CERTIFICATION OF COMPLIANCE AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND LOCHEARN NURSING HOME, LLC

I. PREAMBLE

Lochearn Nursing Home, LLC ("Lochearn") hereby enters into this Certification of Compliance Agreement (CCA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS).

Effective June 1, 2005, Lochearn acquired the right to operate the facility formerly known as the Villa St. Michael Nursing and Rehabilitation Center ("the Facility"), including the right to hold the license to operate the Facility. Given various events that occurred at the Facility during the time period that the Facility was owned by Villa St. Michael Limited Partnership, the United States Department of Justice and the OIG began an investigation of the Facility and Villa St. Michael Limited Partnership for allegedly engaging in the following conduct: During the period from January 1, 2000 through June 20, 2003, Villa St. Michael Limited Partnership failed to furnish adequate and quality care for residents as set forth in the OIG subpoena dated June 20, 2003, and submitted and/or caused the submission of false claims for reimbursement to the Medicare program in connection therewith ("Covered Conduct"). The parties hereto agree that the investigation by the United States Department of Justice and the OIG pertains to matters that occurred during the time period that the Facility was owned and operated by Villa St. Michael Limited Partnership, an entity that has no relationship to Lochearn or its owners or affiliates.

In light of the fact that Lochearn was not involved in the ownership or operation of the Facility during the applicable time period as set forth above, and in consideration of the obligations of Lochearn in this CCA, the OIG agrees to release and refrain from instituting, directing or maintaining any administrative actions seeking civil monetary penalties and/or exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Lochearn under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct. This CCA shall be binding upon Lochearn or such other successor, assign, or transferee that operates the Facility.

The effective date of this CCA shall be the date on which the final signatory of this CCA executes this CCA (Effective Date). Each one-year period, beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

"Covered Persons" within the meaning of this CCA includes the following:

- 1. all Lochearn, L.L.C. Members, owners, officers, directors, and employees, solely to the extent that the activities of these individuals relate directly or indirectly to the operation of Lochearn; and
- 2. all contractors, subcontractors, agents, and other persons who, on a regular basis (*i.e.*, more often than two weeks over a 52-week period) on behalf of Lochearn: (1) perform patient care or resident care duties; (2) make assessments of patients or residents that affect treatment decisions or reimbursement; (3) perform billing, coding, audit or review functions relating to quality of care; (4) make decisions or provide oversight about staffing, patient care, resident care, reimbursement, policies and procedures, or this CCA; or (5) perform any function that relates to or is covered by this CCA, including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions (excluding the Independent Monitor).

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

Notwithstanding the above, any nonemployee private caregivers and/or attending physicians hired by any resident or the family or friends of any resident of Lochearn are not Covered Persons, regardless of the hours worked per year at Lochearn.

II. <u>Integrity Requirements</u>

Lochearn shall, for a period of three years from the Effective Date of this CCA, do the following:

A. Continued Implementation of Compliance Program. For purposes of this CCA, it is recognized that Lochearn does not have an independent Compliance Program, but that Lochearn relies upon, and participates in, the Compliance Program of its manager's affiliate. Lochearn may satisfy its Compliance Program obligations under this CCA through the utilization of and participation in the Compliance Program of its manager's affiliate. All records specifically relating directly or indirectly to compliance issues by Lochearn shall be separately maintained by its manager's affiliate, and it is those records that are relevant to and subject to this CCA, and it is those documents that shall be made available to the Independent Monitor pursuant to the terms of this CCA. All references to Lochearn's Compliance Program in this CCA and the attached Declaration shall refer to the Compliance Program of Lochearn's manager's affiliate.

Lochearn shall continue to implement its Compliance Program, as described in the attached Declaration (which is incorporated by reference as Appendix A), and continue to provide, at a minimum, the same level of resources that it currently employs. Lochearn or its manager's affiliate may amend its Compliance Program as it deems necessary, so long as those amendments are consistent with the overall objective of ensuring compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f).

B. Reporting of Overpayments. Lochearn shall promptly refund to the appropriate Federal health care program payor any identified Overpayment(s). For purposes of this CCA, an "Overpayment" shall mean the amount of money Lochearn has received in excess of the amount due and payable under any Federal health care program requirements. If, at any time, Lochearn identifies or learns of any Overpayment, Lochearn shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Lochearn shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, Lochearn 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 shall be done in accordance with the payor's policies and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as Appendix B to this CCA. Notwithstanding the above, notification and repayment of any Overpayment amount that is routinely reconciled or adjusted pursuant to policies and procedures established by the payor (e.g., annual Medicaid cost report) should be handled in accordance with such policies and procedures.

