

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

**I. PREAMBLE**

Indivior Inc. (Indivior) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, Indivior is entering into a Settlement Agreement with the United States. Indivior is also entering into settlement agreements with various states (State Settlement Agreements) and Indivior's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date, Indivior established a compliance program that Indivior represents addresses all seven elements of an effective compliance program and that is designed to address compliance with Federal health care program and FDA requirements (Compliance Program). Indivior shall continue the Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. Indivior may modify the Compliance Program as appropriate. However, at a minimum, Indivior shall ensure that during the term of this CIA, it shall maintain a compliance program to comply with the obligations set forth in this CIA.

**II. TERM AND SCOPE OF THE CIA**

A. The period of the compliance obligations assumed by Indivior 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. The first Reporting Period shall be the period between the Effective Date and July 23, 2021. The second Reporting Period shall be the period from July 24, 2021, through December 31, 2022. The third and fourth Reporting Periods shall be the calendar years 2023 and 2024, respectively. The fifth Reporting Period shall begin on January 1, 2025 and expire on the anniversary of the

Effective Date in 2025.

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Indivior's final Annual Report; or (2) any additional materials submitted by Indivior pursuant to OIG's request, whichever is later.

C. The scope of this CIA is governed by the following definitions:

1. For purposes of this CIA, the term "Covered Persons" includes:

(a) all owners of Indivior 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), all officers and directors of Indivior and all directors of Indivior PLC;

(b) all employees of Indivior; and

(c) all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of Indivior and in that capacity either: (i) interact directly with health care professionals (HCPs), health care institutions (HCIs) or consumers; or (ii) perform activities, provide services, or create materials relating to the Covered Functions and those activities, services, or materials are not reviewed or supervised by an Indivior employee who is a Covered Person prior to execution or dissemination.

Notwithstanding the above, the term Covered Persons does not include part-time or per-diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Government Reimbursed Products" refers to all Indivior products that are: (a) marketed or sold by Indivior 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 Indivior’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 HCPs, HCIs, and Payors about Government Reimbursed Products, including those functions relating to any applicable review committees and those functions relating to Medical Affairs 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 “Covered Functions” refers to “Promotional Functions” and “Product Related Functions,” collectively.

6. 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 Indivior but intended to be independent of Indivior’s control or influence, including but not limited to, continuing medical education (CME), disease awareness, or sponsorship of symposia at medical conferences.

7. The term “Indivior Affiliate” shall mean any entity, including Indivior Treatment Services, Inc. that is owned or controlled directly or indirectly by Indivior, Inc. and whose employees or contractors perform any Covered Functions. All obligations set forth in Section III below shall apply to the Covered Functions performed by any Indivior Affiliate and all references to “Indivior” in the defined terms set forth in this Section II shall mean Indivior and any Indivior Affiliate. In addition, the notice requirements in Section IV and the certification obligations set forth in Section V.C. below shall apply to both Indivior and any Indivior Affiliate.

8. The term “Third Party Personnel” shall mean personnel who perform in Promotional Functions or Product Related Functions who are employees of entities with which Indivior has or may in the future (during the term of this CIA) enter into agreements to co-promote a Government Reimbursed Product or to engage in joint promotional activities in the United States relating to such a product. Indivior has represented that: (a) Third Party Personnel are employed by entities other than Indivior; (b) Indivior does not control the Third Party Personnel; (c) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Indivior agrees to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.7, and V.B.7. Provided that Indivior complies with the requirements of Sections III.B.2, V.A.7, and V.B.7, Indivior shall not be required to fulfill the other CIA obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

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

Indivior 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, Indivior 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 Indivior; shall report directly to the Chief Executive Officer of Indivior; and shall not be, or be subordinate to, the Chief Legal Officer or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Indivior. 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 in person to the Nomination & Governance Committee (NGC) of the Board of Directors of Indivior PLC and shall be



authorized to report on such matters to the NGC at any time. Written documentation of the Compliance Officer's reports to the NGC shall be made available to OIG upon request; and

- c. monitoring the day-to-day compliance activities engaged in by Indivior 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.

Indivior 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 business days after such a change.

2. *Compliance Committee.* Within 90 days after the Effective Date, Indivior 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, regulatory affairs, research and development, human resources, audit, finance, manufacturing, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Indivior'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.

Indivior 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 business days after such a change.

3. *Board Compliance Obligations.* The Nominating & Governance Committee of the Indivior PLC Board (NGC) 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 NGC must include independent (i.e., non-employee and non-executive) members.

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

- a. meeting at least quarterly to review and oversee Indivior'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 NGC, summarizing its review and oversight of Indivior's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA; and
- d. for the first and third Reporting Periods of the CIA, the NGC shall retain an 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 Indivior's Compliance Program (Compliance Program Review). The Compliance Expert shall 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 Indivior's compliance program. The NGC shall review the Compliance Program Review Report as part of its review and oversight of Indivior's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in the first and third Annual Reports submitted by Indivior. In addition, copies of any materials provided to the NGC by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the NGC, shall be made available to OIG upon request.

At minimum, the resolution shall include the following language:

“The Nominating & Governance Committee of the Indivior PLC Board (NGC) has made a reasonable inquiry into the operations of Indivior’s Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the NGC has concluded that, to the best of its knowledge, Indivior has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement.”

If the NGC is unable to provide such a conclusion in the resolution, the NGC 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 Indivior.

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

4. *Management Certifications.* In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Indivior employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Indivior 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 following: Chief Medical Officer; Chief Scientific Officer; Chief Commercial and Strategy Officer; Chief Financial Officer; Senior Vice President of Regulatory Affairs; Senior Vice President Global Medicines Development; Senior Director and Head, MSL and Medical Outcomes and Value Team; Senior Vice President for US Sales and Marketing; and Senior Vice President for US Treatment Access, Support Programs and Business Insights. 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 or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the \_\_\_\_\_ [insert name of the

department or functional area] with all applicable Federal health care program requirements, FDA requirements, obligations of the Corporate Integrity Agreement, and Indivior policies, and I have taken steps to promote such compliance. To the best of my knowledge, the \_\_\_\_\_ [insert name of department or functional area] of Indivior 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 90 days after the Effective Date, Indivior 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).

