CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
WAKEMED RALEIGH CAMPUS

I. PREAMBLE

WakeMed Raleigh Campus (including all divisions/entities operating under WakeMed Raleigh Campus' Medicare Provider Number) (WakeMed) 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 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, WakeMed is entering into a Settlement Agreement and Deferred Prosecution Agreement with the United States.

Prior to the Effective Date of this CIA (as defined below), WakeMed established a voluntary compliance program that includes a Code of Conduct, compliance training, internal audits, Compliance Committees, and a Compliance Officer. WakeMed shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. WakeMed may modify its Compliance Program as appropriate, but, at a minimum, WakeMed shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

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

B. Sections VII, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) WakeMed's final annual report; or (2) any additional materials submitted by WakeMed pursuant to OIG's request, whichever is later.

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

1. "Covered Persons" includes:

   a. all owners, officers, directors, and employees of WakeMed;

   b. all contractors, subcontractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of WakeMed, excluding vendors whose sole connection with WakeMed is selling or otherwise providing medical supplies or equipment to WakeMed and who do not bill the Federal health care programs for such medical supplies or equipment; and

   c. all physicians and other non-physician practitioners who are members of WakeMed's active medical staff.

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

2. "Relevant Billing Covered Persons" includes Covered Persons involved in the preparation or submission of claims or cost reports for reimbursement from any Federal health care program.

3. "Relevant Clinical Covered Persons" includes Covered Persons involved in the delivery of patient care items or services.

4. "Relevant Care Management Covered Persons" includes Covered Persons who work in any department that performs functions relating to or affecting admission or discharge decisions. Relevant Care Management Covered Persons include, but are not limited to, persons working in the following divisions or departments at WakeMed; Patient Access (patient registration pre-admission, patient placement, etc.) Case Management, Care Management, Denial Management, and Utilization Review.

III. CORPORATE INTEGRITY OBLIGATIONS

WakeMed shall establish and maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Committee

1. *Compliance Officer*. Prior to the Effective Date, WakeMed appointed a Covered Person to serve as its Compliance Officer and shall maintain a Compliance Officer for the term of the CIA. The Compliance Officer 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 Compliance Officer shall be a member of senior management of WakeMed, shall report directly to the Chief Executive Officer of WakeMed, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of WakeMed or to the Board Compliance Committee, and shall be authorized to report on such matters to the Board of Directors at any time. The Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by WakeMed as well as for any reporting obligations created under this CIA. Any noncompliance job responsibilities of the Compliance Officer shall be limited to less than a majority of the Compliance Officer's time and effort and must not interfere with the Compliance Officer's ability to perform the duties outlined in this CIA.

WakeMed shall report to OIG, in writing, any change in the identity of the Compliance Officer, or any actions or changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within five days after such a change.

2. *Compliance Committee*: Prior to the Effective Date, WakeMed appointed a Compliance Committee. WakeMed shall continue the Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer 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 Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the WakeMed's risk areas and shall oversee monitoring of internal and external audits and investigations). The Compliance Committee shall meet at least quarterly.

WakeMed shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance

Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors Compliance Obligations.* The Board of Directors (Board) has established, and for the term of this CIA, shall maintain a Compliance Committee (Board Compliance Committee) that shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements and the obligations of this CIA.

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

a. meeting at least quarterly to review and oversee WakeMed's Compliance Program, including but not limited to the performance of the Compliance Officer and Compliance Committee; and

b. for each Reporting Period of the CIA, adopting a resolution, signed by each member of the Board Compliance Committee summarizing its review and oversight of WakeMed's compliance with Federal health care program requirements and the obligations of this CIA.

At minimum, the resolution shall include the following language:

"The Board of Directors Compliance Committee has made a reasonable inquiry into the operations of WakeMed's Compliance Program including the performance of the Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board of Directors Compliance Committee has concluded that, to the best of its knowledge, WakeMed has implemented an effective Compliance Program to meet Federal health care program requirements and the obligations of the CIA."

If the Board Compliance Committee is unable to provide such a conclusion in the resolution, the Board Compliance Committee shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at WakeMed.

