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 ("Agreement") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by McLeod's Emergency Department ("ED"), with Federal Program Requirements. This Agreement shall further serve to promote compliance with Federal Program Requirements by: Physicians, the Allied Health Professionals; and Third Party Billers. Contemporaneously with this CIA, McLeod is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into that Settlement Agreement.

McLeod represents that it has established a compliance program (the "Compliance Program") for its overall operations. McLeod confirms that the billing practices of the ED and of the Physicians are included in the Compliance Program.

Pursuant to this CIA, McLeod agrees to operate the Compliance Program in a manner consistent with the requirements of this CIA and to adopt or modify any components of the Compliance Program in order to be in compliance with all of the corporate integrity obligations under this CIA.

B. Definitions

1. The term "Allied Health Professionals" shall mean any employed or independent contractor nurse practitioner or physician's assistant engaged by McLeod to provide professional services in the ED.

2. The term "Compliance Contact" shall mean the Compliance Office of McLeod Regional Medical Center.

3. The term "Covered Persons" shall mean the Physicians, the Allied Health Professionals, and any Third Party Biller.

4. The term "Emergency Department" or "ED" shall mean the Department of Emergency Medicine of McLeod Regional Medical Center, Florence, South Carolina.

5. The term "Federal Programs" shall mean Medicare, Medicaid and all other federal health care programs as defined by 42 U.S.C. § 1320a-7b(f).

6. The term "Federal Program Requirements" shall mean the statutes, regulations and written directives of the Federal Programs, as defined in 42 U.S.C. § 1320a-7b(f), "Federal health care program requirements."

7. The term "Physicians" shall mean any employed or independent contractor physician granted privileges by McLeod Regional Medical Center to provide emergency physician services in the Emergency Department: provided, however, such definition shall not include any physician on call to the Emergency Department for specialized physician services.

8. The term "Third Party Biller" shall mean those persons or entities employed by or engaged by either McLeod or McLeod Health Services, Inc. (MHSI), to perform billing, registration, coding or claim preparation for services in the ED performed by the Physicians or the Allied Health Professionals and submitted for payment or reimbursement to a Federal Program.

II. TERM OF THE CORPORATE INTEGRITY AGREEMENT

The period of the compliance obligations assumed by McLeod under this CIA shall be three years from the Effective Date of this CIA (unless otherwise specified). The Effective Date of this CIA shall be the date on which the final signatory of this CIA executes this CIA.

Sections VII, VIII, IX, X and XI shall remain in effect until OIG has completed its review of the final Annual Report and any additional materials submitted by McLeod pursuant to OIG's request.

III. INTEGRITY OBLIGATIONS

McLeod hereby agrees to maintain the Compliance Program such that it includes the following elements:

A. Compliance Contact

McLeod represents that it has appointed a Compliance Officer, who will serve as the Compliance Contact under this CIA. At all times during the term of this CIA, there shall be a Compliance Contact who shall have operational responsibility for ensuring McLeod's compliance with the obligations of this CIA. The Compliance Contact shall also be responsible for any reporting obligations created under this CIA. Any changes in the identity or position description of the Compliance Contact, or any actions or changes that would affect the Compliance Contact's ability to perform the duties necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 10 days of such a change.

B. Notice of Compliance

Within 15 days of the Effective Date of this CIA, McLeod shall post in a prominent place accessible to all Covered Persons a notice detailing McLeod's commitment to comply with the Federal Program Requirements in the conduct of the ED's medical practice and in seeking reimbursement from the Federal Programs for services and items furnished by the Physicians and the Allied Health Professionals to patients of the Federal Programs (the "Notice of Compliance"). The Notice of Compliance shall identify a means (i.e., telephone number, address, etc.) through which

matters of concern can be reported anonymously. Within 30 days of the Effective Date of this CIA, McLeod shall distribute a copy of the Notice of Compliance to each Covered Person.

