

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
UNIVERSAL HEALTH SERVICES, INC. AND UHS OF DELAWARE, INC.**

I. PREAMBLE

Universal Health Services, Inc. and UHS of Delaware, Inc. (collectively, UHS), hereby enter into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements). Contemporaneously with this CIA, UHS is entering into a Settlement Agreement with the United States. This CIA applies to UHS's Behavioral Health Division and UHS's oversight and management of that division.

UHS represents that, prior to this CIA, UHS voluntarily established a Compliance Program which provides for, among other things (i) a Corporate Compliance and Privacy Officer, division compliance officers, facility compliance officers and a Compliance Committee, (ii) a compliance training and education program, (iii) an internal process for reviewing quality of care, including performing audits and responding to quality-related incidents, (iv) a confidential disclosure reporting hotline, (v) auditing and monitoring activities, (vi) a disclosure program enabling individuals to disclose any identified issues or questions associated with UHS's policies, conduct, practices, or procedures, and (vii) various policies and procedures aimed at ensuring that UHS's participation in the federal health care programs conforms to all Federal and state laws and Federal health care program requirements. UHS shall continue these and other aspects of its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by UHS 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. For the purposes of this CIA, the term “Behavioral Health Facilities” means UHS Behavioral Division and all facilities or programs in which UHS has an ownership or control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), that are Medicare- or Medicaid-certified to provide inpatient or residential psychiatric services or inpatient or residential substance use disorder treatment services, including but not limited to psychiatric hospitals, mental hospitals, psychiatric residential treatment facilities, or any institution for mental disease.

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

D. For purposes of this CIA, the term “Covered Persons” includes:

1. all owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5% and (2) acquired the ownership interest through public trading), officers, directors, and employees of UHS;
2. all owners, officers, and directors, and employees of the Behavioral Health Facilities; and
3. all contractors, subcontractors, agents, and other persons of the Behavioral Health Facilities who: (1) are involved directly or indirectly in the delivery of patient care; (2) make assessments of patients that affect treatment decisions or reimbursement; (3) perform billing, coding, audit, or review functions; (4) make decisions or provide oversight about staffing, patient care, reimbursement, policies and procedures, or this CIA; or (5) perform any function that relates to or is covered by this CIA, including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions.

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

III. CORPORATE INTEGRITY OBLIGATIONS

UHS 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, UHS shall appoint a Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer must have sufficient compliance and quality assurance experience to effectively oversee the implementation of the requirements of this CIA. The Compliance Officer shall be an employee and a member of senior management of UHS, shall report directly to the President of UHS, Inc., and shall not be or be subordinate to the General Counsel, Chief Financial Officer, or Chief Operating Officer, or have any responsibilities that involve acting in any capacity as legal counsel or supervising legal counsel functions for UHS.

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 Federal health care program requirements;
- b. making periodic (at least quarterly) reports regarding compliance matters directly to the Audit Committee of the Board of UHS, and shall be authorized to report on such matters to the Audit Committee of the Board of UHS at any time. Written documentation of the Compliance Officer's reports to the Audit Committee of the Board of UHS shall be made available to OIG upon request; and
- c. monitoring the day-to-day compliance activities engaged in by UHS and any reporting obligations created under this CIA, and ensuring that UHS is appropriately identifying and correcting quality of care problems.

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.

UHS 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, UHS shall appoint a Compliance Committee.

- a. *General Responsibilities.* This committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and Federal health care program requirements; monitoring the day-to-day compliance activities engaged in by UHS; monitoring any reporting obligations created under this CIA; and ensuring that UHS is appropriately identifying and correcting quality of care problems). The Compliance Committee shall, at a minimum, include the Compliance Officer and other members of UHS senior management necessary to meet the requirements of this CIA (e.g., representatives from among senior personnel responsible for clinical operations and quality of care, human resources, operations and nursing). The Compliance Officer shall chair the Compliance Committee.

The Compliance Committee shall meet, at a minimum, every month. For each scheduled Compliance Committee meeting, senior management of the UHS Behavioral Health Division shall report to the Compliance Committee on the adequacy of care being provided by the Behavioral Health Facilities. The minutes of the Compliance Committee meetings shall be made available to the OIG upon request.

UHS 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.

- b. *Staffing Responsibilities.* The Compliance Committee shall implement processes for identifying staffing-related issues or concerns, assess the adequacy of staffing, and make recommendations regarding how to improve or enhance the staffing at the Behavioral Health Facilities. The Compliance Committee shall consult with appropriate personnel from the Behavioral Health Facilities and the Independent Monitor

required under Section III.D of this CIA in implementing processes and assessing staffing at the Behavioral Health Facilities. The Compliance Committee also shall review the development and implementation of the staffing-related policies and procedures required by Section III.B of this CIA.

- c. *Quality of Care Review Program.* The Compliance Committee shall ensure that, within 120 days after the Effective Date, UHS has a program for performing internal quality audits and reviews (hereinafter “Quality of Care Review Program”) that complies with the following requirements:
 - i. make findings as to whether the patients at the Behavioral Health Facilities are receiving the quality of care and quality of life consistent with professionally recognized standards of care and applicable federal and state statutes, regulations, and directives;
 - ii. review quality of care related incidents and analyze root causes for those incidents; and
 - iii. develop corrective action plans in response to identified quality of care problems and track the implementation and effectiveness of those plans.

- d. *Quality of Care Dashboard.* The Compliance Committee, in consultation with the Monitor required under Section III.D of this CIA, shall create and implement a “Quality of Care Dashboard” (Dashboard). Quality measure data shall be collected and reported on the Dashboard. Within six months after the Effective Date, the Compliance Committee shall:
 - (1) identify and establish the overall quality improvement goals for UHS based on its assessment of UHS’s quality of care risk areas;
 - (2) identify and establish the quality measures related to those goals that UHS will monitor through the data analysis; and
 - (3) establish performance metrics for each quality measure. The Compliance Committee shall measure, analyze, and track the performance metrics for the quality measures on a monthly basis, monitoring progress towards the quality improvement goals. At least annually, the Compliance Committee shall review the quality measures to

determine if revisions are appropriate and shall make any necessary revisions based on such review.