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

B. Written Standards

1. *Code of Conduct.* Prior to the Effective Date, WakeMed developed, implemented, and distributed a written Code of Conduct to all Covered Persons who are WakeMed employees. WakeMed shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. WakeMed'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. WakeMed's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with WakeMed's own Policies and Procedures;

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

d. the possible consequences to both WakeMed and Covered Persons of failure to comply with Federal health care program requirements and with WakeMed'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.E, and WakeMed's commitment to nonretaliation and to maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

Within 120 days after the Effective Date, each Covered Person shall certify, in writing or in electronic form, that he or she has received, read, understood, and shall abide by WakeMed's Code of Conduct, except for Covered Persons who have received the Code of Conduct within 120 days prior to the Effective Date of this CIA and have already provided such certification. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

WakeMed shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Policies and Procedures.* To the extent not already accomplished, within 120 days after the Effective Date, WakeMed shall implement written Policies and Procedures regarding the operation of its compliance program, including the compliance program requirements outlined in this CIA and Provider's compliance with Federal health care program requirements.

At a minimum, the Policies and Procedures shall address:

a. the subjects relating to the Code of Conduct identified in Section III.B.1;

b. billing and reimbursement: these Policies and Procedures shall be designed to ensure WakeMed complies with all Federal health care program requirements on billing and reimbursement, including:

i. ensuring proper and accurate submission of claims and cost reports to Federal health care programs;

ii. ensuring the proper and accurate documentation of medical records;

iii. ensuring the proper and accurate assignment and designation of patients into inpatient, outpatient, or observation status; and

iv. ensuring the necessary and appropriate length of stays and timely discharges for all patients;

c. documentation of medical records: these Policies and Procedures shall be designed to ensure WakeMed complies with Federal health care program requirements applicable to the documentation of medical records:

i. ensuring proper and accurate documentation in the pre-admission, admission, case management, billing, coding and reimbursement process;

ii. ensuring that physicians are aware of relevant objective medical criteria governing admission, and any relevant Medicare regulations regarding treatment of a patient as an inpatient;

iii. the personal obligation of each individual involved in the medical documentation process to ensure that such documentation is accurate;

iv. ensuring proper order authentication practices to ensure: (1) physician orders are not implemented without physician knowledge and consent; and (2) unauthorized markings are not added to physician orders without physician knowledge or consent;

v. ensuring that employees do not disregard physician orders relating to the admission of a patient, except in connection with determinations by the Utilization Review Committee;

vi. the legal sanctions for violations of the Federal health care program requirements; and

vi. examples of proper and improper medical documentation practices.

d. requirements for Care Management employees:

i. the Policies and Procedures for determining the medical necessity and appropriateness of inpatient admissions, including applicable Medicare rules and regulations;

ii. the policies and procedures for proper order authentication and modification;

iii. the role and function of the Utilization Review Committee; and

iv. Care Management Certification Requirements.

Within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be distributed to all Covered Persons 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), WakeMed shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, any such revised Policies and Procedures shall be distributed or made available to all Covered Persons.

C. Training and Education

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

a. CIA requirements; and

b. Compliance Program, including the Code of Conduct 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 in each subsequent Reporting Period.

WakeMed shall not be required to provide General Training to cafeteria, maintenance, and housekeeping employees.

2. *Specific Training.*

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

i. the Federal health care program requirements regarding the accurate coding and submission of claims;

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

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

iv. applicable reimbursement statutes, regulations, and program requirements and directives (including those that define appropriate inpatient - outpatient status designations);

v. the legal sanctions for violations of the Federal health care program requirements; and

vi. examples of proper and improper claims submission practices.

b. Document Training. Within 120 days after the Effective Date, each Relevant Clinical Covered Person shall receive at least one hour of Document Specific Training in addition to the General Training required above. This Specific Training shall include a discussion of:

i. policies, procedures, and other Federal health care program requirements applicable to the documentation of medical records;

ii. the importance of accurate documentation in the billing and coding and reimbursement process;

iii. the personal obligation of each individual involved in the medical documentation process to ensure that such documentation is accurate;

iv. the legal sanctions for violations of the Federal health care program requirements; and

v. examples of proper and improper medical documentation practices.