C. Written Policies and Procedures

McLeod agrees to compile, develop as necessary, and implement in the ED written Policies and Procedures within 60 days of the Effective Date of this CIA. The written Policies and Procedures shall address the following:

1. McLeod's commitment to adhere to honest and accurate billing practices;

2. The proper submission of claims to the Federal Programs, including verification that all claims meet applicable reimbursement standards;

3. The proper documentation of services provided and other billing information as required for the submission of complete and accurate claims to the Federal Programs, and the retention of such information in a readily retrievable form;

4. A mechanism for Covered Persons to make inquiries regarding compliance with Federal Program Requirements without risk of retaliation or other adverse effect;

5. The requirement that McLeod not hire, employ or engage as Covered Persons in the ED any Ineligible Person. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services, but has not yet been excluded, debarred, or otherwise declared ineligible. To prevent hiring or contracting with any Ineligible Person, McLeod shall check all prospective Covered Persons prior to engaging their services against the HHS/OIG List of Excluded Individuals/Entities

(available through the Internet at http://www.hhs.gov/oig) and the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://epls.arnet.gov) and, as appropriate, the state list of exclusions from Medicaid or Medical Assistance programs.

D. Training and Certification

Within 60 days of the Effective Date of this CIA, all Covered Persons shall be trained in the proper reimbursement standards, program policies, and verification procedures to ensure the propriety and accuracy of claims for services and items furnished to Federal Program beneficiaries. The training shall be designed to ensure that each Covered Person is aware of all applicable Federal Health Care Program requirements, and the consequences (i.e., overpayment demands, restitution, penalties, criminal, civil and administrative liability, exclusion from the Federal Programs, etc.) both to the individual and to McLeod that may ensue from any violation of such requirements.

McLeod agrees to arrange for each new Covered Person to participate in such training no later than 15 days after the person begins to work for the ED. Such training may be provided in whole or in part by an outside vendor, including a Health Care Financing Administration ("HCFA") contractor. Until a person has received all required training, such person shall work under the direct supervision of another individual who has completed the required training.

McLeod shall ensure that each Covered Person required to receive this training shall receive no less than four (4) hours of training annually.

At a minimum, the training sessions shall cover the following topics:

1. McLeod's and the ED's obligations under this CIA;

2. All applicable Federal Health Requirements related to reimbursement, and the legal sanctions for improper billing or other violations of these standards.

3. The written Policies and Procedures developed pursuant to Section III.C, above;

Each Covered Person shall date and sign a certification indicating attendance at the training session and further attesting to an understanding of the provisions in the Policies and Procedures developed pursuant to Section III.C and all applicable Federal Program Requirements addressed in training. These certifications will be maintained by McLeod and shall be made available for inspection by OIG or its duly authorized representatives. At least one copy of the training materials or a detailed description of the topics covered during the training session shall be maintained with the certifications.

Notwithstanding that "Physicians" is included in the definition of Covered Person for all other provisions in this CIA, non-employed physicians performing professional services in the ED, if any shall not be considered Covered Persons for purposes of this Training and Certification Section D. With respect to non-employed physicians, McLeod shall make the training described above available to such non-employed physicians but attendance shall not be mandatory for such physicians. McLeod shall notify such physicians of the training and encourage them to attend. McLeod shall keep records reflecting which non-employed physicians attend compliance training and shall include in its Annual Report the number of physicians who attended training during the reporting period. Additionally, McLeod shall have non-employed physicians certify that they have been offered training and have refused it.

E. <u>Third Party Billing Services</u>

McLeod represents that prior to the execution of this CIA, McLeod established an emergency physician billing service to be carried out by McLeod Health Services, Inc. McLeod agrees that it will not engage any third-party billing service other than McLeod Health Services, Inc., for the preparation or submission of claims for physician services provided in and billed through the ED without providing to OIG written notice thirty days in advance of McLeod's utilization of such services.

McLeod shall, as a term of its contract or other agreement with any Third Party Biller other than MHSI require that such Third Party Biller certify to McLeod that all individuals who are involved with the preparation or submission of claims for reimbursement to any Federal Program for physician services provided through the ED receive, at a minimum, annual training regarding applicable Federal Program

Requirements related to emergency medicine physician reimbursement. Such certifications shall be in writing and McLeod shall require such certifications on an annual basis.

F. Annual Review Procedures

1. *Retention of Independent Review Organization.* Within 90 days of the Effective Date of this CIA, McLeod shall retain a person or entity, such as a nurse reviewer, an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform a billing review to assess the Third Party Biller's billing and coding practices for claims it submits for the Physicians and Allied Health Professionals ("Billing Engagement"). The Independent Review Organization retained by McLeod shall have expertise in the billing, coding, reporting and other requirements relevant to McLeod's business.