- C. <u>Reportable Events</u>. Lochearn shall report to OIG in writing within 30 days after making a determination (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) that there is a Reportable Event, which shall mean anything that involves: (1) a substantial Overpayment, or (2) 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. In such report, Lochearn shall include the following information:
 - 1. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section II.B, 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;
 - 2. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
 - 3. a description of Lochearn's actions taken to correct the Reportable Event; and
 - 4. any further steps Lochearn plans to take to address the Reportable Event and prevent it from recurring.
- D. Notification of Government Investigation or Legal Proceedings. Within 30 days after discovery, Lochearn shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Lochearn conducted or brought by a governmental entity or its agents involving an allegation that Lochearn 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. Lochearn shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

- E. <u>Annual Reporting Requirements</u>. Lochearn shall submit to OIG annually a report that sets forth the following information for each Reporting Period (Annual Report):
 - 1. A description of any material amendments to its Compliance Program and the reasons for such changes;
 - 2. Any changes to the level of resources dedicated to its Compliance Program and the reasons for such changes;
 - 3. A summary of all internal or external reviews, audits, or analyses of its Compliance Program (including, at a minimum, the objective of the review, audit, or analysis; the protocol or methodology for the review, audit, or analysis; and the results of the review, audit, or analysis) and any corrective action plans developed in response to such reviews, audits, or analyses;
 - 4. 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: inpatient Medicare, outpatient Medicare, Medicaid (report each state separately, if applicable), 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; and
 - 5. A certification by the Compliance Officer that: (a) to the best of his or her knowledge, except as otherwise described in the Annual Report, Lochearn is in compliance with the requirements of this Section II; and (b) he or she has reviewed the Annual Report and has made reasonable inquiry regarding its content and believes that the information in the Annual Report is accurate and truthful.

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

F. <u>Notifications and Submission of Annual Reports</u>. Unless otherwise specified in writing after the Effective Date, all notifications and Annual Reports required under this CCA shall be submitted to the following addresses:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 2020
Telephone: 202-619-2078

Lochearn:

Lochearn Nursing and Rehabilitation Center Attn: Administrator 4800 Seton Drive Baltimore Maryland 21215-3210 Phone (410) 358-3410 Facsimile(410) 358-4938

Facsimile: 202-205-0604

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

G. OIG Inspection, Audit, and Review Rights. In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Lochearn's books, records, and other documents and supporting materials and/or conduct on-site reviews of Lochearn for the purpose of verifying and evaluating: (a) Lochearn's compliance with the terms of this CCA; and (b) Lochearn's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Lochearn to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Lochearn's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Lochearn shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's

request. Lochearn's employees may elect to be interviewed with or without a representative of Lochearn present.

H. <u>Document and Record Retention</u>. Lochearn shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CCA, for four years (or longer if otherwise required by law).

I. <u>Independent Monitor</u>

After consultation with Lochearn, the OIG has appointed Marie Boltz, RN, and Susan Renz, RN (hereinafter collectively referred to as the "Monitor") to monitor Lochearn's implementation of the CCA. The Monitor may retain additional personnel, including, but not limited to, independent consultants, if needed to help meet the Monitor's obligations under this CCA. Lochearn shall be responsible for all costs incurred by the Monitor, including, but not limited to, travel costs, consultants, administrative personnel, office space and equipment, or additional personnel. The Monitor shall charge a reasonable amount for his or her fees and expenses, which shall not exceed \$50,000 per year unless the OIG, after consultation with Lochearn, determines that circumstances necessitate additional expenditures. Failure to pay the Monitor within thirty (30) calendar days of submission of its invoices for services previously rendered shall constitute a breach of the CCA and shall subject Lochearn to one or more of the remedies set forth in Section VI 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 CCA, Lochearn shall retain another Monitor, after approval by the OIG, with the same functions and authorities. The Monitor may confer and correspond with Lochearn and OIG on an ex parte basis.

- 1. The Monitor shall be responsible for assessing the effectiveness, reliability and thoroughness of the following:
 - a. Lochearn's internal quality control systems, including, but not limited to:
 - (1) 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;
 - (2) 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

- (3) whether the training programs are effective and thorough;
- b. Lochearn's response to quality of care issues, which shall include an assessment of:
 - (1) Lochearn's ability to identify the problem;
 - (2) Lochearn's ability to determine the scope of the problem, including, but not limited to whether the problem is isolated or systemic;
 - (3) Lochearn's ability to create a corrective action plan to respond to the problem;
 - (4) Lochearn's ability to execute the corrective action plan; and
 - (5) Lochearn's ability to evaluate whether the assessment, corrective action plan, and execution of that plan was effective, reliable, and thorough;
- c. Lochearn's development and implementation of corrective action plans and the timeliness of such actions;
- d. Lochearn's proactive steps to ensure that each patient and resident receives care in accordance with:
 - (1) basic care, treatment and protection from harm standards;
 - (2) the rules and regulations set forth in 42 C.F.R. Parts 482 and 483;
 - (3) state and local statutes, regulations, and other directives or guidelines; and
 - (4) the policies and procedures adopted by Lochearn and set forth in this CCA.
- 2. The Monitor shall have:

- a. immediate access to the Facility, at any time and without prior notice, to assess compliance with this CCA, to assess the effectiveness of the internal quality assurance mechanisms, and to ensure that the data being generated is accurate;
- b. immediate access to: (1) the CMS quality indicators and quality measures; (2) internal or external surveys or reports; (3) hotline complaints; (4) resident satisfaction surveys; (5) staffing data in the format requested by the Monitor, including information as to whether more than ten (10) percent of the staff are hired on a temporary basis; (6) reports of abuse, neglect, or an incident that required hospitalization or emergency room treatment; (7) reports of any falls; (8) reports of any incident involving a patient or resident that prompts a full internal investigation; (9) patient or resident records; (10) documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, or other such committee; and (11) any other data in the format the Monitor determines relevant to fulfilling the duties required under this CCA; and
- c. immediate access to patients, residents, and staff for interviews outside the presence of Lochearn 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.
- 3. Lochearn's Obligations. Lochearn shall:
 - a. ensure the Monitor's immediate access to the Facility, individuals, and documents, and assist in obtaining full cooperation by its current employees, contractors and agents;
 - b. provide the Monitor a report monthly, or sooner if requested by the Monitor, regarding each of the following occurrences:
 - (1) Deaths or injuries related to use of restraints;
 - (2) Deaths or injuries related to use of psychotropic medications.
 - (3) Suicides;

- (4) Deaths or injuries related to abuse or neglect (as defined in the applicable Federal guidelines),
- (5) Fires, storm damage, flooding, or major equipment failures at the Facility;
- (6) Strikes or other work actions;
- (7) Manmade disasters that pose a threat to residents (e.g., toxic waste spills); and
- (8) Any other incident that involves or causes actual harm to a resident when such incident prompts a full internal investigation.

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

- c. assist in locating and, if requested, obtaining cooperation from past employees, contractors, agents, and residents, patients, and their families;
- d. provide access to current residents and patients, and contact information for their families and guardians, and not impede their cooperation with the Monitor;
- e. provide to its Quality Assurance Compliance Committee or its Board of Director's Quality Assurance Monitoring Committee copies of all documents and reports provided to the Monitor;
- f. if requested by the Monitor or the OIG, 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;
- g. 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;

- h. pay the Monitor's bills for Monitor's Costs within 30 days of receipt. While Lochearn must pay all the Monitor's bills within 30 days, Lochearn may bring any disputed Monitor's Costs or bills to OIG's attention; and
- i. 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 Lochearn 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.
- 4. The Monitor's Obligations. The Monitor shall:
 - a. respect the legal rights, privacy, and dignity of all Covered Persons, residents, and patients;
 - b. where independently required by applicable law or professional licensing standard, report any finding to an appropriate regulatory or law enforcement authority, simultaneously submit copies of such reports to the OIG and to Lochearn;
 - c. at all times act reasonably in connection with its duties under the CCA including when requesting information from Lochearn;
 - d. simultaneously provide quarterly reports to Lochearn and OIG concerning the findings made to date;
 - e. submit bills to Lochearn 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 Lochearn and to OIG. The Monitor shall submit to Lochearn and the OIG an annual report representing an accounting of its costs throughout the year;
 - f. 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 Lochearn, and Lochearn 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 Lochearn from using any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor in any action under the CCA or pursuant to any other OIG authorities or in any other situations not explicitly excluded in this subsection;

g. abide by the legal requirements to maintain the confidentiality of each resident's personal and clinical records. Nothing in this subsection, however, shall limit or affect the Monitor's obligation to provide information, including information from patient and resident clinical records, to the OIG, and, when legally or professionally required, reporting to other agencies;

h. except to the extent required by law, maintain the confidentiality of any proprietary financial and operational information, processes, procedures and forms obtained in connection with its duties under this CCA and not comment publicly concerning its findings except to the extent authorized by the OIG; and

i. visit Lochearn as often as the Monitor believes it necessary to perform its functions. Unless the Monitor, in his or her sole discretion, decides it is impractical to do so, the Monitor shall provide at least 24 hours notice to Lochearn prior to any such visit. In the event that the OIG determines that Lochearn has made satisfactory progress in implementing the CCA, the OIG may in its sole discretion reduce the frequency of the Monitor's visits.

III. Breach and Default Provisions

Lochearn is expected to fully and timely comply with all of the Integrity Requirements set forth in this CCA.

- A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, Lochearn and OIG hereby agree that failure to comply with the Integrity Requirements set forth in this CCA 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 Lochearn fails to establish and implement any of the following compliance program elements as described in Section II and the Declaration attached to this CCA as Appendix A:
 - a. a Compliance Officer;
 - b. a Compliance Committee;
 - c. a written Code of Conduct;
 - d. written Policies and Procedures;
 - e. the annual training of Covered Persons;
 - f. an internal audit/quality assurance function that performs periodic reviews to monitor Lochearn's compliance with Federal health care program requirements;
 - g. a Disclosure Program;
 - h. Ineligible Persons screening and removal requirements; and
 - i. notification of government investigations and legal proceedings.
- 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 Lochearn fails to submit the Annual Reports to OIG in accordance with the requirements of Section II.E by the stated deadlines for submission.
- 3. A Stipulated Penalty of \$1,500 for each day Lochearn fails to grant access to the information or documentation as required in Section II.G of this CCA. (This Stipulated Penalty shall begin to accrue on the date Lochearn fails to grant access.)

- 4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Lochearn as part of its Annual Reports or otherwise required by this CCA.
- 5. A Stipulated Penalty of \$1,000 for each day Lochearn fails to comply fully and adequately with any Integrity Requirements of this CCA. OIG shall provide notice to Lochearn, stating the specific grounds for its determination that Lochearn has failed to comply fully and adequately with the Integrity Requirement(s) at issue and steps Lochearn shall take to comply with the Integrity Requirements of this CCA. (This Stipulated Penalty shall begin to accrue 10 days after Lochearn receives notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section III.A.
- 6. A Stipulated Penalty of \$5,000 (which shall begin to accrue ten (10) days after the date OIG provides notice to Lochearn of the failure to comply) for each day Lochearn fails to comply fully and adequately with an obligation of this CCA that is widespread or systemic in nature or reflective of a pattern or practice. In its notice to Lochearn, the OIG shall state the specific grounds for its determination that the Lochearn has failed to comply fully and adequately with the CCA obligation(s) at issue.
- 7. A stipulated penalty of \$2,500 (which shall begin to accrue ten (10) days after the date OIG provides notice to Lochearn of the failure to comply) for each day Lochearn fails to comply fully and adequately with any of its obligation with respect to the Monitor, as set forth in section III.D.3. In its notice to Lochearn, the OIG shall state the specific grounds for its determination that the Lochearn has failed to comply fully and adequately with the CCA obligation(s) at issue.
- B. <u>Timely Written Requests for Extensions</u>. Lochearn 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 CCA. 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 Lochearn 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 Lochearn 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 Lochearn has failed to comply with any of the obligations described in Section III.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Lochearn of: (a) Lochearn's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").
- 2. Response to Demand Letter. Within 10 days after the receipt of the Demand Letter, Lochearn shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section III.E. In the event Lochearn elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Lochearn cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CCA and shall be grounds for exclusion under Section III.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 OIG at the address set forth in Section II.F.
- 4. Independence from Material Breach Determination. Except as set forth in Section III.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Lochearn has materially breached this CCA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section III.D, below.

D. Exclusion for Material Breach of this CCA.

- 1. Definition of Material Breach. A material breach of this CCA means:
 - a. a failure by Lochearn to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section II.C;
 - b. a repeated or flagrant violation of the obligations under this CCA, including, but not limited to, the obligations addressed in Section III.A;
 - c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section III.C;

- d. a failure to meet an obligation under the CCA that has a material impact on the quality of care rendered to any residents or patients of Lochearn; or
- e. a failure to retain, pay or use the Monitor in accordance with section III.I.
- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CCA by Lochearn constitutes an independent basis for Lochearn's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Lochearn has materially breached this CCA and that exclusion is the appropriate remedy, OIG shall notify Lochearn of: (a) Lochearn's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is referred to as the "Notice of Material Breach and Intent to Exclude").
- 3. Opportunity to Cure. Lochearn shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:
 - a. Lochearn is in compliance with the requirements of the CCA cited by 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 30-day period, but that: (i) Lochearn has begun to take action to cure the material breach; (ii) Lochearn is pursuing such action with due diligence; and (iii) Lochearn has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If, at the conclusion of the 30-day period, Lochearn fails to satisfy the requirements of Section III.D.3, OIG may exclude Lochearn from participation in the Federal health care programs. OIG shall notify Lochearn in writing of its determination to exclude Lochearn (this letter shall be referred to as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section III.E, below, the exclusion shall go into effect 30 days after the date of Lochearn's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Lochearn may apply for

reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution.

- 1. Review Rights. Upon OIG's delivery to Lochearn of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CCA, Lochearn 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 CCA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.
- 2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CCA shall be: (a) whether Lochearn was in full and timely compliance with the requirements of this CCA for which OIG demands payment; and (b) the period of noncompliance. Lochearn shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CCA and orders Lochearn to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Lochearn requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.
- 3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CCA shall be:
 - a. whether Lochearn was in material breach of this CCA;
 - b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Lochearn had begun to take action to cure the material breach within that period; (ii) Lochearn has pursued and is pursuing such action with due diligence; and (iii) Lochearn provided to OIG within that period a reasonable timetable for curing the material breach and Lochearn has followed the timetable.

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

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

IV. DISCLOSURES

Subject to 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 Lochearn prior to any release by OIG of information submitted by Lochearn pursuant to its obligations under this CCA and identified upon submission by Lochearn as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Lochearn shall refrain from identifying any information as trade secrets, commercial, or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

V. <u>EFFECTIVE AND BINDING AGREEMENT</u>

Lochearn and OIG agree as follows:

- A. This CCA shall be binding on the successors, assigns, and transferees of Lochearn;
- B. This CCA shall become final and binding on the date the final signature is obtained on the CCA;
- C. Any modifications to this CCA shall be made with the prior written consent of the parties to this CCA;
- D. OIG may agree to a suspension of Lochearn's obligations under this CCA in the event of Lochearn's cessation of participation in Federal health care programs. If Lochearn withdraws from participation in Federal health care programs and is relieved of its CCA obligations by OIG, Lochearn shall notify OIG at least 30 days in advance of Lochearn's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the CCA should be reactivated or modified.
- E. The undersigned Lochearn signatories represent and warrant that they are authorized to execute this CCA. The undersigned OIG signatory represents that he is signing this CCA in his official capacity and that he is authorized to execute this CCA.

ON BEHALF OF LOCHEARN NURSING HOME, LLC

Gary L. Attman, Managing Member

Lochearn Nursing Home, LLC

Ira L. Oring

Fedder and Garten Professional Association Counsel to Lochearn Nursing Home, LLC 7/28/06 DATE

8/4/06

DATE

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

Gregory E. Demske

Assistant Inspector General for Legal Affairs

Office of Inspector General

United States Department of Health and Human Services

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DECLARATION

The declarant is currently the Administrator for Lochearn and has personal knowledge of the facts stated herein. The following describes the compliance program currently in place at Lochearn.

- 1. Lochearn currently does not have its own compliance program, but rather relies upon, and participates in, the Compliance Program of its manager's affiliate ("Program"). Lochearn satisfies its obligations under the Certificate of Compliance Agreement ("CCA") either directly or through its manager's affiliate, as described below.
- 2. Lochearn, individually and through its manager's affiliate, will continue to devote appropriate resources to the operation of the Program for three years subsequent to the Effective Date of the CCA.
- 3. The Program includes the manager's affiliate's Compliance Officer, who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with Federal health care program requirements. The Compliance Officer, in coordination with the Local Compliance Liaison at Lochearn, is responsible for monitoring the day-to-day compliance activities of Lochearn. The Compliance Officer is a member of senior management of Lochearn's manager's affiliate and is not subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer makes periodic (at least quarterly) reports regarding compliance matters directly to the manager's affiliate's Governance Committee. The Compliance Officer and the Local Compliance Liaison at Lochearn are authorized to report on such matters to any Member of Lochearn, LLC at any time.
- 4. The Program includes the manager's affiliate's Compliance Committee that is chaired by the Compliance Officer and that is made up of other members of senior management necessary to support the Compliance Officer in fulfilling his/her responsibilities under the Program (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations).
- 5. The Program includes a Code of Conduct (termed a "Statement of Corporate Ethics") that includes: (a) Lochearn's commitment to full compliance with all Federal health care program requirements, including its commitment to prepare and submit accurate claims consistent with such requirements; (b) Lochearn's requirement that all of

its personnel are expected to comply with all Federal health care program requirements and with the Policies and Procedures described in Paragraph 6 below; (c) the requirement that all of Lochearn's personnel are expected to report to the Compliance Officer or other appropriate individual designated by Lochearn suspected violations of any Federal health care program requirements or of Lochearn's own Policies and Procedures; (d) the possible consequences to both Lochearn and its personnel of failure to comply with Federal health care program requirements and with Lochearn's own Policies and Procedures and the failure to report such noncompliance; and (e) the right of Lochearn's personnel to use the Disclosure Program described in Paragraph 9 below and Lochearn's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures. Each Covered Person, as that term is defined in the CCA, is required to certify in writing that he or she has received, read, understood, and will abide by the Code of Conduct.

- 6. The Program includes Policies and Procedures regarding the operation of the Program and Lochearn's compliance with Federal health care program requirements. The Policies and Procedures are made available to all relevant Lochearn personnel. At least annually (and more frequently, if appropriate), Lochearn reviews and updates as necessary its Policies and Procedures and, if revisions are made, makes available the relevant portions of any revised Policies and Procedures to all Lochearn personnel whose job functions relate to the revised Policies and Procedures.
- 7. The Program includes an annual training program that requires all Covered Persons to attend at least one hour of annual compliance training that addresses Lochearn's Code of Conduct and the operation of the Program. Lochearn's annual training program also requires additional hours of training as appropriate for all Covered Persons who are involved directly or indirectly in the delivery of patient or resident care (including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions) on behalf of Lochearn. Such additional training addresses, as appropriate and relevant to the Covered Person's position: (a) policies, procedures, and other requirements applicable to the documentation of medical records; and (b) the coordinated interdisciplinary approach to providing care to residents, including, but not limited to, resident assessment and care planning; nutrition; diabetes care; wound care; infection control; abuse and neglect policies and reporting procedures; appropriate drug therapies; appropriate mental health services; provision of basic care needs; incontinence care; resident rights and restraint use; ADL care; therapy services; quality of life, including accommodation of needs and activities; and assessment of the resident's competence to make treatment decisions. Lochearn maintains written or electronic records that identify the type of annual training provided, the date(s) of the

training, and the attendees. Persons providing the training are knowledgeable about the subject area. Lochearn reviews the training content on an annual basis and, as appropriate, updates the training to reflect changes in Federal health care program requirements and/or any issues discovered during the internal audits described in Paragraph 8 below. The training is also updated to address that quality of care issues identified by the Committee and the Compliance Committee. In determining what training should be performed, Lochearn and these Committees 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) or other such private agencies, any internal surveys, and the CMS quality indicators/quality measures.

- 8. The Program includes an internal audit/quality assurance function that performs periodic reviews to monitor Lochearn's compliance with Federal health care program requirements, including focused reviews relating to specific risk areas identified by the OIG and/or through the Program. The internal audits and reviews:
 - a. make findings of whether the patients and residents at Lochearn are receiving the quality of care and quality of life consistent with basic care, treatment, and protection from harm standards, including but not limited to, 42 C.F.R. Parts 482 and 483 and any other Federal and state statutes, regulations, and directives;
 - b. make findings of whether the policies and procedures described in the CCA and this Appendix are created, implemented, and enforced;
 - c. make findings of whether training is performed in accordance with the CCA and this Appendix;
 - d. make findings of whether hotline complaints are appropriately investigated;
 - e. make findings of whether the reporting obligations are complied with in accordance with this CCA; and
 - e. make findings of whether corrective action plans are timely created, implemented, and enforced.

