

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
US WORLDMEDS, LLC AND SOLSTICE NEUROSCIENCES, LLC**

I. PREAMBLE

US WorldMeds, LLC and its wholly owned subsidiary Solstice Neurosciences, LLC (collectively “USWM”) hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance by USWM and USWM Affiliates (as defined below) 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, USWM is entering into a Settlement Agreement with the United States.

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

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by USWM 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) USWM's final Annual Report; or (2) any additional materials submitted by USWM 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 USWM who are natural persons (other than shareholders who: (i) have an ownership interest of less than 5% and (ii) acquired the ownership interest through public trading) and all officers and directors of USWM; (b) all employees of USWM who are engaged in or who supervise personnel who are engaged in Covered Functions (as defined below in Section II.C.7); and (c) all contractors, subcontractors, agents, and other persons who perform any of the Covered Functions on behalf of USWM.

Notwithstanding the above, the term "Covered Person" does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to perform a Covered Function for USWM more than 160 hours per year, except that any such individual shall become a "Covered Person" at the point when they work more than 160 hours on a Covered Function for USWM during the reporting period.

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

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

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

scientific exchange; (b) contracting with HCPs licensed in the United States or with HCIs to conduct post-marketing clinical trials, Investigator-Sponsored Studies (ISSs), and any other types of post-marketing studies relating to Government Reimbursed Products; (c) authorship, publication, and disclosure of articles or study results relating to Government Reimbursed Products; and (d) activities related to the submission of information about Government Reimbursed Products to Compendia (such as Drugdex or other compendia of information about Government Reimbursed Products).

5. The term “Contribution and Assistance Related Functions” includes: all activities, systems, processes, and procedures relating to the following: (a) grants provided by USWM to any outside entity or individual; (b) charitable contributions provided by USWM to any outside entity or individual; (c) donations (in cash or in kind) to any independent third-party patient assistance program (Independent Charity PAP) by USWM or any entity acting on behalf of USWM; and (d) the operation of, or participation in, any patient assistance program by USWM or any entity acting on behalf of USWM.

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

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

8. “USWM Affiliate” shall mean any subsidiary of USWM whose employees or contractors perform Covered Functions. All obligations set forth in Section III below shall apply to USWM Affiliates in the same manner as they apply to USWM and all references to “USWM” in the defined terms set forth in this Section II shall include USWM Affiliates. In addition, the requirements in Section V.C., Section VI, Section VII, Section VIII, and Section X below shall apply to both USWM and any USWM Affiliate(s).

III. CORPORATE INTEGRITY OBLIGATIONS

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

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

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

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

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

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

2. *Compliance Committee.* Within 90 days after the Effective Date, USWM shall appoint a Compliance Committee. The Compliance Committee shall, at a

minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as sales, marketing, legal, medical affairs/medical information, regulatory affairs, research and development, human resources, audit, finance, manufacturing, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of USWM's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly. The minutes of the Compliance Committee meetings shall be made available to OIG upon request.

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

3. *Board of Directors Compliance Obligations.* The Board of Directors (or a committee of the Board) of USWM (Board) 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 at least one independent (i.e., non-executive) member.

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

- a. meeting at least quarterly to review and oversee USWM's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee;
- b. submitting to OIG a description of the documents and other materials it reviewed, as well as any additional steps taken, such as the engagement of an independent advisor or other third party resources, in its oversight of the compliance program and in support of making the resolution below during each Reporting Period; 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 USWM's compliance with Federal health

care program requirements, FDA requirements, and the obligations of this CIA.

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

“The Board of Directors has made a reasonable inquiry into the operations of USWM’s Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, USWM has implemented an effective Compliance Program to meet Federal health care program requirements, FDA requirements, and the obligations of the CIA.”

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

USWM 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 USWM employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable USWM 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, all relevant business units/divisions that perform Covered Functions, including: Senior Vice President; Manager, Sales Operations; Director, Marketing; Director, Brand Management; National Sales Director; and Senior Director, Quality. 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 USWM policies, and I have taken steps to promote such compliance. To the best of my knowledge, the _____ [insert name of department] of USWM is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

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

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

B. Written Standards

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

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

2. appropriate ways to conduct Product Related Functions in compliance with: (i) all applicable Federal healthcare program requirements, including, but not limited to the Federal Anti-Kickback Statute (codified at 42 U.S.C. §1320a 7b(b))

and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733); and (ii) all applicable FDA requirements;

3. The materials and information that may be distributed by USWM sales representatives (including any contract sales force) about Government Reimbursed Products and the manner in which USWM sales representatives respond to requests for information about non-FDA approved (or “off-label”) uses of Government Reimbursed Products.

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

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

6. the materials and information that may be distributed or made available by USWM through social media and/or direct-to-consumer advertising.

7. the development, implementation, and review of call plans for sales representatives (including any contract sales force) and other USWM representatives who promote and sell Government Reimbursed Products.

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

9. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including but not limited to speaker programs, speaker training programs, presentations, consultant task force meetings, advisory boards, ad hoc advisory activities, and any other financial engagement or arrangement with an HCP or HCI) and all events and expenses relating to such engagements or arrangements.

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

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

12. funding of, or participation in, any Third Party Educational Activity as defined in Section II.C.8 above.

13. review of promotional, reimbursement, and disease state materials and information intended to be disseminated outside USWM 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 USWM's review and approval process and are elevated when appropriate.