2. *Frequency of the Billing Engagement.* The Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning with the Effective Date of this CIA. The IRO shall perform all components of each annual Billing Engagement and prepare the required reports in accordance with the procedures detailed in **Appendix A** to this CIA, which is incorporated by reference into this CIA.

3. *Retention of Records.* The IRO and McLeod shall retain and make available to the OIG upon request all work papers, supporting documentation, correspondence, and draft reports related to the engagements.

4. *Validation Review.* In the event the OIG has reason to believe that: (a) McLeod's Billing Engagement fails to conform to the requirements of this CIA or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing Engagement complies with the requirements of the CIA and/or the findings or Claims Review results are inaccurate. McLeod agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated by the OIG before one year after the final Annual Report is received by the OIG.

G. Reporting of Overpayments and Material Deficiencies

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 Program requirements. McLeod may not subtract any underpayments for purposes of determining the amount of relevant "overpayments" for purposes of reporting under this CIA; provided, however, such reporting requirement shall not be construed to mean McLeod may not properly request and receive such underpayments.

b. Reporting of Overpayments. If, at any time, McLeod identifies or learns of any overpayments received by the ED, McLeod shall notify the payor (e.g., Medicare fiscal intermediary or carrier) and repay any identified overpayments within 30 days of discovery and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Notification and repayment to the contractor should be done in accordance with the contractor policies.

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 potential violation of criminal, civil, or administrative laws applicable to any Federal 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 that there is a Material Deficiency in the ED, McLeod shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

(i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in Section III.G.1b, and shall include all of the information provided to the payor, 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) on which the overpayment was repaid/refunded;

(ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal 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.

H. Notification of Government Investigations or Legal Proceedings

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

IV. 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 the Third Party Biller or the ED 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 McLeod, through the ED, 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 McCleod'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; provided, however, every effort shall be made to not disrupt patient care of the ED for such interviews. McLeod agrees to 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.

V. REPORTS

A. IMPLEMENTATION REPORT

Within 90 days of the Effective Date of this CIA, McLeod shall provide the OIG with a written report demonstrating that McLeod has complied with the requirements of this CIA. This report, known as the "Implementation Report," shall include:

1. The name, address, and telephone and facsimile numbers of the Compliance Contact, as described in Section III.A;

2. A copy of the posted Notice of Compliance described in Section III.B, and a description of where such Notice of Compliance is posted;

3. A description, schedule and topic outline of the training programs implemented or relied upon pursuant to Section III.D. of this CIA, and a certification signed by the Compliance Contact attesting that all Covered Persons have completed the initial training required by Section III.D (the individual training certifications required by Section III.D. and the training materials will be made available to OIG upon request);

4. The identity of the IRO and the proposed start and completion dates of the first Billing Engagement; and

5. A certification from the Compliance Contact stating that he or she has reviewed the Implementation Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information provided in the Implementation Report is accurate and truthful and that McLeod has met each of its obligations under this CIA.

B. ANNUAL REPORTS

McLeod agrees to make three annual written reports (each one of which is referred to throughout this CIA as the "Annual Report") to OIG describing the measures taken to implement and maintain the CIA and ensure compliance with the terms of this CIA. Each Annual Report shall include:

1. A description, schedule and topic outline of the training programs implemented or relied upon pursuant to Section III.D. of this CIA, and a certification signed by the Compliance Contact attesting that all Covered Persons have completed the annual training required by Section III.D. The individual training certifications required by Section III.D and the training materials will be made available to OIG upon request;

2. A copy of the Claims Review Report prepared pursuant to Section III.F of this CIA and relating to the year covered by the Annual Report; and a description of any corrective actions taken in response to the findings of the Billing Engagement;

3. A report of the aggregate overpayments for services provided by the Physician and Allied Health Professional that have been identified through the Compliance Program and returned to the Federal Programs during the one-year period covered by the Annual Report, pursuant to Section III.G. Overpayment amounts should be broken into the following categories: Medicare, Medicaid (report each applicable state separately), and other Federal Programs; and

4. A certification signed by the Compliance Contact certifying that he or she has reviewed the Annual Report, has made a reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful and that McLeod has met each of its obligations under this CIA.

