

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ESSILOR OF AMERICA, INC. AND
ESSILOR LABORATORIES OF AMERICA, INC.**

I. PREAMBLE

Essilor of America, Inc. and Essilor Laboratories of America, Inc. (collectively, “Essilor”) hereby enter 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, Essilor is entering into a Settlement Agreement with the United States.

Essilor represents that, prior to the Effective Date (as defined below), Essilor established a compliance program that addresses all seven elements of an effective compliance program and is designed to address compliance with Federal health care program requirements (Compliance Program). Essilor further represents that its Compliance Program includes a Compliance Officer and Compliance Committee. It also includes a Code of Conduct, written policies and procedures, educational and training initiatives, a disclosure program, a risk management assessment system, and internal auditing procedures. Essilor shall continue the Compliance Program throughout the term of the CIA and shall do so in accordance with the terms set forth below. Essilor may modify the Compliance Program, as appropriate. However, at a minimum, Essilor 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 Effective Date of this CIA shall be the date on which the final signatory of this CIA executes this CIA. The term of this CIA shall be five years from the Effective Date. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, X, and XI shall expire no later than 120 days after OIG’s receipt of: (1) Essilor’s final Annual Report; or (2) any additional materials submitted by Essilor 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 Essilor who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading); (b) all officers, directors and employees of Essilor; and (c) all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of Essilor. Notwithstanding, the term “Covered Persons” does not include part-time or per diem employees, contractors, subcontractors, agents, or persons who are not reasonably expected to work more than 160 hours during a fiscal year, except that any such persons shall become Covered Persons at the point when they work more than 160 hours during the fiscal year.

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

3. The term “Covered Functions” includes: (a) the selling, marketing, advertising, promoting, or branding of Government Reimbursed Products, including the negotiation of contracts for the purchase of Government Reimbursed Products and direct-to-consumer sales of Government Reimbursed Products; (b) the preparation or external dissemination of promotional materials or information about, or the provision of services relating to, Government Reimbursed Products, including those functions relating to Essilor’s review and approval processes for promotional materials and any applicable review committee(s); (c) the preparation or external dissemination of non-promotional materials about Government Reimbursed Products, including those functions relating to

Essilor's review and approval process for any non-promotional materials and any applicable review committees; (d) contracting with eye care professionals, including optometrists, opticians or ophthalmologists (ECPs) or entities that (i) employ or contract with ECPs, (ii) manage or operate optical or ophthalmology practices, or (iii) otherwise provide optical care or services (referred to herein as Eye Care Institutions or ECIs for any Co-Marketing Activity; and (e) reviewing and/or approving requests for grants or charitable contributions.

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

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

6. The term "Co-Marketing Activity" shall mean any marketing or other promotional activity that Essilor performs with or on behalf of (in addition to itself) one or more ECPs or ECIs involving a Government Reimbursed Product.

III. COMPLIANCE PROGRAM REQUIREMENTS

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

A. Compliance Officer, Compliance Committee, Board of Directors Oversight, and Management Certifications

1. *Compliance Officer.* Within 90 days after the Effective Date, Essilor 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 Essilor; shall report directly to the President of Essilor; and shall not be, or be subordinate to, the General Counsel or Chief Financial Officer or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for Essilor. The Compliance Officer shall be responsible for, without limitation:

*Essilor of America, Inc. and Essilor Laboratories of America, Inc.
Corporate Integrity Agreement*

- 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 to the Board of Directors (Board) and shall be authorized to report on such matters to the Board at any time. Written documentation of the Compliance Officer's reports to the Board shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by Essilor as well as any reporting requirements 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.

Essilor 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 requirements in this CIA, within five business days after such a change.

2. *Compliance Committee.* Within 120 days after the Effective Date, Essilor shall appoint a Compliance Committee. The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as sales, marketing, legal, medical affairs/medical information, regulatory affairs, research and development, human resources, audit, finance, manufacturing, and operations). The Compliance Officer shall chair the Compliance Committee and the Compliance Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of Essilor'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.

Essilor 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 requirements in this CIA, within 15 business days after such a change.

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

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

- a. meeting at least quarterly to review and oversee Essilor's compliance program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period;
- c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board, summarizing its review and oversight of Essilor's compliance with Federal health care program requirements, FDA requirements, and the requirements of this CIA; and
- d. for each Reporting Period of the CIA, the Board 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 Essilor'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 Essilor's compliance program. The Board shall review the Compliance Program Review Report as part of its review and oversight of Essilor's compliance program. A copy of the Compliance Program Review report shall be provided to OIG in each Annual Report submitted by Essilor. In addition, copies of any materials provided to the Board by the Compliance Expert, along with minutes of any meetings between the Compliance Expert and the Board, shall be made available to OIG upon request.

At minimum, the resolution shall include the following language:

“The Board has made a reasonable inquiry into the operations of Essilor's compliance program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Essilor has implemented an effective compliance program to meet Federal health care program requirements, FDA requirements, and the requirements of the Corporate Integrity Agreement.”

