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

I. PREAMBLE

ACell, Inc. (ACell) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements).

Contemporaneously with this CIA, ACell is entering into a Settlement Agreement with the United States. ACell is also entering into settlement agreements with various states (State Settlement Agreements) and ACell's agreement to this CIA is a condition precedent to those agreements.

ACell represents that, prior to the Effective Date (as defined below), it implemented a compliance program that includes the following elements with regard to its business operations in the United States: a Chief Compliance Officer (CCO), a Corporate Compliance Committee, training and education, Standards of Business Ethics & Conduct, written policies and procedures, a helpline for reporting compliance issues, and monitoring and auditing activities (the "Compliance Program"). ACell shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. ACell may modify its Compliance Program as appropriate but, at a minimum, ACell shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by ACell under this CIA shall be five years from the effective date of this CIA. The "Effective Date" shall be the date on which the final signatory of this CIA executes this CIA. Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) ACell's final Annual Report; or (2) any additional materials submitted by ACell 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 ACell who are natural persons who have an ownership interest of more than 5% and are engaged in Covered Functions;

   (b) all officers, directors and employees of ACell; and

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

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

2. "Government Reimbursed Products" refers to all ACell products that are: (a) marketed or sold by ACell 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, detailing, marketing, advertising, promoting, or branding 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 ACell's review and approval processes for promotional materials and applicable review and approval functions; (c) the preparation or external dissemination of non-promotional materials or information about Government Reimbursed Products, including the functions relating to ACell's review and approval processes for any non-promotional materials; (d) contracting with HCPs for consulting services, research services, or other fee-for-service arrangements related to Government Reimbursed Products; (e) other activities, services, or advice related to recalls, nonconforming product procedures, complaint handling, quality-related activities, or providing coding or reimbursement advice with regard to Government Reimbursed Products; and (f) 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 ACell products, including healthcare-related conventions and conference sponsorships, symposia, 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 HCPs conducted by a third party and supported by ACell, including but not limited to, continuing medical education (CME) or disease awareness activities, or symposia at medical conferences.

III. CORPORATE INTEGRITY OBLIGATIONS

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

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

1. *Chief Compliance Officer*. Within 90 days after the Effective Date, ACell shall appoint a CCO and shall maintain a CCO for the term of the CIA. The CCO shall be an employee and a member of senior management of ACell and shall report directly to the Board of Directors of ACell and serve on the staff of ACell's President and Chief Executive Officer (CEO). The CCO 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 ACell. The CCO shall be responsible for, without limitation:

a. developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program and FDA requirements;

b. making periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of ACell or a committee thereof (currently the Nominations, Governance and Compliance Committee) (hereafter "Board") and shall be authorized to report on such matters to the Board at any time. Written documentation of the CCO'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 ACell as well as any reporting obligations created under this CIA.

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

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

2. *Corporate Compliance Committee*. Within 90 days after the Effective Date, ACell shall appoint a Corporate Compliance Committee. The Corporate Compliance Committee shall, at a minimum, include the CCO and other members of

senior management necessary to meet the requirements of this CIA (e.g., executives or heads of relevant departments who have knowledge and oversight of compliance matters within such departments, such as sales, marketing, legal, clinical, human resources, finance, and quality). The CCO shall chair the Corporate Compliance Committee and the Committee shall support the CCO in fulfilling his/her responsibilities (e.g., shall assist in the analysis of ACell's risk areas and shall oversee monitoring of internal and external audits and investigations). The Corporate Compliance Committee shall meet at least quarterly. The minutes of the Corporate Compliance Committee meetings shall be made available to OIG upon request.

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

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

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

a. meeting at least quarterly to review and oversee ACell's Compliance Program, including but not limited to the performance of the CCO and Corporate 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; and

c. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board, summarizing its review and oversight of ACell's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA.

At minimum, the resolution shall include the following language:

> "The Board of Directors has made a reasonable inquiry into the operations of ACell's Compliance Program including the performance of the Chief Compliance Officer and the Corporate Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, ACell has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement."

If the 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 ACell.

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

4. *Management Certifications*: In addition to the responsibilities set forth in this CIA for all Covered Persons, certain ACell officers or employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable ACell business unit is in compliance with applicable Federal health care program and FDA requirements and with the obligations of this CIA.

These Certifying Employees shall include, at a minimum, the following: (i) the President and CEO; the Chief Science Officer; the Chief Financial Officer; (ii) the following officers or employees of ACell: the Vice President of Regulatory Affairs and Quality Assurance; the Vice President of Sales; the Vice President of Marketing; Director, Product Marketing; and Director, Product Management; and (iii) to the extent that an ACell business unit performs Covered Functions and is not covered by the certifications of one of the above-listed individuals, such other ACell executives, vice presidents, or leaders of business units as would be necessary to ensure that there is a Certifying Employee from each such business unit engaged in Covered Functions.

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

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

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

B. Written Standards

Within 90 days after the Effective Date, ACell 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 ACell's compliance with Federal health care program and FDA requirements (Policies and Procedures). Throughout the term of this CIA, ACell shall enforce its Policies and Procedures and shall make compliance with its Policies and Procedures an element of evaluating the performance of all Covered Persons. 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 all: (i) applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. § 1320a-7b(b)) and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements;

b. the materials and information that may be distributed by ACell sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which ACell sales representatives respond to requests for information about non-FDA approved (or "off-label") uses of Government Reimbursed Products. These Policies and Procedures shall require that sales representatives: (i) not engage (directly or indirectly) in promotion of Government Reimbursed Products for non-approved uses (i.e., sales representatives shall not promote the Government Reimbursed Products for usages, dosages, length of treatment, or patient populations other than those in, or consistent with, the FDA-approved label); (ii) use only materials that have been reviewed and approved consistent with Policies and Procedures; and (iii) refer all requests for information about non-approved uses of Government Reimbursed Products to the Chief Science Officer or the Medical Director;

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

d. the manner and circumstances under which ACell medical personnel interact with or participate in meetings or events with HCPs, HCIs, or payers (either alone or with ACell sales representatives) and the role of the ACell medical personnel at such meetings or events, as well as how they handle responses to requests for information about off-label uses of Government Reimbursed Products;

e. the materials and information that may be distributed or made available by ACell through social media and/or direct-to-consumer advertising, if any;

f. the development, implementation, and review of all 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 HCPs and HCIs belonging to specified medical specialties or types of clinical practices may receive Evaluation Product from ACell (including, separately, from sales representatives, or through other channels). The Policies and Procedures shall also require that ACell modify the Evaluation Product Policy as necessary to ensure that ACell is promoting Government Reimbursed Products in a manner that complies with all applicable Federal health care program and FDA requirements;

g. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to HCPs who serve as Key Opinion Leaders (KOLs) or participate in speaker programs (if applicable), speaker training programs, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, labs, wound symposia, and any other financial engagement or arrangement) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;

h. review and approval of, and payment for, travel and related expenses for HCPs including those in connection with HCPs' participation in educational, research, training, or other ACell-sponsored programs or activities;

i. programs by HCPs to educate sales representatives, including but not limited to presentations by HCPs at sales meetings, preceptorships (if any), tutorials, and experience-based learning activities;

j. funding of grants (including educational grants) or charitable contributions;

k. funding of, or participation in, any Sponsorships or Third Party Educational Activity as defined in Sections II.C.4 and 5 above;

l. review of promotional, reimbursement and/or coding, and disease state materials and information intended to be disseminated outside ACell 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 ACell's review and approval process and are elevated when appropriate;

m. compensation (including through salaries, bonuses, or other means) for Covered Persons who are sales representatives and their field-based managers. These Policies and Procedures shall: (i) be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of ACell's Government Reimbursed Products; and (ii) include mechanisms, where appropriate, designed to exclude from incentive (variable) compensation sales that indicate improper promotion of Government Reimbursed Products has occurred;

n. recalls, corrections and removals procedures, risk management and nonconforming product procedures, product complaint handling, and management implementation of Corrective and Preventative Actions;

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

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

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

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

C. Training and Education

1. *Covered Persons Training.* Within 90 days after the Effective Date, ACell shall develop a written plan (Training Plan) that outlines the steps ACell will take to ensure that: (a) all Covered Persons receive at least annual training regarding ACell's CIA requirements and Compliance Program, and (b) all Covered Persons who engage in Covered Functions or supervise individuals who engage in Covered Functions shall receive at least annual training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions; (ii) topics relating to quality issues, including recalls and product complaint handling; and (iii) all ACell Policies and Procedures and other requirements applicable to Covered Functions.

The Training Plan shall include information regarding the following: (i) training topics, (ii) categories of Covered Persons required to attend each training session,

(iii) length of the training session(s), (iv) schedule for training, and (v) format of the training. ACell shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training*. Within 90 days after the Effective Date, each member of the Board of Directors shall receive at least two hours of training. This training shall address ACell's CIA requirements and Compliance Program, 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 of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 90 days after the Effective Date, whichever is later.

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

D. Risk Assessment and Internal Review Process

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

E. Review Procedures

1. *General Description.*

a. *Engagement of Independent Review Organization*. Within 90 days after the Effective Date, ACell shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews referenced 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 ACell shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and ACell) related to the IRO reviews.