3. *Board of Directors Compliance Obligations.* The Audit Committee of the Board of UHS (Audit Committee of the Board) shall be responsible for the review and oversight of matters related to compliance with the requirements and obligations of this CIA, Federal health care program requirements, and professionally recognized standards of care. The Audit Committee of the Board must include independent (i.e., non-executive) members. The Audit Committee of the Board shall be readily available to the Compliance Officer and the Monitor required under Section III.D of this CIA to respond to any issues or questions that might arise.

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

- a. meeting at least quarterly to review and oversee UHS's compliance program, including, but not limited to, the performance of the Compliance Officer, the Behavioral Health Division Compliance Officer and the Compliance Committee;
- b. reviewing the adequacy of UHS's system of internal controls and quality assurance monitoring;
- c. ensuring that UHS's response to state, federal, internal, and external reports of quality of care problems is complete, thorough, and resolves the problem(s) identified;
- d. ensuring that UHS adopts and implements policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA, Federal health care program requirements, and professionally recognized standards of care;
- e. reviewing and responding to the data analysis presented on the Dashboard and ensuring that UHS implements effective responses when the data indicates potential quality problems or that UHS is not meeting its established goals; and
- f. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board summarizing its review and oversight of UHS's

compliance with the obligations of this CIA, Federal health care program requirements, and professionally recognized standards of care.

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

“The Board of Directors has made a reasonable inquiry into the operations of UHS’s Compliance Program, including the performance of the Compliance Officer, Behavioral Health Division Compliance Officer and the Compliance Committee. The Board has also provided oversight on quality of care issues. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, UHS has implemented an effective Compliance Program to meet the obligations of the CIA, Federal health care program requirements, and professionally recognized standards of care.”

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 UHS.

UHS 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 UHS employees (Certifying Employees) are expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable UHS department is in compliance with applicable Federal health care program requirements, with the obligations of this CIA, and with professionally recognized standards of healthcare. These Certifying Employees shall include, at a minimum, the following: Chief Executive Officer, President, Chief Financial Officer, Senior Vice Presidents of the Behavioral Health Division, and at each Facility, the Facility’s Chief Executive Officer. 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 UHS division, department or facility], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of UHS division, department or facility] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and UHS policies, and I have taken steps to promote such compliance. To the best of

my knowledge, [insert name of UHS division, department or facility] is in compliance with all applicable Federal health care program requirements, and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

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

Within 90 days after the Effective Date, UHS 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 90 days after the Effective Date, UHS shall develop and implement written Policies and Procedures regarding the operation of UHS’s compliance program, including the compliance program requirements outlined in this CIA, compliance with Federal health care program requirements, and professionally recognized standards of care (Policies and Procedures). Throughout the term of this CIA, UHS 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 address:

1. Medical necessity of patient admissions;
2. Appropriate use of involuntary commitment;
3. Medical necessity of continuing stays;
4. The requirement to provide active and individualized treatment;
5. Physician participation in and supervision of care;
6. The proper use and monitoring of physical and chemical restraints and seclusion;
7. Interdisciplinary, patient-centered, care planning; and

8. Appropriate staffing levels, qualification, licensure, supervision, and training to meet patients' needs and to comply with Federal and State requirements.

The Policies and Procedures shall be made available to all Covered Persons. At least annually (and more frequently, if appropriate), UHS 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, UHS shall develop a written plan (Training Plan) that outlines the steps UHS will take to ensure that all Covered Persons receive (a) at least annual training regarding UHS's CIA requirements and Compliance Program, and (b) adequate on-going training regarding: (i) policies, procedures, and other requirements applicable to the documentation of medical records; (ii) the policies implemented pursuant to Section III.B of this CIA, as appropriate for the job category of each Covered Person; (iii) the personal obligation of each individual involved in patient care to ensure that care is appropriate and meets professionally recognized standards of care; (iv) examples of proper and improper care, including proper and improper use of restraints and seclusion; and (v) reporting requirements and legal sanctions for violations of the Federal health care program requirements. The Training Plan shall also include training to address quality of care problems identified by the Compliance Committee. In determining what training should be performed, the Compliance Committee shall review complaints received, satisfaction surveys, staff turnover data, state or federal surveys, internal surveys, and the findings, and recommendations of the Monitor required under Section III.D of this CIA.

Training required in this section shall be competency-based. Specifically, the training must be developed and provided in such a way as to focus on Covered Persons achieving learning outcomes to a specified competency and to place emphasis on what a Covered Person has learned as a result of the training.

2. *Board Member Training.* Within 90 days after the Effective Date, each member of the UHS Board shall receive at least two hours of training. This training shall address the corporate governance responsibilities of UHS Board members, and the responsibilities of UHS 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 the OIG's guidance on Board member responsibilities.

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

3. *Training Records.* UHS 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.

4. UHS may provide the training required under this CIA through appropriate computer-based training approaches. If UHS chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

D. Independent Monitor

Within 60 days after the Effective Date, UHS shall retain an appropriately qualified monitoring team (the “Monitor”), selected by OIG after consultation with UHS. The Monitor may retain additional personnel, including but not limited to independent consultants, if needed to help meet the Monitor’s obligations under this CIA. The Monitor may confer and correspond with UHS or OIG individually or together. The Monitor and UHS shall not negotiate or enter into a financial relationship, other than the monitoring engagement required by this section, and the Monitor shall refrain from recruiting or hiring any employee of UHS until after the date of OIG’s CIA closure letter to UHS or six months after the expiration of this CIA, whichever is later.