Lochearn manager's affiliate has full-time qualified employees who are assigned to review Lochearn's compliance with Federal health care program requirements.

9. The Program includes a Disclosure Program that includes a mechanism to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Lochearn's policies, conduct, practices, or procedures with respect to a Federal health care program believed by the individual to be a potential violation of criminal, civil, or administrative law. Lochearn publicizes the existence of the disclosure mechanism to all personnel.

The Disclosure Program emphasizes a nonretribution, nonretaliation policy and includes a reporting mechanism for anonymous communications for which appropriate confidentiality is maintained. Each disclosure is reviewed by the Compliance Officer, who either investigates the disclosure or refers the disclosure to the relevant department or manager for follow up and any appropriate corrective action.

The Compliance Officer (or designee) maintains a disclosure log, which includes a record and summary of each disclosure received (whether anonymous or not), the status of Lochearn's internal review of the allegations, and any corrective action taken in response to the internal review.

10. The Program includes a policy and procedure for screening all prospective Lochearn, LLC Members, employees, contractors, and agents to ensure that they are not Ineligible Persons¹ by: (a) requiring such persons to disclose whether they are an Ineligible Person; 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 shall hereinafter be referred to as the "Exclusion Lists"). Lochearn also performs annual screening of its current Members, employees, contractors, and agents against the Exclusion Lists and requires all Members, employees, contractors, and agents to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

An "Ineligible Person" is an individual or entity who: (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or (ii) 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, debarred, suspended, or otherwise declared ineligible.

The Program also includes a policy that, if Lochearn has actual notice that one of its Members, employees, contractors, or agents has become an Ineligible Person, Lochearn will remove such person from responsibility for, or involvement with, Lochearn's business operations related to the Federal health care programs and will remove such person from any position for which the person's compensation or items or services furnished, ordered, or prescribed by the person are paid in whole or in 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. (Nothing in this Declaration affects the responsibility of Lochearn to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded individuals or Lochearn's liability for overpayments received by Lochearn as a result of billing any Federal health care program for such items or services.).

The undersigned signatory represents and warrants that he/she is authorized to execute this declaration on behalf of Lochearn.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 1st day of August, 2006.

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR			
Date:			i
Contractor Deposit Control # Contractor Contact Name:	Date of Deposit:		·
Contractor Contact Name:	Phone #		
Contractor Address:			_
Contractor Fax:			- ·
TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER			
Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.			
information about a society and	ancare Contractor. This form,	or a similar document	containing the jouowing
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5CHECK DATE			
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REFUND INFORMATION			
For each Claim, provide the follo			·
Patient Name	HI	C #	
Medicare Claim Number	Claim Amount Refunded	1\$	
Medicare Claim Number Reason Code for Claim Adjustment:	(Select reason code from list below.	Use one reason per claim)
(Please list <u>all</u> claim numbers involved. Attach separate sheet, if necessary)			
<u> </u>			
Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling,			
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overpayment:			
For Institutional Facilities Only:			
Cost Report Year(s)			•
Cost Report Year(s)(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)			
For OIG Reporting Requirements:			
Do you have a Corporate Integrity	A greement with OIC?	Vog No	·
	Agreement with Old?	Yes No	·
Reason Codes:			
Billing/Clerical Error MS	P/Other Payer Involvement	Miscellaneous	
01 - Corrected Date of Service 08 -	MSP Group Health Plan Insurance	13 - Insufficient Docume	ntation
09 - Duplicate	MSP No Fault Insurance	14 - Patient Enrolled in a	n HMO
03 - Corrected CPT Code 10 -	MSP Liability Insurance	15 - Services Not Render	red
11 - Not Our Patient(s)	MSP. Workers Comp.(Including	16 - Medical Necessity	
l05 - Modifier Added/Removed	Black Lung	17 - Other (Please Specif	y)
	Veterans Administration		
07 - Corrected CPT Code			• [