B. Written Standards

1. *Policies and Procedures.* Within 90 days after the Effective Date, Indivior 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 Indivior’s compliance with Federal health care program and FDA requirements (Policies and Procedures). Throughout the term of this CIA, Indivior 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. the materials and information that may be distributed by Indivior sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which Indivior sales representatives respond to requests for information about non-FDA approved (or “off-label”) uses of Government Reimbursed Products;
- d. the materials and information that may be distributed by Medical Information about Government Reimbursed Products and the mechanisms through, and manner in which, Medical Information receives and responds to requests for information from an HCP or another individual or entity about off-label uses of Government Reimbursed Products; the form and content of information disseminated by Indivior in response to such requests; and the internal review process for the information disseminated;
- e. the manner and circumstances under which medical personnel interact with or participate in meetings or events with HCPs, HCIs, or Payors (either alone or with Indivior 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;
- f. the materials and information that may be distributed or made available by Indivior through social media and/or direct-to-consumer advertising;
- g. the development, implementation, and review of call plans for sales representatives (including any contract sales force) and

other Indivior representatives who promote and sell Government Reimbursed Products;

- h. 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 Indivior (including, separately, from sales representatives, or through other channels);
- i. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements;
- j. 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;
- k. sponsorship or funding of grants (including educational grants) or charitable contributions;
- l. funding of, or participation in, any Third-Party Educational Activity as defined in Section II.C.6 above;
- m. review of promotional, coding, billing, reimbursement, and disease state materials and information intended to be disseminated outside Indivior 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 Indivior's review and approval process and are elevated when appropriate;

- n. compensation (including through salaries, bonuses, or other means) for Covered Persons engaged in Promotional Functions;
- o. 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 Indivior's discovery of erroneous or scientifically unsound information or data associated with the information in the Compendia and the publication of new study results.);
- p. 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;
- q. 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 Indivior 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

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

At least annually (and more frequently, if appropriate), Indivior 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.

2. *Third Party Personnel.* Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Indivior shall send, electronically or in hard copy format, a letter to each entity employing Third Party Personnel. The letter shall outline Indivior's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of Indivior's Compliance Program. Indivior shall include with the letter a copy of its Code of Conduct and shall request the entity employing Third Party Personnel to either: (a) make a description of Indivior's Compliance Program available to its Third Party Personnel; or (b) represent to Indivior that it has and enforces a substantively comparable compliance program for its Third Party Personnel.

### C. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, Indivior shall develop a written plan (Training Plan) that outlines the steps Indivior will take to ensure that: (a) all Covered Persons receive at least annual training regarding Indivior'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 Indivior 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. Indivior shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.



2. *NGC Training.* In addition to the training described in Section III.C.1, within 90 days after the Effective Date, each member of the NGC shall receive training regarding 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 NGC and should include a discussion of OIG's guidance on board member responsibilities.

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

3. *Training Records.* Indivior shall make available to OIG, upon request, training materials and records verifying that the training described in Sections III.C.1 and III.C.2 has been provided as required.

#### D. Risk Assessment and Mitigation Process

Within 120 days after the Effective Date, Indivior shall develop and implement a centralized annual risk assessment and mitigation process to identify and address risks associated with Indivior's compliance with Federal health care program requirements and FDA requirements, including risks associated with the sales, marketing, and promotion of Government Reimbursed Products. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and mitigation process. The Risk Assessment and Mitigation Process (RAMP) shall require compliance, legal, and business unit leaders, at least annually, to: (1) evaluate and identify emerging risks (e.g., new products or activities) and assess relevant, material changes to previously identified RAMP risk areas, (2) prioritize, develop, update (as relevant), and implement specific risk mitigation plans related to the identified, prioritized risks, (3) implement the risk mitigation plans (which may include compliance auditing and monitoring activities), and (4) track the implementation of the risk mitigation plans to assess the effectiveness of such plans. Indivior shall maintain the RAMP 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, Indivior 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 Indivior shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Indivior) related to the reviews.
- c. *Access to Records and Personnel.* Indivior 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. *System, Transaction, 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 Indivior’s systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in Indivior’s relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the first and fourth Reporting Periods. If Indivior 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 Indivior 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 Indivior and may consider internal audit and monitoring work conducted by Indivior, the Government Reimbursed Product portfolio, the nature and scope of Indivior’s promotional and other practices, the nature and scope of Indivior’s arrangements with HCPs and HCIs, and other information known to OIG.

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 Indivior 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 Indivior and IRO.

F. Disclosure Program

Within 90 days after the Effective Date, Indivior 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 Indivior’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. Indivior 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 Indivior'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 Indivior. 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, Indivior 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 all disclosures, whether or not related to a potential violation of criminal, civil or administrative law related to Federal health care programs or FDA requirements, 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 individual or department responsible for reviewing the disclosure, the status of the review, and any corrective action taken in response to the review.

#### 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.* Indivior shall ensure that all prospective and current Covered Persons are not Ineligible Persons by implementing the following screening requirements.

- a. Indivior 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. Indivior shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on an annual basis thereafter.
- c. Indivior shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

Nothing in this Section III.G affects Indivior’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. Indivior understands that items or services furnished, ordered, or prescribed by excluded persons are not payable by Federal health care programs and that Indivior may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Indivior meets the requirements of Section III.G.

3. *Removal Requirement.* If Indivior has actual notice that a Covered Person has become an Ineligible Person, Indivior shall remove such Covered Person from responsibility for, or involvement with, Indivior’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 Indivior 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, Indivior 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.* Indivior 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 or tolerate improper promotion, sales and marketing of Indivior's products; and (2) include mechanisms, where appropriate, to exclude from incentive compensation any sales that may indicate off-label promotion of Indivior'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. *Executive Financial Recoupment Program.* Indivior 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 two years of annual performance pay for a Covered Executive who is discovered to have been involved in any significant misconduct (Executive Financial Recoupment Program). 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, Indivior shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Indivior conducted or brought by a governmental entity or its agents involving an allegation that Indivior 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. Indivior 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 Indivior.

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

2. *Reporting of Reportable Events.* If Indivior determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Indivior shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. Indivior 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 Indivior'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 Indivior 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 Indivior and the FDA that materially discusses Indivior's or a Covered Person's actual or potential unlawful or improper promotion of Indivior's products (including any improper dissemination of information about off-label indications), Indivior shall provide a copy of the report, correspondence, or communication to OIG. Indivior 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 90 days after the Effective Date, Indivior 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 off-label promotional activities 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.*

Within 90 days after the Effective Date:

- a. Indivior shall establish a process to develop an annual budget and needs assessment process that identifies the business needs for, and the estimated numbers of, speaker program activities for the following year. As part of the process, Indivior shall identify the business need for the planned speaker programs and shall collect specific details about the speaker programs (e.g., the expected number of programs, the

topics of the programs, and the identity and qualifications of the proposed speakers.) The annual speaker program budget shall identify the total budgeted amounts to be spent on speaker programs. Indivior compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of approved plans. The purpose of this review shall be to ensure that speaker programs and related events (including speaker training events) are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and Indivior Policies and Procedures;

- b. Indivior shall implement a process to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements regarding the use of Indivior approved materials and requirements that speakers may not directly or indirectly promote the product for off-label uses.).
- c. Indivior shall establish a centralized 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.
- d. Indivior shall ensure that speakers are paid according to a centrally managed, pre-set rate structure determined based on a third-party fair-market value analysis.
- e. Indivior shall maintain a comprehensive list of speaker program attendees through a centralized system. In addition, Indivior shall use a centralized system to handle all logistics and spending associated with speaker programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs.