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

15. the submission of information about any Government Reimbursed Product to any compendia such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia").

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

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

18. arrangements and interactions with (including donations to and sponsorship of) Independent Charity PAPs. These Policies and Procedures shall be designed to ensure that USWM's arrangements and interactions comply with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that USWM's arrangements and interactions (including donations and sponsorship) comply with all guidance issued by OIG relating to the support and funding of patient assistance programs, including but not limited to, the OIG's Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005) and OIG's Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014);

19. the operation of, or participation in, any patient assistance program by USWM or any entity acting on behalf of USWM. These Policies and Procedures shall be designed to ensure that USWM's operation of or in participation in such programs complies with all applicable Federal health care program requirements. The Policies and Procedures shall also be designed to ensure that USWM's operation of or participation in any such patient assistance program complies with all guidance issued by OIG relating to assistance provided to patients by pharmaceutical manufacturers to reduce or eliminate the cost of copayments for drugs, including but not limited to, the OIG's Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014);

20. the materials and information that may be distributed by appropriate USWM personnel about Independent Charity PAPs or Contribution and Assistance Related Functions and the manner in, and circumstances under, which appropriate USWM personnel may respond to requests for information about Independent Charity PAPs or Contribution and Assistance Related Functions; and

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

At least annually (and more frequently, if appropriate), USWM 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, USWM shall develop a written plan (Training Plan) that outlines the steps USWM will take to ensure that: (a) all Covered Persons receive at least annual training regarding USWM's CIA requirements and compliance program, and (b) all Covered Persons who engage in Covered Functions receive at least annual training regarding: (i) all applicable Federal health care program and FDA requirements relating to Covered Functions and (ii) all USWM Policies and Procedures and other requirements applicable to Covered Functions. The Training Plan shall include information regarding the following: training topics, categories of Covered Persons and required to attend each training session, length of the training session(s), schedule for training, and format of the training. USWM shall furnish training to its Covered Persons pursuant to the Training Plan during each Reporting Period.

2. *Board Member Training.* Within 120 days after the Effective Date, each member of the Board of Directors shall receive at least two hours of training. This training shall address the corporate governance responsibilities of board members, and the responsibilities of board members with respect to review and oversight of the Compliance Program. Specifically, the training shall address the unique responsibilities of health care Board members, including the risks, oversight areas, and strategic approaches to conducting oversight of a health care entity. This training may be conducted by an outside compliance expert hired by the Board and should include a discussion of OIG's guidance on Board member responsibilities.

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

3. *Training Records.* USWM 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, USWM 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 each product. The risk assessment and internal review process shall require compliance, legal, and department leaders, at least annually, to: (1) identify and prioritize risks, (2) develop internal audit work plans related to the identified risk areas, (3) implement the internal audit work plans, (4) develop corrective action plans in response to the results of any internal audits performed, and (5) track the implementation of the corrective action plans in order to assess the effectiveness of such plans. USWM 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, USWM shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform the reviews listed in this Section III.E. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.
- b. *Retention of Records.* The IRO and USWM shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and USWM) related to the reviews.

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

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

- a. *Systems Review.* The Systems Reviews shall assess USWM's systems, processes, policies, and procedures relating to the Covered Functions. If there are no material changes in USWM's relevant systems, processes, policies, and procedures, the Systems Reviews shall be performed for the second and fourth Reporting Periods. If USWM 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 second through fifth 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.* As part of the Transactions Review, each IRO review shall also include a review of up to three additional areas or practices of USWM identified by OIG in its discretion (hereafter "Additional Items"). For purposes of identifying the Additional Items to be included in the IRO review for a particular Reporting Period, OIG will consult with USWM and may consider internal audit and monitoring work conducted by USWM, the Government Reimbursed

Product portfolio, the nature and scope of USWM'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 Appendix B.

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

F. Disclosure Program

Within 90 days after the Effective Date, USWM shall establish a Disclosure Program that includes a mechanism (e.g., a toll free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with USWM'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. USWM shall appropriately publicize the existence of the Disclosure Program and the disclosure mechanism (e.g., via periodic e-mails to employees, or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. The Disclosure Program also shall include a requirement that all of USWM's Covered Persons shall be expected to report suspected violations of any Federal health care program or FDA requirements to the Compliance Officer or other appropriate individual designated by USWM. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it

reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, USWM shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

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

G. Ineligible Persons

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

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

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

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

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

3. *Removal Requirement.* If USWM has actual notice that a Covered Person has become an Ineligible Person, USWM shall remove such Covered Person from responsibility for, or involvement with, USWM'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 USWM 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, USWM 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, USWM shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to USWM conducted or brought by a governmental entity or its agents involving an allegation that USWM 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. USWM 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 employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.G.1.a; or
- d. the filing of a bankruptcy petition by USWM.

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

2. *Reporting of Reportable Events.* If USWM determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, USWM 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 USWM's actions taken to correct the Reportable Event and prevent it from recurring.