The Annual Reports shall be due within 45 days of each end of the one-year period covered by the CIA. The first one-year period shall commence on the Effective Date of this CIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise modified in accordance with Section IX.D. below, all correspondence, notifications and reports required under the terms of this CIA shall be submitted to the entities listed below:

If to OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Cohen Building, Room 5527
Washington, DC 20201
Telephone : (202) 619-2078
Facsimile: (202) 205-0604

If to McLeod: Preston Wilson, Compliance Officer
McLeod Regional Medical Center
Medical Office Building - East, Suite 299
555 Cheves Street
Florence, South Carolina 29501
Telephone: (843) 777-5000
Facsimile: (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. DOCUMENT AND RECORD RETENTION

McLeod shall maintain for inspection all documents and records relating to reimbursement from the Federal Programs, or to compliance with this CIA, for four years (or longer if otherwise required).

VIII. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the 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). McLeod shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

IX. BREACH AND DEFAULT PROVISIONS

Full and timely compliance by McLeod shall be expected throughout the duration of this CIA with respect to all of the obligations herein agreed to by McLeod.

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 $1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day:

a. a Covered Person fails to attend the training required by Section III.D. of the CIA within the time frames required in that Section;

b. McLeod fails to annually submit the IRO's Claims Review Report and Process Review Report as required in Section III.F and Appendix A; or

c. McLeod fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

2. A Stipulated Penalty of $750 (which shall begin to accrue on the date the failure to comply began) for each day McLeod employs, or contracts with, in the ED an Ineligible Person and that person: (i) has responsibility for, or involvement with, McLeod's business operations related to the Federal Programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal Programs (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which McLeod can demonstrate that McLeod did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.C.5.) as to the excluded status of the person).

3. A Stipulated Penalty of $750 for each day McLeod fails to grant access to the information or documentation as required in Section IV of this CIA. (This Stipulated Penalty shall begin to accrue on the date McLeod fails to grant access.)

4. A Stipulated Penalty of $750 for each day McLeod fails to comply fully and adequately with any obligation of this CIA not already covered in Sections IX.A.1-3,

above. 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 must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to McLeod of the failure to comply.)

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 two 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 IX.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 of the receipt of the Demand Letter, McLeod shall respond by either: (a) curing the breach to OIG's satisfaction, notifying OIG of its corrective actions, and paying the applicable Stipulated Penalties; or (b) sending in writing to OIG a request for 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 IX.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 IX.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 IX.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 IX.D, below.

D. <u>Exclusion for Material Breach of this CIA</u>

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.G;

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section IX.A.1;

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

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 should be imposed, 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 full compliance with this CIA;

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 IX.D.3, OIG may exclude McLeod from participation in the Federal Programs. OIG will 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 IX.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 non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, McLeod wishes to apply for reinstatement, McLeod must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. <u>Dispute Resolution</u>

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 ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the

request for a hearing involving Stipulated Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of 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. 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.

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. No further action shall be taken by either party with respect to the particular issues raised in the Demand Letter filed by the OIG in the matter, pursuant to Section IX.C.

X. 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 the OIG agree as follows:

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

2. This CIA shall become final and binding on the Effective Date the final signature is obtained on the CIA;

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

4. 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.

FOR: MCLEOD REGIONAL MEDICAL CENTER OF THE PEE DEE, INC.

_____ _____

Marie Segars
Vice President of Patient Services
McLeod Regional Medical Center of the Pee Dee, Inc.

Date

_____ _____

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FOR: OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

7/30/09

Lewis Morris, Esquire
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

Date

For: McLeod Regional Medical Center of the Pee Dee, Inc.

Marie G. Segars

[Name] Marie G. Segars

[Position] Vice President for Patient Servies

June 8, 2001

Date

[Name]

[Position]

Date

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6/26/01

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APPENDIX A

A. Billing Engagement

The Billing Engagement shall be composed a "Claims Review." The IR shall prepare Claims Review Reports to report the findings of the Claims Review.

1. ***Claims Review.*** The IR shall perform a Claims Review to identify any Overpayments through an appraisal of Paid Claims submitted by McLeod to the Medicare and Medicaid programs.

2. ***Claims Review Report.*** The IR shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be submitted to the OIG in the Annual Report.

