prescribed large numbers and high dosages of Subsys for patients, most of whom were not diagnosed with cancer, and for which the Federal health care programs, as defined below, paid.

2. The Medicare Program (“Medicare”), Medicaid Program (“Medicaid”), and TRICARE Program (“TRICARE”) are and at all times relevant were “Federal health care program[s],” as defined in Title 42, United States Code, Section 1320a-7b(f).

### **Insys and Subsys**

3. Insys is a Delaware corporation that maintains a principal place of business in Chandler, Arizona. At all times relevant to this Statement of Facts, Insys Pharma, Inc., was a wholly owned subsidiary of Insys Therapeutics, Inc., and was its main operating subsidiary.

4. Insys developed and owns a drug called Subsys, a spray formulation of fentanyl to be applied under a patient’s tongue (also called a sublingual spray). The United States Food and Drug Administration (“FDA”) approved Subsys in or about January 2012 for the management of breakthrough pain in patients 18 years of age or older with cancer who are already receiving and who are already tolerant to opioid therapy for their underlying persistent cancer pain. Subsys is in a category of drugs called Transmucosal Immediate Release Fentanyl (“TIRF”) products, which includes other fentanyl-based rapid onset opioids that competed with Subsys.

5. From in or about March 2012 to the present, Insys marketed and sold Subsys in interstate commerce, including in the District of Massachusetts.

6. Subsys could only be prescribed by a licensed medical practitioner who was registered with the DEA and able to prescribe opioids in the usual course of professional practice for a legitimate medical purpose.

7. Market demand for Subsys was driven in large part by the practitioners who wrote prescriptions for their patients. Practitioners willing to write prescriptions for Subsys had a number of competing medications from which to choose. In addition to other brand name TIRF drugs, practitioners could also prescribe a generic TIRF medicine.

8. Depending on the dosage and number of units prescribed, a prescription for Subsys often cost thousands of dollars each month. Most patients relied on commercial insurance and/or publicly funded insurance, including Medicare, Medicaid, and TRICARE, to subsidize the cost of taking Subsys.

9. Insys knew that insurers would not authorize payment for Subsys if the prescription was written in exchange for a bribe, or kickback, and was not medically necessary. In general, patients had to have a specific medical diagnosis before the insurer, including the Federal health care programs, would authorize payment for Subsys. Many insurers would not pay for Subsys until the patient had tried and failed certain other preferred medications.

10. Beginning in August 2012 and continuing until June 2015, Insys paid bribes to certain practitioners as part of a scheme to defraud patients and insurers, including the Federal health care programs. Insys paid the bribes in order to induce certain practitioners to write unnecessary Subsys prescriptions.

11. Specifically, Insys used pharmacy data acquired from third parties to identify practitioners who either prescribed high volumes of rapid-onset opioids or who had demonstrated a capacity to prescribe large volumes of rapid-onset opioids.

12. Insys paid bribes to certain practitioners to prescribe Subsys through its Speaker Program. The Speaker Program was a marketing program that purported to increase brand awareness of Subsys by sponsoring peer-to-peer educational lunches and dinners. Purportedly in exchange for a practitioner educating other prescribers about Subsys, Insys agreed to pay the speaker a fee, also referred to as an “honoraria,” for each speaking event.

13. The Speaker Program included certain speaker practitioners who had the potential to prescribe Subsys, and was used to induce them to write more, medically unnecessary prescriptions in exchange for payment of money by Insys in the form of honoraria. Insys fashioned the payments to these certain practitioners as speaker fees, or honoraria, in order to hide the fact that they were in fact bribes paid to induce certain practitioners to write Subsys prescriptions.

14. Rather than educational gatherings, Speaker Program events often did not involve any education or presentations about the drug. Frequently, Speaker Program events did not have attendees who were licensed to prescribe Subsys, but rather included support staff employed by the speaker. Many speaker events had no attendees at all. When this occurred, Insys's sales representatives were directed by management to falsify the names of attendees and their signatures on sign-in sheets. Sham Speaker Program events occurred at restaurants within the District of Massachusetts and elsewhere, and functioned as bribes in the form of free dinners for speakers, friends, and, at times, family, and served as a vehicle to pay a bribe to the speaker in the disguised form of an honoraria.

15. In a number of instances, high-level officers, directors, executives, managers, and the executive chairman of Insys's Board of Directors expressly required a practitioner to write a minimum number of Subsys prescriptions, write prescriptions at a minimum dosage, and write prescriptions for a minimum number of units of Subsys, in order for the speaker to continue receiving the bribe, that is, the so-called honoraria, for sham events. For all speakers during certain periods, Insys tracked its so-called return on investment: it measured the effect of the payments, which functioned as bribes to certain practitioners, on the speaker's prescribing habits, and, correspondingly, the effect of the bribes on the revenue that each bribed speaker generated for it. If a speaker failed to meet the minimum prescription and return on investment requirements, Insys took

Speaker Program payments away from practitioners, or reduced the total amount of Speaker Program payments paid to practitioners, unless and until the practitioner wrote a satisfactory number of new prescriptions, or raised the dosage and volume of existing Subsys prescriptions. Each new prescription, refill, or existing prescription written for a higher dose of Subsys generated greater income to Insys.