The Monitor is not an agent of OIG. However, the Monitor may be removed by OIG at its sole discretion. If the Monitor resigns or is removed for any other reasons prior to the termination of the CIA, UHS shall retain, within 60 days of the resignation or removal, another Monitor selected by OIG, with the same functions and authorities.

1. *Scope of Review.* The Monitor shall be responsible for assessing the effectiveness, reliability, and thoroughness of the following:

- a. UHS’s internal quality control systems, including but not limited to:
 - i. whether the systems in place to promote quality of care and to respond to quality of care problems are operating in a timely and effective manner;

- ii. whether the communication system is effective, allowing for accurate information, decisions, and results of decisions to be transmitted to the proper individuals in a timely fashion; and
 - iii. whether the training programs are effective, thorough, and competency-based.
- b. UHS's and the Behavioral Health Facilities' response to quality of care issues, which shall include an assessment of their ability to:
 - i. identify quality of care problems;
 - ii. determine the scope of the quality of care problems identified, including but not limited to whether the problem is isolated or systemic;
 - iii. identify and analyze the root cause for the problem identified;
 - iv. create an action plan to respond to the problem;
 - v. execute the action plan; and
 - vi. monitor and evaluate whether the assessment, action plan, and execution of that plan was effective, reliable, and thorough;
- c. UHS's proactive steps to promote the Behavioral Health Facilities' provision of patient care in accordance with:
 - i. professionally recognized standards of health care;
 - ii. Federal, State, local statutes, regulations, and other directives or guidelines; and
 - iii. the Policies and Procedures adopted by UHS, including those implemented under Section III.B of this CIA;
- d. UHS's steps to implement processes for identifying staffing-related issues or concerns at the Behavioral Health Facilities,

assess the adequacy of staffing at the Behavioral Health Facilities, and make recommendations regarding how to improve or enhance the staffing at the Behavioral Health Facilities, as provided in section III.A.2.b;

- e. UHS's ability to analyze outcome measures, and other data;
- f. UHS's Quality of Care Review Program required under Section III.A of this CIA; and
- g. UHS's Quality of Care Dashboard required under Section III.A of this CIA.

2. *Access.* The Monitor shall have:

- a. immediate access to UHS and the Behavioral Health Facilities, at any time and without prior notice, to assess compliance with this CIA, to assess the effectiveness of the internal quality assurance mechanisms, and to ensure that the data being generated is accurate and complete;
- b. immediate access to:
 - i. internal or external audits, surveys, reviews or reports;
 - ii. Disclosure Program complaints;
 - iii. patient satisfaction surveys;
 - iv. staffing data;
 - v. reports of abuse, neglect, serious occurrences, death or an incident that required hospitalization or emergency room treatment;
 - vi. orders for restraint or seclusion, reports of any use of restraint or seclusion, and any related documents;
 - vii. reports of any incident involving a patient that prompts a full internal investigation;
 - viii. patient records;

- ix. documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, utilization review committee, or other such committee; and
 - x. any other data in the format the Monitor determines relevant to fulfilling the duties required under this CIA;
- c. immediate access to Covered Persons at the Behavioral Health Facilities for interviews outside the presence of UHS supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals; and
 - d. immediate access to patients provided such access is in accordance with all applicable laws and the rights of patients. The Monitor shall give full consideration to a patient's clinical condition, in consultation with relevant UHS clinical staff, before interacting with a patient.
3. *Systems Assessments.* On a semi-annual basis, the Monitor shall:
- a. complete an assessment of the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.D.1 and UHS's response to recommendations made in prior written assessment reports;
 - b. in conducting these assessments, visit at least six Behavioral Health Facilities (selected by the Monitor) and, at a minimum, observe corporate compliance meetings, observe Behavioral Health Facility care planning meetings, observe meetings of the Audit Committee of the Board relating to matters covered by the CIA, interview key employees, review relevant documents, and observe patient care at the Behavioral Health Facilities in a manner that does not disrupt patient care and treatment provided; and
 - c. submit a written report to UHS and OIG that sets forth, at a minimum:
 - i. a summary of the Monitor's activities in conducting the assessment;

- ii. the Monitor's findings regarding the effectiveness, reliability, scope, and thoroughness of each of the systems described in Section III.D.1;
- iii. the Monitor's recommendations to as to how to improve the effectiveness, reliability, scope, and thoroughness of the systems described in Section III.D.1; and
- iv. the Monitor's assessment of UHS's response to the Monitor's prior recommendations.

For each Reporting Period, one assessment shall be based on the first six months of the Reporting Period and the other assessment shall be based on the second six months of the Reporting Period. The Monitor shall submit written reports no later than 30 days after the end of the relevant six-month period to UHS and OIG.

4. *Financial Obligations of UHS and the Monitor.*

- a. UHS shall be responsible for all reasonable costs incurred by the Monitor in connection with this engagement, including but not limited to labor costs (direct and indirect); consultant and subcontract costs; materials cost (direct and indirect); and other direct costs (travel, other miscellaneous).
- b. UHS shall pay the Monitor's bills within 30 days of receipt. Failure to pay the Monitor within 30 calendar days of submission of the Monitor's invoice for services previously rendered shall constitute a basis to impose stipulated penalties or exclude UHS, as provided under Section X of this CIA. While UHS must pay all of the Monitor's bills within 30 days, UHS may bring any disputed Monitor's costs or bills to OIG's attention.
- c. The Monitor shall charge a reasonable amount for its fees and expenses, and shall submit monthly invoices to UHS with a reasonable level of detail reflecting all key category costs billed.
- d. The Monitor shall submit a written report for each Reporting Period representing an accounting of its costs throughout the year to UHS and to OIG by the submission deadline of UHS's

Annual Report. This report shall reflect, on a cumulative basis, all key category costs included on monthly invoices.

