# CORPORATE INTEGRITY AGREEMENT
## BETWEEN THE
## OFFICE OF INSPECTOR GENERAL
## OF THE
## DEPARTMENT OF HEALTH AND HUMAN SERVICES
## AND
## MCLEOD REGIONAL MEDICAL CENTER OF THE PEE DEE, INC.

## I. PREAMBLE

McLeod Regional Medical Center of the Pee Dee, Inc. ("McLeod") 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 McLeod with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. §1320a-7b(f)) ("Federal health care program requirements"). Contemporaneously with this CIA, McLeod is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

## II. TERM AND SCOPE OF THE CIA

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

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (a) McLeod's final Annual Report; or (b) any additional materials submitted by McLeod pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "McLeod" shall mean: McLeod Regional Medical Center of the Pee Dee, Inc.; Saint Eugene Medical Center; Wilson Medical Center; McLeod Physician Services, Inc. d/b/a McLeod Physician Associates, Inc.; Pee Dee Ambulatory Surgery

Center d/b/a McLeod Ambulatory Surgery Center, Inc.; Home Health, Inc. d/b/a McLeod Home Health, Inc.; and McLeod Health Services, Inc.

2. "Covered Persons" shall mean:

a. McLeod's officers and employees, excluding child care employees, food service employees, housekeeping and laundry staff, maintenance employees, grounds keepers, and mailroom staff;

b. members of McLeod's Boards of Trustees; and

c. McLeod's contractors, agents, and third parties engaged to:

i. prepare or submit claims, reports, or other requests for reimbursement for items or services reimbursable by Federal health care programs;

ii. provide, market, or document items or services reimbursable by Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)), but excluding vendors whose sole connection with McLeod is selling medical supplies and equipment to McLeod; or

iii. perform any function that relates to or is covered by this CIA, except McLeod's outside legal counsel.

3. "Relevant Covered Persons" shall mean Covered Persons who are involved in either: (i) the provision of patient care items or services reimbursable by Federal health care programs as a health care professional; or (ii) the preparation or submission of claims, reports, or other requests for reimbursement from any Federal health care program.

## III. CORPORATE INTEGRITY OBLIGATIONS

McLeod warrants and represents that it currently operates and maintains a compliance program ("Compliance Program"). Pursuant to and for the duration of this CIA, McLeod shall maintain its current Compliance Program, and, as required below,

amend the Compliance Program to adhere to and include the following obligations or elements.

A. Corporate Compliance Officer and Compliance Committees.

1. *Corporate Compliance Officer.* For the duration of this CIA, McLeod shall continue to maintain an individual to serve as its Corporate Compliance Officer ("CCO"). At a minimum, the CCO shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The CCO shall be a member of senior management of McLeod, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Trustees of McLeod Regional Medical Center of the Pee Dee, Inc., and shall be authorized to report on such matters to this Board of Trustees at any time. The CCO shall be responsible for monitoring the day-to-day Compliance Program activities engaged in by McLeod as well as for any reporting obligations created under this CIA.

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

2. *Compliance Committees.* McLeod warrants and represents that it currently maintains the following committees as part of its Compliance Program: Executive Corporate Compliance Steering Committee ("Executive Compliance Committee"), Hospital Executive Compliance Committee, Home Health Division Executive Compliance Committee, and the McLeod Physician Services Executive Compliance Committee (collectively, "Compliance Committees"). With the exception of the Home Health Division Executive Compliance Committee, which meets quarterly, each of these committees meets monthly. For the duration of this CIA, McLeod shall continue to maintain all of the Compliance Committees, and all of the Compliance Committees shall continue to meet according to the current schedule. At a minimum, the Executive Compliance Committee shall include a member of the Board of Trustees, the CCO, and other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The CCO shall chair the Executive Compliance Committee, which shall support the Compliance Officer in fulfilling his/her responsibilities under the Compliance Program (e.g., shall assist in the analysis of the

organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

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

B. Written Standards.

1. *Policy on Business Practices.* For the duration of this CIA, McLeod shall continue to maintain its Policy on Business Practices, and to the extent necessary, shall amend the Policy on Business Practices within 120 days after the Effective Date to ensure that the Policy on Business Practices meets the requirements set forth below. The revised Policy on Business Practices shall be made available to all Covered Persons within 120 days after the Effective Date. McLeod shall make the promotion of, and adherence to, the Policy on Business Practices an element in evaluating the performance of all employees. The Policy on Business Practices shall, at a minimum, set forth:

a. McLeod'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. McLeod's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with McLeod's own Policies and Procedures as implemented pursuant to Section III.B.2 (including the requirements of this CIA);

c. the requirement that all of McLeod's Covered Persons shall be expected to report to the CCO or other appropriate individual designated by McLeod suspected violations of any Federal health care program requirements or of McLeod's own Policies and Procedures;

d. the possible consequences to both McLeod and Covered Persons of failure to comply with Federal health care program requirements

and with McLeod's own Policies and Procedures and the failure to report such noncompliance; and

e. the right of all individuals to use the Disclosure Program described in Section III.F, and McLeod's commitment to maintain confidentiality, as appropriate, and nonretaliation with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by McLeod's revised Policy on Business Practices. New Covered Persons shall receive the Policy on Business Practices and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

McLeod shall periodically review the Policy on Business Practices to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such Policy on Business Practices revisions shall be distributed within 30 days after finalizing such changes. Each Covered Person shall certify that he or she has received, read, understood, and shall abide by the revised Policy on Business Practices within 30 days after the distribution of such revisions.

2. *Policies and Procedures.* Within 120 days after the Effective Date, McLeod shall review, and where appropriate, revise or develop written policies and procedures regarding the operation of McLeod's Compliance Program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Policy on Business Practices identified in Section III.B.1;

b. the proper preparation and submission of cost reports to Medicare and Medicaid, including, but not limited to Federal and State requirements regarding unallowable costs and allowable costs;

c. the procedures for proper and timely refunding of any Overpayments (as defined in Section III.I.1.) received from a Federal health care program;

d. the commitment of McLeod to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, bulletins, newsletters, or other correspondence from McLeod's fiscal intermediary(ies) and carrier(s) related to Federal health care program requirements;

e. compliance with 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute") and 42 U.S.C. § 1395nn (the "Stark Law"), and the regulations and other guidance documents related to these statutes; and

f. the requirements set forth in Section III.D.

Within 120 days after the Effective Date, McLeod shall create and distribute a list of the relevant Policies and Procedures and a copy of those Policies and Procedures to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), McLeod shall assess and update as necessary the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant revised Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

1. *General Training*. Within 120 days after the Effective Date, McLeod shall provide at least two hours of General Training to each Covered Person. This General Training, at a minimum, shall explain McLeod's:

a. CIA requirements; and

b. McLeod's Compliance Program (including the Policy on Business Practices and the Policies and Procedures as they pertain to general compliance issues).

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date,

whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training annually.

2. *Documentation Training*. Within 120 days after the Effective Date, each Covered Person who is directly involved in the delivery of patient care items or services, but who is not a "Relevant Covered Person," shall receive two hours of Documentation Training in addition to the General Training required above. This Documentation Training shall include a discussion of:

a. policies, procedures, and other requirements applicable to the documentation of patient care items and services; and

b. the importance of accurate documentation in the billing and coding processes.

Persons providing the training must be knowledgeable about the subject area.

Covered Persons subject to this Section III.C.2 shall receive this training within 30 days of the beginning of their employment or becoming Covered Persons or within 120 days of the Effective Date, whichever is later. A McLeod employee who has completed the Documentation Training shall review a new Covered Person's work, to the extent that the work relates to the delivery of patient care items or services, until such time as the new Covered Person completes his/her applicable training.

After receiving the initial training described in this Section III.C.2, every Covered Person subject to this Section III.C.2 shall receive at least one hour of Documentation Training annually.

Training provided to Covered Persons within 60 days prior to the Effective Date that satisfies the requirement of this Section III.C.2 shall be deemed to meet the initial training requirements of this subsection.

3. *Specific Training*. Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least six hours of Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

a. the submission of accurate claims for services rendered to Federal health care program beneficiaries;

b. policies, procedures, and other requirements applicable to the documentation of medical records;

c. the proper and timely refunding of overpayments received from Federal health care programs;

d. the personal obligation of each individual involved in the claims preparation submission process to ensure that such claims are accurate;

e. applicable reimbursement statutes, regulations, and program requirements and directives;

f. the legal sanctions for submission of improper claims;

g. examples of proper and improper claims submission and billing practices;

h. the legal sanctions and consequences for improper contracting or financial arrangements;

i. examples of violations of the Anti-Kickback Statute and Stark Law; and

j. a review of McLeod's contracting Policies and Procedures related to contracts with potential referral sources or referral recipients as developed pursuant to Sections III.B.2 and III.D and the personal obligation of each individual involved in the development or maintenance of contract relationships to know applicable legal requirements and McLeod's Policies and Procedures.

Persons providing the training shall be knowledgeable about the subject area.

Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120

days after the Effective Date, whichever is later. A McLeod employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her applicable training.

After receiving the initial training described in this Section, in subsequent years, each Relevant Covered Person shall receive at least three hours of Specific Training annually. McLeod shall annually review the Specific Training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or IRO audits, and any other relevant information.

Training provided to Relevant Covered Persons within 60 days prior to the Effective Date that satisfies the requirement of this Section III.C.3 shall be deemed to meet the initial training requirements of this subsection.

4. *Cost Report Training.* Within 120 days after the Effective Date, each Relevant Covered Person who is directly involved in the preparation and submission of cost reports to Federal health care programs shall receive at least two hours of Cost Report Training, in addition to the General and Specific Training required above. This cost report training shall include:

a. the submission of proper and accurate cost reports to Federal health care programs;

b. the personal obligation of each individual involved in the cost reporting, billing, or refunding/reconciliation process to ensure that such cost reports, billings, or refunds are accurate;

c. the legal sanctions for submission of improper cost reports; and

d. examples of proper and improper cost reporting practices.

Persons providing the training shall be knowledgeable about the subject area.

Relevant Covered Persons who are required to receive the Cost Report Training shall receive this training within 30 days after the beginning of their employment or

becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A McLeod employee who has completed the Cost Report Training shall review a new Relevant Covered Person's work, to the extent that the work relates to the preparation and submission of cost reports to Federal health care programs, until such time as the new Relevant Covered Person completes his or her applicable training.

After receiving the initial training described in this Section, in subsequent years, each Relevant Covered Person who is required to receive the Cost Report Training shall receive at least one hour of Cost Report Training annually. McLeod shall annually review the Cost Report Training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or IRO audits, and any other relevant information.

Training provided to Relevant Covered Persons within 60 days prior to the Effective Date that satisfies the requirement of this Section III.C.4 shall be deemed to meet the initial training requirements of this subsection.

5. *Exception for Certain Physicians.* The following shall constitute McLeod's obligations under this Section III.C with respect to physicians who have staff privileges at McLeod and with whom McLeod does not have an employment or contractual relationship ("Excepted Physicians"). McLeod shall make the General Training and the Specific Training of Sections III.C.1 and 3 available to Excepted Physicians and shall use its best efforts to encourage their attendance and participation at such training. Each Excepted Physician who attends training shall certify, in writing, that he or she has received the training. The certification shall specify the type of training received and the date received. The Compliance Officer (or his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

The Compliance Officer shall also maintain records of the number of Excepted Physicians, the percentage of all Excepted Physicians who attend the General and Specific training, and the efforts utilized to encourage their attendance and participation, and shall provide such records to OIG as part of its Implementation and Annual Reports.

After evaluating the records provided by McLeod regarding the Excepted Physicians, OIG may, at its sole discretion, and at any point during the term of this CIA, terminate the exception provided by this Section III.C.5.

6. *Certification.* Each individual who is required to attend training shall certify, in writing, that he or she has received the required training. The certification shall specify the type of training received and the date received. The CCO (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Contractual Compliance with the Anti-Kickback Statute and the Stark Law.

This Section shall apply to every arrangement or transaction that:

(1) (a) involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; and (b) is between McLeod and any actual or potential source of health care business or referrals to McLeod or any actual or potential recipient of health care business or referrals from McLeod. The term "source" shall mean any physician, contractor, vendor, or agent and the term "health care business or referrals" shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing of any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program; or

(2) is between McLeod and a physician (or a physician's immediate family member (as defined at 42 C.F.R. § 411.351)) who makes a referral (as defined at 42 U.S.C. § 1395nn(h)(5)) to McLeod for designated health services (as defined at 42 U.S.C. § 1395nn(h)(6)),

The arrangements and transactions described above, and the written versions thereof, are collectively referred to as "Arrangements." The party(ies) to an Arrangement other than McLeod shall be referred to herein as a "contractor."

Within 120 days after the Effective Date, McLeod shall create procedures reasonably designed to ensure that each Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law, and shall implement procedures to evaluate all existing Arrangements, to the extent not already so evaluated, to determine whether such Arrangements violate the Anti-Kickback Statute and/or the Stark Law. McLeod shall summarize all Arrangements in the form provided at Appendix C. McLeod shall update the summary at Appendix C annually and shall submit the summary with each Annual Report.

Prior to entering into new Arrangements or renewing existing Arrangements, McLeod shall ensure that all Arrangements are in compliance with the Anti-Kickback Statute and Stark Law, and the regulations, directives, and guidance related to these statutes, and comply with the following requirements:

1. The Arrangement shall be set forth in writing and signed by McLeod and the contractor(s);

2. The Arrangement shall include a provision that all individuals who meet the definition of Covered Persons shall comply with McLeod's Compliance Program, including the training related to the Anti-Kickback Statute and the Stark Law. Additionally, McLeod shall provide each contractor with a copy of its Policy on Business Practices and Stark and Anti-Kickback Policies and Procedures;

3. McLeod shall certify and shall require the contractor(s) to certify, at the time of signing the Arrangement and upon contract renewal, that the Arrangement is not intended to generate referrals for services or supplies for which payment may be made in whole or in part under any Federal health care program; and

4. McLeod shall require the contractor(s) to certify, at the time of signing the Arrangement, that the contractor(s) shall comply with McLeod's compliance program and with the Anti-Kickback Statute and the Stark Law.

McLeod shall retain and make available to OIG, upon request, copies of all Arrangements subject to this Section and, to the extent available, all non-privileged communications related to the Arrangements and the actual performance of the duties under the Arrangements. Nothing in this CIA, or any other communication or report made pursuant to this CIA, shall constitute a waiver by McLeod of its attorney-client, attorney work-product, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by McLeod to avoid its obligations to comply with the provisions of this CIA.

E. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 120 days after the Effective Date, McLeod shall retain an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist McLeod in assessing and evaluating its cost reporting practices and certain other obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by McLeod shall have expertise in the cost 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 McLeod seeks reimbursement. Each IRO shall assess, along with McLeod, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or engagements that may exist. The IRO(s) review shall analyze whether McLeod sought payment for certain unallowable costs ("Unallowable Cost Review") and shall conduct a review of McLeod's cost reporting to the Medicare program ("Cost Reporting Engagement").

b. Frequency of Unallowable Cost Review. The IRO shall perform the Unallowable Cost Review for the first Reporting Period.

c. Frequency of Cost Reporting Engagement. The Cost Reporting Engagement shall be performed annually and shall cover each of the one-year Reporting Periods. The IRO(s) shall perform all components of each annual Cost Reporting Engagement.

d. Retention of Records. The IRO and McLeod shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and McLeod) related to the reviews.

2. *Unallowable Cost Review.* The IRO shall conduct a review of McLeod's compliance with the unallowable cost provisions of the Settlement Agreement.

The IRO shall determine whether McLeod 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 McLeod or any of its subsidiaries. To the extent that such cost reports, cost statements, information reports, or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO shall determine if such adjustments were proper. 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.

3. *Unallowable Cost Review Report.* 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 Cost Review and whether McLeod 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.

*4. Cost Reporting Engagement.* McLeod represents that it has already retained an IRO with expertise in cost reporting and that the preparation of all current and future cost reports will be performed by the IRO. The IRO has assumed the responsibility for every entry on the Medicare cost report, subject to the reliability of McLeod's underlying financial records and subject to McLeod's responsibility for all required cost report certifications. McLeod represents that the IRO has a familiarity with McLeod and its personnel and has unrestricted access to all of the relevant documents and records. While the IRO may seek occasional assistance from McLeod's finance staff, the IRO performs the entire cost reporting function independently. To the extent that the IRO is not already performing the following functions in the course of preparing and submitting McLeod's cost reports, the IRO shall perform a Cost Reporting Engagement, which includes the Cost Report Systems Review and Cost Report Review.

If during the course of this CIA, McLeod contracts with a different IRO or begins to prepare and submit its own cost reports, McLeod shall notify the OIG in writing of this fact within 30 days. If McLeod begins to prepare and submit its own cost reports,

McLeod is still required to obtain an IRO to perform the procedures described in Section III.E.4.

The Cost Reporting Engagement shall consist of the following:

a. Cost Report Systems Review. The IRO shall conduct a review of McLeod's cost report preparation and submission process ("Cost Report Systems Review"). The Cost Report Systems Review shall consist of a thorough review of McLeod's cost report, cost statement, information statement, and payment request preparation processes relating to any and all costs submitted to Federal health care programs (including, but not limited to, the steps McLeod takes to ensure that the proper information is being recorded on submissions to Federal health care programs and safeguards to ensure that only proper costs and dollar amounts are being submitted for reimbursement to such programs); and

b. Cost Report Review. In addition to the Cost Report Systems Review described above, the IRO shall also perform a review that, at a minimum includes the procedures outlined in Appendix A ("Cost Report Review").

*5. Cost Reporting Engagement Report.* The IRO shall prepare a report based upon the Cost Reporting Engagement. The Cost Reporting Engagement Report shall include the IRO's findings and supporting rationale regarding:

a. the strengths and weaknesses in McLeod's cost report, cost statement, information statement, and payment request preparation processes relating to any and all costs submitted to Federal health care programs;

b. any recommendations the IRO may have to improve any of these systems, operations, and processes; and

c. a summary of the conclusions from the Cost Report Review.

6. *Validation Review.* In the event OIG has reason to believe that: (a) McLeod's Unallowable Cost Review or Cost Reporting Engagement fails to conform to the requirements of this CIA; or (b) the IRO's findings or results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Unallowable Cost Review or Cost Reporting Engagement complied with the requirements of the CIA and/or the findings or results are inaccurate ("Validation Review"). McLeod shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents so long as it is initiated within one year after McLeod's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify McLeod of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, McLeod may request a meeting with OIG to discuss the results of the Unallowable Cost Review or Cost Reporting Engagement submissions or findings; present any additional or relevant information to clarify the results of the Unallowable Cost Review or Cost Reporting Engagement; or propose alternatives to the proposed Validation Review. McLeod shall provide any additional information as may be requested by OIG under this Section in an expedited manner. OIG will attempt in good faith to resolve any Unallowable Cost Review or Cost Reporting Engagement issues with McLeod 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 OIG.

7. *Independence Certification.* The IRO shall include in its report(s) to McLeod a certification or sworn affidavit that it has evaluated its professional independence with regard to the Unallowable Cost Review or Cost Reporting Engagement and that it have concluded that it is, in fact, independent.

F. Disclosure Program.

For the duration of this CIA, McLeod shall continue to maintain its Disclosure Program, which shall include a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the CCO or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with McLeod'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. McLeod shall appropriately publicize the existence of the disclosure

mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the CCO (or designee) shall gather all relevant information from the disclosing individual. The CCO (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, McLeod shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The CCO (or designee) 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 reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request.

G. Ineligible Persons.

1. *Definition*. For purposes of this CIA, an "Ineligible Person" shall be an individual or entity who: (a) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement 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, debarred, suspended, or otherwise declared ineligible.

2. *Screening Requirements*. McLeod shall not hire as employees, engage as contractors, or grant clinical privileges to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, McLeod shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting clinical 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 shall hereinafter be referred to as the

"Exclusion Lists"). Nothing in this Section affects the responsibility of (or liability for) McLeod to refrain from billing Federal health care programs for services of the Ineligible Person.

3. *Review and Removal Requirement.* Within 120 days after the Effective Date, McLeod shall review its list of current employees, contractors, and physicians with clinical privileges against the Exclusion Lists, unless such review has been conducted within the 60-day period immediately preceding the Effective Date. Thereafter, McLeod shall review its list of current employees, contractors, and physicians with clinical privileges against the Exclusion Lists annually. In addition, McLeod shall require employees, contractors ,and physicians with clinical privileges to disclose immediately any debarment, exclusion, or other event that makes the employee, contractor, or a physician with clinical privileges an Ineligible Person.

If McLeod has actual notice that an employee, contractor, or physician with clinical privileges has become an Ineligible Person, McLeod shall remove such person from responsibility for, or involvement with, McLeod's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation 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 McLeod has actual notice that an employee, contractor, or a physician with clinical privileges is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment, contract term, or, in the case of a physician, during the term of the physician's medical staff membership, McLeod shall take all appropriate actions to ensure that the responsibilities of that employee, contractor, or physician with clinical privileges have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, McLeod shall notify OIG, in writing, of any ongoing investigation known to McLeod or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that McLeod 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. McLeod 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 proceedings, if any.

I. Reporting.

1. *Overpayments.*

a. Definition of Overpayments. For purposes of this CIA, an "Overpayment" shall mean the amount of money McLeod has received in excess of the amount due and payable under any Federal health care program requirements.

b. Reporting of Overpayments. If, at any time, McLeod identifies or learns of any Overpayment, McLeod 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, McLeod 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, McLeod 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 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 McLeod determines through any means that there is a Material Deficiency, McLeod shall notify OIG, in writing, within 30 days after making the determination that the Material Deficiency exists. The report to OIG shall include the following information:

i. If the Material Deficiency results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.I.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 McLeod's actions taken to correct the Material Deficiency; and

iv. any further steps McLeod plans to take to address the Material Deficiency and prevent it from recurring.

J. Temporary Staff Requirements.

"Temporary Staff" includes any staff retained to work at McLeod on a contractual basis or otherwise for 160 hours or less out of any consecutive 52-week period during the term of this CIA. Temporary staff who work greater than 160 hours are required to fulfill all obligations required of Covered Persons. Within 5 business days of commencing work for McLeod, McLeod shall obtain written documentation from its Temporary Staff showing:

1. *Policy on Business Practices*. That the Temporary Staff has received and read McLeod's Policy on Business Practices and that the Temporary Staff understands that McLeod's Policy on Business Practices applies to the Temporary Staff.

2. *Policies and Procedures*. That the Temporary Staff has received and read all of McLeod's Policies and Procedures, if any, applicable to the job functions for which the Temporary Staff has been engaged.

3. *Disclosure Program*. That the Temporary Staff has received notice of, and education on, the appropriate use of the Disclosure Program.

4. *General and Specific Training*. That the Temporary Staff has received appropriate training for the services for which the Temporary Staff has been engaged by McLeod. Except as provided in this Section, Temporary Staff are not required to receive either General or Specific Training required by this CIA, provided McLeod obtains and maintains all documentation evidencing compliance with this Section III.J.

## IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, McLeod changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, McLeod shall notify OIG of this fact as soon as possible, but no later than within 30 days after the

date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare provider number (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at each such business unit or location shall be subject to the applicable requirements in this CIA (e.g., completing certifications and undergoing training).

## V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date, McLeod shall submit a written report to 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 the CCO required by Section III.A, and a summary of other noncompliance job responsibilities the CCO may have;

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

3. a copy of McLeod's Policy on Business Practices required by Section III.B.1;

4. a copy of all Policies and Procedures required by Sections III.B.2 and III.D;

5. a summary of all training materials (with examples) used for the training required by Section III.C, a description of such training, which may include a topic outline, 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;

6. a certification by the CCO that:

   a. the Policies and Procedures required by Section III.B have been developed, are being implemented, and have been made available to all appropriate Covered Persons;

b. all Covered Persons have completed the Policy on Business Practices certification required by Section III.B.1; and

c. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C.

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

7. a description of the Disclosure Program required by Section III.F;

8. the identity of the IRO(s), a summary/description of all engagements between McLeod and the IRO, including, but not limited to, any outside financial audits, reimbursement, or legal consulting, and the proposed start and completion dates of the Unallowable Cost Review and Cost Reporting Engagement;

9. certifications from the IRO(s) regarding its professional independence from McLeod;

10. a summary of personnel actions (other than hiring) taken pursuant to Section III.G;

11. a list of all of McLeod's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s), and the name and address of the Medicare contractor(s) to which McLeod currently submits claims;

12. the information required by Section III.D, in the form provided at Appendix C;

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

14. the certification required by Section V.C.

B. Annual Reports. McLeod shall submit to OIG Annual Reports with respect to the status of, and findings regarding, McLeod's compliance activities for each of the five Reporting Periods.

Each Annual Report shall include:

1. any change in the identity, position description, or other noncompliance job responsibilities of the CCO and any change in the membership of the Compliance Committees described in Section III.A;

2. a certification by the CCO that:

a. all Covered Persons have completed any Policy on Business Practices certifications required by Section III.B.1;

b. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C; and

c. McLeod 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 the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs.

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

3. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and III.D and the reasons for such changes (e.g., change in contractor policy) and copies of revised Policies and Procedures;

4. a summary of all training materials (with examples) used for the training required by Section III.C (to the extent it has not already been provided as part of the Implementation Report), a description of such training conducted

during the Reporting Period, which may include a topic outline, 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;

5. a complete copy of all reports prepared pursuant to the IRO(s)' Unallowable Costs Review and Cost Reporting Engagement, including a copy of the methodology used, along with a copy of the IRO engagement letters;

6. McLeod's response and corrective action plan(s) related to any issues raised by the IRO(s);

7. a revised summary/description of all engagements between McLeod and the IRO(s), including, but not limited to, any outside financial audits, compliance program engagements, reimbursement or legal consulting, if different from what was submitted as part of the Implementation Report;

8. certifications from the IRO(s) regarding its professional independence from McLeod;

9. a summary of Material Deficiencies (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

10. 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 applicable 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;

11. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

12. a description of any personnel actions (other than hiring) taken by McLeod as a result of the obligations in Section III.G, and the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.G, and the actions taken in response to the obligations set forth in that Section;

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

14. a description of all changes to the most recently provided list (as updated) of McLeod's locations (including addresses) as required by Section V.A.11, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s), and the contractor name and address that issued each Medicare provider number;

15. the updated information required by Section III.D, in the form provided at Appendix C;

16. the certification required by Section V.C; and

17. the certification required by Section X.

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

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

D. Designation of Information. McLeod 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. McLeod shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:
Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, D.C. 20201
Phone: 202.619.2078
Fax: 202.205.0604

McLeod:
F. Preston Wilson
Corporate Compliance Officer
McLeod Regional Medical Center
555 East Cheves Street
Florence, South Carolina 29506
Phone: 843-777-8097
Fax: 843-662-4208

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 OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of McLeod's books, records, and other documents and supporting materials and/or conduct on-site

reviews of any of McLeod's locations for the purpose of verifying and evaluating: (a) McLeod's compliance with the terms of this CIA; and (b) McLeod's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by McLeod 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 McLeod'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. McLeod shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. McLeod's employees may elect to be interviewed with or without a representative of McLeod present.

## VIII. DOCUMENT AND RECORD RETENTION

McLeod 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

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify McLeod prior to any release by OIG of information submitted by McLeod pursuant to its obligations under this CIA and identified upon submission by McLeod as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, McLeod shall have the rights set forth at 45 C.F.R. § 5.65(d).

## X. BREACH AND DEFAULT PROVISIONS

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

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, McLeod and 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 McLeod fails to have in place any of the obligations described in Section III:

a. a CCO;

b. a Compliance Committee;

c. a written Policy on Business Practices;

d. written Policies and Procedures;

e. a requirement that Covered Persons be trained; and

f. 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 McLeod fails to retain an IRO, as required in Section III.E.

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 McLeod fails to meet any of the deadlines for the submission of 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 McLeod employs, contracts with, or grants clinical privileges to an Ineligible Person and that person: (a) has responsibility for, or involvement with, McLeod's business operations related to the Federal health care programs; or (b) 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. If the Ineligible Person is a physician with clinical privileges at McLeod, then the Stipulated Penalty shall accrue for each day that the Ineligible Person provided, ordered, or prescribed any items or services at McLeod that were payable in whole or in part by any Federal health care program (the Stipulated Penalty described in this Subsection shall not be demanded for any time period during which McLeod 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 for each day McLeod fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date McLeod fails to grant access.)

6. A Stipulated Penalty of $1,000 for each day McLeod fails to comply fully and adequately with any obligation of this CIA. In its notice to McLeod, OIG shall state the specific grounds for its determination that McLeod has failed to comply fully and adequately with the CIA obligation(s) at issue and steps McLeod shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after McLeod 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 1-5 of this Section.

B. Timely Written Requests for Extensions. McLeod 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 McLeod 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 McLeod 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 McLeod has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify McLeod of: (a) McLeod's failure to comply; and (b) 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 10 days after the receipt of the Demand Letter, McLeod shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative

law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event McLeod elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until McLeod cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by 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 VI.

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

D. Exclusion for Material Breach of this CIA.

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

a. a failure by McLeod to report a Material Deficiency, take corrective action, and make the appropriate refunds, as required in Section III.I;

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

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

d. a failure to retain and use an IRO in accordance with Section III.E.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by McLeod constitutes an independent basis for McLeod's

exclusion from participation in the Federal health care programs. Upon a determination by OIG that McLeod has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify McLeod of: (a) McLeod's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* McLeod 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. McLeod is in compliance with the obligations of the CIA 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) McLeod has begun to take action to cure the material breach; (ii) McLeod is pursuing such action with due diligence; and (iii) McLeod has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, McLeod fails to satisfy the requirements of Section X.D.3, OIG may exclude McLeod from participation in the Federal health care programs. OIG shall notify McLeod in writing of its determination to exclude McLeod (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 shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. If, at the end of the period of exclusion, McLeod wishes to apply for reinstatement, McLeod shall submit 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 McLeod of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, McLeod shall be afforded certain review rights

comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

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 McLeod was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. McLeod shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders McLeod to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless McLeod 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 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 McLeod was in material breach of this CIA;

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) McLeod had begun to take action to cure the material breach within that period; (ii) McLeod has pursued and is pursuing such action with due diligence; and (iii)

McLeod provided to OIG within that period a reasonable timetable for curing the material breach and McLeod 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 McLeod, only after a DAB decision in favor of OIG. McLeod's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude McLeod 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 McLeod 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. McLeod 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 McLeod, McLeod shall be reinstated effective on the date of the original exclusion.

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

## XI. EFFECTIVE AND BINDING AGREEMENT

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

A. This CIA shall be binding on the successors, assigns, and transferees of McLeod;

B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA;

D. OIG may agree to a suspension of McLeod's obligations under the CIA in the event of McLeod's cessation of participation in Federal health care programs. If McLeod withdraws from participation in Federal health care programs and is relieved of its CIA obligations by OIG, McLeod shall notify OIG at least 30 days in advance of McLeod's intent to reapply as a participating provider or supplier with the Federal health care programs. Upon receipt of such notification, OIG shall evaluate whether the CIA should be reactivated or modified.

E. The undersigned McLeod signatories represent and warrant that they are 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 MCLEOD REGIONAL MEDICAL CENTER OF THE PEE DEE, INC.**

ROB COLONES
CEO for McLeod

Oct 31, 2002
DATE

WILLIAM R. MITCHELSON, JR.
Counsel for McLeod

Oct. 31, 2002
DATE

F. PRESTON WILSON
McLeod Corporate Compliance Officer

DATE

**ON BEHALF OF MCLEOD REGIONAL MEDICAL CENTER OF THE PEE DEE, INC.**

ROB COLONES
CEO for McLeod

DATE

WILLIAM R. MITCHELSON, JR.
Counsel for McLeod

October 31, 2002
DATE

F. PRESTON WILSON
McLeod Corporate Compliance Officer

10-31-02
DATE

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

LEWIS MORRIS
Chief Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

10/31/02
DATE

## APPENDIX A
## Cost Reporting Engagement Review Procedures

The following procedures represent the minimum expectations for performance by the IRO in meeting the objectives of Section III.E.4.b.

1. Test the accuracy of column 3, Worksheet A on McLeod's cost report, by tracing each cost center's total to McLeod's working trial balance.

2. Select a minimum of three cost centers and trace the accounts included in the cost center to McLeod's general ledger.

3. Review capital cost centers for any items that appear to be unallowable (e.g., building amortization, goodwill amortization, etc.). If such items exist, follow up with McLeod to obtain explanations.

4. Review Worksheet A-6, A-8, B-1, and any other necessary Worksheets to ensure that McLeod is properly incorporating the Medicare fiscal intermediary adjustments in the preparation of its cost reports.

5. Review Worksheet B-1 to ensure that McLeod has properly included allocation statistics for non-allowable cost centers.

6. The IRO shall perform a comparison analysis of the current year's cost report to the prior year's cost report for each of the following items:

   a. Compare Worksheet A expenses by cost centers. For increases or decreases of 25% or greater, follow up with McLeod to obtain an explanation.

   b. To ensure consistency of cost classifications, compare account groupings by cost center. If costs have been grouped inconsistently follow up with McLeod as to the reason for the inconsistency and verify that the fiscal intermediary has approved such changes in grouping.

   c. Compare the accounts included in the Administrative and General ("A&G") cost center. Perform detailed testing on accounts included in the A&G cost center that may be highly susceptible to abuse or misallocation of costs (e.g., recruiting, marketing, physician-related costs, relocation costs, etc.).

   d. Compare Worksheet A-6 cost reclassifications

   e. Compare Worksheet A-8 cost adjustments.

f. Compare the cost to charge ratios by cost center on Worksheet C. For increases or decreases of 25% or greater, follow up with McLeod to obtain explanations.

g. Compare the allocation statistics on Worksheet B-1 of the cost report. For increases or decreases of 25% of greater, follow up with McLeod to obtain explanations.

APPENDIX B

# OVERPAYMENT REFUND

## TO BE COMPLETED BY MEDICARE CONTRACTOR

Date:_____
Contractor Deposit Control #_____ 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.*

PROVIDER/PHYSICIAN/SUPPLIER NAME_____
ADDRESS_____
PROVIDER/PHYSICIAN/SUPPLIER #_____
CHECK NUMBER#_____
CONTACT PERSON:_____
PHONE #_____ AMOUNT OF CHECK $_____
CHECK DATE_____

## REFUND INFORMATION

**For each Claim, provide the following:**

Patient Name_____
HIC #_____
Medicare Claim Number_____
Claim Amount Refunded $_____
Reason Code for Claim Adjustment:_____ (Select reason code from list below. Use one reason per claim)

***(Please list all claim numbers involved. Attach separate sheet, if necessary)***

*Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment:*_____

**For Institutional Facilities Only:**

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 Agreement with OIG? _____ Yes _____ No

**Reason Codes:**

Billing/Clerical Error
01 - Corrected Date of Service
Documentation
02 - Duplicate
HMO
03 - Corrected CPT Code
04 - Not Our Patient(s)
05 - Modifier Added/Removed
06 - Billed in Error
07 - Corrected CPT Code

MSP/Other Payer Involvement
08 - MSP Group Health Plan Insurance
09 - MSP No Fault Insurance
10 - MSP Liability Insurance
11 - MSP, Workers Comp.(Including Black Lung
12 - Veterans Administration

Miscellaneous
13 - Insufficient
14 - Patient Enrolled in an
15 - Services Not Rendered
16 - Medical Necessity
17 - Other (Please Specify)
_____

# APPENDIX C

## CONTRACTS WITH REFERRAL SOURCES AND REFERRAL RECIPIENTS

| Parties | Relationship(s) between the parties | Term (start & expiration dates (incl. automatic renewal provisions)) | Description (including contract type (e.g., lease), subject of contract/ type of services or supplies, etc) | Payment Methodology | How was fair market value evaluated? | If applicable (e.g., contract involves designated health services), does a Safe Harbor or Stark Law exception apply? |
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