B. Claims Review

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

a. Claims Review Sample: A statistically valid, randomly selected, sample of items selected for appraisal in the Claims Review.

b. Item: Any discrete unit that can be sampled (e.g., code, line item, beneficiary, patient encounter, etc.).

c. Overpayment: For purposes of this CCA, 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. For the purposes of the Claims Review and all reporting to the OIG under this CCA, McLeod shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.

d. Paid Claim: A code or line item submitted by McLeod and for which McLeod has received reimbursement from the Medicare or Medicaid programs.

e. Population: All Items for which McLeod has submitted a code or line item and for which McLeod has received reimbursement from the Medicare

or Medicaid programs (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.

f. Probe Sample: A sample of Items selected through simple random sampling from the Population for the purpose of estimating the mean and standard deviation of the Population. The estimated mean and standard deviation of the Population are to be used to calculate the minimum number of Items to be included in the Claims Review Sample.

g. RAT-STATS: The OIG's Office of Audit Services Statistical Sampling Software. RAT-STATS is publicly available to download through the Internet at "www.hhs.gov/the OIG/oas/ratstat.html".

2. ***Description of Claims Review***. The Claims Review shall consist of an appraisal of a statistically valid sample of Items (the Claims Review Sample) that can be projected to the total Population.

a. Claims Review Sample Size Options.

Option 1: Review a sufficient number of Items so that if the Overpayments identified in the Claims Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (i.e., semi-width of the confidence interval) of plus or minus 25% of the point estimate.

To determine how many Items must be included in the Claims Review Sample, the mean and standard deviation of overpayments in the Population must be estimated. These estimates shall be developed through the use of a single Probe Sample. The Probe Sample shall include at least 30 Items, and shall be selected through the use of RAT-STATS "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, a text file containing the overpayment value of each Item examined shall be created. For purposes of these estimates, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. The "Difference Values Only" of the Variable Appraisals function of RAT-STATS shall be used to

calculate the estimated mean and standard deviation of overpayments in the Population.

After the estimated mean and standard deviation of the population has been calculated the number of Items that must be included in the Claims Review Sample (in order to meet the 90% confidence and 25% precision requirement) shall be determined. This determination shall be made using RAT-STATS' "Sample Size Estimators" (located under the "Utility Program" file). The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the Claims Review Sample.

If no Overpayments are found in this Probe Sample, then the Claims Review can be terminated with the results of the Probe Sample. The results of the Probe Sample shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see section B, below); or

Option 2: Review a minimum 100 Items Claims Review Sample. The 100 Items shall be selected for appraisal through the use of RAT-STATS' "Random Numbers" function. All Paid Claims associated with these Items shall be reviewed and reported on in the Claims Review Report (See section B, below).

b. Item Appraisal. For each Item appraised (either as part of the Claims Review Sample or of the Probe Sample), only Paid Claims shall be evaluated. Every Paid Claim in the Claims Review Sample shall be evaluated by the IR to determine whether the claim submitted was correctly coded, submitted, and reimbursed. Each appraisal must be sufficient to provide all information required under the Claims Review Report.

c. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review and/or the Probe Sample, any Paid Claim for which McLeod cannot produce any documentation (i.e., missing medical records) to support the Paid Claim shall be reported as an error and the total reimbursement received by McLeod for such Paid Claim

conducted and what was evaluated.

2. ***Statistical Sampling Documentation***

a. Documentation Required Under Option 1:

i. The number of Items appraised in the Probe Sample and in the Claims Review Sample.

ii. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function for the Probe Sample and the Claims Review Sample.

iii. A copy of the RAT-STATS printout of the "Sample Size Estimators" results used to calculate the minimum number of Items for inclusion in the Claims Review Sample.

iv. A copy of the RAT-STATS printout of the "Variable Appraisals" function results for the Probe Sample.

v. The Sampling Frame used in the Probe Sample and the Claims Review Sample shall be available to the OIG upon request.

b. Documentation Required Under Option 2:

i. The number of Items appraised in the Claims Review Sample.

ii. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function for the Claims Review Sample.

iii. The Sampling Frame used in the Claims Review Sample shall be available to the OIG upon request.

3. ***Claims Review Results***

a. Total number and percentage of instances in which the IR determined that the Paid Claim submitted by McLeod ("Claim Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless