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

I. PREAMBLE

Integrated Health Services, Inc., hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by IHS (as this term is defined herein), and by all Covered Persons and Covered Contractors (as these terms are defined herein) with the requirements 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"). IHS's compliance with the terms and conditions in this CIA shall constitute an element of IHS's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, IHS is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into that Settlement Agreement, as embodied in a Plan of Reorganization to be filed in IHS's Chapter 11 of the Bankruptcy Code proceeding in the United States Bankruptcy Court for the District of Delaware (the "Bankruptcy Court"). The scope of this CIA shall be governed by the following definitions:

- A. "IHS": any corporation, subsidiary, affiliate, joint venture or other organization or entity in which Integrated Health Services, Inc. owns greater than 50%, or which IHS operates, performs billing functions, or has a management contract or arrangement to provide management and administrative services that give it control over the day-to-day operations over the organization or entity (hereinafter "related entity"). Notwithstanding the above, the CIA shall not apply to Symphony Health Services, Inc. or any related entity that provides rehabilitation related services. By separate agreement signed this same date Symphony Diagnostic Services, Inc. ("SYMPHONY") has entered into a CIA with the OIG as part of the IHS settlement.
- B. "Covered Persons": includes all officers, directors, and employees. The term also includes those employees of contractors and agents who, on a regular basis, (i.e., more often than two weeks over a 52-week period):
 - 1. Are involved in patient or resident care to Federal health care program beneficiaries;

- 2. Participate in IHS's billing or related submissions to the Federal health care programs; or
- 3. Otherwise carry out the duties and responsibilities of this CIA (excluding the Monitor and the Independent Review Organization ("IRO")).
- C. "Covered Contractor": any entity or individual with whom IHS has entered into a contract or other arrangement and does not fall within the definition of "Covered Persons."

II. TERM OF THE CIA.

The period of the compliance obligations assumed by IHS under this CIA shall be five (5) years from the Effective Date of this CIA (unless otherwise specified). Notwithstanding the foregoing, upon completion of the third year of this CIA, the OIG, in its sole discretion, may waive IHS's obligations under Section III.D.1 to retain an Independent Monitor for one or more of the remaining two years of the CIA. IHS may apply for such waiver of its Independent Monitor obligations prior to the end of the third year of the CIA.

The Effective Date of this CIA will be same as the Effective Date of the Settlement Agreement into which this CIA is incorporated by reference (the "Effective Date").

Sections VII, VIII, IX, X and XI shall remain in effect until the OIG has completed its review of the final Annual Report and any additional materials submitted by IHS pursuant to OIG's request, which request must be made within one year of the OIG's receipt of IHS's final Annual Report.

III. CORPORATE INTEGRITY OBLIGATIONS.

Prior to the execution of this CIA, IHS established a Compliance Program and hereby agrees to maintain its Compliance Program for the duration of this CIA. In addition, to the extent not already implemented and for the duration of this CIA, IHS agrees to supplement its Compliance Program by adhering to the obligations contained in this CIA, including the maintenance of a Compliance Program that includes the following elements:

A. Program Infrastructure.

IHS shall, within 120 days of the Effective Date of this CIA, review its current compliance program infrastructure, and, to the extent not already in existence, create an internal structure whereby individuals are given responsibility at the facility and corporate levels to address quality of care concerns. These individuals shall not be the same individuals who are charged with responsibilities concerning the financial aspects of IHS's facilities. There shall be in place a mechanism and structure to provide the individuals who are charged with quality of care concerns with direct access to the Compliance Officer, the Medical Director Advisory Board, and the Facility Operations Performance Improvement Committee ('FOPIC")(as defined below).

As part of this internal structure, IHS shall maintain or establish, as necessary, the following positions and committees. If IHS changes its Compliance Program infrastructure in a way that affects these positions and committees, IHS shall ensure that under the new structure IHS devotes at least equal resources to its Compliance Program as are devoted under the structure described herein and in Section III.B and provide notice to the OIG within 15 days of any such change.

1. Board of Directors' Compliance Committee. IHS currently has a Compliance Committee that serves as part of its Board of Directors. During the term of this CIA, this committee shall:

- a. Review IHS's system of internal controls, accounting policies, financial reporting practices, and the quality and integrity of IHS's financial reporting to Federal health care programs;
- b. Ensure that IHS adopts and implements policies and procedures designed to ensure that IHS complies with all applicable statutes, regulations, policies, and this CIA;
- c. Ensure that IHS has a system in place to respond to federal, state, internal, and external reports of quality of care issues and that such system functions adequately; and
- d. Ensure that IHS adopts and implements policies and procedures that are designed to ensure that each individual that is cared for at a IHS facility receives at least the level of care required by law.

The individuals who serve on the Board Committee shall be available to the Compliance Officer, the Monitor, and the IRO required under this CIA, to respond to any issues or questions that might arise. The names of the Board Committee members and the Charter for the committee shall be provided to the OIG within 150 days of the Effective Date of this CIA. When new members are appointed, or the responsibilities or authorities of the Board Committee are substantially changed, IHS shall notify OIG, in writing, within 30 days of such a change.

- 2. Compliance Officer. IHS has appointed a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to promote compliance with the requirements set forth in this CIA and with the requirements of the Federal health care programs. The Compliance Officer shall be a member of senior management of IHS (i.e., not subordinate to IHS's general counsel or chief financial officer), and shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and the Board Committee. The Compliance Officer shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall remain responsible for monitoring the day-to-day activities engaged in by IHS to further its compliance objectives as well as any reporting obligations created under this CIA. The Compliance Officer or his or her designees shall also ensure that financial or quality of care issues are appropriately identified and addressed through corrective action plans. In the event a new Compliance Officer is appointed during the term of this CIA, IHS shall notify OIG, in writing, within 15 days of such a change.
- 3. Compliance Committee. IHS has a corporate compliance committee composed of the Compliance Officer and other appropriate officers or individuals who have the authority and responsibility to ensure quality of care at IHS's facilities, ensure proper billing to Federal health care programs, and to appropriately and thoroughly implement the requirements of this CIA. The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities.
- 4. Internal Audit Functions. IHS shall create a program for performing internal audits. The internal audit function shall:
 - a. Make findings of whether the cost reports, claims, and submissions to Federal health care programs that affect reimbursement are accurate and in accordance with applicable law:
 - b. Conduct an annual Minimum Data Set ("MDS") billing review of claims submitted by IHS's long term care facilities; and
 - c. Perform other internal audits designed to ensure that this CIA is being appropriately implemented and to ensure that IHS is meeting its obligations under applicable law.
- 5. Facility Administrators. Each IHS facility is managed by an Administrator. The Administrators will continue to be responsible for compliance in their respective facilities. Execution of compliance duties shall be a component of the performance evaluations of Administrators. Should it become necessary to pursue employment of a new Administrator, IHS shall appoint an acting Administrator who shall be granted authority equal to that of the

Administrator to carry out all required duties, including those with respect to IHS's Compliance Program.

- 6. Facility Operations Performance Improvement Committee. IHS shall maintain its corporate-level Facility Operations Performance Improvement Committee ("FOPIC") that regularly meets to identify, track, and plan issues requiring quality assessment or action. The FOPIC shall perform reviews that focus all levels of management on quality improvement opportunities for clinical care throughout IHS. The FOPIC shall conduct reviews on a quarterly basis to support the identification, analysis, reporting, and improvement of focused clinical care areas.
- 7. Corporate Medical Directors. The IHS Medical Directors Advisory Board ("MDAB") consists of 8 medical directors retained by IHS representing separate geographic regions. Appointment to the MDAB will be for a term of one year and may be extended by mutual agreement. Coordinated by the Senior Vice President of Clinical Services, the MDAB meets twice a year in person and conducts meetings via teleconference on an as needed basis. The duties of the MDAB include:
 - a. The provision of expert geriatric medicine content and guidance regarding:
 - i. Clinical services;
 - ii. Standards of Practice and Clinical Practice Guidelines Development;
 - iii. Relationships with providers of Physician Services;
 - iv. Physician Credentialing;
 - v. The role of the Medical Director and Attending Physicians;
 - vi. Recruitment and retention of clinical staff;
 - vii. Quality measurement, monitoring and improvement activities;
 - viii. Participation with American Medical Directors Association; and
 - ix. New program development.
 - b. Guidance to the Long Term Care Compliance Committee;
 - c. Guidance to the FOPIC; and
 - d. Mentoring and acting as a liaison to all IHS Medical Directors in particular geographic regions.
 - B. Written Standards.

- 1. Standards of Conduct. IHS has established a Standards of Conduct. Within 120 days of the Effective Date of this CIA, the Standards of Conduct shall be reviewed by the Compliance Officer to ensure they meet the requirements set forth herein.
 - a. Contents. The Standards of Conduct shall, at a minimum, include:
 - i. IHS's commitment to compliance with all statutes, regulations, directives, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program requirements, which includes procedures or instructions communicated by appropriate regulatory agencies, e.g., the Centers for Medicare and Medicaid Services (formerly known as the Health Care Financing Administration or HCFA) (hereinafter "CMS") and fiscal intermediaries or carriers;
 - ii. IHS's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with IHS's own Policies and Procedures (including the requirements of this CIA);
 - iii. The requirement that all Covered Persons shall be expected to report suspected violations of any Federal health care program requirements or of IHS's own Policies and Procedures, and if there are credible allegations of resident or patient harm, such report shall be made in accordance with applicable law;
 - iv. The possible consequences to both IHS and to any Covered Person for failure to comply with all Federal health care program requirements and with IHS's own Policies and Procedures or for failure to report such non-compliance; and
 - v. The right of all individuals to use the Disclosure Program, as well as IHS's commitment to confidentiality and non-retaliation with respect to disclosures.
 - b. <u>Distribution and Certification</u>. IHS shall distribute the Standards of Conduct to all employees during each employee's orientation, and thereafter, as revisions occur. Within 120 days of the Effective Date of this CIA, IHS shall distribute the Standards of Conduct to all Covered Persons who have not already received a copy that reflects the required contents as set forth herein. Within 120 days of the Effective Date of this CIA, each Covered Person who has not already done so shall certify, in writing,

that he or she has received, read, understood, and will abide by IHS's Standards of Conduct.