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

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

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

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

J. Notification of Communications with FDA

Within 30 days after the date of any written report, correspondence, or communication between USWM and the FDA that materially discusses USWM's or a Covered Person's actual or potential unlawful or improper promotion of USWM's products (including any improper dissemination of information about off-label indications), USWM shall provide a copy of the report, correspondence, or communication to OIG. USWM 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, USWM shall establish a comprehensive Field Force Monitoring Program (FFMP) to evaluate and monitor its sales personnel's interactions with HCPs and HCIs. The FFMP shall be a formalized process designed to directly and indirectly observe the appropriateness of sales personnel's interactions with HCPs and HCIs and to identify potential off-label promotional activities or other improper conduct. As described in more detail below, the FFMP shall include: (1) a Speaker Monitoring Program; (2) direct field observations (Observations) of sales personnel; and (3) the monitoring and review of other records relating to sales personnel's interactions with HCPs and HCIs (Records Reviews).

1. *Speaker Program Activities.*

- a. With regard to speaker programs, USWM shall implement a process to require all speakers to complete training and enter written agreements that describe the scope of work to be performed, the speaker fees to be paid, and compliance obligations for the speakers (including requirements

regarding the use of USWM approved materials and requirements that speakers may not directly or indirectly promote the product for off-label uses.)

- b. USWM 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. The controls shall also be designed to ensure that there is a legitimate need for the speaker programs.
- c. USWM 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 USWM.
- d. USWM shall maintain a comprehensive list of speaker program attendees through its centralized system. In addition, USWM 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. USWM shall require certifications by sales representatives or other USWM personnel that a speaker program complied with USWM requirements, or in the event of non-compliance, USWM shall require the identification of the policy violation and ensure appropriate follow up activity to address the violation.
- f. USWM shall institute a Speaker Monitoring Program under which USWM compliance or other appropriately trained USWM personnel who are independent from the functional area being monitored (Monitoring Personnel) shall attend 20 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 USWM sales representative activities during the program to assess whether the programs were conducted in a manner consistent with USWM's Policies and Procedures.

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

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

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

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

Monitoring Personnel shall conduct at least 10 Observations during each Reporting Period. Monitoring Personnel shall have access to all relevant records and information necessary to assess field representatives' interactions with HCPs and HCIs and to identify potential or actual compliance violations.

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

- a. For each Reporting Period, USWM shall develop and implement a plan for conducting Records Reviews associated with at least 3 Government Reimbursed Products. The Records Reviews shall include a review of records relating to the activities of sales representatives in every separate district and/or region (as applicable) who promoted the products under review.
- b. The Records Reviews shall include the monitoring and review of: (1) records and systems associated with field sales representatives' interactions with HCPs and HCIs (including records relating to speaker program activities, samples, travel and entertainment, expense reports, any payments to HCPs or HCIs, and sales communications from managers); (2) message recall studies or other similar records (such as Verbatims) purporting to reflect the details of representatives interactions with HCPs and HCIs; (3) records relating to requests for medical information about or Inquiries relating to, the Government Reimbursed Products under review; (4) field sales representative call notes; (5) field sales representatives' e-mails and other electronic records; and (6) recorded results of the Observations of field sales force representatives, coaching guides, and district manager notes.

4. *Reporting and Follow-up.* Results from the FFMP shall be compiled and reported to the Compliance Officer for review and remediation as appropriate. Potential violations related to improper promotion of a Government Reimbursed Product or potential violations of Federal health care program or FDA requirements shall be reported to the Compliance Officer for appropriate follow-up

activity. In the event that a compliance issue, including but not limited to any potential improper promotion or noncompliance with USWM's Policies and Procedures or legal or compliance requirements, is identified during any portion of the FFMP, USWM 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 Compliance Officer.

L. Monitoring of Non-Promotional Activities

Within 120 days after the Effective Date, USWM shall develop and implement a monitoring program for the following types of activities: (1) consultant arrangement activities and (2) medical education grants. This program shall be referred to as the Non-Promotional Monitoring Program (NPMP).

1. *Consulting Arrangement Activities.* To the extent that USWM engages HCPs for services other than for speaker programs, Research-related activities, or publication activities (e.g., as a member of an advisory board or to attend consultant meetings), such HCPs shall be referred to herein as Consultants.

- a. USWM 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 USWM.
- b. Within 120 days after the Effective Date, USWM 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. USWM 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 USWM Policies and Procedures.

- c. Within 120 days after the Effective Date, USWM 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 USWM compliance personnel.
- d. Within 120 days after the Effective Date, USWM 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, USWM received the work product generated by the Consultant.
- e. Within 120 days after the Effective Date, USWM shall establish a Consultant Monitoring Program through which it shall conduct audits (Consultant Program Audits) of at least 3 consultant programs with HCPs during each Reporting Period. The Consultant Monitoring Program shall select Consultant arrangements for review using either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review needs assessment documents, Consultant contracts, and materials relating to the program or work of the Consultant (including work product resulting from any program or event), to assess whether the

programs and arrangements were conducted in a manner consistent with USWM's Policies and Procedures. Results from the Consultant Program Audits, including the identification of potential violations of USWM policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow up as appropriate.