Relevant Billing Covered Persons who are also Relevant Clinical Covered Persons shall undergo both Billing and Reimbursement Specific Training and Documentation Specific Training.

c. Care Management Training. Within 120 days after the Effective Date, each Relevant Care Management Covered Person shall receive at least two hours of Care Management Specific Training in addition to the Billing and Reimbursement Specific Training, the Document Specific Training, and the General Training required above. This Care Management Training shall include a discussion of:

i. the policies and procedures for determining the medical necessity and appropriateness of inpatient admissions, including applicable Medicare rules and regulations; and

ii. the role and function of the Utilization Review Committee.

New Relevant Billing Covered Persons, new Relevant Clinical Covered Persons, and new Relevant Care Management Covered Persons shall receive this training, as appropriate to their responsibilities, within 30 days after the beginning of their employment or becoming new Relevant Billing Covered Persons, new Relevant Clinical Covered Persons, or new Relevant Care Management Covered Persons, or within 120 days after the Effective Date, whichever is later. Each new Relevant Billing Covered Person, new Relevant Clinical Covered Person, and new Relevant Care Management Covered Person shall have his or her work reviewed by a WakeMed employee who has completed the Specific Training, to the extent that the work relates to (i) the delivery of patient care items or services, (ii) the preparation or submission of claims or cost reports for reimbursement from any Federal health care program, or (iii) any Care Management, or Utilization Review, or Denial Management function, until such time as the new Relevant Billing Covered Person, new Relevant Clinical Covered Person, or new Relevant Care Management Covered Person completes his or her Specific Training as required above.

After receiving the initial Specific Training described in this Section, each Relevant Billing Covered Person shall receive at least one hour of Billing and Reimbursement Specific Training in each subsequent Reporting Period, each Relevant Clinical Covered Person shall receive at least one hour of Documentation Specific Training in each subsequent Reporting Period, and each Relevant Care Management Covered Person shall receive at least one hour of Care Management Training in each subsequent Reporting Period.

d. Care Management Certification. Within 120 days, WakeMed will establish requirements for Care Management employees, and WakeMed will maintain those requirements, as described in this paragraph, for the term of this CIA. In addition to receiving the General and Specific Training described above, each Relevant Care Management Covered Person must be a graduate of an accredited school of nursing and must have and for the term of this CIA maintain a current license as a registered nurse in North Carolina. Within one year of becoming eligible to take the exam, each Relevant Care Management Covered Person shall also obtain, and for the term of this CIA shall maintain, a current certification as either:

i. Certified Case Manager; or

ii. Any other comparable accreditation or certification program approved by WakeMed.

3. *Board Member Training.* Within 120 days after the Effective Date, WakeMed shall provide at least two hours of training to each member of the Board of Directors, in addition to the General Training. This training shall address the responsibilities of board members and corporate governance.

New members of the Board of Directors shall receive the Board Member Training described above within 30 days after becoming a member or within 120 days after the Effective Date, whichever is later.

4. *Certification.* Each individual who is required to attend training shall certify, in writing or in electronic form, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials.

5. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area.

6. *Update of Training.* WakeMed shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during internal audits or the Inpatient Medical Necessity and Appropriateness Review, Unallowable Costs Review, and any other relevant information.

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

8. *Exception for Active Medical Staff Members.* WakeMed shall make the General Training, Document Training and Care Management Training (as appropriate) as described in this section available to all WakeMed active medical staff members and shall use its best efforts to encourage such active medical staff members to complete the training. The Compliance Officer shall maintain records of all active medical staff members who receive training, including the type of training and the date received.

D. Review Procedures

1. *General Description*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, WakeMed shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform the reviews to assist WakeMed in assessing and evaluating the medical necessity and appropriateness of inpatient admissions and certain other obligations pursuant to this CIA, the Settlement Agreement, and the Deferred Prosecution Agreement. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

The IRO shall perform an Inpatient Medical Necessity and Appropriateness Review, as described in Appendix B. The IRO shall also perform a Systems Review, as described in Appendix B. The IRO shall also perform an Unallowable Cost Review.

b. *Frequency of Inpatient Medical Necessity and Appropriateness Review.* The Inpatient Medical Necessity and Appropriateness Review shall be performed annually and shall cover each of the Reporting Periods. The IRO(s) shall perform all components of each annual Inpatient Medical Necessity and Appropriateness Review.

c. *Frequency of Unallowable Cost Review.* The IRO shall perform the Unallowable Cost Review at the end of the first Reporting Period.

d. *Frequency of Systems Review.* The Systems Review shall be performed at a minimum at the end of the first and second and fourth Reporting Periods and shall cover the first, second, and fourth Reporting Periods respectively.