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

Essilor shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the requirements 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 Essilor employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Essilor business unit is in compliance with applicable Federal health care program and FDA requirements and with the requirements of this CIA. These Certifying Employees shall include, at a minimum, the following: President of Essilor North America, President of Distributor Channels,

Chief Financial Officer, Chief Marketing Officer, Senior Vice President of Customer Development, and Senior Vice President of Sales. For each Reporting Period, each Certifying Employee shall sign a certification that states:

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

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

Within 120 days after the Effective Date, Essilor 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 120 days after the Effective Date, Essilor 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 Essilor’s compliance with Federal health care program and FDA requirements (Policies and Procedures). Throughout the term of this CIA, Essilor 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 Covered 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;
- b. ensuring that any discounts, rebates, or other reductions in price offered to ECP or ECI purchasers of Government Reimbursed Products comply with the Federal Anti-Kickback Statute;
- c. the materials and information that may be distributed by Essilor sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which Essilor sales representatives respond to requests for information about uses of Government Reimbursed Products that are not FDA approved, cleared or exempt (“non-FDA approved uses”);
- d. the materials and information that may be distributed and the mechanisms through, and manner in which, Essilor receives and responds to requests for information from an ECP or another individual or entity about non-FDA approved uses of Government Reimbursed Products; the form and content of information disseminated by Essilor in response to such requests; and the internal review process for the information disseminated;
- e. the manner and circumstances under which Essilor medical personnel interact with or participate in meetings or events with ECPs, ECIs, or payors (either alone or with Essilor sales representatives) and the role of Essilor medical personnel at such meetings or events, as well as how they handle responses to requests for information about non-FDA approved uses of Government Reimbursed Products;

- f. the materials and information that may be distributed or made available by Essilor through social media and/or direct-to-consumer advertising;
- g. the development, implementation, and review of policies for the distribution of Government Reimbursed Products for evaluation purposes (Evaluation Product). This shall include a review of the bases upon, and circumstances under, which ECPs and ECIs belonging to specified medical specialties or types of clinical practice may receive Evaluation Product from Essilor (including, separately, from sales representatives, or through other channels);
- h. agreements or arrangements with ECPs or ECIs for the purchase or licensing of intellectual property (including, but not limited to, patents, patent applications, and the payment of royalties);
- i. programs by ECPs to educate sales representatives, including but not limited to presentations by ECPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;
- j. review and approval of, and payment for, travel and related expenses for ECPs including those in connection with ECP participation in educational, research, training, or other Essilor-sponsored programs or activities;
- k. sponsorship or funding of grants (including educational grants) or charitable contributions involving ECPs and ECIs;
- l. funding of, or participation in, any Sponsorships, Third Party Educational Activity, or Co-Marketing Activity as defined in Sections II.C.4, II.C.5, and II.C.6 above;
- m. review of promotional, reimbursement-related, and disease state materials and information intended to be disseminated outside Essilor 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 Essilor's review and approval process and are elevated when appropriate;

- n. compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives and their managers; and
- o. disciplinary policies and procedures for violations of Essilor's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

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

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

C. Training and Education

1. *Covered Persons Training.* Within 120 days after the Effective Date, Essilor shall develop a written plan (Training Plan) that outlines the steps Essilor will take to ensure that: (a) all Covered Persons receive at least annual training regarding Essilor'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 Essilor 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 required to attend each training session, length of the training session(s), schedule for training, and format of the training. Essilor shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Training.* In addition to the training described in Section III.C.1, within 120 days after the Effective Date, each member of the Board 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 Board and should include a discussion of OIG's guidance on board member responsibilities.

New members of the Board shall receive the Board Training described above within 30 days after becoming a member or within 120 days after the Effective Date, whichever is later.

3. *Training Records.* Essilor 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 Internal Review Process

Within 120 days after the Effective Date, Essilor shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with each Government Reimbursed Product, including risks associated with the Covered Functions. The Compliance Committee shall be responsible for implementation and oversight of the risk assessment and internal review process. The risk assessment and internal review process shall be conducted annually and shall require Essilor to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. Essilor shall maintain the risk assessment and internal review process for the term of the CIA.

E. Review Procedures

1. *General Description.*

- a. *Engagement of Independent Review Organization.* Within 120 days after the Effective Date, Essilor 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 Essilor shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Essilor) related to the reviews.
- c. *Access to Records and Personnel.* Essilor shall ensure the IRO has access to all records and personnel necessary to complete the reviews listed in this Section III.E., and that all records furnished to the IRO are accurate and complete.

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

- a. *Systems Review.* The Systems Reviews shall assess Essilor's systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in Essilor's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the first and fourth Reporting Periods. If Essilor 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 Essilor 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 Essilor and may consider internal audit and monitoring work conducted by Essilor, the Government Reimbursed Product portfolio, the nature and scope of Essilor’s promotional and other practices, the nature and scope of Essilor’s arrangements with ECPs and ECIs, 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 Essilor 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 Essilor and IRO.

F. Disclosure Program

Within 120 days after the Effective Date, Essilor 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 Essilor’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. Essilor 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 Essilor'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 Essilor. 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, Essilor 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.* Essilor shall ensure that all prospective and current Covered Persons are not Ineligible Persons by implementing the following screening requirements.