5. *Additional UHS Obligations.* UHS shall:
- a. within 30 days after receipt of each each written report of the Systems Assessments, submit a written response to OIG and the Monitor to each recommendation contained in those reports stating what action UHS took in response to each recommendation or why UHS has elected not to take action based on the recommendation;
 - b. provide the Monitor a report monthly, or sooner if requested by the Monitor, regarding each known occurrence:
 - i. of patient abuse, neglect, serious incident, death, or other incident that UHS or the Behavioral Health Facilities would be required to report to a government regulatory body under federal or state laws or regulations;
 - ii. that presents an imminent danger to the health, safety, or well-being of patients or places patients unnecessarily in high-risk situations; or
 - iii. of suicide or attempted suicide;
- Each such report shall contain, if applicable, the full name and date of birth of the patients(s) involved, the persons involved, the date of death or incident, a brief description of the events surrounding the death or incident, actions taken to address the situation, and a summary of any related reports made to Federal or state regulatory or enforcement agencies or to professional licensing bodies.
- c. provide to the Compliance Committee and the Audit Committee of the Board copies of all documents and reports provided to the Monitor;
 - d. ensure the Monitor's access as set forth in paragraph III.D.2, and assist in obtaining full cooperation by its current employees, contractors, and agents;

- e. assist in locating and, if requested, attempt to obtain cooperation from past employees, contractors, and agents; and
- g. not sue or otherwise bring any action against the Monitor related to any findings made by the Monitor or related to any exclusion or other sanction of UHS under this CIA; provided, however, that this clause shall not apply to any suit or other action based solely on the dishonest or illegal acts of the Monitor, whether acting alone or in collusion with others.

6. *Additional Monitor Obligations.* The Monitor shall:

- a. abide by all state and federal laws and regulations concerning the privacy, dignity, and employee rights of all Covered Persons, and patients;
- b. abide by the legal requirements of UHS to maintain the confidentiality of each patient's personal and clinical records. Nothing in this subsection, however, shall limit or affect the Monitor's obligation to provide information, including information from patient clinical records, to OIG, and, when legally or professionally required, to other agencies;
- c. at all times act reasonably in connection with its duties under the CIA including when requesting information from UHS;
- d. if the Monitor has concerns about action plans that are not being enforced or systemic problems that could affect UHS's ability to render quality care to its patients, then the Monitor shall:
 - i. report such concerns in writing to OIG; and
 - ii. simultaneously provide notice and a copy of the report to UHS's Compliance Committee and Board of Directors Committee referred to in Section III.A of this CIA;
- e. where independently required to do so by applicable law or professional licensing standards, report any finding to an appropriate regulatory or law enforcement authority, and

simultaneously submit copies of such reports to OIG and to UHS;

- f. not be bound by any other private or governmental agency's findings or conclusions, including, but not limited to, Joint Commission, CMS, or the state survey agency. Likewise, such private and governmental agencies shall not be bound by the Monitor's findings or conclusions. The Monitor's reports shall not be a basis for determining deficiencies by the state survey agencies. The parties agree that CMS and its contractors shall not introduce any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence into any proceeding involving a Medicare or Medicaid survey, certification, or other enforcement action against UHS, and UHS shall similarly be restricted from using material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence in any of these proceedings. Nothing in the previous sentence, however, shall preclude OIG or UHS from using any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor in any action under the CIA or pursuant to any other OIG authorities or in any other situations not explicitly excluded in this subsection;
- g. abide by the provisions of the Health Insurance Portability and Accountability Act (HIPAA) of 1996 to the extent required by law including, without limitation, entering into a business associate agreement with UHS; and
- h. except to the extent required by law, maintain the confidentiality of any proprietary financial and operational information, processes, procedures, and forms obtained in connection with its duties under this CIA and not comment publicly concerning its findings except to the extent authorized by OIG.

E. Review Procedures

1. *General Description*

- a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, UHS 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 UHS shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and UHS) related to the reviews.
- c. *Access to Records and Personnel.* UHS shall ensure that 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. *Claims Review.* The IRO shall review claims submitted by Behavioral Health Facilities and reimbursed by the Medicare, Medicaid, and TRICARE programs, to determine whether the items and services furnished were medically necessary and appropriately documented and whether the claims were correctly coded, submitted and reimbursed (Claims Review) and shall prepare a Claims Review Report, as outlined in Appendix B to this CIA, which is incorporated by reference.

3. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to UHS 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 all current and prior engagements between UHS and the IRO.

F. Risk Assessment and Internal Review Process

Within 90 days after the Effective Date, UHS shall develop and implement a centralized annual risk assessment and internal review process to identify and address risks associated with UHS’s participation in the Federal health care programs, including but not limited to the risks associated with standards of care, staffing, and the submission of claims for items and services furnished to Medicare and Medicaid program beneficiaries. The risk assessment and internal review process shall require the Chief Compliance Officer, the Behavioral Health Division Compliance Officer, the Behavioral Health Division Chief Nursing Officer, and other legal, risk and/or 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. UHS shall maintain the risk assessment and internal review process for the term of the CIA.

G. Disclosure Program

Within 90 days after the Effective Date, UHS shall ensure that it has a Disclosure Program that complies with the following requirements: 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 UHS's policies, conduct, practices, or procedures with respect to quality of care or a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. UHS shall appropriately publicize the existence of 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 UHS's Covered Persons shall be expected to report suspected violations of any Federal health care program requirements to the Compliance Officer or other appropriate individual designated by UHS. 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, UHS shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted. If the inappropriate or improper practices places patients at risk of harm, then UHS will ensure that that practice ceases immediately and that appropriate action is taken.

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.

The disclosure log shall be sent to the Monitor required under Section III.D of this CIA not less than monthly.