16. Insys agreed with certain practitioners, including but not limited to certain practitioners in New Hampshire and Illinois, to conduct Speaker Programs, which were solely a mechanism to pay bribes to these practitioners for prescribing Subsys.

17. One such practitioner targeted by Insys and to whom Insys, through certain employees, offered bribes was a physician's assistant ("P.A.") who practiced with a pain clinic based in Somersworth, New Hampshire.

18. During the first year that Subsys was on the market, the P.A. did not write any Subsys prescriptions. In or about April 2013, a sales representative working on behalf of Insys catered a lunch at the P.A.'s pain clinic. In or about June 2013, the P.A. wrote his first prescription for Subsys. The sales representative encouraged the P.A. to submit his resume for consideration in the Insys Speaker Program, which the P.A. did on the same day.

19. Approximately one month later, Insys approved the P.A. as a speaker on the recommendation of Insys's then Vice President of Sales.

20. The P.A. and Insys's sales representative frequently discussed new patients for whom the P.A. could prescribe Subsys.

21. On or about November 14, 2013, the sales representative arranged a Speaker Program event at a restaurant in Portsmouth, New Hampshire at which the P.A. was the purported Subsys speaker. No other medical practitioners who could prescribe Subsys were present at the dinner, and the P.A. did not make a presentation about the drug. The signature of physician's assistant S.T. was forged on a sign-in sheet to make it appear S.T. was present at the dinner when he was not.

22. On or about November 21, 2013, Insys issued check number 801 to the P.A. in the amount of \$1,200 as payment in part for the November 14, 2013 Speaker Program event.

23. On or about November 19, 2013, the sales representative arranged a Speaker Program event at a second restaurant in Portsmouth, New Hampshire at which the P.A. was the purported Subsys speaker. No other practitioners who could prescribe Subsys were present at the dinner, and the P.A. did not make a presentation about the drug. The signature of nurse practitioner K.T. was forged on a sign-in sheet to make it appear K.T. was present at the dinner when she was not.



24. On or about November 25, 2013, Insys issued check number 935 to the P.A. in the amount of \$2,000 as payment in part for the November 19, 2013 Speaker Program event.

25. On or about January 13, 2014, the sales representative arranged a Speaker Program event at a restaurant in Boston, Massachusetts at which the P.A. purportedly spoke about Subsys. No other medical practitioners who could prescribe Subsys were present at the dinner, and the P.A. did not make a presentation about the drug. The signatures of physician's assistant L.C. and medical assistant P.M. were forged on a sign-in sheet to make it appear they were present at the dinner when they were not.

26. Insys issued check number 1550 to the P.A. in the amount of \$1,000 as payment in part for the January 13, 2014 Speaker Program event.

27. On March 11, 2014, Insys arranged a Speaker Program event at a second restaurant in Boston, Massachusetts at which the P.A. was the purported speaker. No other medical professionals who could prescribe Subsys were present, and the P.A. did not make a presentation about the drug. The only attendees at the dinner were the P.A., a relative of the P.A., and Insys's sales representative. The signature of physician's assistant L.C. was forged on a sign-in sheet to make it appear she was present at the dinner when she was not.

28. On or about March 20, 2014, Insys issued check number 2408 to the P.A. in the amount of \$2,000 as payment in part for the March 11, 2014 Speaker Program event.

29. On July 28, 2014, Insys arranged a Speaker Program event at a third restaurant in Portsmouth, New Hampshire at which the P.A. was the purported speaker. No other medical practitioners who could prescribe Subsys were present at the dinner, and the P.A. did not make a presentation about the drug. The signatures of S.M. and T.C. were forged on a sign-in-sheet to make it appear they were present at the dinner when they were not.

30. On or about August 4, 2014, Insys's agent, on behalf of Insys, issued check number 25662 to the P.A. in the amount of \$1,000 as payment in part for the July 28, 2014 Speaker Program event.

31. Between August 2013 and October 2014, Insys's employees invited the P.A. to approximately 44 Speaker Program events at various restaurants and other locations. For each of the events, the P.A. was paid a fee of between \$500 and \$2,000. Insys paid the P.A. approximately \$44,000 for purportedly speaking about Subsys at Speaker Program events when, in fact, he had not. Instead, they were bribes paid by Insys to the P.A. for the purpose of inducing the P.A. to write medically unnecessary Subsys prescriptions.

32. Had the insurers known that Insys paid bribes to the P.A. that caused the P.A. to write medically unnecessary Subsys prescriptions, the insurers would not have authorized payment for those prescriptions.

33. Insys caused each of the bribes in the form of the above-described honoraria checks to be sent and delivered in interstate commerce by the United States Postal Service and by private and commercial interstate carriers.

34. The payments made by Insys to the P.A. for sham Speaker Program events, as described in this Statement of Facts, violated Title 18, United States Code, Section 1341.

35. Insys agreed with and paid certain other practitioners, including a practitioner in Illinois, to conduct sham Speaker Program events that were solely to induce this practitioner and certain others to prescribe Subsys, in violation of Title 18, United States Code, Section 1341.

36. Insys's net revenues were approximately \$95.8 million in 2013 due to sales of Subsys. That amount rose to approximately \$219.5 million in 2014.