- a. Essilor 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. Essilor shall screen all current Covered Persons against the Exclusion List within 120 days after the Effective Date and on an annual basis thereafter.
- c. Essilor shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

3. *Removal Requirement.* If Essilor has actual notice that a Covered Person has become an Ineligible Person, Essilor shall remove such Covered Person from responsibility for, or involvement with, Essilor’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 Essilor 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, Essilor 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. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, Essilor shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Essilor conducted or brought by a governmental entity or its agents involving an allegation that Essilor 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. Essilor 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.

I. 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 marketing or sale of Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below;

- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by Essilor.

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

2. *Reporting of Reportable Events.* If Essilor determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Essilor shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.

3. *Reportable Events under Sections III.I.1.a and III.I.1.b.* For Reportable Events under Sections III.I.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 Essilor's actions taken to correct the Reportable Event and prevent it from recurring.

4. *Reportable Events under Section III.I.1.c.* For Reportable Events under Section III.I.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 Essilor 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.I.1.d.* For Reportable Events under Section III.I.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.

J. Notification of Communications with FDA

Within 30 days after the date of any written report, correspondence, or communication between Essilor and the FDA that materially discusses Essilor's or a Covered Person's actual or potential unlawful or improper marketing or sale of Essilor's products, Essilor shall provide a copy of the report, correspondence, or communication to OIG. Essilor shall also provide written notice to OIG within 30 days after the resolution of any such disclosed matter, and shall provide OIG with a description of the findings and/or results of the matter, if any.

K. Requirements Relating to Certain Promotional Activities

Within 120 days following the Effective Date, Essilor shall establish and implement the following requirements relating to: (1) Co-Marketing Activities; and (2) arrangements with ECPs or ECIs that involve the offering of discounts, rebates, reductions in price or other remuneration in connection with the ordering or purchasing of Government Reimbursed Products (Discount Arrangements).

1. *Co-Marketing Activities.* Essilor shall establish and implement:
 - a. a process to ensure that a needs assessment has been completed for any Co-Marketing Activity. The needs assessment shall identify the business need for performing the Co-Marketing Activity and provide details about the Co-Marketing Activity (i.e., information about the type of Co-Marketing Activity and the role and contribution of each ECP or ECI involved in the Co-Marketing Activity);
 - b. a centralized, electronic system to track all Co-Marketing Activity;
 - c. a process to evaluate the fair market value of any Co-Marketing Activity; and
 - d. a process to ensure that all arrangements to engage in Co-Marketing Activities are set forth in a written agreement that describes the scope of work to be performed by all parties to the arrangement, the fees to be paid, and any work product that will be produced.

2. *Discount Arrangements.* Essilor shall establish and implement a written review and approval process for Discount Arrangements, the purpose of which is to ensure that all existing, new or renewed Discount Arrangements do not violate the Anti-Kickback Statute, and that includes at least the following:

- a. creating and maintaining a centralized tracking system for all existing and new or renewed Discount Arrangements;

- b. documenting the names and positions of the Covered Person(s) involved in the negotiation, review, and approval of all Discount Arrangements;
- c. a legal review of all Discount Arrangements by counsel with expertise in the Anti-Kickback Statute;
- d. tracking all remuneration to and from all parties to Discount Arrangements to ensure that the parties are complying with the financial terms of the Discount Arrangements and that the Discount Arrangements are commercially reasonable;
- e. a process for specifying and documenting the business need or business rationale for all Discount Arrangements;
- f. a process to ensure that discounts, rebates, or other reductions in price are determined and approved in accordance with a centrally managed, pre-set rate structure established by Essilor;
- g. ensuring that all Discount Arrangements are set forth in writing and describe the discount, rebate or other reduction in price being offered to the ECP or ECI; and
- h. requiring the Compliance Officer to review the Discount Arrangements Tracking System and internal review and approval process on at least an annual basis and to provide a report on the results of such review to the Compliance Committee.

L. Field Force Monitoring and Review Efforts

Within 120 days after the Effective Date, Essilor shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with ECPs and ECIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with ECPs and ECIs and to identify potential improper promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: (1) direct

field observations (Observations) of sales personnel and (2) the monitoring and review of other records relating to sales personnel's interactions with ECPs and ECIs (Records Reviews).

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

At the completion of each Observation, Monitoring Personnel shall prepare a report which includes: (a) the identity of the sales representative; (b) the identity of the Monitoring Personnel who conducted the Observation; (c) the date and duration of the Observation; (d) the product(s) promoted during the Observation; (e) an overall assessment of compliance with Essilor Policies and Procedures; and (f) the identification of any potential improper promotional activity or other improper conduct by the field sales representative.

Monitoring Personnel shall conduct at least five (5) Observations during each Reporting Period. Monitoring Personnel shall have access to all relevant records and information necessary to assess sales representatives' interactions with ECPs and ECIs and to identify potential or actual compliance violations.

2. *Records Reviews.* As a component of the FFMP, Essilor shall also review various types of records to assess sales representatives' interactions with ECPs and ECIs and to identify potential or actual compliance violations.

- a. For each Reporting Period, Essilor shall develop and implement a plan for conducting Records Reviews associated with at least five (5) Government Reimbursed Products. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate region (as applicable) who promoted the products under review.

- b. The Records Reviews shall include the monitoring and review of:
 - (i) records and systems associated with sales representatives' interactions with ECPs and ECIs (including records relating to any payments to ECPs or ECIs, and sales communications from managers);
 - (ii) records relating to requests for medical information about or inquiries relating to, the Government Reimbursed Products under review;
 - (iii) sales representative call notes;
 - (iv) sales representatives' e-mails and other electronic records; and
 - (v) recorded results of the Observations of sales force representatives, coaching guides, and manager notes.

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

M. Requirements Relating to Grants and Contributions Activities

To the extent that Essilor engages in grant and charitable contribution activities involving ECPs and ECIs, within 120 days following the Effective Date, Essilor shall establish a centralized system which shall be the exclusive mechanism through which requestors may request or be awarded amounts for Third Party Educational Activities, other grant activities involving ECPs and ECIs (referred to below as "Grants"), and charitable contributions involving ECPs and ECIs supported by Essilor (referred to below as "Contributions"). In addition, within 120 days following the Effective Date, Essilor shall establish a process to review requests for Grants and Contributions according to standardized, objective criteria developed by Essilor (such as based upon the qualifications of the requestor, or the quality of the program funded by the Grant or Contribution) and to ensure that Grants or Contributions are provided only pursuant to a written agreement with the funding recipient and that payments to the funding recipient are consistent with the

written agreement. Essilor's sales and marketing personnel shall not be involved in, or influence, the review and approval of requests for Grants or Contributions.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, Essilor 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. Essilor 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, Essilor 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, Essilor 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 150 days after the Effective Date, Essilor 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 Board members who are responsible for satisfying the Board compliance requirements 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 Board of Directors training required by Section III.C.2 (including a summary of the topics covered, the length of the training and when the training was provided);
7. a description of the risk assessment and internal review process required by Section III.D;
8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to Essilor that includes a summary of all current and prior engagements between Essilor and the IRO;
9. a description of the Disclosure Program required by Section III.F;
10. a description of the Ineligible Persons screening and removal process required by Section III.G;
11. a description of policies, procedures, and systems implemented pursuant to the Requirements Relating to Certain Promotional Activities outlined in Section III.K;
12. a description of the FFMP required by Section III.L;
13. a description of the policies, procedures, and systems implemented pursuant to the Requirements Relating to Grants and Contributions Activities outlined in Section III.M;

14. a list of all of Essilor'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 Essilor'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

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

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board compliance requirements; and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Compliance Committee, Board, and Certifying Employees;

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 Board (written documentation of such reports shall be made available to OIG upon request);

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

5. a list of any new or revised Policies and Procedures required by Section III.B.1 developed during the Reporting Period;

6. a description of any changes to Essilor's Training Plan developed pursuant to Section III.C and a summary of any Board of Directors training provided during the Reporting Period;

7. a description of any changes to the risk assessment and internal review process required by Section III.D, including the reasons for such changes;

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

9. a complete copy of all reports prepared pursuant to Section III.E and Essilor's response to the reports, along with corrective action plan(s) related to any issues raised by the reports;

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

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

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

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. 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;

14. a summary of Reportable Events (as defined in Section III.I)

identified during the Reporting Period;

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

16. a summary of any changes to the policies, procedures, and systems relating to the Requirements Relating to Certain Promotional Activities described in Section III.K, including the reasons for such changes;

17. 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 conduct occurred and a description of the action(s) that Essilor took as a result of such determinations;

18. a summary of any changes to the policies, procedures, and systems relating to the Requirements Relating to Grants and Charitable Contributions Activities described in Section III.M, including the reasons for such changes;

19. a description of all changes to the most recently provided list of Essilor's locations (including addresses) as required by Section V.A.15;

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

21. 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, Essilor shall include the certifications of Certifying Employees as required by Section III.A.4;

2. *Compliance Officer and President.* The Implementation Report and each Annual Report shall include a certification by the Compliance Officer and President

*Essilor of America, Inc. and Essilor Laboratories of America, Inc.
Corporate Integrity Agreement*

that:

- a. to the best of his or her knowledge, except as otherwise described in the report, Essilor 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

Essilor 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. Essilor 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

Essilor:

David M. Boone
Chief Compliance Officer
Essilor of America, Inc.
13555 N. Stemmons Freeway
Dallas, Texas 75234
Telephone: 469-394-8735
david.boone@essilorusa.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, Essilor 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 Essilor's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Essilor's locations for the purpose of verifying and evaluating: (a) Essilor's compliance with the terms of this CIA and (b) Essilor's compliance with Federal health care program requirements and with all applicable FDA requirements. The documentation described above shall be made available by Essilor 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 Essilor'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. Essilor shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Essilor's owners, employees, contractors and directors may elect to be interviewed with or without a representative of Essilor present.

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

A. Stipulated Penalties

OIG may assess:

1. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section III.A;
2. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section III.B;
3. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section III.C;
4. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section III.D;
5. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section III.E;
6. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section III.F;

7. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section III.G;

8. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section III.H;

9. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section III.I;

10. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section III.J;

11. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section III.K;

12. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section III.L;

13. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section III.M;

14. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section IV;

15. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section V;

16. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section VII;

17. A Stipulated Penalty of up to \$2,500 for each day Essilor fails to comply with Section VIII; or

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

B. Timely Written Requests for Extensions

Essilor 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. 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 Essilor fails to meet the revised deadline set by OIG. 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 Essilor 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.* If OIG determines that a basis for Stipulated Penalties under Section X.A exists, OIG shall notify Essilor of: (a) Essilor's failure to comply; and (b) OIG's demand for payment of Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 15 business days after the date of the Demand Letter, Essilor shall either: (a) 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.

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.

D. Exclusion for Material Breach of this CIA

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

- a. failure to comply with any of the requirements of this CIA for which OIG has previously issued a demand for Stipulated Penalties under Section X.C;
- b. failure to comply with Section III.A.1;

- c. failure to comply with Section III.E;
- d. failure to comply with Section III.I;
- e. failure to comply with Section V;
- f. failure to respond to a Demand Letter in accordance with Section X.C;
- g. failure to pay Stipulated Penalties within 20 days after an ALJ issues a decision ordering Essilor to pay the Stipulated Penalties or within 20 days after the HHS Departmental Appeals Board (DAB) issues a decision upholding the determination of OIG; or
- h. failure to come into compliance with a requirement of this CIA for which OIG has demanded Stipulated Penalties, pursuant to the deadlines listed in Section X.E.2.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Essilor constitutes an independent basis for Essilor’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 for each material breach. Upon a preliminary determination by OIG that Essilor has materially breached this CIA, OIG shall notify Essilor of: (a) Essilor’s material breach; and (b) OIG’s intent to exclude Essilor (this notification is hereinafter referred to as the “Notice of Material Breach and Intent to Exclude”).

3. *Response to Notice.* Essilor shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude to submit any information and documentation for OIG to consider before it makes a final determination regarding exclusion.

4. *Exclusion Letter.* If OIG determines that exclusion is warranted, OIG shall notify Essilor in writing of its determination to exclude Essilor (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 the Exclusion Letter. The exclusion shall have national effect. The effect of the exclusion shall be that no Federal health care program payment may be made for any

items or services furnished, ordered, or prescribed by Essilor, including administrative and management services, except as stated in regulations found at 42 C.F.R.

§1001.1901(c). Reinstatement to program participation is not automatic. At the end of the period of exclusion, Essilor may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's issuing a Demand Letter or Exclusion Letter, and as an agreed-upon remedy for the resolution of disputes arising under this CIA, Essilor shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the DAB, in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21, but only to the extent this CIA does not provide otherwise. Notwithstanding the language in 42 C.F.R. § 1005: (a) the request for a hearing involving Stipulated Penalties shall be made within 15 business days after the date of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after the date of the Exclusion Letter; and (b) no discovery shall be available to the parties. 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 Essilor was in full and timely compliance with the requirements of this CIA for which OIG demands payment; and (b) the period of noncompliance. Essilor shall have the burden of proving its full and timely compliance. If the ALJ upholds the OIG's determination that Essilor has breached this CIA and orders Essilor to pay Stipulated Penalties, Essilor must (a) come into compliance with the requirement(s) of this CIA that resulted in the OIG imposing Stipulated Penalties, and (b) pay the Stipulated Penalties within 20 days after the ALJ issues a decision, unless Essilor properly and timely requests review of the ALJ decision by the DAB. If the ALJ decision is properly and timely appealed to the DAB and the DAB upholds the determination of OIG, Essilor must (a) come into compliance with the requirement(s) of this CIA that resulted in the

OIG imposing Stipulated Penalties, and (b) pay the Stipulated Penalties within 20 days after the DAB issues its decision.

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

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. The parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA and Essilor agrees not to seek additional review of the DAB's decision (or the ALJ's decision if not appealed) in any judicial forum.

XI. EFFECTIVE AND BINDING AGREEMENT

Essilor and OIG agree as follows:

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

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

C. All requirements and remedies set forth in this CIA are in addition to and do not affect (1) Essilor'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 Essilor 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 ESSILOR

/David Milan/

DAVID J. MILAN, ESQ.
General Counsel
Essilor of America, Inc., and
Essilor Laboratories of America, Inc.

2/25/22

DATE

/Samantha Groden/

GADI WEINREICH, ESQ.
SAMANTHA L. GRODEN, ESQ.
Dentons US LLP
Counsel for Essilor of America, Inc., and
Essilor Laboratories of America, Inc.

April 1, 2022

DATE

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

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

03/07/2022
DATE

/Felicia Heimer/
FELICIA E. HEIMER
Senior Counsel
Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

April 4, 2022
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. Essilor shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by Essilor in response to a request by OIG, whichever is later, OIG will notify Essilor if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Essilor may continue to engage the IRO.

2. If Essilor 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, Essilor shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by Essilor at the request of OIG, whichever is later, OIG will notify Essilor if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Essilor 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 medical device 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 medical devices and the Federal Anti-Kickback Statute and False Claims Act.

2. assign individuals to design and select the samples for the IRO Transactions Review 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 inquires 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. Essilor Responsibilities

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

APPENDIX B

INDEPENDENT REVIEW ORGANIZATION REVIEWS

A. IRO Engagement, General Description

As specified more fully below, Essilor shall retain an IRO to perform engagements to assist Essilor in assessing and evaluating certain of its systems, processes, policies, and procedures related to Essilor's Covered Functions (as defined in Section II.C.3 of the CIA) (IRO Review). The IRO Review shall consist of three components—a systems review (Systems Review), a transactions review (Transactions Review), and an Additional Items Review as described more fully below. Essilor may engage, at its discretion, a single entity 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 Essilor's systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform the Systems Review of certain systems, processes, policies and procedures relating to Covered Functions (as set forth below) for the first and fourth Reporting Periods. If Essilor materially changes its systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform a Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review as set forth above. The additional Systems Review(s) shall consist of: (1) an identification of the material changes, and (2) 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.

B. IRO Systems Review

The Systems Review shall be a review of Essilor's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Covered Functions. More specifically, the IRO shall review Essilor's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1. Essilor's systems, policies, processes, and procedures for conducting Covered Functions in compliance with all applicable Federal health care program requirements and all applicable FDA requirements;

2. Essilor’s systems, policies, processes, and procedures for ensuring that all Discount Arrangements as defined in Section III.K of the CIA comply with the Federal Anti-Kickback Statute;

3. Essilor’s systems, policies, processes, and procedures relating to the materials and information that may be distributed by Essilor sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which Essilor sales representatives respond to requests for information about uses of Government Reimbursed Products that are not FDA approved, cleared, or exempt (“non-FDA approved uses”);

4. Essilor’s systems, policies, processes, and procedures relating to the materials and information that may be distributed and the mechanisms through, and manner in which, Essilor receives and responds to requests for information from an ECP or another individual or entity about non-FDA approved uses of Government Reimbursed Products; the form and content of information disseminated by Essilor in response to such requests; and the internal review process for the information disseminated;

5. Essilor’s systems, policies, processes, and procedures relating to the manner and circumstances under which Essilor medical personnel interact with or participate in meetings or events with ECPs, ECIs, or payors (either alone or with Essilor sales representatives) and the role of Essilor medical personnel at such meetings or events, as well as how they handle responses to requests for information about non-FDA approved uses of Government Reimbursed Products;

6. Essilor’s systems, policies, processes, and procedures relating to the materials and information that may be distributed or made available by Essilor through social media and/or direct-to-consumer advertising;

7. Essilor’s systems, policies, processes, and procedures relating to the development, implementation, and review of all polices for the distribution of Government Reimbursed Products for evaluation purposes (Evaluation Product). This shall include a review of the bases upon, and circumstances under, which ECPs and ECIs belonging to specified medical specialties or types of clinical practice may receive Evaluation Product from Essilor (including, separately, from sales representatives, or through other channels);

8. Essilor’s systems, policies, processes, and procedures relating to agreements or arrangements with ECPs or ECIs for the purchase or licensing of intellectual property (including, but not limited to, patents, patent applications, and payment of royalties);

9. Essilor's systems, policies, processes, and procedures relating to programs by ECPs to educate sales representatives, including but not limited to presentations by ECPs at sales meetings, preceptorships, tutorials, and experience-based learning activities;

10. Essilor's systems, policies, processes, and procedures relating to the review and approval of, and payment for, travel and related expenses for ECPs including those in connection with an ECP's participation in educational, research, training, or other Essilor-sponsored programs or activities;

11. Essilor's systems, policies, processes, and procedures relating to the sponsorship or funding of Grants (including educational grants) or Contributions as defined in Section III.M of the CIA involving ECPs or ECIs;

12. Essilor's systems, policies, processes, and procedures relating to funding of, or participation in, any Sponsorships, Third Party Educational Activity, or Co-Marketing Activity as defined in Section II.C.4, II.C.5, and II.C.6 of the CIA;

13. Essilor's systems, policies, processes, and procedures relating to the review of promotional, reimbursement-related, and disease state materials and information intended to be disseminated outside Essilor 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 Essilor's review and approval process and are elevated when appropriate;

14. Essilor's systems, policies, processes, and procedures relating to compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives and their managers; and

15. Essilor's systems, policies, processes, and procedures relating to disciplinary policies and procedures for violations of Essilor's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

C. IRO Systems Review Report

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

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

2. a detailed description of Essilor's systems, policies, processes, and procedures relating to the items identified in Sections B.1-15 above, including a general description of Essilor's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;

3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections B.1-15 above are made known or disseminated within Essilor;

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

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

D. IRO Transactions Review

The Transactions Review shall include a review of: (1) a sample of Co-Marketing Activities, (2) a sample of Discount Arrangements, and (3) a sample of Grants and Contributions involving ECPs and ECIs. The IRO shall report on all aspects of its reviews in the Transactions Review Report.