H. 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 any Federal health care program; 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.* UHS shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

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

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

3. *Removal Requirement.* If UHS has actual notice that a Covered Person has become an Ineligible Person, UHS shall remove such Covered Person from responsibility for, or involvement with, UHS'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 or the items or services furnished, ordered, or prescribed by the Covered Person are 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 UHS 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, UHS 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.

I. Notification of Government Investigation or Legal Proceeding

Within 30 days after discovery, UHS shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to UHS conducted or brought by a governmental entity or its agents involving an allegation that UHS or a Behavioral Health Facility 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. UHS also shall provide written notice to OIG within 30 days after the resolution of the matter, and a description of the findings and/or results of the investigation or proceeding, if any.

In addition, within 15 days after notification, UHS shall notify OIG, in writing, of any adverse final determination made by a federal, state, or local government agency or accrediting or certifying agency (e.g., Joint Commission) relating to quality of care issues at any Behavioral Health Facility.

J. Overpayments

1. *Definition of Overpayment.* An "Overpayment" means any funds that a Behavioral Health Facility receives or retains under any Federal health care program to which the Behavioral Health Facility, after applicable reconciliation, is not entitled under such Federal health care program.

2. *Overpayment Policies and Procedures.* Within 90 days after the Effective Date, UHS shall develop and implement written policies and procedures

regarding the identification, quantification, and repayment of Overpayments received from any Federal health care program associated with its Behavioral Health Facilities.

K. Reportable Events

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

- a. a substantial Overpayment to a Behavioral Health Facility;
- b. 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;
- c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.H.1.a; or
- d. the filing of a bankruptcy petition by UHS.

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

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

3. *Reportable Events under Section III.K.1.a and III.K.1.b.* For Reportable Events under Section III.K.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;
- d. a description of the steps taken to identify and quantify any Overpayments; and
- e. a description of the actions taken to correct the Reportable Event and prevent it from recurring.

If the Reportable Event involves an Overpayment, within 60 days of identification of the Overpayment, the Behavioral Health Facility shall repay the Overpayment, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable CMS guidance and provide OIG with a copy of the notification and repayment.

4. *Reportable Events under Section III.K.1.c.* For Reportable Events under Section III.K.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 completed before and/or during the Ineligible Person's employment or contract and any flaw or breakdown in the screening process that led to the hiring or contracting with the Ineligible Person;
- d. a description of how the Ineligible Person was identified; and
- e. a description of any corrective action implemented to prevent future employment or contracting with an Ineligible Person.

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

7. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves solely a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by UHS to CMS through the self-referral disclosure protocol (SRDP), with a copy to the OIG. If UHS identifies a probable violation of the Stark Law and repays the applicable Overpayment directly to the CMS contractor, then

UHS is not required by this Section III.K to submit the Reportable Event to CMS through the SRDP.

IV. SUCCESSOR LIABILITY

In the event that, after the Effective Date, UHS proposes to (a) sell any or all of its behavioral health business, business units, or locations (whether through a sale of assets, sale of stock, or other type of transaction) relating to the furnishing of items or services that may be reimbursed by a Federal health care program, or (b) purchase or establish a new behavioral health business, business unit, or location relating to the furnishing of items or services that may be reimbursed by a Federal health care program, the CIA shall be binding on the purchaser of any behavioral health business, business unit, or location and any new behavioral health 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. UHS shall give notice of such sale or purchase to OIG at least 30 days prior to the closing of the transaction.

If, in advance of a proposed sale or a proposed purchase, UHS 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, UHS must notify OIG in writing of the proposed sale or purchase and include the following information at least 30 days in advance: a description of the business, business unit, or location to be sold or purchased, a brief description of the terms of the transaction and, in the case of a proposed sale, the name and contact information of the prospective purchaser.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report.

Within 120 days after the Effective Date, UHS 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, 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;
3. the names of the Board members who are responsible for satisfying the Audit Committee of the Board compliance obligations described in Section III.A;

4. a description of the Quality of Care Review Program required by Section III.A.2;
5. a description of the Dashboard required by Section III.A.2;
6. the names and positions of the Certifying Employees required by Section III.A.4 and a copy of the written process for completing the certification required by Section III.A.4;
7. a list of all Policies and Procedures required by Section III.B;
8. 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);
9. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; and (d) a certification from the IRO regarding its professional independence and objectivity with respect to UHS that includes a summary of all current and prior engagements between UHS and the IRO;
10. a description of the risk assessment and internal review process required by Section III.F;
11. a description of the Disclosure Program required by Section III.G;
12. a description of the Ineligible Persons screening and removal process required by Section III.H;
13. copy of UHS's policies and procedures regarding the identification, quantification, and repayment of Overpayments required by Section III.J;
14. a description of UHS's corporate structure, including identification of any individual owners and investors, parent and sister companies, subsidiaries, affiliates, and their respective lines of business;
15. a list of all of UHS corporate offices and the Behavioral Health Facilities (including legal names and mailing addresses), the corresponding name under which each location is doing business, and the location's Medicare and state Medicaid program provider number and/or supplier number(s); and

16. the certifications required by Section V.C.

B. Annual Reports.

UHS shall submit to OIG a report 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; and a description of any changes to the written process for completing the certification required by Section III.A.4;
2. the dates of each report made by the Compliance Officer to the Board (written documentation of such reports shall be made available to OIG upon request);
3. a summary of activities and findings under UHS's Quality of Care Review Program and a summary of any corrective action taken in response to any problems identified through its Quality of Care Review Program as required by Section III.A.2;
4. a summary of the Compliance Committee's measurement, analysis, and tracking of the performance metrics included in UHS's Dashboard, UHS's progress towards its quality improvement goals, and any changes to the Dashboard and the reasons for such changes, and activities, assessments, recommendations, and findings related to staffing and UHS's response to those findings;
5. 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;
6. a list of any new or revised Policies and Procedures developed during the Reporting Period;
7. a description of any changes to UHS's Training Plan developed pursuant to Section III.C and summary of any Board of Directors training provided during the Reporting Period;

8. UHS's response and action plan(s) related to any written recommendations of the Monitor pursuant to Section III.D;
9. a complete copy of all reports prepared pursuant to Section III.E and UHS's response to the reports, along with corrective action plan(s) related to any issues raised by the reports, including UHS's determination of whether the CMS overpayment rule requires the repayment of an extrapolated Overpayment (as defined in Appendix B);
10. a certification from the IRO regarding its professional independence and objectivity with respect to UHS, including a summary of all current and prior engagements between UHS and the IRO;
11. a description of any changes to the risk assessment and internal review process required by Section III.F, including the reasons for such changes;
12. 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;
13. a summary of the disclosures in the disclosure log required by Section III.G that relate to Federal health care programs and delivery of patient care, including at least the following information: (a) a description of the disclosure, (b) the date the disclosure was received, (c) the resolution of the disclosure, and (d) the date the disclosure was resolved (if applicable). The complete disclosure log shall be made available to OIG upon request;
14. a summary of Reportable Events (as defined in Section III.K) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
15. a description of any changes to the Ineligible Persons screening and removal process required by Section III.H, including the reasons for such changes;
16. a description of any changes to the Overpayment policies and procedures required by Section III.J, including the reasons for such changes;
17. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

18. a description of all changes to the most recently provided list of UHS's locations as required by Section V.A.15;

19. a description of any changes to UHS's corporate structure, including any individual owners and investors, parent and sister companies, subsidiaries, affiliates, and their respective lines of business; and

20. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 90 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, UHS shall include the certifications of Certifying Employees as required by Section III.A.4;

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

- a. to the best of his or her knowledge, except as otherwise described in the report, UHS has implemented and is in compliance with all of the requirements of this CIA;
- b. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and
- c. he or she understands that the certification is being provided to and relied upon by the United States.

D. Designation of Information.

UHS 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. UHS 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

UHS:

Mia Meloni
Chief Compliance Officer and Privacy Officer
Universal Health Services
367 S. Gulph Rd.
King of Prussia, PA 19406
Telephone: (610) 382-3471

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

VIII. DOCUMENT AND RECORD RETENTION

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

X. BREACH AND DEFAULT PROVISIONS

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

A. Specific Performance of CIA Provisions.

The parties agree that, if OIG determines that UHS is failing to comply with a provision of this CIA, OIG may seek specific performance of that provision. OIG shall provide UHS with prompt written notification of such determination. (This notification shall be referred to as the "Noncompliance Notice.") UHS shall have 30 days from receipt of the Noncompliance Notice within which to either: (1) cure the alleged failure to comply; or (2) reply in writing that UHS disagrees with the determination of noncompliance and request a hearing before an HHS administrative law judge (ALJ), pursuant to the provisions set forth in Section X.F of this CIA.

B. Stipulated Penalties for Failure to Comply with Certain Obligations.

As a contractual remedy, UHS 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 UHS 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;
- d. a Quality of Care Review Program;
- e. a Dashboard;
- f. the management certification obligations and the development and implementation of a written process for Certifying Employees, as required by Section III.A.4;
- g. written Policies and Procedures;
- h. the development of a written training plan and the training and education of Covered Persons and Board Members;
- i. retention of a Monitor;
- j. a risk assessment and internal review process;
- k. a Disclosure Program;
- l. Ineligible Persons screening and removal requirements;
- m. notification of Government investigations or legal proceedings;
- n. policies and procedures regarding the repayment of Overpayments; and
- o. reporting of Reportable Events.

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 UHS fails to engage and use an IRO, as required by Section III.E, Appendix A, or Appendix B.

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

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

5. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day UHS fails to submit any Claims Review Report in accordance with the requirements of Section III.E and Appendix B or fails to repay any Overpayment identified by the IRO, as required by Appendix B.

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

7. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day UHS fails to pay a Monitor, as required in Section III.D.5.

8. A Stipulated Penalty of \$2,500 for each day UHS fails to comply fully and adequately with any of its obligations with respect to the Monitor, including but not limited to the obligation to grant the Monitor access, as set forth in Section III.D.2, and the obligation to adequately and timely respond to any written recommendation of the Monitor, as set forth in Section III.D.6. OIG shall provide notice to UHS stating the specific grounds for its determination that UHS has failed to comply fully and adequately with the CIA obligation(s) at issue and steps UHS shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after UHS receives this notice from OIG of the failure to comply.)

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

10. A Stipulated Penalty of \$1,000 for each day UHS fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to UHS stating the specific grounds for its determination that UHS has failed to comply fully and adequately with the CIA obligation(s) at issue and steps UHS shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date UHS 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 1-9 of this Section.

C. Timely Written Requests for Extensions.

UHS 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 UHS 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 UHS 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.

D. Payment of Stipulated Penalties

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

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, UHS shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an ALJ to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.F. In the event UHS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until UHS 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.E.

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

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

E. 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 UHS to report a Reportable Event, take corrective action, or make the appropriate refunds, as required in Section III.K;
- c. a violation of any obligation under this CIA that has a material impact on the quality of patient care;
- d. a failure to respond to a Noncompliance Notice concerning specific performance in accordance with Section X.A;
- e. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.D;
- f. a failure to retain, pay, or use the Monitor, or failure to respond to the recommendations of the Monitor, in accordance with Section III.D; or
- g. a failure to engage and use an IRO in accordance with Section III.E, Appendix A, or Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by UHS constitutes an independent basis for UHS's exclusion from participation in the Federal health care programs. The length of the exclusion shall be in the OIG's discretion, but not more than five years per material

breach. Upon a determination by OIG that UHS has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify UHS of: (a) UHS’s material breach; and (b) OIG’s intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the “Notice of Material Breach and Intent to Exclude.”) The exclusion may be directed at one or more of the Behavioral Health Facilities or corporate entities, depending upon the facts of the breach.

3. *Opportunity to Cure.* UHS shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate 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) UHS has begun to take action to cure the material breach; (ii) UHS is pursuing such action with due diligence; and (iii) UHS has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, UHS fails to satisfy the requirements of Section X.E.3, OIG may exclude UHS from participation in the Federal health care programs. OIG shall notify UHS in writing of its determination to exclude UHS. (This letter shall be referred to as the “Exclusion Letter.”) Subject to the Dispute Resolution provisions in Section X.F, below, the exclusion shall go into effect 30 days after the date of UHS’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, UHS may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

F. Dispute Resolution

1. *Review Rights.* Upon OIG’s delivery to UHS of its Noncompliance Notice, Demand Letter, or Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, UHS 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 specific performance, Stipulated Penalties, or exclusion sought pursuant to this CIA. Specifically, OIG’s determination to demand specific performance, payment of Stipulated Penalties, or 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 specific performance or 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/division/civil/procedures/divisionprocedures.html>.

2. *Specific Performance 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 specific performance of CIA provisions shall be:

- a. whether, at the time specified in the Noncompliance Notice, UHS was in full and timely compliance with the obligations of this CIA for which OIG seeks specific performance; and
- b. whether UHS failed to cure.

UHS 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 specific performance. If the ALJ agrees with OIG, UHS shall take the actions OIG deems necessary to cure within 20 days after the ALJ issues such a decision unless UHS 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, UHS shall take the actions OIG deems necessary to cure within 20 days after the DAB issues its decision.

3. *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 UHS was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. UHS 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 UHS to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless UHS 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.

4. *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 UHS was in material breach of this CIA and, if so, whether:

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

5. *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

UHS 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. OIG may agree to a suspension of UHS's obligations under this CIA based on a certification by UHS that it is no longer providing health care items or services that will be billed to any Federal health care program and it does not have any ownership or control interest, as defined in 42 U.S.C. § 1320a-3, in any entity that bills any Federal health care program. If UHS is relieved of its CIA obligations, UHS shall be required to notify OIG in writing at least 30 days in advance if UHS plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

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

E. The undersigned UHS 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 capacities and that they are authorized to execute this CIA.

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

ON BEHALF OF UHS

/Mia Meloni/

MIA MELONI
Vice President and Chief Compliance Officer
Universal Health Services

July 6, 2020

DATE

/Jonathan Phillips/

JONATHAN M. PHILLIPS
Gibson, Dunn & Crutcher LLP
Counsel for UHS

7/6/2020

DATE

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

/Lisa M. Re/

06/26/2020

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

DATE

/Katherine Matos/

6 July 2020

KATHERINE MATOS
Senior Counsel
Office of Inspector General
U. S. Department of Health and Human Services

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. UHS shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph E. Within 30 days after OIG receives the information identified in Section V.A.9 of the CIA or any additional information submitted by UHS in response to a request by OIG, whichever is later, OIG will notify UHS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, UHS may continue to engage the IRO.

2. If UHS 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, UHS shall submit the information identified in Section V.A.9 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by UHS at the request of OIG, whichever is later, OIG will notify UHS if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, UHS may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Claims Review who have expertise in the Medicare, state Medicaid, and TRICARE program requirements applicable to the claims being reviewed;

2. assign individuals to design and select the Claims Review sample who are knowledgeable about the appropriate statistical sampling techniques;

3. assign individuals to conduct the coding review portions of the Claims Review who have a nationally recognized coding certification and who have maintained this certification (e.g., completed applicable continuing education requirements);

4. assign licensed nurses or physicians with relevant education, training and specialized expertise (or other licensed health care professionals acting within their scope

of practice and specialized expertise) to make the medical necessity determinations required by the Claims Review; and

5. 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 Claims Review in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare, state Medicaid, and TRICARE program rules and reimbursement guidelines in making assessments in the Claims Review;

3. request clarification from the appropriate authority (e.g., Medicare contractor), if in doubt of the application of a particular Medicare, state Medicaid, or TRICARE program policy or regulation;

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. UHS Responsibilities

UHS 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 the Claims Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the U.S. Government Accountability Office.

F. IRO Removal/Termination

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

APPENDIX B

CLAIMS REVIEW

A. Claims Review. The IRO shall perform the Claims Review annually to cover each of the five Reporting Periods. The Claims Review shall be conducted at 8 of the Behavioral Health Facilities (“Subject Facilities”) for each Reporting Period. For each 20 additional facilities that UHS may acquire after execution of this Agreement during the term of this CIA and that meet the definition of a Behavioral Health Facility, 1 additional facility will be added to the Subject Facilities for each Reporting Period. The IRO shall perform all components of each Claims Review.

1. *Definitions*. For the purposes of the Claims Review, the following definitions shall be used:

- a. Overpayment: The amount of money a Subject Facility or Facilities have received in excess of the amount due and payable under Medicare program, a state Medicaid program, or the TRICARE program requirements, as determined by the IRO in connection with the Claims Review performed under this Appendix B.
- b. Paid Claim: A claim submitted by a Subject Facility and for which the Subject Facility has received reimbursement for inpatient or residential psychiatric services or inpatient or residential substance use disorder treatment services from the Medicare program, a state Medicaid program, or the TRICARE program.
- c. Population: The Population shall be defined as all Paid Claims during the 12-month period covered by the Claims Review. In OIG’s discretion, OIG may limit the Population to one or more subset(s) of Paid Claims to be reviewed and shall notify UHS and the IRO of its selection of the Population at least 30 days prior to the end of each Reporting Period.