New Covered Persons shall receive the Standards of Conduct during orientation or at the time of their appointment, employment or contract, or within 120 days of the Effective Date of the CIA, whichever is later. All Covered Persons shall complete the required certification within 30 days after the commencement of their appointment, employment, or contract or within 120 days of the Effective Date of the CIA, whichever is later. IHS shall continue to make the promotion of, and adherence to, the Standards of Conduct an element in evaluating the performance of employees.

IHS shall annually review the Standards of Conduct and will revise or supplement it as necessary. IHS shall distribute revisions or supplements of the Standards of Conduct to Covered Persons within 30 days of such changes being completed. Covered Persons shall certify on an annual basis that they have received, read, understood and will abide by the Standards of Conduct that is currently in place.

- c. Covered Contractor Requirements. For each of its Covered Contractors, IHS shall: i) require in its contract with the Covered Contractor that the Covered Contractor acknowledges IHS's Compliance Program and Standards of Conduct; ii) for any Covered Contractor with whom IHS has an existing contract, IHS shall in good faith seek to reform the contract to require the Covered Contractor to acknowledge the Compliance Program and Standards of Conduct; and iii) ensure that the Standards of Conduct is provided (either by IHS or the Covered Contractor) to all Covered Contractor employees.
- 2. Policies and Procedures. IHS has established written Policies and Procedures regarding its Compliance Program and its compliance with relevant federal and state requirements, including, but not limited to, the requirements of Federal health care programs. IHS shall continue to assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. The Policies and Procedures shall be available to the OIG upon request. To the extent not already accomplished, IHS shall ensure that the relevant portions of its Policies and Procedures are available to the appropriate Covered Persons within 120 days of the Effective Date of this CIA. Compliance staff or supervisors shall continue to be available to explain any and all Policies and Procedures. Within 120 days of the Effective Date of this CIA, IHS shall review and analyze its Polices and Procedures to ensure that, at a minimum, such Policies and Procedures specifically address and/or include:
 - a. Measures designed to ensure that IHS fully complies with applicable portions of Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and all regulations, directives, and guidelines promulgated pursuant to these statutes, including, but not limited to, 42 C.F.R. Parts 424, 482, and 483,

- and any other state or local statutes, regulations, directives, or guidelines applicable to long term care facilities or hospitals;
- b. Measures designed to ensure that IHS complies with all applicable requirements of Medicare's Prospective Payment System ("PPS") for long term care facilities, including, but not limited to: ensuring the accuracy of the clinical data required under the Minimum Data Set ("MDS") as specified by the <u>Resident Assessment Instrument User's Manual</u>; ensuring that facilities are appropriately and accurately using the current Resource Utilization Groups ("RUG") classification system; and ensuring the accuracy of billing and cost report preparation policies and procedures;
- c. Measures designed to ensure the provision of coordinated interdisciplinary care to long term care residents, including, but not limited to the following areas addressed in 42 C.F.R. Part 483: resident assessment and care planning; nutrition; disease specific care; wound care; infection control; appropriate drug therapies; appropriate mental health services; provision of basic care needs, including the provision of Activities of Daily Living ("ADL"); incontinence care; resident rights; physical and chemical restraint use; therapy services; quality of life, including accommodation of needs and activities; and assessment of resident competence to make treatment decisions; and professional services. Such Policies and Procedures shall include the following specific items:
 - i. Nutrition: Measures designed to facilitate nutritional care of residents by the Registered Dietitian including:
 - (A) Nutritional measures for residents with wounds:
 - (B) Measures to accurately assess all residents' appropriate body weight in order to determine an appropriate healthy weight range for each resident on a regular and consistent basis and clearly document such findings in the residents' charts; and
 - (C) Measures designed to ensure that IHS identifies and provides timely clinical responses to all "nutritionally at risk" and "nutritionally compromised" residents at the earliest possible time.
 - ii. Provision of Basic Care Needs, including those Activities of Daily Living, such as bathing, oral care, and positioning;
 - iii. Use of Chemical & Physical Restraints, pursuant to acceptable professional standards, including:

- (A) Measures designed to ensure that physical and chemical restraints are used only pursuant to accepted professional standards when less restrictive alternatives are not effective and that they are never used as punishment or for the convenience of staff;
- (B) Measures designed to ensure that appropriate physicians' orders are obtained and followed before physical restraints are used; and
- (C) Measures designed to ensure that psychotropic medication is used only in accordance with accepted professional standards and only where there is an appropriate psychiatric or neuropsychiatric diagnosis, and that psychotropic medication is never used as punishment, in lieu of a training program, for behavior control or in lieu of a psychiatric or neuropsychiatric diagnosis or for the convenience of staff.
- Measures designed to ensure that IHS provides appropriate wound care (decubitus ulcer) treatment and appropriate nutrition for residents with wounds; and
- v. Measures to assess that the resident's drug regime is free of unnecessary medications.
- d. Measure designed to ensure the provision of a safe and functional environment for all residents, allowing all residents to be free from mistreatment, verbal, sexual, physical and mental abuse, corporal punishment, involuntary seclusion, neglect and misappropriation of property; Such measures shall include:
 - i. Measures designed to ensure that IHS adequately supervises, monitors and safeguards all residents, including those with histories of exhibiting behaviors that cause injury to themselves or others; and
 - ii. Measures designed to ensure that residents shall be protected from being victimized by other aggressive residents.
- e. Measure designed to ensure the provision for an ongoing program of meaningful activities both during the week and on the weekends, which are structured and designed to meet individual needs and interests and the physical, mental, and psychosocial well-being of the residents;
- f. Measures designed to ensure the provision of medically-related social services to address the individual interests and physical, mental, and psychosocial well-being of each resident, and provides medically-related social services to attain or

- maintain the highest practicable physical, mental, and psychosocial well-being of each resident;
- g. Measures designed to ensure that physician services are provided in a manner set forth in 42 C.F.R. 483.40;
- h. Measures designed to ensure the provision of Nursing Services as outlined in applicable portions of 42.C.F.R. 483.30; and that nursing care is provided in keeping with the accepted professional standards of care such as assessment, planning, implementing and evaluating the care of the long term care resident. Examples of such are:
 - i. Physician notification of health-related issues;
 - ii. Monitoring and interviewing in keeping with professional standards of care; and
 - iii. Keeping appropriate records of the residents' health care status.
- Measures designed to ensure that residents and patients are discharged only for the reasons authorized by and in accordance with the procedures established by applicable law and are not discharged for financial reasons unless authorized by law;
- j. Measures designed to ensure that staffing is in compliance with Federal health care program requirements and state laws, including, but not limited to, 42 C.F.R. sections 483.23(a) and (b) (hospitals) and 483.30 (nursing services, sufficient staff), and not based on financial considerations;
- k. Measures that specify that if the director of nursing (or other person who is making staffing decisions at the facilities) disagrees with a staffing determination made by the Administrator or other individuals at the regional or corporate level and that person believes this staffing decision may not be in compliance with state or federal regulations or this CIA and may significantly affect resident care, then that person must call the hotline and the Monitor;
- Measures designed to minimize the number of individuals working at any IHS
 facility who are not Covered Persons, i.e., are on a temporary assignment or not
 employed by IHS, and measures designed to create and maintain a standardized
 system to track the usage of such individuals at each facility so that the
 number/proportion of or changing trends in such staff can be adequately identified
 by IHS and/or the Monitor. Use of temporary staff will be reported to the Monitor
 on an ongoing basis;

- m. Measures designed to ensure compliance with the completion of accurate clinical assessments as required by applicable federal law;
- n. Measures designed to ensure that all residents and patients are served in the least restrictive environment and most integrated setting appropriate to their needs;
- o. Disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues through the Disclosure Program required by section III.E;
- p. Measures designed to promote adherence to the compliance and quality of care standards set forth in the applicable statutes, regulations, and in this CIA, by including such adherence as a significant factor in determining the compensation to Administrators of the facilities, and the individuals responsible for such compliance at the regional and corporate level;
- q. Measures designed to ensure cooperation by IHS and its employees, contractors, and agents with the Monitor in the performance of his or her duties as set forth in this CIA;
- r. Measures designed to ensure that compliance issues identified internally (e.g., through reports to supervisors, hotline complaints, internal audits, patient satisfaction surveys, CHSRA quality indicators, facility specific key indicators, or internal surveys) or externally (e.g., through CMS or state survey agency reports, consultants, audits performed by the Independent Review Organization, or Monitor's reports) are promptly and appropriately investigated and, if the investigation substantiates compliance issues, IHS assesses the nature and scope of the problems, implements appropriate corrective action plans, and monitors compliance with such plans:
- s. Measures designed to effectively collect and analyze staffing data, including staffto-resident ratio and staff turnover;
- t. Measures designed to ensure that individuals and entities who fall within the ambit of the Covered Contractor definition are appropriately supervised to ensure that the Covered Contractor is acting within the parameters of IHS's Policies and Procedures and the requirements of Federal health care programs;
- u. Measures designed to ensure that the internal audits are performed by appropriate and qualified individuals;

- v. Non-retaliation policies and methods for employees to make disclosures or otherwise report on compliance issues through the Disclosure Program required by section III.E; and
- w. Disciplinary guidelines to reflect the Standards of Conduct requirements as specified in Section III.B.1.

C. Training and Education.

Prior to the execution of this CIA, IHS established a training program for all its Covered Persons and agrees that it shall continue to conduct training programs that meet the requirements of this CIA. Persons providing the training must be knowledgeable about the subject area covered by the training.

- 1. General Compliance Training. IHS shall provide at least one hour of general compliance training to each Covered Person. This general training, at a minimum, shall explain IHS's:
 - a. Corporate Integrity Agreement requirements; and
 - b. Compliance Program (including the Standards of Conduct and Policies and Procedures as they pertain to general compliance issues).

These training materials shall be made available to OIG, upon request.

New Covered Persons shall receive the general training described above during orientation, but not later than 30 days after the beginning of their employment or within 120 days after the Effective Date of this CIA, whichever is later. During the term of this CIA, every Covered Person shall receive such general training on an annual basis.

2. Specific Training. Within 120 days of the Effective Date of this CIA, IHS shall initiate specific training of certain designated Covered Persons, as set forth in this Section. Each Covered Person who is involved in the delivery of patient or resident care (including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions), the preparation or submission of claims for reimbursement or cost reports, or the assignment of procedure codes or other diagnostic assessments that might affect reimbursement, for any Federal health care programs (hereinafter, "Relevant Covered Persons") shall receive at least 2 hours of specific training pertinent to his or her responsibilities (as described below) in addition to the general training required above. This training shall be conducted at least annually thereafter, and shall include a discussion of the policies and procedures set forth in Section III.B.2, including, but not limited to:

- a. The submission of accurate information (e.g., MDS, claims, bills, and cost reports) for services rendered to Medicare or Medicaid beneficiaries, including, but not limited to, the requirements for an accurate clinical assessment, if relevant to the person's duties;
- b. Policies, procedures and other requirements applicable to the documentation of medical records, if relevant to the person's duties;
- c. The personal obligation of each individual involved in the patient or resident care, documentation, or reimbursement processes to ensure that such submissions are accurate;
- d. Applicable Federal health care program requirements, if relevant to the person's duties;
- e. The legal sanctions for improper submissions to Federal health care programs;
- f. Examples of relevant reimbursement practices related to Federal health care programs found to have been improper, if relevant to the person's duties; and
- g. For persons who provide patient or resident care: the coordinated interdisciplinary approach to providing care to residents or patients, including, but not limited to, resident assessment and the applicable requirements of 42 C.F.R. § 483.

Affected new Relevant Covered Persons shall receive this training within 60 days of the beginning of their employment or contract, or within 120 days after the effective date of this CIA, whichever is later. New Relevant Covered Persons involved in the delivery of patient or resident care or in the preparation or submission of information (including, but not limited to, claims, bills, MDS, or cost reports) to any Federal health care program shall be adequately supervised by trained employees until they have completed the specific training relevant to their duties. Each Relevant Covered Person shall receive the appropriate Specific Training on an annual basis.

In addition, each facility shall conduct periodic training on an "as needed" basis (but at least semi-annually) on those quality of care issues identified by the facility's Performance Improvement Committee. In determining what training should be performed, the FOPIC will review the complaints received, satisfaction surveys, staff turnover data, any state or federal surveys, including those performed by the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO"), any internal surveys, and either the CHSRA quality indicators (for long term care facilities) or other relevant indicators (for other types of facilities). Such training will be for the length of time necessary to teach the subject matter. Such training will be provided to all Covered Persons at the facility who are responsible for patient or resident care, or whose job function allows them to contribute to the correction of the alleged deficiency. IHS shall

implement mechanisms to evaluate that training participants comprehended and (where appropriate) implemented the content of the training received.

- 3. Certification. Each Covered Person shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or his/her designee) shall retain the certifications, along with specific course materials. These shall be made available to OIG upon request.
- 4. Prior Training. Training of any type provided to affected Covered Persons within 6 months prior to the Effective Date of this Agreement that meets with the requirements of Section III.C.2 shall be deemed to meet the timeframe obligations for initial training imposed by this Section, but does not obviate the requirement for attendance certifications.

D. Review Procedures.

- 1. Independent Monitor (Quality Engagement). Within 60 days of the effective date of this CIA, IHS shall appoint an appropriately qualified monitoring team (the "Monitor"), approved by the OIG. The Monitor shall charge a usual and customary rate for his or her fees and expenses. 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. IHS shall be responsible for all fees and expenses incurred by the Monitor, including, but not limited to, travel costs, consultants, administrative personnel, office space and equipment, or additional personnel. In the event there are no more than 80 facilities covered by the CIA, the Monitor's costs shall not exceed \$1,100,000 annually, except in the event that special circumstances arise that require the Monitor to expend additional resources to fulfill its duties under the CIA. If more than 80 facilities are covered by the CIA, the maximum allowable Monitor costs shall increase proportionately. Thus, if 100 facilities are covered by the CIA, the Monitor's costs shall not exceed \$1,300,000 annually. Similarly, if 130 facilities are covered by the CIA, the Monitor's costs shall not exceed \$1,500,000 annually. Failure to pay the Monitor within 30 calendar days of submission of its invoices for services previously rendered shall constitute a breach of the CIA and shall subject IHS to one or more of the remedies set forth in Section XI infra. The Monitor may be removed solely at the discretion of the OIG. If the Monitor resigns or is removed for any reason prior to the termination of the CIA, IHS shall appoint another Monitor, after approval by the OIG, with the same functions and authorities.
 - a. The Monitor shall be responsible for assessing the effectiveness, reliability and thoroughness of the following:
 - i. IHS's internal quality control systems, including, but not limited to, whether the systems in place to promote quality of care and to respond to quality of care issues are acting in a timely and effective manner; 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 whether the training programs are effective and thorough;

- ii. IHS's response to quality of care issues, which shall include an assessment of:
 - (A) IHS's ability to identify issues;
 - (B) IHS's ability to assess the scope of issues, (e.g., including, but not limited to whether the problem is isolated or systemic);
 - (C) IHS's ability to create a corrective action plan to respond to issues;
 - (D) IHS's ability to execute a corrective action plan;
 - (E) IHS's ability to evaluate whether the assessment, corrective action plan and execution of that plan was effective, reliable, and thorough.
- iii. IHS's development and implementation of corrective action plans and the timeliness of such actions;
- iv. IHS's proactive steps to determine that each patient and resident receives care in accordance with: (A) basic care, treatment and protection from harm standards; (B) the applicable rules and regulations set forth in 42 C.F.R. Parts 482 and 483; (C) applicable state and local statutes, regulations, and other directives or guidelines; and (D) the policies and procedures adopted by IHS and set forth in this CIA.
- b. Access. The Monitor shall have access to:
 - i. Facilities, at any time and without prior notice;
 - ii. The following types of documents: (1) the CMS quality indicators (for nursing facilities); (2) internal or external surveys or reports; (3) IHS's hotline complaints relating to patient care; (4) resident or patient satisfaction surveys; (5) staffing data in the format reasonably requested by the monitor, including but not limited to reports setting forth the staff to patient or resident ratios, temporary staffing levels, and staff turnover data, as well as reports of any facility where temporary agency staff constitutes more than 10 percent of the direct care staff within a calendar month; (6) incident,

accident, abuse, neglect or death reports; (7) reports of incidents involving a patient or resident that prompt a full internal investigation; (8) patient or resident records; (9) financial data; (10) self-evaluative reports including, but not limited to, those from medical review committees, quality assurance committees, or peer review committees; and (11) any other pre-existing data, including the reconfiguring of existing data, that the Monitor may determine relevant to fulfilling the duties required under this CIA in the format requested by the Monitor, to the extent practicable; and

iii. Immediate access to patients, residents, and staff for interviews outside the presence of IHS supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals. The Monitor shall give full consideration to an individual's clinical condition before interviewing a resident or patient.

c. IHS's Obligations. IHS shall:

- i. Not impede the Monitor's access to its facilities (pursuant to the provisions of this CIA) and shall provide any requested documentation within the time frame specified by the Monitor, subject to any extensions and modifications requested by IHS and granted by the Monitor;
- ii. Assist in contacting and arranging interviews of Covered Persons, and not impede the cooperation by such individuals;
- iii. Provide access to current residents or patients and contact information for their families and guardians, in a manner consistent with the rights of such individuals under state or federal law, and not impede their cooperation;
- iv. Provide the last known contact information for former employees, contractors, and agents, and not impede the cooperation from such individuals, including, but not limited to, refraining from placing confidentiality requirements in termination agreements that would limit such cooperation;
- v. Provide the last known contact information for former residents, patients, their families, or guardians consistent with the rights of such individuals under state or federal law, and not impede their cooperation;

- vi. Address any written recommendation made by the Monitor either by substantially implementing the Monitor's recommendations or by explaining in writing why it has elected not to do so;
- vii. Pay the Monitor's bills for Monitor's Costs within 30 days of receipt. While IHS must pay all the Monitor's bills within 30 days, IHS may bring any disputed Monitor's Costs or bills to the OIG's attention;
- viii. 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 IHS under this Agreement; 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; and
- ix. Provide the Monitor a report within 48 hours of any of the following occurrences:
 - (A) Deaths or injuries that may be related to use of restraints;
 - (B) Deaths or injuries that may be related to use of psychotropic medications;
 - (C) Apparent suicides; and
 - (D) Deaths or injuries that may be related to abuse or neglect (as defined in the applicable federal guidelines).

Each such report shall contain the full name, social security number, and date of birth of the resident or patient, the date of death or incident, and a brief description of the events surrounding the death or incident.

- d. The Monitor's Obligations. The Monitor shall:
 - i. Respect the legal rights, privacy, and dignity of all Covered Persons, residents, and patients;
 - ii. Promptly report to appropriate regulatory or law enforcement entities when warranted. Where independently required by applicable law or professional licensing standard to report any finding to an appropriate regulatory or law enforcement authority, simultaneously submit copies of such reports to OIG and to IHS;

- iii. At all times act reasonably in connection with its duties under the CIA, including when requesting information from IHS;
- iv. Provide quarterly reports to IHS and the OIG concerning the findings made to date;
- v. Submit bills to IHS on a consolidated basis no more than once per month, and submit an annual summary representing an accounting of its costs throughout the year to IHS and to the OIG. IHS shall have the opportunity to review such bills and bring any issue of disputed bills or costs to the attention of the OIG;
- vi. Not be bound by any other private or governmental agency's findings or conclusions, including, but not limited to JCAHO, 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 the sole 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 IHS, and IHS 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 the OIG or IHS 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 fora not explicitly excluded in this subsection;
- vii. Abide by the legal requirements of IHS's facilities to maintain the confidentiality of each resident's or patient's personal and clinical records, and to maintain confidential and not to disclose the records of IHS's Corporate Compliance Committee and self-evaluative reports including, but not limited to, those from medical review committees, quality assurance committees or peer review committees. Nothing in the prior sentence, however, shall limit or affect the Monitor's obligation to provide information, including information from patient and resident clinical records, to the OIG, and, when legally or professionally required, reporting to other agencies; and

viii. 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 the OIG.

e. Miscellaneous Provisions

- i. The Monitor may confer and correspond with IHS and OIG on an exparte basis at any time.
- ii. If, after consulting with IHS, the Monitor has concerns about corrective action plans that are not being enforced or systemic or repeated problems that could impact IHS's ability to render quality care to its patients and residents, then the Monitor shall: (A) report such concerns in writing to the Consortium, in care of the OIG at the address set forth in Section VI of this CIA (the Consortium consists of representatives of the OIG, CMS, and the Department of Justice); and (B) provide notice and a copy of the report to the Compliance Officer and the Board Committee. IHS shall be provided an opportunity to respond to the Consortium concerning any such report;
- iii. The Consortium shall seek to resolve any such dispute between the Monitor and IHS prior to the OIG seeking any remedies pursuant to the terms of this CIA;
- iv. The Monitor shall not control, manage or operate HIS;
- v. As a condition to retaining the Monitor, IHS shall require the Monitor to enter into a subcontract with an individual or entity, approved by the OIG, that has the requisite expertise, capacity and access to MDS data directly from CMS to perform quarterly Quality Indicator data analysis reports of the type described in the attached Appendix C.

2. Financial Reviews.

a. General Description

i. <u>Retention of Independent Review Organization</u> Within 120 days of the Effective Date of this CIA, IHS shall engage an entity, such as an accounting,

auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to assist IHS in assessing and evaluating its billing, coding and claims submission practices pursuant to this CIA and the Settlement Agreement. The IRO retained by IHS shall have expertise in the billing, coding, reporting and other requirements of the particular section of the health care industry pertaining to this CIA and in the general requirements of the Federal health care program(s) from which IHS seeks reimbursement. The IRO(s) review shall address and analyze IHS's billing and coding to the Federal health care programs ("MDS Audits and shall analyze whether IHS sought payment for certain unallowable costs ("Unallowable Costs Review"). The MDS Audit described below shall be accomplished by a combination of reviews performed by the IRO and the IHS Internal Review Team pursuant to the provisions set forth below. The IRO shall assess, along with IHS, whether it can perform the IRO engagements in a professionally independent fashion, taking into account any other business relationships or other engagements that may exist.

- ii. <u>Frequency of MDS Audits</u>. The MDS Audits shall be performed annually and shall cover each of the one-year periods of the CIA beginning with the Effective Date of this CIA ("Reporting Period"). Both the IRO and IHS's Internal Review Team shall perform the MDS Audits and when a Systems Review is required the IRO shall perform the Systems Review.
- iii. <u>Frequency of Unallowable Cost Reviews</u>. The Unallowable Cost Review shall be performed by the IRO for the first one-year reporting period beginning with the Effective Date of the CIA.
- iv. <u>Retention of Records</u>. IHS and the IRO shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence and draft reports, if any, (those exchanged between the IRO and IHS) related to the review for at least one year after expiration of the CIA.
- v. <u>Independence Certification</u>. The IRO shall include in its report(s) to IHS a certification or sworn affidavit that it has evaluated its professional independence with regard to the MDS Audits or Unallowable Cost Review and that it has concluded that it was, in fact, independent.

b. Selection of IHS Internal Review Team.

i. <u>Identification of Team Members</u>. IHS's Corporate Compliance Officer shall identify prospective team members based upon the candidate's MDS Audit experience (<u>i.e.</u>, has performed similar MDS audits within the 6 months prior to becoming part of IHS's Internal Review Team, hereinafter "Internal Review

Team"), qualifications, and clinical background. The IRO and Corporate Compliance Officer shall independently assess each respective candidate's experience, qualifications, and clinical background. Both the IRO and IHS shall draft independent recommendations for each prospective Internal Review Team member regarding whether each member should serve on the Internal Review Team. The IRO and IHS shall mutually agree on IHS's proposed Internal Review Team members for the purposes of Credentialing as set forth below.

- Credentialing of the Internal Review Team. To credential the ii. Internal Review Team, the following protocol will be used. Within 120 days of the Effective Date of this CIA and prior to the initiation of any MDS Audits, the IRO shall randomly select in a statistically valid manner 25 sampling units from IHS's nursing facilities. The identities of the patients in the selected sampling units will be redacted to preserve patient confidentiality. These 25 sampling units will be used to train and assess the candidates for the Internal Review Team. Using the audit procedures set forth in Appendix A, the IRO will train the prospective Internal Review Team members using the first 10 randomly generated sampling units. Following the demonstration training, and using the remaining 15 randomly selected sampling units, each of the candidates will independently make coding and overpayment determinations on these units based on defined audit procedures agreed to by IHS and the IRO as set forth below. Each prospective Internal Review Team member will be evaluated on how they scored each test sampling unit. Each reviewer's percentage score will be calculated based on pre-selected objective audit elements. These pre-selected objective audit elements and the credentialing standard shall be mutually agreed upon by IHS and the IRO and shall be submitted to the OIG for review. At any time during the term of the CIA, the OIG may provide IHS with comments, recommendations, or may reject any or all of the preselected objective audit elements or credentialing standard and may create its own audit elements and credentialing standard and apply it to select the Internal Review Team. Any comments provided, recommendations made or the lack thereof or the lack of rejection of any or all of the pre-selected objective audit elements or credentialing standard shall not constitute acceptance of the pre-selected objective audit elements or the credentialing standard. Those Internal Review Team Candidates with credentialing scores at or above the credentialing standard will be selected as members of the Internal Review Team.
- iii. Reporting the Selection of the Internal Review Team. As part of IHS's Implementation Report, IHS's Corporate Compliance Officer shall provide the OIG with his/her justification and the IRO's recommendations for each proposed Internal Review Team member. Both IHS's justification and the IRO's recommendation shall include a narrative evaluation of each prospective team member's audit test performance for each selected Internal Review Team member.

IHS shall also include each candidate's resume, audit test results, and credentialing score that supports each candidate's selection as an Internal Review Team member as part of its justification.

iv. <u>Replacement of Internal Review Team Members</u>. If at any time during the term of this CIA, an Internal Review Team member needs to be replaced, the protocol described in Section III.D.2.b.i-iii. herein shall be implemented to select a new Internal Review Team member. However, IHS's justification and the IRO's recommendation, as described in Section III.D.2.b.ii herein, shall be submitted to the OIG prior to engaging the new Internal Review Team member.

c. Annual IRO Verification Review

- i. At the end of each Audit Period (as defined in Appendix A) of the CIA, the IRO will verify a sample of each Internal Review Team member's MDS Audit determinations to ensure the reviewer is making accurate judgments. To conduct the verification review, the IRO will review either 10% or 15 sampling units from each Internal Review Team member's previous year's MDS Audits, whichever is greater, and the accuracy of the reviewer's determinations shall be recorded. The IRO shall randomly select each reviewer's sample in a statistically valid manner. Based on the pre-selected objective audit elements, any incorrect MDS Audit determinations made by a Team member will constitute an error and the financial impact of any incorrect RUG assignment, if any, will be included in calculating the reviewer's net financial Error Rate. If 5% or more of a team member's determinations are incorrect or if the reviewer's net financial Error Rate, as defined in Appendix A, is 5% or more, the Internal Review Team member will be removed from the Team unless retention of the Internal Review Team member is otherwise recommended by the IRO and accepted by the OIG. The number of claims sampled, the audit tests results, and the financial error rate for each Internal Review Team member, and any recommendation or supporting rationale will be included in each Annual Report to the OIG. The OIG will have discretion to remove any person from the Internal Review Team at any time.
- ii. Team Members that Exceed the Net Financial Error Rate. If an Internal Review Team member has a net financial Error Rate of 5% or more: (1) the Internal Review Team member will be removed from the Team unless retention of the Internal Review Team member is otherwise recommended by the IRO and approved by the OIG; and (2) the IRO shall perform the following:
 - (A) Identify all Paid Claims that the reviewer reviewed during the Audit Period (and any subsequent reviews, providing he/she has already started evaluating Paid Claims for the next Audit Period);

- (B) Identify the reviewer's Paid Claims for facilities where a Full Sample was conducted and where only a Discovery Sample was conducted;
- (C) For the reviewer's Paid Claims for which only a Discovery Sample was conducted, the IRO shall retest all Paid Claims;
 - For those Paid Claims in which incorrect payment determinations were made, the IRO shall recalculate the Error Rate for each affected Discovery Sample;
 - (ii) For those Discovery Samples in which the recalculated Error Rate equals or exceeds 5% (after the IRO review), a Full Sample shall be performed.
- (D) For the reviewer's Paid Claims for which a Full Sample was conducted, the IRO shall retest all of these Paid Claims.
 - (i) For those Paid Claims in which incorrect payment determinations were made, the Full Sample will be redone by the IRO.

d. Facility Selection Methodology

- i. For each annual MDS Audit, the nursing facilities will be stratified for the purposes of these audits. The basis of such stratification shall be the total dollar amount the facility was reimbursed by Medicare during the year prior to the Audit Period. Each facility will be percentile ranked based on such criteria. Facilities with no Medicare reimbursement will not be included in sample of facilities for that year. All other facilities will be divided into "small," "medium," and "large" dollars groups. Facilities in the top 20th percentile will be designated in the large dollar group. Facilities in the lowest 25th percentile will be designated in the small dollar group. The rest of the facilities will be designated in the medium dollar group (the dollar groups are hereinafter referred to as "strata").
- ii. IHS will randomly select facilities for the MDS Audit in the following manner: 20% of the large strata; 15% of the medium strata; 20% of the small strata. Every facility in the strata shall be included in the population for sampling each year.

iii. Notwithstanding the above, any new facility acquired by IHS shall not be subject to inclusion in the Audit selection process until 6 months after its acquisition by IHS.

e. MDS Audit.

The MDS Audit shall include a Discovery Sample by IHS. If necessary, a Full Sample shall be done by the IRO or IHS, as appropriate, and a Systems Review shall be done by the IRO. The IRO and/or IHS's Internal Review Team shall perform an MDS Audit to identify any overpayments through a variable appraisal of Paid Claims submitted by IHS to the Medicare program. The MDS Audit shall be performed in accordance with the procedures set forth in Appendix A to this CIA.

- i <u>Discovery Sample</u>. The IHS's Internal Review Team shall select a statistically valid random sample of a minimum of 50 Paid Claims from each facility for review. If the reviewer chooses to stratify the Discovery Sample, the strata shall be determined prior to selecting the random sample of Paid Claims and an explanation of how the strata were determined shall be included in the MDS Audit Report. Each Paid Claim shall be reviewed based on the supporting documentation available at IHS or under IHS's control and the applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.
 - (A) If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review for that facility required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, IHS should, as appropriate, further analyze any errors identified in the Discovery Sample. IHS recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)
 - (B) If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO and/or IHS shall perform a Full Sample and the IRO shall perform a Systems Review for that facility, as described below.
- ii. <u>Full Sample</u>. If necessary, as determined by procedures set forth in Section III.D.2.e., the IRO and/or IHS shall perform an additional sample of Paid

Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample shall be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform to the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at IHS or under IHS's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO and/or IHS may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample, if statistically appropriate. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from IHS to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

- iii. <u>Internal Full Sample Review Option</u>. For the first Reporting Period (as defined in Section III.D.2.a.ii.), IHS may conduct any MDS Audit Full Sample ("Full Sample"), that is required to be performed. After the first Reporting Period and for each Reporting Period, thereafter, following its review of IHS's most recently submitted Annual report, if, in its sole discretion, OIG determines that IHS's internal MDS Audits satisfactorily establish the adequacy of IHS's internal billing and compliance practices as well as its review and audit capabilities, OIG may allow IHS to perform, in the next Reporting Period, any required Full Sample. For any Reporting Period that the OIG does not allow IHS to perform any required Full Sample(s), then the IRO shall perform the Full Sample(s).
- iv. MDS Audit Report. The IRO shall prepare a report based upon each MDS Audit performed for each facility the IRO reviewed ("MDS Audit Report"). IHS shall prepare an MDS Audit Report for each facility it reviewed. The MDS Audit Report shall be created in accordance with the procedures set forth in Appendix A to this CIA and shall be submitted to OIG by IHS as part of IHS's Annual Reports.
- v. <u>Systems Review</u>. If the Discovery Sample at any of the IHS facilities selected for review identifies an Error Rate of 5% or greater, then the IRO shall perform a Systems Review at that facility ("Systems Review"). The Systems Review shall include testing or verification of IHS's systems, processes and/or operations as described below for each Paid Claim that resulted in an Overpayment

in the Discovery Sample or Full Sample ("Overpayment Claim"). The Systems Review shall consist of a thorough review and inquiry of the following:

- (A) IHS's documentation, coding, billing and reporting operations relating to the Overpayment Claim. As part of this review, the IRO may evaluate the presence, application and adequacy of:
 - (1) IHS's billing and medical record documentation and coding process;
 - (2) IHS's billing policies and procedures to ensure proper coding and billing;
 - (3) IHS's internal controls to ensure accurate coding and claims submission;
 - (4) IHS's reporting operations or mechanisms that ensure appropriate communication between IHS and its fiscal intermediaries; and/or
 - (5) corrective action plans to correct any inaccurate coding or billing processes or individual claim forms.
- (B) For each Overpayment Claim, the IRO shall attempt to quantify any actual or potential overpayments and shall make a report to IHS (and to the OIG as described below) that shall include the IRO's recommendations to correct the identified deficiency and prevent future deficiencies. In addition, the IRO shall test the applicable IHS system(s) to ensure the potential deficiency is not a systemic problem. IHS will correct any identified deficiency within three (3) months of the discovery of the deficiency or provide the OIG with a reason why it cannot correct the deficiency within that time frame. IHS will report its findings regarding any potential deficiencies and corrective actions in the System Review Report portion of the MDS Audit Report.

f. Unallowable Cost Review.

i. The IRO shall determine whether IHS has complied with its obligations not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in

payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by IHS or any of its subsidiaries, and to request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous years.

- ii. <u>Unallowable Cost Review Report</u>. The IRO shall prepare a report based upon the Unallowable Cost Review performed. The Unallowable Cost Review Report shall include the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether IHS has complied with its obligation not to charge to, or otherwise seek payment from, federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable federal or state payors any unallowable costs included in payments previously sought from such payor.
- g. <u>Validation Review</u>. In the event the OIG has reason to believe that: (a) any IHS MDS Audit or Unallowable Cost Review fails to conform to the requirements of this CIA; or (b) any IRO or IHS MDS Audit or findings or results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the MDS Audit or Unallowable Cost Review complied with the requirements of the CIA and/or the findings or MDS Audit results are inaccurate ("Validation Review"). IHS agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after IHS's final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify IHS of its intent to do so and provide a written explanation of why the OIG believes such a review is necessary. To resolve any concerns raised by the OIG, IHS may request a meeting with the OIG to discuss the results of any MDS Audit or Unallowable Cost Review submissions or findings; present any additional or relevant information to clarify the results of the MDS Audit or Unallowable Cost Review to correct the inaccuracy of the MDS Audit or Unallowable Cost Review; and/or propose alternatives to the proposed Validation Review. IHS agrees to provide any additional information as may be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve any MDS Audits or Unallowable Cost Review with IHS prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

E. Disclosure Program.

IHS has established a Disclosure Program that includes two types of toll free hotlines. Within 120 days of the Effective Date of this CIA, IHS shall review its Disclosure Program and ensure that it is in compliance with the requirements of this Section. The Disclosure Program shall include mechanisms (e.g., a toll-free compliance telephone line) to enable any individual 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 IHS's policies, practices, or procedures with respect to quality of care or a Federal health care program, believed by the individual to be inappropriate. IHS shall publicize the existence of the disclosure mechanism, and, at a minimum, shall post it prominently in the lobby and gathering areas (e.g., dining rooms, activity rooms, waiting rooms) of each of its facilities and locations and publicize it in training and newsletters to employees.

The Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. 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 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, IHS shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal review, and any corrective action taken in response to the internal review. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

- 1. Definition. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs or in federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, suspended, debarred or otherwise declared ineligible.
- 2. Screening Requirements. IHS shall not hire as employees, engage as contractors, or grant staff privileges to any Ineligible Person. To prevent hiring,

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contracting, or granting staff privileges with or to any Ineligible Person, IHS shall screen all prospective employees and contractors prior to engaging their services, and screen all physicians prior to granting staff privileges by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://oig.hhs.gov) (these lists and reports will hereinafter be referred to as the "Exclusion Lists"). Nothing in this section affects the responsibility of (or liability for) IHS to refrain from billing Federal health care programs for services of Ineligible Persons.

3. Review and Removal Requirement. Within 120 days of the Effective Date of this CIA, IHS will review its list of current employees, agents, contractors, and physicians with staff privileges against the Exclusion Lists. Thereafter, IHS shall review its current employees, and contracts and physicians with staff privileges against the Exclusion Lists annually. In addition, IHS shall require employees and contractors to disclose immediately any debarment, suspension, exclusion, or other event that makes the employee an Ineligible Person.

If IHS has actual notice that an employee, agent, contractor, or physician with staff privileges has become an Ineligible Person, IHS will remove such person from responsibility for, or involvement with, IHS's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. Pending Charges and Proposed Exclusions. If IHS has actual notice that an employee, agent, contractor, or physician with staff privileges is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, IHS shall take all appropriate actions to ensure that the responsibilities of that employee, agent, contractor, or physician do not adversely affect the quality of care rendered to any patient or resident or the accuracy of any claims submitted to any Federal health care program.

G. Notification of Proceedings.

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

H. Reporting.

1. Overpayments

- a. Definition of "Overpayment." For purposes of this CIA, an "Overpayment" shall mean the amount of money IHS has received in excess of the amount due and payable under the Federal health care program requirements.
- b. Reporting of Overpayments. If, at any time, IHS identifies or learns of any overpayments, IHS shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the overpayment and take remedial steps within 60 days of identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days of identification of the overpayment, IHS shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, IHS shall notify the payor of its efforts to quantify the overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor should be done in accordance with the payor's policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix C to this CIA. Notwithstanding the above, notification and repayment of any overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Material Deficiencies

- a. Definition of "Material Deficiency." For purposes of this CIA, a "Material Deficiency" means anything that involves:
 - (i) a substantial Overpayment; or
 - (ii) 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.

A Material Deficiency may be the result of an isolated event or a series of occurrences.

- b. Reporting of Material Deficiencies. If IHS determines through any means that there is a Material Deficiency (as defined herein), IHS shall notify the OIG in writing within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:
 - i. If the Material Deficiency results in an Overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in section III.H.1, and shall include all of the information on the Overpayment Refund Form, as well as:
 - (A) the payor's name, address, and contact person to whom the Overpayment was sent; and
 - (B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;
 - ii. a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
 - iii. a description of IHS's actions taken to correct the Material Deficiency;
 - iv. Any further steps IHS plans to take to address the Material Deficiency prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date of this CIA, IHS changes locations or sells, closes, purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, IHS shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, sale, closure, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at such locations shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training), except as otherwise noted in the Financial Reviews section regarding the MDS Audits (see section III.D.2.c.iii.)

V. <u>IMPLEMENTATION AND ANNUAL REPORTS</u>

- A. <u>Implementation Report</u>. Within 150 days after the Effective Date of this CIA, IHS shall submit a written report to the OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:
 - 1. the name, address, phone number and position description of all individuals in positions described in Section III.A;
 - 2. the Charter for the Board of Directors' Committee as required in Section III.A.1;
 - 3. a description of all training required by section III.C, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held. A copy of all training materials shall be made available to the OIG upon request.
 - 4. a certification by the Compliance Officer that:
 - a. the Policies and Procedures required by section III.B.2 have been developed, are being implemented, and have been made available to all appropriate Covered Persons;
 - b. all Covered Persons have completed the Standards of Conduct certification required by Section III.B.1;
 - c. all Covered Persons have completed the applicable training and executed the certification required by Section III.C.

The documentation supporting this certification shall be available to the OIG, upon request.

- 5. the identity of the Independent Review Organization(s) and the proposed start and completion date of the engagements for the first year;
- 6. a summary of personnel actions taken pursuant to Section III.F;
- 7. a list of all of IHS's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding telephone numbers and facsimile numbers, each location's Federal health care program provider identification numbers(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number; and
- 8. The certification required by section V.C.
- B. <u>Annual Reports</u>. IHS shall submit to the OIG Annual Reports with respect to the status of, and findings regarding, IHS's compliance activities for each of the five one-year periods beginning on the Effective Date of the CIA (The one year period covered by each Annual Report shall be referred to as "the Reporting Period"). Each Annual Reports shall include:
 - 1. any change in the identity or position description of individuals in positions described in Section III.A, a change in any of the committees' structure or charter, any change in the internal audit and review program, or any change in the quality of care infrastructure;
 - 2. a certification by the Compliance Officer that:
 - a. all Covered Persons and Covered Contractors have completed the annual Standards of Conduct certification required by Section III.B.1;
 - b. all Covered Persons have completed the training and executed the certification required by Section III.C;
 - c. IHS has complied with its obligations under the Settlement Agreement:
 (i) not to resubmit to any Federal health care program payors any previously denied claims related to covered conduct addressed in the Settlement Agreement, and its obligation not to appeal any such denials of claims; and (ii) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement) and its

obligation to identify and adjust any past charges or claims for unallowable costs;

- d. IHS has effectively implemented all plans of correction related to problems identified under this CIA, IHS's Compliance Program, or internal audits or reviews.
- 3. a summary of any changes or amendments to the Policies and Procedures required by Section III.B.2 and the reasons for such changes (e.g., change in contractor policy);
 - 4. a description of all training conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held. A copy of all training materials used for the training required by section III.C. shall be made available to the OIG upon request;
 - 5. a summary of the facilities audited or reviewed pursuant to IHS's internal audit and review program, a summary of the findings of such audit or review, and a summary of the corrective actions taken under the program for internal audits and reviews;
 - 6. a complete copy of all reports prepared pursuant to the IRO engagements, including all the information required in Section III.D, a copy of the methodology used, and a copy of any IRO engagement letters;
 - 7. IHS's response/corrective action plan to any issues raised by the IRO;
 - 8. IHS's response/corrective action plan to any issues raised by the Monitor;
 - 9. a revised summary/description of all engagements between IHS and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;
 - 10. A certification from the IRO regarding its professional independence from IHS;
 - 11. a summary of Material Deficiencies (as defined in III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

- 12. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid (report each applicable state separately), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate overpayment report;
- 13. a summary of the disclosures in the disclosure log required by Section III.E that (a) related to Federal health care programs; or (b) allege abuse or neglect of patients;
- 14. a description of any personnel actions (other than hiring) taken by IHS as a result of the obligations in Section III.F, and the name, title, and responsibilities of any person who falls within the ambit of Section III.F.3 and 4, and the actions taken in response to the obligations set forth in that Section;
- 15. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. 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;
- 16. a description of all changes to the most recently provided list (as updated) of IHS's locations (including locations and mailing addresses) as required by section V.A.7, the corresponding name under which each location is doing business, the corresponding telephone numbers and facsimile numbers, each location's Federal health care program provider identification numbers(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number; and
- 17. the certification required by section V.C.

The first Annual Report shall be received by the OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer that: (1) except as otherwise described in the applicable report, IHS is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. <u>Designation of Information</u>: IHS 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. IHS 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 subsequent to the Effective Date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

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, SW

Washington, DC 20201 Phone: 202-619-2457 Fax: 202-205-0604

IHS:

Cheri Batee

Integrated Health Services, Inc.

The Highlands

910 Ridgebrook Road Sparks, MD 21152 Phone: 410-773-1000 Fax: 410-773-1147

Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

In addition to any other rights the OIG may have by statute, regulation, or contract, the OIG or its duly authorized representative(s), may examine or request copies of IHS's books, records, and other documents and supporting materials and/or conduct an on-site review of any of IHS's facilities, locations, or operations for the purpose of verifying and evaluating: (a) IHS's compliance with the terms of this CIA; and (b) IHS's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be

made available by IHS to the OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, the OIG or its duly authorized representative(s) may interview any of IHS's employees, contractors, or agents who consent to be interviewed at the individuals' place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and the OIG. IHS agrees to assist the OIG or its duly authorized representatives in contacting and arranging interviews with such individuals upon the OIG's request. IHS's employees may elect to be interviewed with or without a representative of IHS present.

VIII. DOCUMENT AND RECORD RETENTION

IHS shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA for six years (or longer if otherwise required by law).

IX. DISCLOSURES AND PRIVILEGES

Nothing in this CIA, or any communication or report made pursuant to this CIA, shall constitute or be construed as a waiver by IHS of IHS's attorney-client, work product, peer review, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect IHS's obligations to comply with the provisions of this CIA.

Consistent with HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify IHS prior to any release by the OIG of information submitted by IHS pursuant to its obligations under this CIA and identified upon submission by IHS as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. With respect to the disclosure of information, IHS shall have the rights set forth in 45 C.F.R. § 5.65(d). IHS shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

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

A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, IHS and the OIG hereby agree that failure to comply with certain obligations 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 IHS fails to have in place any of the following:
 - a. a Compliance Officer;
 - b. Compliance Committees, including FOPIC;
 - c. Compliance Committee of the Board of Directors;
 - d. a program for performing internal audits and reviews;
 - e. a written Standards of Conduct;
 - f. written Policies and Procedures;
 - g. a requirement that Covered Persons be trained; and
 - h. a Disclosure Program.
- 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 IHS fails to retain an IRO or Monitor, as required by section III.D.
- 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 IHS fails meet any of the deadlines (or any extension granted by the OIG) to submit the Implementation Report or the Annual Reports to OIG.
- 4. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day IHS employs or contracts with or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, IHS's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with federal funds (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which IHS can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in section III.F) as to the status of the person).
- 5. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date IHS fails to grant access) for each day IHS fails to grant access to the information or documentation as required in Section VII of this CIA.

- 6. A Stipulated Penalty of \$1,000 (which shall begin to accrue 10 days after the date that the OIG provides notice to IHS of the failure to comply) for each day IHS fails to comply fully and adequately with any obligation of this CIA. In its notice to IHS, the OIG shall state the specific grounds for its determination that IHS has failed to comply fully and adequately with the CIA obligation(s) at issue and steps IHS must take to comply with the CIA. A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under paragraphs 1-5 of this section.
- B. <u>Timely Written Requests for Extensions</u>. IHS 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 IHS fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after IHS receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

- 1. Demand Letter. Upon a finding that IHS has failed to comply with any of the obligations described in Section X.A and determining that Stipulated Penalties are appropriate, the OIG shall notify IHS of: (a) IHS's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").
- 2. Response to Demand Letter. Within 15 days of the date of the Demand Letter, IHS shall either: (a) cure the breach to the OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event IHS elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until IHS cures, to the OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a Material Breach of this CIA and shall be grounds for exclusion under Section X.D.
- 3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to "Secretary of the Department of Health and Human Services," and submitted to the OIG at the address set forth in Section VI.

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

D. Exclusion for Material Breach of this CIA

- 1. Definition of Material Breach. A "Material Breach" of this CIA means:
 - a. a failure to address concerns raised by the Monitor regarding the quality of care provided to patients or residents, as set forth in Section III.D.1.i of this CIA;
 - b. a failure by IHS to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in Section III.H;
 - c. repeated, systemic, or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A of this CIA;
 - d. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C above; or
 - e. a failure to retain and use an Independent Review Organization or a Monitor in accordance with Section III.D.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a Material Breach of this CIA by IHS constitutes an independent basis for IHS's exclusion from participation in the Federal health care programs. Upon a determination by the OIG that IHS has Materially Breached this CIA and that exclusion should be imposed, the OIG shall notify IHS of:

 (a) IHS's Material Breach; and (b) the OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").
- 3. Opportunity to Cure. IHS shall have 35 days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:
 - a. IHS is in full compliance with these obligations of the CIA cited by the OIG as being the basis for the Material Breach;
 - b. the alleged Material Breach has been cured; or

- c. the alleged Material Breach cannot be cured within the 35 day period, but that: (i) IHS has begun to take action to cure the Material Breach; (ii) IHS is pursuing such action with due diligence; and (iii) IHS has provided to the OIG a reasonable timetable for curing the Material Breach.
- 4. Exclusion Letter. If at the conclusion of the thirty-five (35) day period, IHS fails to satisfy the requirements of Section X.D.3, the OIG may exclude IHS from participation in the Federal health care programs. The OIG will notify IHS in writing of its determination to exclude IHS (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, IHS wishes to apply for reinstatement, IHS must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

D. Dispute Resolution

- 1. Review Rights. Upon the OIG's delivery to IHS of its Demand Letter or its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, IHS shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an ALJ and, in the event of an appeal, the 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), a request for a hearing involving Stipulated Penalties shall be made within 15 days of the date of the Demand Letter, and the request for a hearing involving exclusion shall be made within 30 days of the date of the Exclusion Letter.
- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether IHS was in full and timely compliance with the obligations of this CIA for which OIG demands payment; (b) the period of noncompliance. IHS shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with the OIG with regard to a finding of a breach of this CIA and orders IHS to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

- 3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 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:
 - (a) whether IHS was in Material Breach of this CIA;
 - (b) whether such breach was continuing on the date of the Exclusion Letter;
 - (c) whether the alleged Material Breach could not be cured within the 35 day period, but that:
 - (i) IHS had begun to take action to cure the Material Breach within that period,
 - (ii) IHS has pursued and is pursuing such action with due diligence, and
 - (iii) IHS provided to OIG within that period a reasonable timetable for curing the Material Breach and IHS has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG, or if the ALJ rules for IHS, only after a DAB decision in favor of the OIG. IHS's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude IHS upon the issuance of the ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that IHS 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. IHS agrees to 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 IHS, IHS will be reinstated effective on the date of the original exclusion.

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

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which this CIA is entered, and into which this CIA is incorporated, IHS and the OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns, and transferees of IHS, except that any facilities divested as part of a divestiture or group of divestitures aggregating ten or fewer facilities to a single entity or to a group of related entities shall be excused from the obligations under this CIA upon verified proof to the OIG's satisfaction that such transactions constitute disposition of the assets of such facilities to an independent entity unrelated in any manner to IHS; that the successor has acquired its interest at fair market value in an arms' length transaction; and that the successor has policies, procedures and practices in effect to ensure its compliance with the requirements of Medicare, Medicaid and all other Federal health care programs as well as a history of such compliance.
- B. This CIA shall become final and binding on the same date as the Effective Date of the Settlement Agreement in which this CIA is incorporated by reference.
- C. Any modifications to this CIA shall be made only with the prior written consent of the parties to this CIA.
- D. OIG may agree to a suspension of IHS's obligations under the CIA in the event of IHS's cessation of participation in Federal health care programs. If IHS withdraws from participation in Federal health care programs and is relieved from its CIA obligations by the OIG, IHS agrees to notify OIG 30 days in advance of IHS's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the CIA should be reactivated or modified.
- E. Nothing in this CIA precludes IHS from lawfully contesting the legality, enforceability or applicability of any Federal health care program requirement.
- F. The undersigned IHS signatory represents and warrants that he/she is authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF INTEGRATED HEALTH SERVICES, INC.

DATED: August , 2003

William Johnsen

Senior Vice President

DATED: August , 2003

W. Bradley Bennett

Executive Vice President

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

August 28, 2003

ARRY J. GOLDBERG

Assistant Inspector General for Legal Affairs Office of Counsel to the Inspector General Office of Inspector General U. S. Department of Health and

Human Services

Appendix A

FINANCIAL REVIEW - MINIMUM DATA SET AUDIT GUIDELINES

A. General

- 1. The MDS Audits shall consist of a variable appraisal sample (dollar amount in error). For purposes of determining dollar amounts associated with errors, the final sampling unit shall be a single UB-92 bill and all associated MDS information on the UB-92 bill shall be reviewed.
- 2. The audit period for the first year MDS Audits shall begin on the Effective Date of the CIA and will end with the date the MDS Audit begins for each respective Claim Pool (as identified in the annual facility selection methodology of Section III.D.2.d. of the CIA) (the "Audit Period"). The Audit Period for each subsequent MDS Audit shall begin at the end of the preceding year's Audit Period for each Claim Pool and shall end 12 months later. For the first MDS Audit, the universe from which the IRO and/or IHS will randomly select the UB-92 bills to review will include those UB-92s that were paid and have a date of service during the relevant Audit Period. For the remaining MDS Audits, the universe from which the IRO and/or IHS will randomly select the UB-92 bills to review will include those UB-92s that were paid during the relevant Audit Period.
- 3. IHS and the IRO shall ensure that only qualified individuals, including, but not limited to, clinical and medical personnel, are selected for the Internal Review Team pursuant to the procedures set forth in section III.D.2.b of the CIA. To the extent that any facility personnel are involved in the MDS Audits, IHS shall ensure that the individual who was involved in preparing the original claim, including the input of the entries on the MDS, on behalf of the IHS facilities, is not involved in the review of that particular facility's claims submission to federal health care programs.
- 4. If, in any Audit Period, IHS's Internal Review Team cannot perform the number of MDS Discovery Audits required, the IRO shall perform the remainder of the MDS Audits in that year.
- 5. If IHS becomes aware that any facility (including those not selected to be included as part of an annual MDS Audit) is potentially experiencing non-compliance with the Federal health care program requirements for claims submissions, IHS shall, after reasonably determining whether further review is warranted, in addition to its other CIA obligations, conduct a review of the potential area of non-compliance. If warranted, IHS shall develop a corrective action plan and conduct appropriate follow-up to ensure that any inappropriate or improper practice(s) related to claims submission is appropriately addressed. All such instances of inappropriate or improper claims submission, regardless of whether the facility was selected in the MDS Audit, shall be reported to OIG, pursuant to Section III.H. of this CIA.

B. MDS Audit

1. Definitions.

For the purposes of the MDS Audit, the following definitions shall be used:

- a. Overpayment: The amount of money IHS has received in excess of the amount due and payable under any Federal health care program requirements.
- b. <u>Item</u>: Any discrete unit that can be sampled (<u>e.g.</u>, code, line item, beneficiary, patient encounter, etc.).
- c. <u>Paid Claim</u>: A UB-92 for which IHS has received reimbursement from the Medicare program.
- d. <u>Population</u>: All Items for which IHS has submitted a code or line item and for which IHS has received reimbursement from the Medicare program (<u>i.e.</u>, a Paid Claim) during the Audit Period.
- e. <u>Error Rate</u>: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample. For those audits that IHS is permitted to conduct, the following payment errors should be included in calculating the error rate: (i) all payment errors identified by IHS's Internal Review Team and not verified by the IRO; (ii) all payment errors identified by the IRO and not identified by IHS and; (iii) all payment errors identified by IHS and verified by the IRO.

2. Sample Selection.

For each Discovery Sample and Full Sample MDS Audit, the IRO and/or IHS shall perform the following steps:

a. For the first year reviews, the IRO and/or IHS shall obtain a computer download (in either an ASCII, Lotus 1-2-3 or Microsoft Excel format), of the total Medicare Part A Paid Claims that had dates of service during the Audit Period for each of IHS's randomly selected nursing facilities (if a computer download is not available, then a computer-generated printout can be used). For subsequent year

reviews, the IRO and/or IHS shall obtain a computer download of the total Medicare Part A Paid Claims for each randomly selected facility;

- b. The IRO and/or IHS shall identify the universe of Paid Claims for each nursing facility in the audit year in accordance with Section A.3 of this Appendix. Based on the results of the Discovery Sample, the IRO and/or IHS shall select a sufficient number of sampling units to meet the parameters of Section III.D.2.e.ii. of the CIA from each nursing facility's total Medicare Part A claims population for the Full Sample;
- c. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)), the Paid Claims associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample; and
- d. The IRO and/or IHS shall notify each nursing facility of the paid UB-92s that were selected for review. The IRO and/or IHS shall obtain all appropriate medical records, billing and related supporting documentation. If IHS cannot produce the medical records or any other supporting documentation necessary to make an accurate claim determination, the IRO and/or IHS shall consider the relevant portion of the UB-92 which lacks proper documentation to be billed in error. Replacement sampling for Paid Claims with missing documentation is not permitted.

C. Conducting the MDS Audit

- 1. The IRO shall assist IHS with the development of the necessary MDS Audit tools and with executing the appropriate sampling methodology.
- 2. For each Paid Claim selected in the Discovery and Full Sample, the IRO and/or IHS shall review the MDS and the medical record documentation supporting the MDS. The review process shall entail an evaluation of the MDS and verification that each entry that affects the RUG code outcome for the MDS is supported by the medical record for the corresponding period of time consistent with the assessment reference date ("ARD") specified on the MDS.
- 3. The IRO and/or IHS shall perform the steps identified in Section B.2 of this Appendix for the Discovery Sample and/or the Full Sample, as appropriate.
- 4. The IRO and/or IHS shall perform an evaluation of the data on the UB-92 and determine whether the variables that affect the RUG assignment outcome for the MDS are supported by the medical record for the corresponding time period consistent with the assessment reference date specified in the MDS. This shall include the following issues:

- a. The accuracy of the MDS coding and the resulting RUG category selection based on the documentation within the medical record. The review of the MDS and related documentation shall include the following:
 - assessment reference date for accuracy;
 - activities of daily living and the look-back period used;
 - special treatments and procedures along with the look-back periods;
 - nursing restorative with look-back periods;
 - supplement for PPS with look-back periods used (e.g., estimated therapies and minutes for the 5-Day MDS); and
 - resulting RUG category.
- b. The demonstration of medical necessity in the medical record by verifying the presence of physician orders for the services reflected as necessary in the MDS.
- c. The accuracy of the associated UB-92s. At a minimum these claims shall be reviewed for the following:
 - coverage period;
 - revenue codes;
 - HIPPS codes (RUG categories and the modifiers for assessment type); and
 - units of service.
- 5. In those cases where an incorrect MDS has been identified, the IRO shall reenter data from that MDS into the IRO's grouper software to verify that the correct RUG code assignment was properly assigned on the UB-92. If an incorrect RUG code was assigned, this shall be considered an error.
- 6. If there is insufficient support for an MDS data point(s) that results in a downward change in RUG assignment, the IRO should consider the dollar difference to be an overpayment.
- 7. If an incorrect RUG was used, but it did not result in an overpayment, it will be noted in the MDS audit report ("MDS Audit Report").
- **D.** MDS Audit Report. The following information, as applicable, shall be included for each discovery and full MDS audit in the MDS Audit Report:
 - 1. MDS Audit Methodology
 - a. <u>MDS Audit Objective:</u> A clear statement of the objective intended to be achieved by the MDS Audit.

- b. Sampling Unit: A description of the Item, as that term is utilized for the MDS Audit. The sampling unit shall be paid UB-92s during the relevant Audit Period.
- MDS Audit Population: A description of the Population subject to the MDS Audit.
- d <u>Sampling Frame</u>: A description of the sampling frame, which is the totality of Items from which the discovery and full sample have been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.
- e. <u>Sources of Data:</u> A description of the documentation relied upon by the Internal Review Team or IRO when performing the MDS Audit (e.g. medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).
- f. <u>Review Protocol:</u> A narrative description of how the MDS Audit was conducted and what was evaluated.

2. Statistical Sampling Documentation

- a. The number of sampling units appraised in each discovery sample and each full sample.
- b. A copy of all printouts of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO for selection of each discovery sample and each full sample.
- c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample.
- d. A description or identification of the statistical sampling software package used to conduct the sampling.
- e. The sampling frame used in the discovery and full samples will be available to the OIG upon request.

3. MDS Audit Findings

a. Narrative Results.

- i. A description of IHS's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
- ii. A narrative explanation of the IRO's and/or IHS's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the MDS Audit, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment.

b. Quantitative Results.

- i. The total number and percentage of instances in which the IRO and/or IHS determined that the Paid Claim submitted by IHS and reimbursed by the fiscal intermediary differed from what should have been submitted by IHS and reimbursed by the fiscal intermediary (the "Correct Claim"), regardless of the effect on the payment.
- ii. The total number and percentage of instances in which the IRO and/or IHS determined the Paid Claim submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to IHS.
- iii. Based on the IRO's and/or IHS's MDS Audit, the total dollar amount of all Paid Claims in the MDS Audit Sample and the net Overpayment associated with the sample.
- iv. For each Discovery Sample and Full Sample performed by IHS: (i) the number of Items the IRO verified; (ii) the number of instances in which the IRO disagreed with HIS's payment determinations; and (iii) the dollars associated with the difference between the IRO's and IHS's payment determinations.
- v. Error Rate in each sample, as defined in section B.1.e of this Appendix.
- vi. The level of precision achieved by the Full MDS Audit at a 90% confidence level.
- vii. A spreadsheet of the MDS Audit results (for both the Discovery and Full samples) that includes the following information for each paid claim appraised: beneficiary health insurance claim number, date of service, RUG submitted, RUG reimbursed, allowed amount

reimbursed by payor, correct RUG (as determined IHS or the IRO), (if applicable) correct RUG (as determined by the IRO verification), correct allowed amount (as determined by IHS or the IRO), (if applicable) correct allowed amount (as determined by the IRO verification), dollar difference between the allowed amount reimbursed by payor and the correct allowed amount (as determined by IHS or the IRO), (if applicable) dollar difference between the allowed amount reimbursed by payor and the correct allowed amount (as determined by the IRO verification).

4. Systems Review Report.

The Systems Review Report shall include the IRO's findings and supporting rationale regarding:

- a. any identified deficiencies in IHS's medical record documentation, coding process, policies and procedures, internal controls, reporting mechanisms or corrective action plans;
 - b. any weakness or potential weaknesses in IHS's medical record documentation, coding process, policies and procedures, internal controls, reporting mechanisms or corrective action plans; and .
 - c. any recommendations the IRO may have to improve any of these systems, operations, or processes.

5. Credentials.

The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the MDS Audit; (2) performed the MDS Audit; and (3) performed the verification review, if applicable.

APPENDIX B

A. Claims Review.

- 1. Definitions. For the purposes of the Claims Review, the following definitions shall be used:
 - a. <u>Overpayment</u>: The amount of money Symphony has received in excess of the amount due and payable under any Federal health care program requirements.
 - b. <u>Item</u>: Any discrete unit that can be sampled (<u>e.g.</u>, code, line item, beneficiary, patient encounter, etc.).
 - c. <u>Paid Claim</u>: A code or line item submitted by Symphony and for which Symphony has received reimbursement from the Medicare program.
 - d. <u>Population</u>: All Items for which Symphony has submitted a code or line item and for which Symphony has received reimbursement from the Medicare program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.
 - e. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be

included as part of the net Overpayment calculation.)

The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

IHS CIA Appendix B 7/22/02

2. Other Requirements.

- a. <u>Paid Claims without Supporting Documentation</u>. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which Symphony cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by Symphony for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.
- b. <u>Use of First Samples Drawn</u>. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample.
- B. <u>Claims Review Report.</u> The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).
 - 1. Claims Review Methodology.
 - a. <u>Sampling Unit</u>. A description of the Item as that term is utilized for the Claims Review.
 - b. <u>Claims Review Population</u>. A description of the Population subject to the Claims Review.
 - c. <u>Claims Review Objective</u>. A clear statement of the objective intended to be achieved by the Claims Review.

2

d. <u>Sampling Frame</u>. A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.

- e. <u>Source of Data</u>. A description of the documentation relied upon by the IRO or IHS when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).
- f. <u>Review Protocol</u>. A narrative description of how the Claims Review was conducted and what was evaluated.

2. Statistical Sampling Documentation.

- a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.
- b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.
- c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.
- d. A description or identification of the statistical sampling software package used to conduct the sampling.

3. Claims Review Findings.

a. Narrative Results.

i. A description of Symphony's billing and coding system(s), including the identification, by position description, of the personnel

involved in coding and billing.

ii. 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 Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment.

IHS CIA Appendix B 7/22/02

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b. Quantitative Results.

- i. Total number and percentage of instances in which the IRO or IHS determined that the Paid Claims submitted by Symphony ("Claim Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.
- ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to Symphony.
- iii. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.
- iv. Error Rate in the sample.
- v. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by the IRO or IHS), correct allowed amount (as determined by the IRO or IHS), and dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)
- 4. Systems Review. Observations, findings, and recommendations on possible improvements to the system(s) and process(es) that generated the Overpayment(s).

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5. Credentials. The names and credentials of the individuals who: (a) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (b) performed the Claims Review.

Attachment 1

Claim Review Results

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Dollar Difference between Amt Reimbursed and Correct Allowed Amt		
Correct Allowed Amt Reimbursed (IRO determined)		
Correct Procedure Code (IRO determined)		•
Allowed Amount Reimbursed		
Procedure Procedure Code Code Submitted Reimbursed		
Procedure Code Submitted		
Bene Date of HIC# Service		
Bene HIC#		
Federal Health Care Program Billed		

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Appendix C to IHS CIA - Data Analysis Subcontract Description

Below is a description of the kinds of reports to be provided under the Monitor's subcontract with a data analysis expert, as required by section III.D of the IHS CIA.

- a. Facility Reports: a summary report for each facility covered by the Amendment, showing facility-level quality indicator (QI) values and information on the MDS assessments underlying these values. The reports will provide the facility's QI ratios as well as information regarding the placement of these values within the distribution of results for appropriate comparison groups. Initially, two comparison groups will be available. The first comparison group will be all nursing facilities within the subcontractor's MDS assessment database. The second group will be all nursing facilities within the Provider Group. The subcontractor may make additional comparison groups available if such groups can be readily identified using the facility identification codes within the subcontractor's MDS assessment database.
- b. Resident Reports: a resident-level report showing which QI numerators were triggered by each resident in the Facility Report tabulation.
- c. Database Extracts: a facility-level database table of QI values for the Provider Group. This extract will be produced quarterly by the subcontractor and mailed to the Monitor on CD, along with a printed summary of the table contents. These tables will be in a format suitable for use in spreadsheets and/or simple database applications to allow the monitor to manipulate/rearrange the data supporting the QI reports.
- d. Documentation: The subcontractor will provide the Monitor with a QI User Guide, which will describe the report format and contents, provide QI definitions in terms of the underlying MDS assessment items, and outline the QI tabulation process.
- e. QI Report Distribution: The Facility and Resident reports will be produced quarterly by the subcontractor.
- f. QI Analyses: Throughout the term of this subcontract, the subcontractor will analyze the available QI information relating to the Provider Group in an effort to refine and expand the information provided to the Monitor.

FIRST AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF THE INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND

INTEGRATED HEALTH SERVICES, INC.

LTC Holdings, Inc. (LTC), successor in interest to Integrated Health Services, Inc. (IHS), and Tri-State Health Investors (Tri-State), in its role as manager of LTC facilities, hereby enter into this First Amendment (Amendment) to the Corporate Integrity Agreement (CIA) with the Office of the Inspector General (OIG) of the Department of Health and Human Services to amend the CIA that was executed by and between IHS and OIG and that became effective August 28, 2003.

LTC, Tri-State, and OIG agree as follows:

- 1. With respect to the nine LTC facilities managed by Tri-State and identified in Paragraph 3 (the Tri-State Facilities), the Effective Date of the CIA shall be the date the final signatory signs the Amendment (Amended Effective Date).
- 2. All terms and conditions of the CIA shall be in effect, with the following modifications:
 - a. Section III.D.1 of the CIA shall continue with an Effective Date of August 28, 2003 and shall not be governed by this Amendment.
 - b. Annual Reports submitted for Reporting Periods beginning on or after the Amended Effective Date need not include the information set forth in Section V.B.8 of the CIA.
 - c. The number of Tri-State Facilities to be used in the MDS Audit shall be determined by OIG prior to performance of the MDS Audit for each Reporting Period. OIG may use the results of the methodology described in Section III.D.2.c.d as applied to the other LTC facilities governed by the CIA as a reference point in determining the number of Tri-State Facilities to be audited. LTC or Tri-State may make a recommendation regarding the number of facilities to be selected. However, the final determination shall be made at the sole discretion of the OIG.

- d. The requirement for a Board of Directors Compliance Committee, set forth at Section III.A.1 of the CIA, is waived. The requirement for a Compliance Committee, set forth at Section III.A.3, shall remain in effect for the duration of the CIA.
- 3. The Tri-State Facilities governed by this Amendment are:
 - a. Alabaster Health Care Center Provider Number 01-5144
 - b. Integrated Health Services of Kansas City at Alpine North Provider Number 26-5379
 - c. Riverbend Post Acute Continuing Care Provider Number 23-5226
 - d. Integrated Health Services of Erie at Bayside Provider Number 39-5404
 - e. Integrated Health Services of New Jersey at Somerset Valley Provider Number 31-5002
 - f. Integrated Health Services of Greater Pittsburgh Provider Number 39-5851
 - g. Integrated Health Services of Huber Heights at Spring Creek Provider Number 36-5627
 - h. Integrated Health Services of New London at Firelands Provider Number 36-5656
 - i. Integrated Health Services of West Carrollton at Elm Creek Provider Number 36-5598

4. For purposes of Section VI of the CIA, unless otherwise stated in writing after the Amended Effective Date, the contact for LTC and Tri-State with respect to the Tri-State Facilities shall be:

Alicia Dietrich Compliance Officer Tri-State Health Investors 1680 Michigan Avenue, Suite 736 Miami Beach, FL 33159 Telephone: (740) 687-2136

Facsimile: (740) 687-2138

- 5. On July 26, 2005, LTC and Tri-State paid a Stipulated Penalty of \$10,000 under the CIA in accordance with the July 12, 2005 Demand Letter issued by OIG. LTC, Tri-State, and OIG agree that payment of this Stipulated Penalty is final and not subject to appeal. Subject to LTC and Tri-State entering into this Amendment, the OIG agrees not to pursue additional stipulated penalties for other breaches of the CIA that occurred in connection with the Tri-State Facilities prior to Amended Effective Date.
- 6. The undersigned LTC and Tri-State signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.
- 7. This Amendment may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Amendment. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

On Behalf of LTC Holdings, Inc.

HARRY GRUNSTEIN
President
LTC Holdings, Inc.

4. For purposes of Section VI of the CIA, unless otherwise stated in writing after the Amended Effective Date, the contact for LTC and Tri-State with respect to the Tri-State Facilities shall be:

Alicia Dictrich
Compliance Officer
Tri-State Health Investors
1680 Michigan Avenue, Suite 736
Miami Beach, FL 33159
Telephone: (740) 687-2136
Facsimile: (740) 687-2138

- 5. On July 26, 2005, LTC and Tri-State paid a Stipulated Penalty of \$10,000 under the CIA in accordance with the July 12, 2005 Demand Letter issued by OIG. LTC, Tri-State, and OIG agree that payment of this Stipulated Penalty is final and not subject to appeal. Subject to LTC and Tri-State entering into this Amendment, the OIG agrees not to pursue additional stipulated penalties for other breaches of the CIA that occurred in connection with the Tri-State Pacilities prior to Amended Effective Date.
- 6. The undersigned LTC and Tri-State signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.
- 7. This Amendment may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Amendment. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

On Behalf of LTC Holdings, Inc.

HARRY GRUNSTEIN

President

LTC Holdings, Inc.

First Amendment to the CIA between IHS, Inc. and OIG

On Behalf of Tri-State

President

Tri-State Health Investors

Counsel for LTC and Tri-State

On Behalf of the Office of the Inspector General

LEWIS MORRIS

Chief Counsel to the Inspector General

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