- f. Indivior shall require certifications by sales representatives or other Indivior personnel that a speaker program complied with Indivior requirements, or in the event of non-compliance, Indivior shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.
  
- g. Indivior shall institute a Speaker Monitoring Program under which Indivior compliance or other appropriately trained Indivior personnel who are independent from the functional area being monitored (Monitoring Personnel) or third party consultants appropriately trained by Indivior and under the supervision of Indivior shall attend 30 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 Indivior sales representative activities during the program to assess whether the programs were conducted in a manner consistent with Indivior's Policies and Procedures.

Indivior 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 Indivior 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 Indivior'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 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 Indivior 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 20 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, Indivior shall also review various types of records to assess field sales representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

- a. For each Reporting Period, Indivior 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 using either a risk-based targeting approach or a random sampling approach.
- 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 Indivior's Policies and Procedures or legal or compliance requirements, is identified during any portion of the FFMP, Indivior 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 90 days after the Effective Date, Indivior 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 Indivior 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. Indivior 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 third-party fair-market value analysis.
- b. Within 90 days after the Effective Date, Indivior shall establish a process and an Indivior Consultant Review Committee to review and approve each business needs assessment for each Consultant arrangement. Indivior compliance personnel shall chair the Consultant Review Committee and shall be involved in the review and approval of the business needs assessment for each Consultant engagement, including any subsequent modification of an approved Consulting activity. The sales and marketing functions shall not be represented on the Consultant Review Committee. The purpose of the Consultant Review Committee review shall be to ensure that Consultant arrangements and activities are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and Indivior Policies and Procedures. Indivior shall maintain the process within its annual budget planning cycle that requires oversight and approval by senior management responsible for annual budget setting, including any budget allocated toward Consultant engagements.
- c. Within 90 days after the Effective Date, Indivior shall establish a process that requires an HCP nomination to be

submitted to justify the retention of a named Consultant prior to the retention of the named Consultant. The HCP nomination shall identify the criteria and business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the qualifications of the HCP to be engaged, a description of the proposed work to be done, the type of work product to be generated, and, based on a FMV analysis, the proposed amount to be paid to the Consultant). Any deviations from an approved HCP nomination shall be documented in the centralized consultant review system and shall be subject to review and approval by Indivior compliance personnel.

- d. Within 90 days after the Effective Date, Indivior 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, Indivior received the work product generated by the Consultant.
- e. Within 90 days after the Effective Date, Indivior shall establish a Consultant Monitoring Program through which it shall conduct audits (Consultant Arrangement Audits) of at least ten Consultant arrangements 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 Indivior Consultant Review Committee documents (including HCP nominations), 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 Indivior's Policies and Procedures. Results from the Consultant Arrangement Audits, including the identification of potential violations of Indivior 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 Indivior engages or supports U.S.-based HCPs or HCIs to conduct Research (as defined above in Section III.B.1.p), such HCPs and HCIs shall be referred to collectively as “Researchers.”

- a. Indivior 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 by Indivior, and compliance obligations for the Researchers, including the requirement that the Researchers disclose the financial and other support received from Indivior and any other current financial relationship with Indivior.
- b. Researchers retained to conduct Research shall be paid according to a centrally managed, pre-set rate structure that is determined based on a third-party fair-market value analysis conducted.
- c. Within 90 days after the Effective Date, Indivior 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 Researcher arrangements to be entered into during the year. The annual Researcher budgeting plan shall also identify the budgeted amounts to be spent on Researcher arrangements during the year. Indivior 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 are used for legitimate purposes in accordance with Indivior Policies and Procedures and with Federal health care program and FDA requirements.
- d. Within 90 days after the Effective Date, Indivior 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 Indivior compliance personnel.

- e. Within 90 days after the Effective Date, Indivior 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 90 days after the Effective Date, Indivior shall establish a Researcher Monitoring Program through which it shall conduct audits for each Reporting Period (Researcher Arrangement Audits). Indivior shall review three 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 Arrangement Audits shall review needs assessment documents, proposal and/or protocol documents, approval documents, contracts, and payments in order to assess whether the arrangements were supported by Indivior (financially or otherwise) and performed by the Researchers in a manner consistent with Indivior's Policies and Procedures. Results from the Researcher Arrangement 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 Indivior 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. Indivior 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, including the requirement that Authors disclose the financial and other current relationships with Indivior. Authors shall be paid according to a centrally managed, pre-set rate structure that is determined based on a third-party fair-market value analysis.
- b. Within 90 days after the Effective Date, Indivior shall establish a process to develop annual plans that identify the business needs for and the estimated number of Publication Activities (Publication Plan). The annual Publication Plan shall also identify the budgeted amounts to be spent on Publication Activities. Indivior's compliance personnel shall be involved in the review and approval of each annual Publication Plan, including any modification of an approved plan. The purpose of this review shall be to ensure that Publication Activities are used for legitimate purposes in accordance with Indivior Policies and Procedures and with Federal health care program and FDA requirements.
- c. Within 90 days after the Effective Date, Indivior 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 Publication Plan shall be documented in the needs assessment form (or elsewhere, as appropriate) and shall be subject to review and approval by Indivior compliance personnel.
- d. Within 90 days after the Effective Date, Indivior shall establish a Publication Monitoring Program through which it shall conduct audits for each Reporting Period of at least five

Publication Activities. The Publication Monitoring Program shall select Publication Activities 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 Publication Activities), in order to assess whether the Publication Activities were conducted in a manner consistent with Indivior's Policies and Procedures. Results from the Publication Monitoring Program, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

4. *Grant and Charitable Contribution Activities.* To the extent that Indivior awards grants for independent medical education or other educational activities or provides charitable contributions, to HCPs or HCIs, such awards shall be referred to as "Grants."

- a. Within 90 days after the Effective Date, Indivior shall establish a centralized process which shall be the exclusive mechanism through which requestors may request or be awarded Grants.
- b. Grants requests shall be processed in accordance with standardized, objective criteria developed by Indivior. In addition, Grants shall be provided only pursuant to a written agreement with the funding recipient and in a manner consistent with the written agreement. Indivior's sales and marketing personnel shall have no involvement in, or influence over, the review and approval of Grants.
- c. Within 90 days after the Effective Date, Indivior shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least three Grants. The Grants Monitoring Program shall select Grants for review on either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall

review proposal documents (including Grants requests), approval documents, written agreements, payments and materials relating to the 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 Indivior'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.

5. *Follow Up Reviews and Reporting.* In the event that a potential violation of Indivior'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, Indivior 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. Notice to Health Care Providers and Entities

Within 30 days after the Effective Date, Indivior 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 Indivior's Chief Executive Officer containing the language set forth below:

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

In general terms, the Government alleges that Indivior engaged in certain unlawful and improper conduct relating to the promotion of Suboxone Film. To address criminal liability, a subsidiary of Indivior agreed to plead guilty to criminal charges of making materially false statements relating to

health care matters and agreed to pay almost \$300 million in criminal fines and forfeiture. In addition, to resolve liability under the Federal False Claims Act, Indivior agreed to enter into a civil settlement agreement and pay \$300 million. Further, Indivior has agreed to a stipulated injunction with the Federal Trade Commission. More information about this settlement may be found at the following: **[Indivior shall include a link to the USAO, OCL, and Indivior websites in the letter.]**

As part of the global settlement, Indivior also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, Indivior 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 Indivior's representatives to Indivior's Compliance organization or the FDA using the information set out below.

Please call Indivior at [insert toll free number] or visit us at [insert web link] if you have questions about the settlement referenced above. Please call Indivior at [insert toll free number] or visit us at [insert web address] to report any instances in which you believe that an Indivior 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 Indivior Representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about Indivior products to [insert toll free number].

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.

O. Reporting of Physician Payments

1. *Reporting of Payment Information.* Within 90 days after the Effective Date, Indivior 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)) and this information and link shall be maintained on the Indivior website at least throughout the term of the CIA. Indivior 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 Indivior.

2. *Definitions.* For purposes of this Section III.O, 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.

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

In the event that, after the Effective Date, Indivior 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. Indivior 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, Indivior 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, Indivior 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, Indivior 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, business address, business 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 NGC members who are responsible for satisfying the NGC 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 copy of the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;
5. a list of the Policies and Procedures required by Section III.B.1;
6. the Training Plan required by Section III.C.1 and a description of the NGC 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) a copy of the letter (including all attachments) required by Sections II.C.8 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' responses to Indivior's letter;
8. a description of the risk assessment and mitigation process required by Section III.D;
9. 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 Indivior that includes a summary of all current and prior engagements between Indivior and the IRO;

10. a description of the Disclosure Program required by Section III.F;
11. a description of the Ineligible Persons screening and removal process required by Section III.G;
12. a certification by the Compliance Officer that the notice required by Section III.N was posted in the manner required by Section III.N 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 Indivior's website as required by Section III.O;
14. a list of all of Indivior'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 Indivior'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

Indivior 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 NGC members who are responsible for satisfying the NGC 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, NGC, and Certifying Employees;
2. a description of any changes to the written process for Certifying Employees to follow in order to complete the certification required by Section III.A.4;



3. the dates of each report made by the Compliance Officer to the NGC (written documentation of such reports shall be made available to OIG upon request);
4. the NGC Board resolution required by Section III.A.3 and a description of the documents and other materials reviewed by the NGC, as well as any additional steps taken, in its oversight of the compliance program and in support of making the resolution;
5. for the first and third Reporting Periods, a copy of the Compliance Review Report prepared by the Compliance Expert for the NGC;
6. a list of any new or revised Policies and Procedures required by Section III.B.1 developed during the Reporting Period;
7. (a) a copy of the letter (including all attachments) required by Sections II.C.8 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all existing co-promotion and other applicable agreements with the party employing the Third Party Personnel; and (c) a description of the entities' responses to Indivior's letter;
8. a description of any changes to Indivior's Training Plan developed pursuant to Section III.C and a summary of any NGC training provided during the Reporting Period;
9. a description of any changes to the risk assessment and mitigation process required by Section III.D, including the reasons for such changes;
10. a summary of the following components of the risk assessment and mitigation process during the Reporting Period: (a) identification of new or updated risks; (b) mitigation plans developed; (c) implementation of mitigation plans; and (d) steps taken to track the implementation of the mitigation plans. Copies of any identified risks, mitigation plans, records relating to the implementation of the mitigation plans, and tracking reports shall be made available to OIG upon request;
11. a complete copy of all reports prepared pursuant to Section III.E and Indivior's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

12. a certification from the IRO regarding its professional independence and objectivity with respect to Indivior, including a summary of all current and prior engagements between Indivior and the IRO;

13. 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;

14. a description of any changes to the Ineligible Persons screening and removal process required by Section III.G, including the reasons for such changes;

15. a description of the Incentive Compensation Restriction and Financial Recoupment programs required by Section III.H, including any changes to the programs during the Reporting Period and the reasons for the changes, and the annual reports to OIG required under Section E of Appendix C;

16. 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;

17. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period;

18. 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;

19. 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 Indivior took as a result of such determinations;

20. 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 Indivior's policies or that improper promotion of

Government Reimbursed Products occurred and a description of the action(s) Indivior took as a result of such determinations;

21. a summary of the calls and messages received in response to the notice required by Section III.N and the disposition of those calls and messages;
22. a certification from the Compliance Officer that information regarding Payments has been posted on Indivior's website as required by Section III.O;
23. a description of all changes to the most recently provided list of Indivior's locations (including addresses) as required by Section V.A.13;
24. a description of any changes to Indivior's corporate structure, including any parent and sister companies, subsidiaries, and their respective lines of business; and
25. 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, Indivior 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, Indivior 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; and
  - c. he or she understands that the certification is being provided

to and relied upon by the United States.

D. Designation of Information

Indivior 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. Indivior 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

Indivior:

Cindy Cetani  
Chief Integrity & Compliance Officer  
Indivior Inc.  
10710 Midlothian Turnpike  
North Chesterfield, VA 23235  
Telephone: 804-594-1880  
Email: [Cindy.cetani@indivior.com](mailto:Cindy.cetani@indivior.com)

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, Indivior 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).

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

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

Indivior 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 Indivior prior to any release by OIG of information submitted by Indivior pursuant to its obligations under this CIA and identified upon submission by Indivior as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Indivior shall have the rights set forth at 45 C.F.R. § 5.42 (a).

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

Indivior 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, Indivior 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) per obligation for each day Indivior 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 NGC 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 and the development and implementation of a written process for Certifying Employees, as required by Section III.A.4;
- e. written Policies and Procedures;
- f. the development of a written training plan and the training and education of Covered Persons and NGC members;
- g. a risk assessment and mitigation 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. notification to HCPs and HCIs; and
- q. 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 Indivior fails to engage and use an IRO as required by Section III.E and Appendix 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 Indivior fails to timely submit (a) a complete Implementation Report or Annual Report, (b) a certification to OIG in accordance with the requirements of Section V, or (c) a complete response to any request for information from OIG.

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 Indivior fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendix B.

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

6. A Stipulated Penalty of \$50,000 for each false certification

submitted by or on behalf of Indivior 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 Indivior 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 Indivior 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 Indivior fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Indivior stating the specific grounds for its determination that Indivior has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Indivior shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 business days after the date Indivior 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

Indivior 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 Indivior 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 business days after Indivior 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 business 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 Indivior 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 Indivior of: (a) Indivior'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 business days after the receipt of the Demand Letter, Indivior 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 Indivior elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Indivior 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 Indivior 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 any of the following:

- 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 Indivior to report a Reportable Event and take corrective action as required in Section III.I;
- c. a failure to engage and use an IRO in accordance with Section III.E and Appendix B;

- d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
- e. the continued employment of a Suboxone sales force by Indivior in the United States or continued sales of Suboxone through Indivior sales representatives following the Effective Date of the CIA; or
- f. the involvement of Shaun Thaxter, former CEO of Indivior, Inc., in the daily activities, business decisions, operations, Board of Directors duties, management, or control of Indivior following the Effective Date of the CIA.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Indivior constitutes an independent basis for Indivior's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in OIG's discretion, but not more than five years per material breach. Upon a determination by OIG that Indivior has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Indivior of: (a) Indivior's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Indivior 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:

- a. the alleged material breach has been cured; or
- b. the alleged material breach cannot be cured within the 30 day period, but that: (i) Indivior has begun to take action to cure the material breach; (ii) Indivior is pursuing such action with due diligence; and (iii) Indivior has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, Indivior fails to satisfy the requirements of Section X.D.3, OIG may exclude Indivior from participation in the Federal health care programs. OIG shall notify Indivior in writing of

its determination to exclude Indivior (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 Indivior’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, Indivior may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG’s delivery to Indivior of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Indivior 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. 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 Indivior was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Indivior 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 Indivior to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Indivior 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.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether Indivior was in material breach of this CIA and, if so, whether:

- a. Indivior 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 Indivior's receipt of the Notice of Material Breach:
  - (i) Indivior had begun to take action to cure the material breach within that period; (ii) Indivior pursued such action with due diligence; and (iii) Indivior 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 Indivior, only after a DAB decision in favor of OIG. Indivior's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Indivior 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 Indivior 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. Indivior 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 Indivior, Indivior shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. 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**

Indivior and OIG agree as follows:

*Indivior Corporate Integrity Agreement*

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) Indivior'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 Indivior 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 INDIVIOR INC.**

Cynthia C Cetani  
CYNTHIA (CINDY) CETANI  
Chief Integrity & Compliance Officer  
Indivior Inc.

7/24/2020  
DATE

\_\_\_\_\_  
JAVIER RODRIGUEZ  
Chief Legal Officer  
Indivior Inc.

\_\_\_\_\_  
DATE

\_\_\_\_\_  
VIRGINIA A. GIBSON  
THOMAS BEIMERS  
ELIZA ANDONOVA  
Hogan Lovells US LLP  
Counsel for Indivior

\_\_\_\_\_  
DATE


ON BEHALF OF INDIVIOR INC.

CYNTHIA (CINDY) CI FANI  
Chief Integrity & Compliance Officer  
Indivior Inc.

DATE

  
\_\_\_\_\_  
JAVIER RODRIGUEZ  
Chief Legal Officer  
Indivior Inc.

DATE 7/24/20

  
\_\_\_\_\_  
VIRGINIA A. GIBSON  
THOMAS BEIMERS  
ELIZA ANDONOVA  
Hogan Lovells US LLP  
Counsel for Indivior

DATE 7/24/20

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



\_\_\_\_\_  
LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Inspector General  
U.S. Department of Health and Human Services



\_\_\_\_\_  
DATE



\_\_\_\_\_  
MARY E. RIORDAN, Senior Counsel  
MADELINE BAINER, Senior Counsel  
Office of Inspector General  
U.S. Department of Health and Human Services



\_\_\_\_\_  
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. Indivior 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.9 of the CIA or any additional information submitted by Indivior in response to a request by OIG, whichever is later, OIG will notify Indivior if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Indivior may continue to engage the IRO.

2. If Indivior 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, Indivior shall submit the information identified in Section V.A.9 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 Indivior at the request of OIG, whichever is later, OIG will notify Indivior if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Indivior 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. respond to all OIG inquiries in a prompt, objective, and factual manner; and
4. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. Indivior Responsibilities

Indivior 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. *Indivior and IRO.* If Indivior terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, Indivior 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. Indivior 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 Indivior in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. Indivior 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 Indivior regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify Indivior in writing that Indivior shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. Indivior 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 Indivior to engage a new IRO shall be made at the sole discretion of OIG.

## APPENDIX B

### INDEPENDENT REVIEW ORGANIZATION REVIEWS

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

As specified more fully below, Indivior shall retain an Independent Review Organization (IRO) (or IROs) to perform reviews (IRO Reviews) to assist Indivior in assessing and evaluating certain systems, processes, policies, procedures, and practices. The IRO Review shall consist of two components - a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. Indivior 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 Indivior relating to reviewed Policies and Procedures described below, the IRO shall perform the Systems Review for the first and fourth Reporting Periods. If Indivior materially changes applicable systems, processes, policies, and procedures, 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 Indivior relating to Promotional Functions, Product Related Functions, and other systems as described below. Where practical, Indivior 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 Indivior in accordance with the preceding sentence.

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

1. Indivior’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 Indivior 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 Indivior’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, payors, and formulary decision-makers by Indivior; (d) the systems, processes, policies, and procedures to track requests to Medical Affairs for information about off-label uses of products and responses to those requests; (e) the manner in which Indivior collects 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 Indivior identify situations in which it appears that off-label or other improper promotion may have occurred; and (g) Indivior’s processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving improper promotion;

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

3. Indivior’s systems (including any centralized systems), processes, policies, and procedures relating to speaker programs, speaker training programs, and all events and expenses relating to such engagements or arrangements;

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

5. Indivior's systems, policies, processes, and procedures applicable to Indivior's internal review of promotional materials related to Government Reimbursed Products that are disseminated to HCPs, HCIs, and payors or individuals or entities acting on behalf of HCPs, HCIs or payors (e.g., PBMs);

6. Indivior's systems, policies, processes, and procedures applicable to Indivior's internal review of non-promotional materials related to Government Reimbursed Products (e.g., disease state awareness materials, information on social media platforms, etc.) disseminated to HCPs, HCIs, payors, patients, or other individuals or entities;

7. Indivior's systems, policies, processes, and procedures applicable to patient outreach efforts and materials used in connection with such efforts, including direct-to-consumer advertising, patient education, and the dissemination of materials/information through social media;

8. Indivior's systems, policies, processes, and procedures applicable to the development and review of Indivior processes relating to incentive compensation for Covered Persons who are 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 or tolerate the improper promotion, sales, and marketing of Government Reimbursed Products. To the extent that Indivior establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;

9. Indivior's systems, policies, processes, and procedures applicable to the development and review of Indivior'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 expected utilization of Government Reimbursed Products for FDA-approved uses or non-FDA-approved uses;

10. Indivior's systems, policies, processes, and procedures applicable to the development and review of Sample Distribution Plans (as defined in Section III.B.1.h 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 Indivior (including, separately, from Indivior sales representatives and other Indivior personnel or components). It shall also include a review of whether samples of Government Reimbursed Products are distributed by Indivior through sales representatives or are distributed from a central location and the rationale for the manner of distribution;

11. Indivior'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.1.o 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;

12. Indivior's systems, processes, policies, and procedures of Indivior's funding, directly or indirectly, of Third-Party Educational Activities (as defined in Section II.C.6 of the CIA) and all events and expenses relating to such activities;

13. Indivior's systems, processes, policies, and procedures applicable to Research (as defined in Section III.B.1.p), 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;

14. Indivior's systems, processes, policies, and procedures relating to authorship-related practices (as defined in Section III.B.1.q of the CIA), including, but not limited to, the disclosure of all financial relationships between the author and Indivior, 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;

15. Indivior's systems, processes, policies, and procedures applicable 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;

16. Indivior's systems, processes, policies, and procedures relating to its risk assessment and mitigation process outlined in Section III.D of the CIA. This review shall assess whether the risk assessment and mitigation process identifies and addresses relevant and appropriate risks for Indivior's compliance with Federal health care program and FDA requirements, including risks relating to Government Reimbursed Products and other applicable risks.

B. 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 Section II.A 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 Section II.A above, including a general description of the control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Section II.A above are made known or disseminated within the Indivior;
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 sales representatives and their direct managers, including a description of the bases upon which compensation is determined. To the extent that Indivior may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;
6. findings relating to whether the risk assessment and mitigation processes identify and address relevant prioritized risks associated with Indivior's compliance with Federal health care program and FDA requirements;



7. findings relating to whether the risk assessment and mitigation processes result in the implementation of appropriate prioritized mitigation plans and appropriate tracking and monitoring of such mitigation plans;

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

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

### III. Transactions Review

As described more fully below, the Transactions Review shall include: (1) a review of Indivior's call plans and the call plan review process; (2) a review of Consulting Activities; (3) a review of selected compliance auditing and monitoring activities; and (4) 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 Indivior's review of its call plans for Government Reimbursed Products.

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

2. *Selection of Sample.* 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 Indivior in conducting its review and/or modifying the

call plan. The IRO shall seek to determine whether Indivior followed its criteria and Policies and Procedures in reviewing and modifying the call plan.

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

B. 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. This shall include, but not be limited to, speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, research and development meetings, product training and education sessions, ad hoc advisory activities, research and any other financial engagements or arrangements with an HCP or HCI and all expenses relating to the engagements or arrangements.

2. *Selection of Sample.* For the first Reporting Period, the IRO shall select and review a sample of 30 of the Consulting Activities for which Indivior retained HCPs or HCIs and all related expenses. Of this number, at least 20 speaker program activities shall be reviewed. The IRO shall select at least 3 of the remaining Consulting Activities from the Advisory Board Services category, 2 from the Conferences and Meetings category, and 5 from the General Consulting Services category

For the second and subsequent Reporting Periods, at least 60 days prior to the end of the applicable Reporting Period, Indivior shall provide the following information to OIG: (a) a description of each type of Consulting Activity undertaken during the Reporting Period and a description of the services to be provided under each Consulting Activity; (b) the number of each type of Consulting Activity undertaken during the Reporting Period; and (c) the overall budgeted amount spent in connection with each type of Consulting Activity during the Reporting Period. For the second and subsequent Reporting Periods, the IRO shall review 30 Consulting Activities which shall include a review of specified numbers of each type of Consulting Activities as determined by 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 paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure established by Indivior and was consistent with any compensation limits for the Consulting Activity established by Indivior Policies and procedures;
- c. the rate structure referenced in Section III.B.3.b was established based on an independent FMV analysis;
- d. the Consulting Activity was approved by the Consultant Review Committee in accordance with Indivior policies and procedures, including with regard to an assessment of the business need for the Consulting Activity;
- e. the HCP or HCI was reviewed and approved by the Consultant Review Committee for the Consulting Activity in accordance with Indivior's policies relating to the identification, selection, and approval of a Consultant;
- f. Indivior 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
- g. the activity undertaken by the Consultant and/or the work product generated by the HCP or HCI was used by Indivior in a manner consistent with the need identified by the Consultant Review Committee process that was completed prior to the initiation of the Consulting Activity.

In addition, for each Consulting Activity selected for review, Indivior shall provide the IRO with information about the total aggregate annual Payments (as defined in Section III.O of the CIA) by Indivior to the associated HCP or HCI (including, e.g., Payments for Consulting Activities other than the particular Consulting Activity selected for review.) The IRO shall assess whether Indivior paid the HCP or HCI an amount that exceeded the annual cap on compensation established in accordance with Indivior's Policies and procedures.

C. IRO Review of Select Audits. Each year, Indivior conducts a Risk Assessment and Mitigation Process (RAMP) as described in Section III.D of the CIA. As part of the annual risk assessment process, Indivior develops and implements specific risk mitigation plans related to identified, prioritized risk areas which may include compliance auditing and monitoring activities.

For the second through fifth Reporting Periods, Indivior shall provide the IRO and OIG with: i) the output of the RAMP from the prior year and ii) Indivior's mitigation plan(s) relating to identified risk areas. The OIG will select for review by the IRO seven of the Indivior compliance auditing and monitoring activities conducted at the Indivior business units performing Covered Functions and identified in the mitigation plans for prioritized risk areas ("Selected Audits").

For each of the Selected Audits, Indivior shall provide the IRO with: i) the compliance auditing and monitoring activities work plan; ii) the compliance auditing and monitoring activities report(s); iii) any materials or documentation reviewed as part of the compliance auditing and monitoring activities, and iv) documentation of any corrective action taken by Indivior as a result of the compliance auditing and monitoring activities.

For each of the Selected Audits, the IRO shall: i) evaluate whether the compliance auditing and monitoring work plan was reasonably designed to address the identified risk the plan was meant to address; and ii) note any instances in which Indivior failed to follow its compliance auditing and monitoring work plan or failed appropriately to identify and address the compliance related concerns related to the identified risk areas. The IRO shall report on its findings from the reviews in the Transactions Review Reports.

D. IRO Review of Additional Items. As set forth in Section III.E.2.c 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 Indivior 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 Indivior 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 Indivior's systems, processes, policies, and procedures based on its review of each Additional Item).

2. Indivior may propose to the OIG that its internal audit(s), reviews, or monitoring activities, including those conducted as part of the Field Force Monitoring Program described in Section III.L or the Monitoring of Non-Promotional Activities described in Section III.M of the CIA and/or other reviews conducted by outside entities at Indivior's request 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 Indivior'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 Indivior's planned internal audit work or compliance monitoring or audit activities, the results of the Transactions Review(s) during prior Reporting Period(s), and Indivior's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Indivior's request to permit its internal audit work or compliance monitoring or audit activities to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Indivior shall engage the IRO to perform the Review as outlined in this Section III.E.

4. If the OIG agrees to permit certain of Indivior's internal audit work or compliance monitoring or audit activities 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.

E. 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 items shall be included in each Transaction Review Report:

- a. Relating to the Call Plan Review:
  - i. a list of the Government Reimbursed Products promoted by Indivior 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 Indivior 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 Indivior's criteria relating to the call plan and/or Indivior's Policies and Procedures; and iv) a description of all instances in which it appears that Indivior failed to follow its

criteria or Policies and Procedures relating to call plans;

- iii. the findings and supporting rationale regarding any weaknesses in Indivior's systems, processes, policies, procedures, and practices relating to call plans, if any; and
- iv. recommendations, if any, for changes in Indivior's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to call plans.

b.

Relating to the Review of Consulting Activities.

- i. A description of each type of Consulting Activity reviewed, including the number of each type of Consulting Activity reviewed and an identification of the types of documents and information reviewed for each Consulting Activity;
- ii. For each Consulting Activity, the aggregate annual amount paid by Indivior to the associated HCP or HCI for all purposes;
- iii. 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

- Indivior and was consistent with any compensation limits for the Consulting Activity established by Indivior policies and procedures;
- c. the rate structure was established based on an independent FMV analysis;
  - d. the Consulting Activity was approved by the Consultant Review Committee in accordance with Indivior Policies and procedures, including Policies and procedures relating to the identification, selection and approval of a given HCP or HCI and the completion of a needs assessment;
  - e. Indivior collected and retained a record of the specific activity performed by the HCP or HCI and, if applicable, a copy of the work product generated in connection with the Consulting Activity;
  - f. the activity undertaken by the Consultant and/or the work product generated was used by Indivior in a manner consistent with Consultant Review Committee approval completed prior to the initiation of the Consulting Activity;
  - g. the aggregate amount paid by Indivior to the HCP or HCI exceeded the applicable cap established under Indivior's Policies and procedures;
  - h. the IRO identified any weaknesses in Indivior's systems, processes, policies, procedures and/or practices relating to Consulting Activities; and
  - i. the IRO has recommendations for improvements to Indivior's systems, processes,



policies, procedures and/or practices relating to Consulting Activities.

c. Relating to IRO Review of Selected Audits

- i. A description of each Selected Audit reviewed by the IRO, including the documentation reviewed for each Selected Audit;
- ii. The IRO's findings and supporting rationale regarding whether:
  - a. Indivior's report from the compliance auditing and monitoring activities was consistent with the compliance auditing and monitoring activities work plan and documentation reviewed by Indivior in the process;
  - b. the IRO agreed with the findings in Indivior's compliance auditing and monitoring report or, if applicable, the basis for the IRO's disagreement;
  - c. the compliance auditing and monitoring work plan was reasonably designed to address the identified risk areas;
  - d. Indivior took appropriate corrective action in response to any compliance auditing and monitoring findings and, if applicable, the IRO's recommendations regarding any additional or alternative corrective action;
  - e. Indivior took appropriate follow-up steps to ensure that any corrective action was appropriately implemented and, if applicable, the IRO's recommendations regarding any additional or alternative follow-up steps; and

- f. the compliance auditing and monitoring activities were reasonably designed to identify and address any compliance related concerns related to the Selected Audit risk areas and, if applicable, a description of any compliance related concerns that were not reasonably identified and addressed.

d. 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 Indivior'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 Indivior'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**  
**Executive Financial Recoupment Program**

Within 120 days after the Effective Date of the CIA, Indivior shall establish and maintain throughout the term of the CIA two programs relating to compensation for its employees and executives. The first shall be an Employee and Executive Incentive Compensation Restriction Program as described below in Section A. The second shall be an Executive Financial Recoupment Program as described below in Section B.

**(A) Employee and Executive Incentive Compensation Restriction Program**

Indivior's Incentive Compensation Policy ("ICP") outlines the criteria that Indivior Employees must satisfy as a prerequisite to earning incentive compensation. Incentive compensation is designed to reward and drive performance and behaviors consistent with Indivior's mission, Code of Conduct, and policies, values, and strategy. For the Addiction Sciences business unit, incentive compensation is designed so that financial incentives do not inappropriately incentivize Employees to engage in or tolerate marketing, promoting, or selling of Company products (1) for unapproved uses, (2) to prescribers of buprenorphine products who are not DATA 2000-waivered or prescribers who practice within an excluded specialty, and (3) to prescribers on a government debarred list or who have been delisted pursuant to Indivior's Prescriber Concern Report Policy. For the Behavioral Health business unit, incentive compensation is designed so that financial incentives do not inappropriately incentivize Employees to engage in or tolerate marketing, promoting, or selling of Company products (1) for unapproved uses, (2) to prescribers who practice within an excluded specialty, and (3) to prescribers on a government debarred list or who have been delisted pursuant to Indivior's Prescriber Concern Report Policy. Under the ICP, Employees may not be eligible or may have limited eligibility for incentive compensation where they have been found to have committed violations of company policies and procedures, have not completed compliance training, or have unsatisfactory job performance.

**(B) Executive Financial Recoupment Program**

Within 120 days after the Effective Date of the CIA, Indivior shall establish a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 2 years of annual performance pay (including Cash and Equity Awards as defined below) for any Covered Executive (as defined below) who is the subject of an Affirmative Recoupment Determination. This program shall be known as the Executive Financial Recoupment Program. This recoupment program shall apply to Covered Executives who, at the time of a Recoupment Determination, are either current Indivior employees or became former Indivior employees at any time 120 days or more after the Effective Date of the CIA.

Within 120 days after the Effective Date of the CIA, Indivior shall establish policies and procedures (and modify employment and other contracts as necessary) to provide that incentive awards, bonuses, and other similar awards on an after tax/net basis (collectively “Cash Awards”) for each Covered Executive is at risk of forfeiture in the event of Significant Misconduct (i.e., a violation of a law or regulation or a significant violation of an Indivior policy) that is discovered by Indivior before the bonus is paid. In the event of Significant Misconduct by any Covered Executive, Indivior shall also reserve the right and full discretion to void and forfeit any unvested market value options, unvested conditional awards, unvested deferred bonus awards, and other unvested rights to receive company ordinary shares (collectively, “Equity Awards”) which are granted 120 days or more after the Effective Date of the CIA. If Indivior discovers any Significant Misconduct that would implicate the forfeitures described in this Paragraph by a Covered Executive, it shall evaluate the situation in accordance with the process outlined below and make a determination about whether any forfeiture, and the terms of such forfeiture, shall be implemented.