1. Review of Co-Marketing Activities. The IRO shall randomly select and review a sample of the greater of 10% or five (5) Co-Marketing Activities entered into by Essilor during the applicable Reporting Period. For each Co-Marketing Activity, the IRO shall determine:

- a. whether Essilor conducted a needs assessment for each Co-Marketing Activity that identified the business need for performing the Co-Marketing Activity and the role and contribution of each ECP or ECI involved in the Co-Marketing Activity, including the financial value of such contribution;
- b. whether Essilor is tracking each Co-Marketing Activity in a centralized, electronic system;
- c. the process used by Essilor to evaluate the fair market value of the Co-Marketing Activity;

- d. whether Essilor reviewed and approved the Co-Marketing Activity agreement in accordance with Essilor's Policies and Procedures; and
- e. whether each Co-Marketing Activity is documented in a written agreement that describes the scope of the work to be performed by all parties to the arrangement, the fees to be paid, and any work product that will be produced.

2. Review of Discount Arrangements. For the first Reporting Period, the IRO shall randomly select and review a sample of the greater of 10% or five (5) Discount Arrangements entered into or renewed by Essilor during the Reporting Period. For the second and each subsequent Reporting Period, prior to the end of the Reporting Period Essilor shall provide the OIG with the following information: (a) a description of each type of Discount Arrangement that was in place during the Reporting Period, and (b) the number of each type of Discount Arrangement that was in place during the Reporting Period. The OIG may, in its discretion, select up to ten (10) Discount Arrangements to be reviewed by the IRO for the applicable Reporting Period. If the OIG does not select the Discount Arrangements to be reviewed, then the Discount Arrangements to be reviewed may be randomly selected by the IRO. For each Discount Arrangement reviewed, the IRO shall verify the following:

- a. that the Discount Arrangement is being tracked in a centralized tracking system and that the names and positions of the Covered Person(s) involved in the negotiation, review, and approval of the Discount Arrangement are documented in the tracking system;
- b. that the Discount Arrangement has been subject to a legal review by counsel with expertise in the Anti-Kickback Statute;
- c. that Essilor is tracking all remuneration to and from the other party to each Discount Arrangement;
- d. that the parties are complying with the financial terms of the Discount Arrangement and that the Discount Arrangement is commercially reasonable;
- e. that the business need or business rationale for the Discount Arrangement has been specified and appropriately documented;

- f. that the discounts, rebates, or other reductions in price under each Discount Arrangement were determined and approved in accordance with a centrally managed, pre-set rate structure established by Essilor;
- g. that a written agreement is in place for each Discount Arrangement which describes the discounts, rebates, or other reductions in price offered to the ECP or ECI; and
- h. that the Discount Arrangement was subject to an internal review and approval process (including both a legal and business review) and obtained the necessary approvals and that such review and approval is appropriately documented.

3. Review of Grants and Charitable Contributions. For purposes of this Appendix B, the term “Grants” shall include any awarded amounts for Third Party Educational Activities (as defined in Section II.C.5 of the CIA) or other grant activities involving ECPs and ECIs, and the term “Contributions” shall include any charitable contributions involving ECPs or ECIs provided by Essilor. For each Reporting Period, the IRO shall review a sample of the greater of 10% or five (5) Grants and Contributions to ECPs or ECIs. For the first Reporting Period, the IRO shall randomly select the sample of Grants and Contributions to be reviewed. For the second and each subsequent Reporting Period, prior to the end of the Reporting Period, Essilor shall provide the following information to OIG: (1) a description of each type of Grant and Contribution provided during the Reporting Period and a description of the purpose of, and activity to be undertaken in connection with, each type of Grant and Contribution; (2) the number of each type of Grant and Contribution provided during the Reporting Period; and (3) the budgeted amount to be spent on each type of Grant and Contribution during the Reporting Period. The OIG may, in its discretion, select the sample of the greater of 10% of five (5) Grants and Contributions to be reviewed by the IRO for the applicable Reporting Period. If the OIG does not select the Grants and Contributions to be reviewed, then the sample may be randomly selected by the IRO.

- a. The IRO’s review shall include, but not be limited to, proposal documents (including Grant and Contribution requests), approval documents, contracts, payments and materials relating to the centralized system’s review of the requests, and documents and materials relating to the Grants and Contributions and any events or activities funded through the Grants and Contributions.

- b. For each Grant and Contribution reviewed, the IRO shall determine whether:
 - i. The request for the Grant or Contribution was submitted through Essilor's centralized system and processed in accordance with standardized objective criteria;
 - ii. The terms of the Grant or Contribution are reflected in a written agreement between Essilor and the recipient of the Grant or Contribution;
 - iii. The Grant or Contribution was reviewed and approved in accordance with Essilor policies and procedures;
 - iv. Essilor records identify the purpose or use for which the Grant or Contribution was requested; and
 - v. Applicable documents or other records verify that the purpose of use for which the Grant or Contribution was requested occurred or was satisfied (e.g., if the Grant or Contribution was provided to sponsor an event, the IRO shall assess whether the event, in fact, occurred.)

E. IRO Transactions Review Report

1. General Elements to be Included in the Report. For each Reporting Period, the IRO shall prepare a report based on its Transactions Review. The report shall include the following:

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

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

a. Relating to the Review of Co-Marketing Activities.