2. *Medical Education Grant Activities.*

- a. Within 120 days after the Effective Date, USWM shall establish a grants management system which shall be the exclusive mechanism through which requestors may request or be awarded grants for independent medical education grants, other grant activities, and charitable contributions supported by USWM. USWM's sales and marketing personnel shall not be involved in, or influence over, the review and approval of medical education grants or charitable contribution requests. Grant and charitable contribution requests shall be processed in accordance with standardized, objective criteria developed by USWM (such as based upon the qualifications of the requestor, or the quality of the program funded by the grant.) In addition, the grants or charitable contributions shall be provided only pursuant to a written agreement with the funding recipient, and if payments to the funding recipient are consistent with the written agreement.
- b. Within 120 days after the Effective Date, USWM shall establish a Grants Monitoring Program through which it shall conduct audits for each Reporting Period of at least 3 medical education grants. The Grants Monitoring Program shall select grants for review both on either a risk-based targeting approach or a random sampling approach. Monitoring Personnel shall review proposal documents (including grant requests), approval documents, contracts, payments and materials relating to the grant management system's review of the requests, and documents and materials relating to the

grants and any events or activities funded through the grants in order to assess whether the activities were conducted in a manner consistent with USWM's Policies and Procedures. Results from the Grants Monitoring Programs, including the identification of potential violations of policies, shall be compiled and reported to the Compliance Officer (or compliance personnel designee) for review and follow-up as appropriate.

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

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

1. *Reporting of Payment Information.* Within 120 days after the Effective Date, USWM 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). USWM 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 USWM.

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

N. Independent Charity Patient Assistance Program Activities

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

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

- a. The Independent Charity Group shall be separate and independent from USWM’s commercial organization.
- b. The Independent Charity Group shall operate independently from USWM’s commercial organization and USWM’s commercial organization shall have no involvement in, or influence over, the review, approval, or implementation of any budget or other decisions or activities relating to Independent Charity PAPs.
- c. USWM shall vest in the Independent Charity Group sole responsibility and authority for communicating with Independent Charity PAPs regarding USWM’s donations to such PAPs and USWM’s commercial organization shall not communicate with, influence, or be involved in any communications with, or receive information from the Independent Charity PAPs.
- d. USWM’s Independent Charity Group shall gather information about Independent Charity PAPs and their disease funds in a manner that does not exert or attempt to exert any direct or indirect control over the entity operating the PAP or over its assistance program.

- e. For purposes of this CIA, the “commercial organization” shall be defined to include the sales, marketing, and similar commercial business units of USWM.

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

- a. The Independent Charity Group shall develop an annual budget for donations to Independent Charity PAPs based on objective criteria in accordance with general guidelines approved by the legal department with input from the compliance department.
- b. USWM shall approve the annual budget for donations to Independent Charity PAPs at a level within the organization above the commercial organization (e.g., at the executive level).
- c. The Independent Charity Group shall have sole responsibility for allocating the approved budget across donations to Independent Charity PAPs and to any disease state fund established by the Independent Charity PAP.
- e. The Independent Charity Group shall have sole responsibility for assessing requests for additional or supplemental funding from Independent Charity PAPs outside of the annual budget using standardized, objective criteria established by the Independent Charity Group. Any such requests also shall be subject to legal and compliance personnel review and approval, to ensure that any supplemental funding to the Independent Charity PAP is provided in accordance with applicable Federal health care program requirements, OIG guidance, and USWM Policies and Procedures.
- f. The commercial organization shall have no involvement in the budget process, and the budget to be used for donations to Independent Charity PAPs shall not be based on monies

allocated to the Independent Charity Group from the commercial organization.

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

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

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

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, USWM proposes to (a) sell any or all of its business, business units or locations (whether through a sale of assets, sale of stock or other type of transaction) that are subject to this CIA; or (b) purchases or establishes a new business, business unit or location related to or engaged in any of the Covered Functions, the CIA shall be binding on the purchaser of any business, business unit or location. Any such new business, business unit or location (and all Covered Persons at each new business, business unit or location) shall be subject to the applicable requirements of this CIA, unless otherwise determined and agreed to in writing by OIG. USWM 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, USWM 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, USWM must notify OIG in writing of the proposed sale or purchase at least 30 days in advance. This notification shall include a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 150 days after the Effective Date, USWM shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

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

2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. the names of the Board members who are responsible for satisfying the Board 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.3;
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 USWM;
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 from the Compliance Officer that information regarding Payments has been posted on USWM's website as required by Section III.M;
12. a description of the Independent Charity PAP policies, procedures, and practices required by Section III.N.
13. a list of all USWM'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 USWM'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

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

1. any change in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer; a current list of the Compliance Committee members; a current list of the Board members who are responsible for satisfying the Board 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 Compliance Committee, Board of Directors, and Certifying Employees;

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

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

4. a copy of the Compliance Review Report;

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

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

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

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

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

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

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

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

13. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

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

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

16. a summary of 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 USWM 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 detailed description of any identified instances in which it was determined that the activities violated USWM's policies or that improper promotion of Government Reimbursed Products occurred and a description of the action(s) USWM took as a result of such determinations;

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

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

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

21. a description of any changes to USWM'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, USWM shall include the certifications of Certifying Employees as required by Section III.A.4;

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

- a. to the best of his or her knowledge, except as otherwise described in the report, USWM has implemented and is in compliance with all requirements of this CIA;
- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful;
- c. he or she understands that the certification is being provided to and relied upon by the United States;
- d. for each disease fund of an Independent Charity PAP to which USWM donated during the Reporting Period, the facts and circumstances relating to the donation were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and USWM policies and procedures (including those outlined in Section III.J); and
- e. for each patient assistance program that USWM or any entity acting on behalf of USWM operates or participates in (e.g., through cash or in-kind donations), the facts and circumstances relating to the program were reviewed by competent legal counsel and were found to be in compliance with all applicable Federal health care program requirements, OIG guidance, and USWM policies and procedures.

D. Designation of Information

USWM 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. USWM 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

USWM:

Compliance Officer
US WorldMeads, LLC
4441 Springdale Road
Louisville, Kentucky 40241
Telephone: 502.815.8197
Facsimile: 888.787.1730

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

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

USWM 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, USWM 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 USWM fails to establish, implement or comply with any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board of Directors compliance obligations, as required by Section III.A.3;
- d. the management certification obligations;
- e. written Policies and Procedures;
- f. the development of a written training plan and the training and education of Covered Persons and Board Members;
- g. a risk assessment and internal review process;
- h. a Disclosure Program;
- i. Ineligible Persons screening and removal requirements;
- j. 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. posting of any Payment-related information; and
- p. the Independent Charity PAP policies, procedures, and practices required by Section III.N.

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 USWM fails to engage and use an IRO as required by Section III.E and Appendix A.

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 USWM 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 USWM fails to submit any IRO Review report in accordance with the requirements of Section III.E and Appendices A and B.

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

6. A Stipulated Penalty of \$50,000 for each false certification submitted by or on behalf of USWM 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 USWM 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 USWM 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 USWM fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to USWM

stating the specific grounds for its determination that USWM has failed to comply fully and adequately with the CIA obligation(s) at issue and steps USWM shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date USWM 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

USWM 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 USWM 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 USWM 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 USWM 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 USWM of: (a) USWM'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, USWM 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 USWM elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until USWM 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 USWM 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 USWM 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 A; 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 USWM constitutes an independent basis for USWM'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 USWM has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify USWM of: (a) USWM'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.* USWM 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) USWM has begun to take action to cure the material breach; (ii) USWM is pursuing such action with due diligence; and (iii) USWM has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, USWM fails to satisfy the requirements of Section X.D.3, OIG may exclude USWM from participation in the Federal health care programs. OIG shall notify USWM in writing of its determination to exclude USWM (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 USWM’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, USWM 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 USWM 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, USWM 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 USWM was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. USWM 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 USWM to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless USWM 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 USWM was in material breach of this CIA and, if so, whether:

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

USWM 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) USWM'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 USWM 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 USWM

/Amy L. Yuda/
AMY YUDA
COMPLIANCE OFFICER
US WORLDMEDS, LLC

3/28/19
DATE

/Jennifer Burgar/
JENNIFER D. BURGAR
Counsel for US WorldMeds, LLC
Arnall Golden Gregory LLP

March 28, 2019
DATE

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

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

4/03/2019
DATE

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

April 1, 2019
DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

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

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

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the IRO Reviews who have expertise in the pharmaceutical industry and in all applicable Federal health care program and FDA requirements relating to the Covered Functions, including but not limited to expertise relating to marketing and promotional activities associated with pharmaceutical products and the Federal Anti-Kickback Statute and False Claims Act.

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

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

C. IRO Responsibilities

The IRO shall:

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

D. USWM Responsibilities

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

E. IRO Independence and Objectivity

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

F. IRO Removal/Termination

1. *USWM and IRO.* If USWM terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, USWM 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. USWM 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 USWM in writing regarding OIG's basis for determining

that the IRO has not met the requirements of this Appendix. USWM 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 USWM regarding the IRO, OIG determines that the IRO has not met the requirements of this Appendix, OIG shall notify USWM in writing that USWM shall be required to engage a new IRO in accordance with Paragraph A of this Appendix. USWM 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 USWM to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

COVERED FUNCTIONS REVIEW

I. Covered Functions Review, General Description

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

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

II. Systems Review

A. Promotional and Product Related Functions Systems Review

The Promotional and Product Related Functions Systems Review shall be a review of systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) of USWM relating to Promotional Functions and Product Related Functions. Where practical, USWM 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 USWM in accordance with the preceding sentence.

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

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

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

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

4. USWM's systems, policies, processes, and procedures applicable to the development and review of USWM processes relating to incentive compensation for Covered Persons who are prescriber-facing sales representatives and their direct managers, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Government Reimbursed Products. To the extent that USWM establishes different methods of compensation for different Government Reimbursed Products, the IRO shall review each type of compensation arrangement separately;

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

6. USWM's systems, policies, processes, and procedures applicable to the development and review of Sample Distribution Plans (as defined in Section III.B.8 of the CIA). This shall include a review of the bases upon, and circumstances under, which HCPs and HCIs belonging to specified medical specialties or types of clinical practice may receive samples from USWM (including, separately, from USWM sales representatives and other USWM personnel or components). It shall also include a review of whether samples of Government Reimbursed Products are distributed by USWM through sales representatives or are distributed from a central location and the rationale for the manner of distribution;

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

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

9. USWM's systems, processes, policies, and procedures of USWM's funding, directly or indirectly, of Third Party Educational Activities (as defined in Section II.C.8 of the CIA) and all events and expenses relating to such activities;

10. USWM's systems, processes, policies, and procedures applicable to the submission of information about any Government Reimbursed Product to any CMS-recognized Compendium (as defined in USWM's Policies and Procedures) such as Drugdex or other published source of information used in connection with the determination of coverage by a Federal health care program for the product (hereafter "Compendia");

11. USWM's systems, processes, policies, and procedures applicable to Research (as defined in Section III.B.16), including the decision to provide financial or other support for Research; the manner in which Research support is provided; the publication of information about the Research, including the publication of information

about the Research results and trial outcomes; and uses made of publications relating to such Research; and

12. USWM's systems, processes, policies, and procedures relating to authorship-related practices (as defined in Section III.B.17 of the CIA), including, but not limited to, the disclosure of all financial relationships between the author and USWM, the identification of all authors or contributors (including professional writers, if any) associated with a given publication, and the scope and breadth of research results made available to each author or contributor.

B. Contribution and Assistance Related Functions Systems Review

The Contribution and Assistance Related Functions Systems Review shall be a review of systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) of USWM relating to Contribution and Assistance Related Functions. Where practical, USWM 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 USWM in accordance with the preceding sentence.

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

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

- a. USWM'S organizational structure as it relates to arrangements and interactions with Independent Charity PAPS, including:
 - i. the identification of all those individuals, departments, or groups within USWM (including, but not limited to, USWM's Compliance Officer [with assistance of the Compliance Committee], Legal and Medical Affairs) that have responsibility for, or involvement with, such arrangements and interactions;
 - ii. the respective scope and nature of the responsibilities of each individual, department, or group with

- responsibility for, or involvement with, arrangements and interactions with Independent Charity PAPs;
- iii. the identification of those individuals, departments, or groups within USWM (e.g., the commercial organization) that are precluded from involvement with arrangements and interactions with Independent Charity PAPs; and
 - iv. the manner by which the separation of Independent Charity PAP-related responsibilities from the commercial organization is enforced.
- b. USWM's written policies and procedures as they relate to arrangements and interactions with Independent Charity PAPs, including:
- i. the criteria governing whether and under what circumstances USWM would donate to an Independent Charity PAP or any specific disease state fund of such a PAP;
 - ii. communications (including any limitations on such communications) between any representatives of USWM and any Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications including the exchange of any data);
 - iii. communications (including any limitations on such communications) between those individuals, departments, or groups within USWM with responsibility for Independent Charity PAPs and the commercial organization of USWM (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications); and
 - iv. communications (including any limitations on such communications) between representatives of USWM and health care providers or patients regarding

assistance available through any Independent Charity PAP.

- c. USWM's policies and practices as they relate to the budgeting process applicable to donations to Independent Charity PAPs as outlined in Section III.N.2 of the CIA, including as it relates to initial or annual donation amounts and any supplemental amounts;
- d. USWM's policies and practices as they relate to the process by which decisions about the following are made and approved: i) whether to donate (or continue to donate) to an Independent Charity PAP; and ii) the amount of the donation (including any initial or annual amount and any supplemental amount);
- e. USWM's criteria, policies, and practices as they relate to donations made by USWM to any Independent Charity PAPs as referenced in Section III.N.3, including the internal review process followed in connection with any donations to Independent Charity PAPs; and
- f. USWM's policies and practices as they relate to information provided, directly or indirectly, to the public about the availability of patient assistance for USWM's products.

2. USWM's systems, policies, processes, and procedures relating to any patient assistance program that was formed or is funded, controlled, or operated (directly or indirectly) by USWM or any person or entity acting on behalf of (or affiliated with) USWM (including, but not limited to, its employees, agents, vendors, officers, shareholders, or contractors). This shall include any programs designed to provide free product or to provide other assistance (e.g., coupons or vouchers) to patients to reduce or eliminate the cost of copayments for drugs. These programs shall be collectively referred to as "Pharmaceutical Manufacturer PAPs." This review shall include an assessment of the following:

- a. USWM's organizational structure as it relates to Pharmaceutical Manufacturer PAPs, including:
 - i. the identification of those individuals, departments, or groups within USWM that have responsibility for, or involvement with Pharmaceutical Manufacturer PAPs; and

- ii. the respective scope and nature of the responsibilities of each individual, department, or group with responsibility for, or involvement with, Pharmaceutical Manufacturer PAPs.
- b. USWM's written policies and procedures as they relate to Pharmaceutical Manufacturer PAPs, including:
 - i. the nature and amounts (or value) of the assistance provided to patients under each of the Pharmaceutical Manufacturer PAPs;
 - ii. the eligibility criteria governing whether and under what circumstances USWM provides assistance to patients under each of the Pharmaceutical Manufacturer PAPs;
 - iii. USWM's external communications about the Pharmaceutical Manufacturer PAPs;
 - iv. the maintenance of records regarding free product and other assistance provided to or through Pharmaceutical Manufacturer PAPs;
 - v. ensuring effective communication between USWM, Pharmaceutical Manufacturer PAPs, or both, and Medicare Part D plans; and
 - vi. billing for free product provided to or through Pharmaceutical Manufacturer PAPs.
- c. USWM's policies and practices as they relate to the budgeting process for financial or in-kind assistance provided under any Pharmaceutical Manufacturer PAPs, including as they relate to initial or annual donation amounts and any supplemental amounts;
- d. USWM's policies and practices as they relate to the process by which decisions about the following are made and approved: (i) whether to provide (or continue to provide) assistance through any Pharmaceutical Manufacturer PAP; and (ii) the amount (or value) of the assistance to be provided through each program (including any initial or annual amount and any supplemental amount);
- e. USWM's policies and practices as they relate to any contracts or arrangements entered between USWM and outside entities relating

to any Pharmaceutical Manufacturer PAPs or the distribution of free product, including the individuals, groups, or departments involved in the negotiation process, the requirements and terms of the contracts or arrangements, and the review and approval of such contracts or arrangements.

C. IRO Systems Review Report

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

1. a description of the documentation (including policies) reviewed and any personnel interviewed;
2. a detailed description of systems, policies, processes, and procedures relating to the items identified in Sections II.A and II.B. above, including a general description of the control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
3. a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A and II.B above are made known or disseminated within the USWM;
4. a detailed description of any system(s) used to track and respond to requests for information about Government Reimbursed Products;
5. a detailed description of the incentive compensation system for Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined. To the extent that USWM may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;
6. a detailed description of any system(s) used to track requests for donations or other assistance from any Independent Charity PAP;
7. a detailed description of any system(s) used to track donations or other assistance provided in response to requests from Independent Charity PAPs;
8. a detailed description of any system(s) used to track requests for donations or other assistance from or through any Pharmaceutical Manufacturer PAP;

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

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

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

III. Transactions Review

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

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

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

2. For each call plan, the IRO shall select a sample of 50 of the HCPs and HCIs included on the call plan. For each call plan, the IRO shall compare the sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by USWM in conducting their review and/or modifying the call plan. The IRO shall seek to determine whether USWM followed their criteria and Policies and Procedures in reviewing and modifying the call plan.

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

instances in which it appears that the USWM failed to follow their criteria or Policies and Procedures.

B. Review of the Distribution of Samples of USWM Government Reimbursed Products. The IRO shall conduct a review and assessment of the distribution of samples of Government Reimbursed Products to HCPs and HCIs.

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

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

3. For each Sampling Event, the IRO shall review all documents and information relating to the distribution of the sample to the HCP or HCI. The reviewed materials shall include materials about the following: i) the quantity, dosage, and form of the samples provided to the HCP or HCI; ii) the identity and type of medical specialty or clinical practice of the HCP or HCI; iii) which individual USWM sales representatives or other USWM personnel provided the sample to the HCP or HCI; and iv) the manner and mechanism through which the sample was requested (e.g., sample request form, letter, or call to the USWM).

4. For each Sampling Event, the IRO shall evaluate whether the sample was provided to an HCP or HCI whose medical specialty or clinical practice is consistent with the uses of the Government Reimbursed Product approved by the FDA and whether the sample was distributed by a USWM's representative in a manner consistent with the Sample Distribution Plan for the product(s) provided during the Sampling Event.

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

C. Review of Physician Payment Listings

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

2. *Selection of Sample for Review.* For each Reporting Period, the OIG shall have the discretion to identify up to 50 Covered Recipients who received Payments from USWM during the prior calendar year who will be subject to the review described below. If the OIG elects to exercise this discretion, it shall notify the IRO at least 90 days prior to the end of the Reporting Period of the Covered Recipients subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 Covered Recipients to be included in the review. For each selected Covered Recipient, the IRO shall review Control Documents relating to Payments to the Covered Recipient for all categories reflected on the Open Payments Data website, except for Food/Beverage and Travel/Lodging categories of Payments.

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

- a. Whether Control Documents are available relating to each Payment for each sampled Covered Recipient;
- b. Whether the Control Documents were completed and archived in accordance with the requirements set forth in USWM’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 Payments(s) reflected in the Control Documents; and

- d. Whether the Control Documents reflect that USWM'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 all applicable policies).

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

- a. A situation in which all required Control Documents relating to Payments for the sampled Covered Recipients do not exist and (i) no corrective action was initiated prior to the selection of the sampled Covered Recipients; or (ii) the IRO cannot confirm that USWM otherwise followed applicable policies and procedures relating to the Payment for the sampled Covered Recipient, including its policies and procedures relating to any Payment(s); or
- b. Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with USWM's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but USWM 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 USWM otherwise followed their policies and procedures with regard to each Payment, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

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

D. Review of Arrangements with Independent Charity PAPs. The IRO shall conduct a review and assessment of USWM's compliance with the Independent Charity PAP processes, policies, and procedures outlined in Section III.N of the CIA. More specifically, the IRO shall review the arrangements and interactions with all Independent

Charity PAPs or disease state funds with which USWM entered charitable donation arrangements during the Reporting Period for which the IRO is conducting the review.

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

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

- a. Whether activities relating to arrangements and interactions with the Independent Charity PAP were undertaken by the appropriate individuals, departments, or groups within USWM in accordance with the company’s policies and procedures including those outlined in Section III.N;
- b. Whether USWM’s commercial organization (as defined in Section III.N) played a role in any arrangement or interaction with the Independent Charity PAP in violation of USWM’s policies and procedures or OIG guidance;
- c. Whether USWM followed the budgeting policies and practices outlined in Section III.N.2 regarding any initial or annual donation amounts to the Independent Charity PAP and any supplemental amounts;
- d. Whether USWM followed the decision-making and approval process outlined in Section III.N of the CIA with regard to any decisions: i) whether to donate (or continue to donate) to

- the Independent Charity PAP; ii) the amount of the donation (including any initial or annual amount and any supplemental amount); and iii) the criteria governing whether USWM would donate to the Independent Charity PAP or any specific disease state fund of such a PAP;
- e. Whether USWM followed the criteria, policies, and practices outlined in Section III.N.3 of the CIA in connection with all donations made by USWM to any Independent Charity PAP, including as they pertain to the internal review of potential donations and the adherence to the criteria specified in Section III.N.3;
 - f. Any communications that occurred between any representatives of USWM and the Independent Charity PAP (including the identity of individuals authorized to engage in such communications, the circumstances of such communications, and the subject matter of such communications (including the exchange of any data)) and whether any such communications complied with USWM'S policies and procedures and OIG guidance;
 - g. Any communications that occurred between the groups or departments within USWM responsible for Independent Charity PAP functions and the commercial organization and whether any such communications complied with USWM's policies and procedures;
 - h. Any communications that occurred between any representatives of USWM and health care providers or patients relating to assistance available through the Independent Charity PAP and whether any such communications complied with USWM's policies and procedures;
 - i. Whether, for each donation from USWM to any Independent Charity PAP, USWM complied with the requirements outlined in Section III.N.3; and
 - j. Whether, based on its review, the IRO found that USWM exerted influence or control over the Independent Charity PAP in violation of USWM'S policies and procedures, including those outlined in Section III.N.3.

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

1. No later than 120 days prior to the end of the applicable Reporting Period, the OIG shall notify USWM 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 USWM shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO’s findings based on its review for each Additional Item; and the IRO’s recommendations for any changes in USWM’s systems, processes, policies, and procedures based on its review of each Additional Item).

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

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

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

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

1. *General Elements to Be Included in Report*

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

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

- a. Relating to the Call Plan Reviews.
 - i. a list of the Government Reimbursed Products promoted by USWM during the Reporting Period and a summary of the FDA-approved uses for such products;
 - ii. for each Government Reimbursed Product which was promoted during the Reporting Period: i) a description of the criteria used by USWM in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans; ii) a description of all instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are inconsistent with USWM's criteria relating to the call plan and/or USWM's policies and procedures; and iv) a description of all instances in which it appears that USWM failed to follow its criteria or policies and procedures relating to call plans;
 - iii. the findings and supporting rationale regarding any weaknesses in USWM's systems, processes, policies, procedures, and practices relating to call plans, if any; and
 - iv. recommendations, if any, for changes in USWM's systems, processes, policies, procedures, and practices

that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to call plans.

b. Relating to the Sampling Event Reviews

- i. for each Government Reimbursed Product distributed during the Reporting Period: i) a description of Sample Distribution Plans (including whether sales representatives may provide samples for the product and, if so, to HCPs or HCIs of which medical specialty or type of clinical practice a sales representative may provide samples); ii) a detailed description of any instances in which it appears that the medical specialty or clinical practice of the HCPs or HCIs that received a sample during a Sampling Event was not consistent with the uses of the product approved by the FDA. This description shall include a description of the process followed by USWM in determining that it was appropriate to provide a sample to such HCP or HCI and the basis for such determination; and iii) a detailed description of any instances in which it appears that USWM failed to follow its Sample Distribution Policies and Procedures for the Government Reimbursed Product(s) provided during the Sampling Event;
- ii. the findings and supporting rationale regarding any weaknesses in USWM's systems, processes, policies, procedures, and practices relating to the distribution of samples of Government Reimbursed Products, if any; and
- iii. recommendations, if any, for changes in USWM's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to the distribution of samples.

c. Relating to the Physician Payment Listing Reviews

- i. a description of the entries on the Open Payments Data website for each selected Covered Recipient and a

description of the Control Documents reviewed in connection with each selected Covered Recipient;

- ii. for each selected Covered Recipient, findings and supporting rationale as to whether: (a) all required Control Documents exist; (b) each Control Document was completed in accordance with all of the requirements set forth in the applicable USWM policy; (c) the aggregate value of the Payment(s) as reflected in the report to CMS for the sampled Covered Recipient is consistent with the value of the Payment(s) reflected in the Control Documents; (d) each Control Document reflects that USWM's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (e) disciplinary action was undertaken in those instances in which USWM's policies were not followed;
- iii. for each selected Covered Recipient reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the Covered Recipient, including a description of the circumstances requiring corrective action and the nature of the corrective action; and
- iv. if any Material Errors are discovered, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error.

d. Relating to the Review of Independent Charity PAP Arrangements

- i. a list of the Independent Charity PAPs with which USWM entered arrangements or had interactions during the Reporting Period;
- ii. for each Independent Charity PAP for which the IRO reviewed arrangements or interactions during the Reporting Period: (a) a description of the review conducted by IRO; and (b) a summary of all instances

in which it appears that USWM failed to follow its policies and procedures and/or OIG guidance regarding its arrangements or interactions with an Independent Charity PAP;

- iii. for each Independent Charity PAP reviewed by the IRO, findings regarding each element specified above in Section III.D above;
 - iv. the findings and supporting rationale regarding any overall weaknesses in USWM's systems, processes, policies, procedures, and practices relating to its arrangements and interactions with Independent Charity PAPs; and
 - v. recommendations, if any, for changes in USWM's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to its arrangements and interactions with Independent Charity PAPs.
- e. Relating to the Review of Additional Items
- i. for each Additional Item reviewed, a description of the review conducted;
 - ii. for each Additional Item reviewed, the IRO's findings based on its review;
 - iii. for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in USWM's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
 - iv. for each Additional Item reviewed, recommendations, if any, for changes in USWM's systems, processes, policies, and procedures that would correct or address any weaknesses or deficiencies uncovered during the review.