UHS, or its IRO on behalf of UHS, may submit proposals identifying suggestions for the subset(s) of Paid Claims to be reviewed at least 90 days prior to the end of each Reporting Period. In connection with limiting the Population, OIG may consider (1) proposals submitted by UHS or its IRO, (2) information furnished to OIG regarding the results of UHS’s internal risk assessment and internal auditing, or (3) information provided by the Independent Monitor. The determination of whether, and in what manner, to limit the Population shall be made at the sole discretion of OIG.

2. *Selection of Facilities.* In connection with limiting the Population, OIG will select the Subject Facilities for the Claims Review in each Reporting Period. In order to facilitate OIG's selection, at least 90 days prior to the end of the Reporting Period, UHS shall furnish to OIG the following information for each Behavioral Health Facility for the prior calendar year: (1) Federal health care program revenues, (2) Federal health care program patient census, (3) Federal health care program payor mix, and (4) average patient lengths of stay. UHS, or its IRO on behalf of UHS, may submit proposals identifying suggestions for the Behavioral Health Facilities to be reviewed at least 90 days prior to the end of each Reporting Period.

3. *Claims Review Sample.* The IRO shall randomly select and review a sample of 50 Paid Claims (Claims Review Sample) for each of the Subject Facilities. The Paid Claims shall be reviewed based on the supporting documentation available at UHS's or the Subject Facility's office or under UHS's control and applicable Medicare program, a state Medicaid program, or the TRICARE program requirements to determine whether the items and services furnished were medically necessary, appropriately documented, and whether the claim was correctly coded, submitted, and reimbursed. For each Paid Claim in the Claims Review Sample that results in an Overpayment, the IRO shall review the system(s) and process(es) that generated the Paid Claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the Paid Claim.

4. *Other Requirements.*

- a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Paid Claims in the Claims Review Sample and UHS or the Subject Facility shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Claims Review Sample. If the IRO accepts any supplemental documentation or materials from UHS or the Subject Facility after the IRO has completed its initial review of the Claims Review Sample (Supplemental Materials), the IRO shall identify in the Claims Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Claims Review Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.
- b. Paid Claims without Supporting Documentation. Any Paid Claim for which the Subject Facility or Facilities cannot produce

documentation shall be considered an error and the total reimbursement received by the Subject Facility or Facilities for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

- c. Use of First Samples Drawn. For the purposes of the Claims Review Sample discussed in this Appendix, the first set of Paid Claims selected shall be used (*i.e.*, it is not permissible to generate more than one list of random samples and then select one for use with the Claims Review Sample).

5. *Repayment of Identified Overpayments.* Subject Facilities shall repay within 60 days any Overpayment(s) identified by the IRO in the Claims Review Sample, in accordance with the requirements of 42 U.S.C. § 1320a-7k(d) and any applicable regulations and Centers for Medicare and Medicaid Services (CMS) guidance (the “CMS overpayment rule”), or TRICARE guidance. If UHS determines that the CMS overpayment rule requires that an extrapolated Overpayment be repaid, Subject Facilities shall repay that amount at the mean point estimate as calculated by the IRO. UHS shall make available to OIG all documentation that reflects the refund of any Overpayment(s) to the payor. OIG, in its sole discretion, may refer the findings of the Claims Review Sample (and any related work papers) received from UHS to the appropriate Medicare, state Medicaid, or TRICARE program contractor for appropriate follow up by that payor.

B. Claims Review Report. The IRO shall prepare a Claims Review Report as described in this Appendix for each Claims Review performed. The following information shall be included in the Claims Review Report.

1. *Claims Review Methodology.*
 - a. Claims Review Population. A description of the Population subject to the Claims Review.
 - b. Claims Review Objective. A clear statement of the objective intended to be achieved by the Claims Review.
 - c. Source of Data. A description of (1) the process used to identify Paid Claims in the Population and (2) the specific documentation relied upon by the IRO when performing the Claims Review (*e.g.*, medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), Medicare carrier or intermediary manual or

bulletins (including issue and date), other policies, regulations, or directives).

- d. Review Protocol. A narrative description of how the Claims Review was conducted and what was evaluated.
- e. Supplemental Materials. A description of any Supplemental Materials as required by Section A.3.a., above.

2. *Statistical Sampling Documentation.*

- a. A copy of the printout of the random numbers generated by the “Random Numbers” function of the statistical sampling software used by the IRO.
- b. A description or identification of the statistical sampling software package used by the IRO.

3. *Claims Review Findings.*

- a. Narrative Results.
 - i. A description of billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
 - ii. A description of controls in place to ensure that all items and services billed to Medicare program, a state Medicaid program, or the TRICARE program are medically necessary and appropriately documented.
 - iii. A narrative explanation of the IRO’s findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Claims Review, including the results of the Claims Review Sample.
- b. Quantitative Results.
 - i. Total number and percentage of instances in which the IRO determined that the coding of the Paid Claims differed from what should have been the correct coding and in which such difference resulted in an Overpayment.
 - ii. Total number and percentage of instances in which the IRO determined that a Paid Claim was not appropriately

documented and in which such documentation errors resulted in an Overpayment.

- iii. Total number and percentage of instances in which the IRO determined that a Paid Claim was for items or services that were not medically necessary and resulted in an Overpayment.
 - iv. Total dollar amount of all Overpayments in the Claims Review Sample.
 - v. Total dollar amount of Paid Claims included in the Claims Review Sample.
 - vi. Error Rate in the Claims Review Sample. The Error Rate shall be calculated by dividing the Overpayment in the Claims Review Sample by the total dollar amount associated with the Paid Claims in the Claims Review Sample.
 - vii. An estimate of the actual Overpayment in the Population at the mean point estimate.
 - viii. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (*e.g.*, DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.
- c. Recommendations. The IRO's report shall include any recommendations for improvements to billing and coding system or to controls for ensuring that all items and services billed to Medicare program, a state Medicaid program, or the TRICARE program are medically necessary and appropriately documented, based on the findings of the Claims Review.

4. *Credentials*. The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review and (2) performed the Claims Review.