Within 120 days after the Effective Date of the CIA, Indivior shall modify and supplement the Annual Incentive Plans, Long-Term Incentive Plan and Deferred Bonus Plan applicable to Covered Executives (and any employment agreements, as appropriate) by imposing the eligibility and repayment conditions described below on future Cash and Equity Awards and making the additional remedies discussed below applicable to all U.S.-based Executive Committee Members and Senior Vice Presidents (collectively, “Covered Executives”). Indivior shall implement policies and procedures and, as necessary, shall modify contracts with Covered Executives so that, beginning no later than calendar year 2021, Cash and Equity Awards which are granted 120 days or more after the Effective Date of the CIA may be recouped if an Affirmative Recoupment Determination is made. The forfeiture and recoupment rights described in this Paragraph shall apply prospectively to Covered Executives beginning no later than the calendar year 2021 bonus plan and Equity Award years.

**(i) Cash Award Eligibility and Repayment Conditions.** Within 120 days after the Effective Date of the CIA, Indivior shall implement an eligibility and repayment condition on Cash Awards that will allow Indivior, as a consequence of a Triggering Event, to pursue repayment from Covered Executives of an amount equivalent to up to two years of Cash Awards paid to the individual. These eligibility and repayment conditions shall be designed to survive the payment of the Covered Executive’s Cash Award and the separation of the Covered Executive’s employment for a period of two years from the payment of the Cash Award. If payment of any portion of a Cash Award is deferred on a mandatory or voluntary basis, the two-year period shall be measured from the date the bonus would have been paid in the absence of deferral.

If an Affirmative Recoupment Determination is made, Indivior shall endeavor to

collect repayment of any Cash Award from the Covered Executive through reasonable and appropriate means according to the terms of its Cash Award 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, Indivior shall file suit against the Covered Executive unless good cause exists not to do so. For purposes of the Executive Financial Recoupment Program, good cause shall include, but not be limited to, a financial inability on the part of the Covered Executive to repay any recoupment amount or Indivior's inability to bring such a suit under the controlling law of the relevant jurisdiction.

**(ii) Equity Awards and Repayment Conditions.** Within 120 days after the Effective Date of the CIA, Indivior shall implement an eligibility and repayment condition on Indivior's Equity Awards that will allow Indivior, as a consequence of a Triggering Event, to pursue repayment from Covered Executives of all or a portion of the value of Equity Awards provided to the Covered Executive for the two years prior to the Affirmative Recoupment Determination Equity Awards. These eligibility and repayment conditions shall be designed to survive the vesting or distribution of the Equity Award and the separation of a Covered Executive's employment for a period of two years from the vesting or distribution.

If an Affirmative Recoupment Determination is made, Indivior shall endeavor to collect repayment of all or a portion of the value of Equity Awards for the two years prior to an Affirmative Recoupment Determination from a Covered Executive through reasonable and appropriate means (including by means of filing suit against the executive, as may be appropriate) to the extent permitted by controlling law of the relevant jurisdiction.

**(iii) Additional Remedies.**

To the extent permitting by controlling law, for the two years during which the Cash and Equity Award eligibility and repayment conditions exist, if Indivior reasonably anticipates that a Triggering Event has occurred, and Indivior has recoupment rights remaining under Paragraphs B(i)-(ii), Indivior shall have the right to notify the Covered Executive that those rights shall be tolled and thereby extended for an additional two years or until the Recoupment Committee determines that a Triggering Event has not occurred, whichever is earlier, to the extent permitted by controlling law of the relevant jurisdiction.

If, after expiration of the time period specified in Paragraphs B(i)-(ii) above, the Recoupment Committee determines that a Triggering Event has occurred, Indivior shall make a determination as to whether to pursue available remedies (e.g., filing suit against the Covered Executive) 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 either of the following (each, a “Triggering Event”):

- (i) Significant Misconduct (*i.e.*, a violation of a law or regulation or a significant violation of an Indivior policy) relating to Covered Functions by the Covered Executive that, if discovered prior to payment, would have made the Covered Executive ineligible for a Cash or Equity Award in that plan year or subsequent plan years; or
- (ii) Significant Misconduct (as defined above) relating to Covered Functions by subordinate employees in the business unit for which the Covered Executive had responsibility on or after 120 days after the Effective Date of the CIA that does not constitute an isolated occurrence and which the Covered Executive knew or should have known was occurring that, if discovered prior to payment, would have made the Covered Executive ineligible for a Cash or Equity Award in that plan year or subsequent plan years.

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

**(i) Initiation.** Indivior shall initiate the Recoupment Determination process within 30 days after: (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 Indivior’s Chief Integrity & 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 healthcare programs. This written notification shall either identify the Covered Executive(s) potentially at issue or provide information (*e.g.*, a description of the alleged misconduct and the applicable time period) to allow Indivior to identify the Covered Executive.

**(ii) Indivior Oversight Committee.** The Recoupment Determination or Recoupment Recommendation shall be made by a committee of senior executives

representing the Compliance, Legal, and Human Resources groups (Indivior Oversight Committee). The Indivior Oversight Committee shall make a Recoupment Recommendation for all Executive Officers or Executive Committee members of Indivior and shall make a Recoupment Determination for all other Covered Executives. A Covered Executive shall not participate in the Indivior Oversight Committee while that individual is subject to a Recoupment Determination. If a Recoupment Determination involves an Executive Officer or Executive Committee member of Indivior, a Recoupment Determination for such individual shall be subject to approval by the Board of Directors (or appropriate committee thereof) of Indivior.

**(iii) Recoupment Determination Process.** Indivior shall initiate the Recoupment Determination process within 30 days after discovery by Indivior, or notification pursuant to Paragraph D(i)(2), of a potential Triggering Event.

As part of the Recoupment Determination process, the Indivior Oversight 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)(2) 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)(2) 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 or Equity Awards (collectively “performance pay”) that will be subject to forfeiture and/or repayment by the Covered Executive, if any; 3) the means that will be followed to implement the forfeiture and/or secure the recoupment of performance pay from the Covered Executive; and 4) the timetables under which Indivior will implement the forfeiture and/or attempt to recoup the performance pay.

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

**(E) Reporting.** The Indivior Oversight Committee shall provide annual reports to the Board of Directors (or an appropriate committee thereof) of Indivior PLC 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 Covered Executives, 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.

The Indivior Oversight Committee shall also provide annual reports to 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 Covered Executives, 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.

Indivior shall provide OIG with additional information regarding any Recoupment Determination where a Triggering Event has occurred upon OIG's request.

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