- i. a description of each Co-Marketing Activity reviewed and an identification of the types of documents and information reviewed for each Co-Marketing Activity reviewed;
- ii. for each Co-Marketing Activity reviewed, the IRO's findings and supporting rationale as to:
 - (a) Essilor's determination of the business need for entering into the Co-Marketing Activity with the ECP(s) and ECI(s) and the role and contribution of each ECP or ECI involved in the Co-Marketing Activity, including the financial value of the contribution;
 - (b) whether Essilor is appropriately tracking each Co-Marketing Activity in a centralized, electronic system;
 - (c) Essilor's process for evaluating the fair market value of the Co-Marketing Activity;
 - (d) whether Essilor reviewed and approved each Co-Marketing Activity in accordance with Essilor's Policies and Procedures; and
 - (e) whether Essilor appropriately documented each Co-Marketing Activity in a written agreement that described the scope of work to be performed by all parties to the arrangement, the fees to be paid, and any work product to be produced.
- iii. whether the IRO identified any weaknesses in Essilor's systems, processes, policies, procedures, and/or practices relating to Co-Marketing Activities and any recommendations for improvements to Essilor's systems, processes, policies, procedures and/or practices relating to Co-Marketing Activities.

- b. Relating to the Review of Discount Arrangements.
- i. a description of each Discount Arrangement reviewed and an identification of the types of documents and information reviewed for each Discount Arrangement reviewed;
 - ii. for each Discount Arrangement reviewed, the IRO's findings and supporting rationale as to:
 - (a) whether the Discount Arrangement was tracked in a centralized tracking system that documents the names and positions of the Covered Person(s) involved in the negotiation, review, and approval of the Discount Arrangement;
 - (b) whether the Discount Arrangement was reviewed by legal counsel with expertise in the Anti-Kickback Statute;
 - (c) whether Essilor is appropriately tracking all remuneration to and from the other party to the Discount Arrangement;
 - (d) whether the parties are complying with the financial terms of the Discount Arrangement and whether such terms are commercially reasonable;
 - (e) whether Essilor has specified and appropriately documented the business need or business rationale for each Discount Arrangement;
 - (f) whether the discounts, rebates, or other reductions in price under each Discount Arrangement were determined and approved in accordance with a centrally managed, pre-set rate structure established by Essilor;
 - (g) whether the Discount Arrangement is documented by a written agreement that describes the discounts, rebates,

or other reductions in price offered to the other party to the Discount Arrangement; and

- (h) whether the Discount Arrangement was subject to Essilor's internal review and approval process (including both a legal and business review), whether Essilor obtained the necessary approvals, and whether such review and approval is appropriately documented.
- iii. whether the IRO identified any weaknesses in Essilor's systems, processes, policies, procedures, and/or practices relating to Discount Arrangements and any recommendations for improvements to Essilor's systems, processes, policies, procedures and/or practices relating to Discount Arrangements.

c. Relating to the Review of Grants and Charitable Contributions

- i. a description of each type of Grant or Contribution reviewed, including the number of each type of Grant or Contribution reviewed and an identification of the types of documents and information reviewed for each Grant or Contribution reviewed;
- ii. for each Grant or Contribution reviewed, the IRO's findings and supporting rationale as to whether:
 - (a) the request for the Grant or Contribution was submitted through the Essilor's centralized system and processed in accordance with standardized objective criteria;
 - (b) the terms of the Grant or Contribution are reflected in a written agreement between Essilor and the recipient of the Grant or Contribution;
 - (c) the Grant or Contribution was reviewed and approved in accordance with Essilor policies and procedures;
 - (d) the purpose or use for which the Grant or Contribution was requested is identified in Essilor records; and

- (e) records verify that the purpose of use for which the Grant or Contribution was requested occurred or was satisfied.
- iii. whether the IRO identified any weaknesses in Essilor's systems, processes, policies, procedures, and/or practices relating to Grants or Contributions and any recommendations for improvements to Essilor's systems, processes, policies, procedures and/or practices relating to Grants or Contributions.

F. IRO Additional Items Review.

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 60 days prior to the end of the applicable Reporting Period, the OIG shall notify Essilor 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 Essilor 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 Essilor's systems, policies, and procedures based on its review of each Additional Item).

2. Essilor may propose to the OIG that its internal audit(s), reviews, or monitoring activities, be substituted, subject to the Verification Review requirements set forth below, for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Essilor'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 Essilor's planned internal audit work or compliance monitoring or audit activities, the results of the Transactions Review(s) during prior Reporting Period(s), and Essilor's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Essilor'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, Essilor shall engage the IRO to perform the Review as outlined in this Section III.E.

4. If the OIG agrees to permit certain of Essilor'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.

G. IRO Additional Items Review Report

1. General Elements to be Included in the Report. For each Reporting Period, the IRO shall prepare a report based on its Additional Items Review. The report shall include the following:

- 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, if applicable, 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 Additional Items Review.

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

- a. for each Additional Item reviewed, a description of the review conducted;
- b. for each Additional Item reviewed, the IRO's findings based on its review;
- c. for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Essilor's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and

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