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

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

a. *Systems Review*. The Systems Reviews shall assess ACell's systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in ACell's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the second and fourth Reporting Periods. If ACell 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 second 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 Transaction Review shall also include a review of up to three additional areas or practices of ACell identified by OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the Transaction Review for a particular Reporting Period, OIG will consult with ACell and may consider internal audit and monitoring work conducted by ACell, the Government Reimbursed Product portfolio, the nature and scope of ACell's promotional practices and arrangements with HCPs and HCIs, and other information known to it.

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

4. *Independence and Objectivity Certification*. The IRO shall include in its report(s) to ACell 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 ACell and the IRO.

F. Disclosure Program

Within 90 days after the Effective Date, ACell shall establish a Disclosure Program that includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose, to the CCO or some other person who is not in the disclosing

individual's chain of command, any identified issues or questions associated with ACell'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. ACell 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, through references in the Standards of Business Ethics & Conduct, or during training).

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 ACell's Covered Persons shall be expected to report suspected violations of any Federal health care program or FDA requirements to the CCO or other appropriate individual designated by ACell.

Upon receipt of a disclosure, the CCO (or designee) shall gather all relevant information from the disclosing individual. The CCO (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, ACell shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The CCO (or designee) shall maintain a disclosure log and shall record each disclosure in the disclosure log within two business days of receipt of the disclosure. The disclosure log shall include a summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews.

G. Ineligible Persons

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

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded from participation in the Federal health care programs; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded.

b. "Exclusion List" means the HHS/OIG List of Excluded Individuals/Entities (LEIE) (available through the Internet at http://www.oig.hhs.gov).

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

a. ACell 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. ACell shall screen all current Covered Persons against the Exclusion List within 90 days after the Effective Date and on an annual basis thereafter.

c. ACell shall maintain a policy requiring all Covered Persons to disclose immediately if they become an Ineligible Person.

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

3. *Removal Requirement.* If ACell has actual notice that a Covered Person has become an Ineligible Person, ACell shall remove such Covered Person from

responsibility for, or involvement with, ACell'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 ACell 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, ACell 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, ACell shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to ACell conducted or brought by a U.S.-based governmental entity or its agents involving an allegation that ACell 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. ACell 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 promotion of

Government Reimbursed Products, unless otherwise reported to the FDA in accordance with Section III.J below;

c. the initiation of a recall of an ACell Government Reimbursed Product by either the FDA or ACell;

d. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or

e. the filing of a bankruptcy petition by ACell.

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

2. *Reporting of Reportable Events*. If ACell determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, ACell 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 ACell'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 complete description of all details relevant to the Reportable Event, including, at a minimum, the facts and circumstances resulting in the initiation of the recall, the time period of the recall and the events that resulted in the recall, the names of individuals and entities believed to be implicated, including an explanation of their roles in the Reportable Event.

5. *Reportable Events under Section III.I.1.d.* For Reportable Events under Section III.I.1.d, 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 ACell 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.

6. *Reportable Events under Section III.I.1.e.* For Reportable Events under Section III.I.1.e, 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 ACell and the FDA that materially discusses ACell's or a Covered Person's actual or potential unlawful or improper promotion or handling of ACell's products (including any improper dissemination of information about non-approved uses or any recall of a Government Reimbursed Product), ACell shall provide a copy of the report, correspondence, or communication to OIG. ACell shall also provide written notice to OIG within 30 days after the resolution of any such disclosed improper promotional matter, and shall provide OIG with a description of the findings and/or results of the matter, if any.

K. Field Force Monitoring and Review Efforts

Within 120 days after the Effective Date, ACell shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: (1) a Speaker Monitoring Program and (2) direct field observations (Observations) of sales personnel.

1. *Speaker Program Activities.*

   a. ACell shall implement a process to require all speakers for ACell speaker programs to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements regarding the use of ACell approved materials and requirements that speakers may not directly or indirectly promote the product for off-label uses).

   b. ACell shall establish a centralized, electronic system to initiate and track all speaker programs that includes controls designed to ensure that speaker programs are used for legitimate and lawful purposes in accordance with all

applicable Federal health care program and FDA requirements.

c. ACell shall ensure that speakers are paid according to a centrally managed, pre-set rate structure determined based on a fair-market value analysis conducted by or for ACell.

d. ACell shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, ACell shall use its centralized system to handle all logistics and spending associated with speaker programs, including the tracking and review of the aggregate amount (including speaker fees, travel, and other expenses) paid to each speaker in connection with speaker programs.

e. ACell shall require certifications by sales representatives or other ACell personnel that a speaker program complied with ACell requirements, or in the event of non-compliance, ACell shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.

f. ACell shall institute a Speaker Monitoring Program under which ACell compliance or other appropriately trained ACell personnel or appropriately trained contractors engaged by ACell who are independent from the functional area being monitored (Monitoring Personnel) shall attend 15 speaker programs during each Reporting Period and conduct live audits of the programs (Speaker Program Audits). The programs subject to Speaker Program Audits shall be selected using either a risk-based targeting approach or a random sampling approach. For each program reviewed, Monitoring Personnel shall review slide materials and other materials used as part of the speaker program, speaker statements made during the program, and ACell sales representative activities during the program to assess whether the programs were conducted in a manner consistent with ACell's Policies and Procedures.

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

2. *Observations*. As a component of the FFMP, sales managers who are not in the observed field sales representative's chain of command or Monitoring Personnel shall conduct observations of field sales representatives (including any contract sales personnel) to assess whether the messages delivered and materials distributed to HCPs and HCIs are consistent with applicable legal requirements and with ACell's Policies and Procedures. These observations shall be full day ride-alongs with field sales representatives (Observations), and each Observation shall consist of directly observing all meetings between a sales representative and HCPs and HCIs during the workday. The Observations shall be scheduled throughout the year, judgmentally selected by the Compliance Department, include a review of each therapeutic area and actively promoted Government Reimbursed Product, and be conducted across the United States.

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

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

Sales managers or Monitoring Personnel shall conduct at least 18 Observations during each Reporting Period. Sales managers and Monitoring Personnel shall have access to all relevant records and information necessary to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

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

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

L. Monitoring of Non-Promotional Activities

Within 120 days after the Effective Date, ACell shall develop and implement a set of policies, controls, and practices for consultant arrangement activities. This program shall be referred to as the Non-Promotional Monitoring Program (NPMP).

1. *Consulting Arrangement Activities*. To the extent that ACell engages HCPs for services other than for speaker programs (e.g., as a Key Opinion Leader, member of an advisory board, or to attend consultant meetings), such HCPs shall be referred to herein as "Consultants."

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

b. Within 120 days after the Effective Date, ACell shall establish a process to develop an annual budgeting plan that identifies the business needs for, and the estimated numbers of, the various Consultant engagements and activities to occur during the following year. The annual Consultant budgeting plan shall also identify the budgeted amounts to be spent on

Consultant-related activities. ACell Compliance personnel shall be involved in the review and approval of such plans, including any subsequent modification of an approved plan. The purpose of this review shall be to ensure that Consultant arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements and ACell Policies and Procedures.

c. Within 120 days after the Effective Date, ACell shall establish a process to ensure that a needs assessment has been completed to justify the retention of a Consultant prior to the retention of the Consultant. The needs assessment shall identify the business need for the retention of the Consultant and provide specific details about the consulting arrangement (e.g., information about the numbers and qualifications of the HCPs and HCIs to be engaged, the agenda for the proposed meeting, and a description of the proposed work to be done and the type of work product to be generated). Any deviations from the Consultant budgeting plans shall be documented in the needs assessment form and shall be subject to review and approval by ACell compliance personnel.

d. Within 120 days after the Effective Date, ACell shall amend its policies and procedures in a manner designed to ensure that each Consultant performed the work for which the Consultant was engaged and that, as applicable, ACell received the work product generated by the Consultant.

2. *Follow Up Reviews and Reporting.* In the event that a potential violation of ACell's Policies and Procedures or of legal or compliance requirements, including but not limited to potential improper promotion, are identified during the NPMP, ACell shall investigate the incident consistent with established policies and procedures for the handling of investigations and shall take all necessary and appropriate responsive action (including disciplinary action) and corrective action, including the disclosure of Reportable Events pursuant to Section III.I above, if applicable.

M. Notice to Health Care Providers and Entities

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

> As you may be aware, ACell recently entered into a civil, criminal, and administrative settlement with the United States and individual states in connection with ACell's promotion and sales of several of its products. This letter provides you with additional information about the global settlement, explains ACell's commitments going forward, and provides you with access to information about those commitments.
>
> ACell has agreed to plead guilty to a misdemeanor under the Federal Food, Drug and Cosmetic Act relating to its failure to properly implement a recall in 2012. In addition, ACell entered into a separate civil settlement relating to allegations that ACell engaged in improper sales and marketing practices. To resolve those allegations, ACell agreed to pay approximately $15 million to federal and state health care programs. More information about this settlement may be found at the following: **[The notice shall include a link to the USAO, OCL, and ACell websites in the letter.]**
>
> As part of the global settlement, ACell also entered into a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at http://oig.hhs.gov/fraud/cia/index.html.Under this agreement, ACell agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by ACell's representatives to ACell's Compliance organization or the FDA using the information set out below.
>
> Please call ACell's Ethics and Integrity Helpline at 1-844-620-0004 or visit us at www.lighthouse-services.com/acell if you have questions about the settlement referenced above or to report any instances in which you believe

that an ACell representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any improper conduct associated with prescription drug marketing committed by an ACell Representative to the FDA's Office of Prescription Drug Promotion at 301-796-1200. You should direct medical questions or concerns about ACell products to 1-844-620-0004 or visit us at www.lighthouse-services.com/acell.

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

N. Reporting of Physician Payments

1. *Reporting of Payment Information.* Within 90 days after the Effective Date, ACell shall post on its website a description of the types of Payments it makes to Covered Recipients and include a link to CMS's Open Payments Data website (www.openpaymentsdata.cms.gov). ACell also shall include on its website instructions regarding how to utilize the CMS Open Payments Data search tool to search for information regarding Payments provided to Covered Recipients from ACell.

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

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, ACell 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) purchase or establish 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 such 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. ACell 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, ACell 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, ACell must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

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

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

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

3. the names of the Board members who are responsible for satisfying the Board of Directors compliance obligations described in Section III.A.3;

4. the names and positions of the Certifying Employees required by Section III.A.4;

5. a list of the Policies and Procedures required by Section III.B;

6. the Training Plan required by Section III.C.1 and a description of the Board 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 ACell;

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 certification by the CCO that the notice required by Section III.M was posted in the manner required by Section III.M and a summary of the calls or messages received in response to the notice;

12. a certification from the CCO that information regarding Payments has been posted on ACell's website as required by Section III.N;

13. a list of all of ACell'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;

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

15. the certifications required by Section V.C.

B. Annual Reports

ACell 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 CCO; a current list of the Corporate Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board of Directors compliance obligations; and a current list of the Certifying Employees, along with the identification of any changes made during the Reporting Period to the Corporate Compliance Committee, Board of Directors, and Certifying Employees;

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

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

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

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

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

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

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

9. a certification from the IRO regarding its professional independence and objectivity with respect to ACell;

10. 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;

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

12. 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;

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

14. 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;

15. a summary describing any recall notices issued during the Reporting Period by ACell for Government Reimbursed Products, a description of ACell's corrective action(s) taken related to any recall(s), and any further steps ACell plans to take related to the recall(s);

16. a summary of the FFMP and the results of the FFMP required by Section III.K, including copies of the Observations for any instances in which it was determined that improper promotion occurred and a description of the action(s) that ACell took as a result of such determinations;

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

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

19. a certification from the CCO that information regarding Payments has been posted on ACell's website as required by Section III.N;

20. a description of all changes to the most recently provided list of ACell's locations (including addresses) as required by Section V.A.13;

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

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

2. *CCO and Chief Executive Officer*. The Implementation Report and each Annual Report shall include a certification by the CCO and Chief Executive Officer that:

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

ACell 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. ACell 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

ACell:

William Hrubes
Chief Compliance Officer
6640 Eli Whitney Drive, Suite 200

Columbia, MD 21046
Telephone: 443.283.2791
Facsimile: 410.715.4511

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

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations

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

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

   a. a CCO;

   b. a Corporate Compliance Committee;

   c. the Board of Directors compliance obligations;

   d. the management certification obligations;

   e. written Policies and Procedures;

   f. the development of a written training plan and the training and education of Covered Persons and Board Members;

g. a risk assessment and internal review process;

h. a Disclosure Program;

i. Ineligible Persons screening and removal requirements;

j. notification of Government investigations or legal proceedings;

k. reporting of Reportable Events;

l. notification of written communications with FDA;

m. the FFMP;

n. the NPMP;

o. notification to HCPs and HCIs; and

p. posting of any Payment-related information.

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

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

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

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

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

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

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

B. Timely Written Requests for Extensions

ACell may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after ACell fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three days after ACell receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties

1. *Demand Letter*. Upon a finding that ACell has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated

Penalties are appropriate, OIG shall notify ACell of: (a) ACell's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter*. Within 10 days after the receipt of the Demand Letter, ACell shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event ACell elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until ACell cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

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

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

D. Exclusion for Material Breach of this CIA

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

a. repeated violations or a flagrant violation of any of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure by ACell to report a Reportable Event and take corrective action as required in Section III.I;

c. a failure to engage and use an IRO in accordance with Section III.E and Appendix B; or

d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C.

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

3. *Opportunity to Cure*. ACell shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. the alleged material breach has been cured; or

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

4. *Exclusion Letter*. If, at the conclusion of the 30 day period, ACell fails to satisfy the requirements of Section X.D.3, OIG may exclude ACell from participation in the Federal health care programs. OIG shall notify ACell in writing of its determination to exclude ACell (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 ACell's receipt of the Exclusion Letter. The exclusion shall have national effect. Reinstatement to program participation is not automatic. At the end of the period of exclusion, ACell may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights*. Upon OIG's delivery to ACell of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, ACell shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter. The procedures relating to the filing of a request for a hearing can be found at http://www.hhs.gov/dab/divisions/civil/procedures/divisionprocedures.html.

2. *Stipulated Penalties Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether ACell was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. ACell shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders ACell to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless ACell requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be whether ACell was in material breach of this CIA and, if so, whether:

a. ACell cured such breach within 30 days of its receipt of the Notice of Material Breach; or

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

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

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

XI. EFFECTIVE AND BINDING AGREEMENT

ACell 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) ACell'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 ACell 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 ACELL INC.

___/Patrick McBrayer/_____ ____5/9/19_____
Patrick McBrayer DATE
President and Chief Executive Officer
ACell, Inc.

___/Melissa Bayer Tearney/_____ _____5/9/19_____
Melissa Bayer Tearney, Esq. DATE
Choate, Hall & Stewart LLP
Counsel for ACell, Inc.

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

____/Lisa M. Re/_____ ___04/16/2019_____
Lisa M. Re DATE
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

_____/Mary E. Riordan/_____ ____05/13/19_____
Mary E. Riordan DATE
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

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. ACell 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 ACell in response to a request by OIG, whichever is later, OIG will notify ACell if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, ACell may continue to engage the IRO.

2. If ACell 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, ACell 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 ACell at the request of OIG, whichever is later, OIG will notify ACell if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, ACell may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and in Federal health care program requirements (including but not limited to, the Federal Anti-Kickback Statute and the False Claims Act) applicable to the Covered Functions and the systems, processes, policies, and procedures being reviewed;

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

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

C. IRO Responsibilities

The IRO shall:

1. perform each component of the IRO Review in accordance with the specific requirements of the CIA;

2. follow all applicable Federal health care program requirements in making assessments in the IRO Review;

3. request clarification from the appropriate authority (e.g., CMS), if in doubt of the application of a particular Federal health care program requirement;

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

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. ACell Responsibilities

ACell shall ensure that the IRO has access to all records and personnel necessary to complete the reviews listed in Section 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 the IRO Review 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. ACell *and IRO*. If ACell terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, ACell 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. ACell 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 ACell in writing regarding OIG's basis for determining that the IRO has not met the requirements of this Appendix. ACell 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 ACell regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify ACell in writing that ACell shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. ACell 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 ACell to engage a new IRO shall be made at the sole discretion of OIG.

Appendix B to CIA for ACell, Inc.

IRO Review

I. IRO Engagement, General Description

As specified more fully below, ACell shall retain an Independent Review Organization(s) (IRO) to perform engagements to assist ACell in assessing and evaluating its systems, processes, policies, and procedures related to ACell's Covered Functions (as defined in the CIA) (collectively "IRO Review"). The IRO Review shall consist of two components – a systems review (Systems Review) and a transactions review (Transactions Review) as described more fully below. ACell may engage, at its discretion, a single entity to perform both components of the IRO Review, provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in ACell's systems, processes, policies, and procedures relating to Covered Functions, the IRO shall perform the Systems Review for the second and fourth Reporting Periods. If ACell 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.

II. IRO Systems Review

A. General Description. The Systems Review shall be a review of ACell's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to Covered Functions. Where practical, ACell personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not required to undertake a de novo review of the information gathered or activities undertaken by ACell pursuant to the preceding sentence.

B. Reviewed Policies and Procedures. The IRO shall review ACell's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1. ACell's systems, policies, processes, and procedures applicable to the manner in which ACell sales and medical personnel handle requests or inquiries relating to information about the uses of products (including non-FDA-approved (i.e.,

off-label) uses) and the dissemination of materials relating to off-label uses of products;

2. ACell's systems, policies, processes, and procedures relating to ACell's internal review and approval of information and materials relating to Government Reimbursed Products that are disseminated in the United States to individuals or entities outside ACell (including HCPs and HCIs);

3. ACell's systems, policies, processes and procedures relating to the provision of any reimbursement and/or coding advice to HCPs or HCIs relating to Government Reimbursed Products and the internal review and approval of any materials used in connection with providing such advice;

4. If applicable, ACell's systems, policies, processes and procedures relating to Evaluation Product distribution (as described in Section III.B.f of the CIA). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive Evaluation Product from ACell (including, separately, from ACell sales representatives and other ACell personnel or components). It shall also include a review of whether Government Reimbursed Products are distributed by ACell as Evaluation Product through sales representatives or are distributed from a central location and the rationale for the manner of distribution; and

5. ACell's systems, policies, processes, and procedures relating to consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to HCPs who serve as Key Opinion Leaders (KOLs) or participate in speaker programs (if applicable), speaker training programs, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, labs, wound symposia, phone consults, and any other financial engagement or arrangement) and all events and expenses relating to such engagements or arrangements.

III. IRO Systems Review Report

A. The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II 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 ACell's systems, policies, processes, and procedures relating to the items identified in Sections II.1-5 above, including a general description of ACell's control and accountability systems (e.g., documentation and

approval requirements) and written policies regarding the Reviewed Policies and Procedures;

3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.1-5 above are made known or disseminated within ACell;

4. findings and supporting rationale regarding any weaknesses in ACell'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.

IV. IRO Transactions Review

As described more fully below in Sections IV.A-D, the Transactions Review shall include: (1) a review of Evaluation Product activities; (2) a review of Consulting Activities; (3) a review of records relating to a sample of the Payments that are reported by ACell to CMS as referenced in Section III.N of the CIA; and (4) a review of up to three additional items identified by the OIG in accordance with Section III.E.2 of the CIA (hereafter "Additional Items"). The IRO shall report on all aspects of its reviews in the Transactions Review Reports.

A. IRO Review of Evaluation Product.

1. *Selection of Sample for Review.* For the first Reporting Period, the IRO shall randomly select and review records relating to a sample of 250 activities in which Evaluation Product is provided to customers. For the second and subsequent Reporting Periods, the IRO shall review records relating to a total of at least 250 activities in which Evaluation Product is provided to customers.

2. *Scope of Review*. The purpose of the IRO's review shall be to verify that ACell is managing and controlling its Evaluation Product in accordance with its Policies and Procedures relating to: (a) the fulfilling of requests, (b) the analysis and reporting of Evaluation Product, (c) the return of Evaluation Product, and (d) the audit of Evaluation Product. The IRO's review shall also verify that all Evaluation Product is managed through a tracking process that records: (a) the provision of Evaluation Product to ACell personnel, customers, prospective customers and third parties; (b) the reason for providing the Evaluation Product; and (c) the amount of Evaluation Product provided.

B. IRO Review of Consulting Activities

1. *Consulting Activities*. For purposes of this Appendix B, the term "Consulting Activities" shall include all consulting and other fee for service arrangements entered with HCPs including but not limited to speaker programs, advisory boards, research and development meetings, product training and education sessions, presentations, labs, wound symposia, phone consults, ad hoc advisory activities, and any other financial engagement or arrangement and all related expenses.

2. *Selection of Sample*. For the first Reporting Period, the IRO shall select and review a sample of 13 Consulting Activities entered into with HCPs and all related expenses. More specifically, the IRO shall review: ten Educational Meals and Other Events and three activities relating to Labs and Symposia.

For the second and subsequent Reporting Periods, at least 60 days prior to the end of the applicable Reporting Period, in order to facilitate the OIG's determination of the number of each type of Consulting Activities to be reviewed by the IRO, ACell shall provide the following information to the OIG: (a) a description of each type of Consulting Activity undertaken during the Reporting Period and a description of the services to be provided under each Consulting Activity; (b) the number of each type of Consulting Activity undertaken during the Reporting Period; and (c) the overall budgeted amount to be spent in connection with each type of Consulting Activity during the Reporting Period. For the second and subsequent Reporting Periods, the IRO shall review a total of at least 13 Consulting Activities which shall include a review of specified numbers of each type of Consulting Activities as determined by the OIG.

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

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

b. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure established by ACell;

c. the rate structure was established based on a FMV analysis conducted by or for ACell;

d. the Consulting Activity was identified in the annual Consultant budgeting plan developed by ACell;

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

f. the Consulting Activity was reviewed and approved in accordance with ACell Policies and Procedures;

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

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

C. IRO Review of Physician Payment Listings

1. *Information to Be Reviewed.* As referenced in Section III.N of the CIA, ACell reports to CMS Payments to Covered Recipients (as defined in Section III.N of the CIA) that are listed on the Open Payments Data website. For purposes of this portion of the IRO Review, the term "Control Documents" shall include all material documents or electronic records associated with each Payment (as defined in Section III.N of the CIA) reflected in the Open Payments database for the applicable calendar year. For example, the term "Control Documents" includes, but is not limited to: documents relating to the nature, purpose, and amount of all Payments; contracts relating to the Payments; documents relating to the occurrence of Payments; documents reflecting any work product generated in connection with the Payments; documents submitted by sales representatives or headquarters personnel to request approval for the Payments; and business rationale or justification forms relating to the Payments.

2. *Selection of Sample for Review.* For each Reporting Period, the OIG shall have the discretion to identify up to 30 Covered Recipients who received Payments from ACell during the prior calendar year and will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the Covered Recipients subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 30 Covered Recipients to

be included in the review.

3. *Scope of Review*. For each selected Covered Recipient, the IRO shall review Control Documents associated with the Payments to the Covered Recipient for all categories reflected in the Open Payments Data website except for the Food/Beverage and Travel/Lodging categories of Payments. Specifically, for each Covered Recipient selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reported to CMS to evaluate the following:

a. whether Control Documents are available relating to each Payment for the sampled Covered Recipient;

b. whether the Control Documents were completed and archived in accordance with the requirements set forth in ACell's policies;

c. whether the aggregate value of the Payment(s) as reflected in the information reported to CMS for the sampled Covered Recipient is consistent with the value of the Payment(s) reflected in the Control Documents; and

d. whether the Control Documents reflect that ACell's policies were followed in connection with Payment(s) reflected in the report to CMS (e.g., all required written approvals for the activity were obtained in accordance with ACell's policies).

4. *Identification of Material Errors and Additional Review.*

a. A Material Error is defined as a situation in which all required Control Documents relating to Payments for the sampled Covered Recipient do not exist and:

i. no corrective action was initiated prior to the selection of the sampled Covered Recipient; or

ii. the IRO cannot confirm that ACell otherwise followed its policies and procedures relating to the Payment for the sampled Covered Recipient, including its policies and procedures relating to any Payment(s); or

iii. information or data is omitted from key fields in the

Control Documents that prevents the IRO from assessing compliance with ACell's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

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

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

D. Review of Additional Items. As set forth in Section III.E.2 of the CIA, for each Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items"). No later than 90 days prior to the end of the applicable Reporting Period, the OIG shall notify ACell 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 ACell 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. If an Additional Items Review is required for a Reporting Period, the IRO shall include information about its review of each Additional Item in the Transactions Review Report as outlined below.

V. Transactions Review Report

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

1. Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;

2. 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 part of the review; and

3. Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Transactions Review.

B. Results to be Included in Report.

1. Relating to Reviews of Evaluation Products. In connection with the IRO's review of Evaluation Product:

a. A description of each type of activity reviewed in which Evaluation Product is provided to customers, including the number of each type of activity reviewed and an identification of the types of documents and information reviewed for each activity;

b. The IRO's findings and supporting rationale as to whether:

i. ACell is managing its Evaluation Product in accordance with its Policies and Procedures for: i) fulfilling requests only when the requests meet applicable requirements; ii) the analysis and reporting of Evaluation Product; and iii) the auditing of Evaluation Product;

ii. the Evaluation Product is tracked by ACell and that such tracking accurately records: i) the provision of Evaluation Product to ACell personnel, customers, prospective customers, and third parties; ii) the reason for providing Evaluation Product; and iii) the amount of Evaluation Product provided;

iii. the IRO identified any weaknesses in ACell systems, processes, policies, procedures and/or practices relating to Evaluation Product; and

iv. the IRO has recommendations, if any, for improvements to ACell's systems, processes, policies, procedures and/or practices relating to Evaluation Product.

2. Relating to the Review of Consulting Activities. In connection with the review of Consulting Activities:

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

b. The IRO's findings and supporting rationale as to whether:

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

ii. the compensation to be paid for the Consulting Activity was determined in accordance with a centrally managed, pre-set rate structure set by ACell;

iii. the rate structure was established based on a FMV analysis conducted by or for ACell;

iv. the Consulting Activity was identified in the annual Consulting budgeting plan developed by ACell;

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

vi. the Consulting Activity was reviewed and approved in accordance with ACell Policies and Procedures;

vii. ACell collected and retained a record of the specific activity performed by the HCP and, if applicable, a copy of the work product generated in connection with

the Consulting Activity;

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

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

x. the IRO has recommendations for improvements to ACell's systems, processes, policies, procedures and/or practices relating to Consulting Activities.

3. Relating to Reviews of Payments. In connection with the review of Payments:

a. A description of the entries in the Open Payments database for each sampled Covered Recipient and a description of Control Documents reviewed in connection with each Covered Recipient;

b. The IRO's findings and supporting rationale as to whether:

i. all required Control Documents exist;

ii. each Control Document was completed in accordance with all of the requirements set forth in the applicable ACell policy;

iii. the aggregate value of the Payment(s) as reflected in the report to CMS for the sampled Covered Recipient is consistent with the value of the Payment(s) reflected in the Control Documents;

iv. each Control Document reflects that ACell's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and

v. any corrective action or disciplinary action was undertaken in those instances in which ACell policies were not followed.

c. For each sampled Covered Recipient reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled Covered Recipients, including a description of the circumstances requiring corrective action and the nature of the corrective action;

d. If any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

e. The findings and supporting rationale regarding any weaknesses in ACell's systems, processes, policies, procedures, and practices relating to the Payments to Covered Recipients; and

f. Recommendations, if any, for changes in ACell's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.

4. Relating to the Review of Additional Items. For each Additional Item reviewed:

a. A description of the review conducted;

b. The IRO's findings based on its review;

c. The findings and supporting rationale regarding any weaknesses in ACell's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and

d. Recommendations, if any, for changes in ACell's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the

review.