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

2. *Inpatient Medical Necessity and Appropriateness Review Report.* The IRO shall prepare a report based upon the Inpatient Medical Necessity and Appropriateness Review performed (Inpatient Medical Necessity and Appropriateness Review Report). Information to be included in the Inpatient Medical Necessity and Appropriateness Review Report is described in Appendix B.

Systems Review Report: The IRO shall prepare a report based upon the Systems Review performed (Systems Review Report). Information to be included in the Systems Review Report is described in Appendix B.

Within 120 days after the Effective Date, the IRO shall develop a proposed work plan for the Systems Review for the first Reporting Period and shall deliver the proposed work plan to the OIG for review. Within 30 days of the beginning of each of the remaining Reporting Periods, the IRO shall deliver to OIG a proposed work plan for the Reporting Period. Within 30 days after OIG receives the proposed work plan, OIG will notify WakeMed if the work plan is unacceptable. Absent notification from OIG that the work plan is unacceptable, the IRO may conduct the Systems Review for the applicable Reporting Period using the work plan.

3. *Repayment of Identified Overpayments.* WakeMed shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. WakeMed shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

4. *Unallowable Cost Review.* For the first Reporting Period, the IRO shall conduct a review of WakeMed's compliance with the unallowable cost provisions of

the Settlement Agreement. The IRO shall determine whether WakeMed 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 costs analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by WakeMed or any affiliates. 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.

5. *Unallowable Cost Review Report.* The IRO shall prepare a report based upon the Unallowable Cost Review performed (Unallowable Cost Review Report). The Unallowable Cost Review, Report shall include the IRO's findings and supporting rationale regarding the Unallowable Cost Review and whether WakeMed 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.

6. *Validation Review.* In the event OIG has reason to believe that: (a) WakeMed's Claims Review, Unallowable Cost Review or Systems Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review, Unallowable Cost Review, or Systems Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review, Unallowable Cost Review, or Systems Review complied with the requirements of the CIA and/or the findings or Claims Review, Unallowable Cost Review, or Systems Review results are inaccurate (Validation Review). WakeMed shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of WakeMed's final Annual Report shall be initiated no later than one year after WakeMed's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify WakeMed 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, WakeMed may request a meeting with OIG to: (a) discuss the results of any Claims Review, Unallowable Cost Review, or Systems Review submissions or findings; (b) present any additional information to clarify the results of the Claims Review, Unallowable Cost Review, or Systems Review to correct the inaccuracy

of the Claims Review, Unallowable Cost Review, or Systems Review and/or (c) propose alternatives to the proposed Validation Review. WakeMed agrees to provide any additional information as may be requested by OIG under this Section III.D.6 in an expedited manner. OIG will attempt in good faith to resolve any Claims Review, Unallowable Cost Review, or Systems Review issues with WakeMed 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 and Objectivity Certification.* The IRO shall include in its report(s) to WakeMed a certification that the IRO has (a) evaluated its professional independence and objectivity with respect to the reviews conducted under this Section III.D and (b) concluded that it is, in fact, independent and objective, in accordance with the requirements specified in Appendix A to this CIA.

E. Disclosure Program

Prior to the Effective Date, WakeMed established a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with WakeMed'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. WakeMed 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 Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, WakeMed shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (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.

F. Ineligible Persons

1. *Definitions.* For purposes of this CIA:

a. an "Ineligible Person" shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the scope of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. "Exclusion Lists" include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at http://www.oig.hhs.gov); and

ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at http://www.epls.gov).

2. *Screening Requirements.* WakeMed shall ensure that all prospective and current Covered Persons are not Ineligible Persons, by implementing the following screening requirements.

a. WakeMed shall screen all prospective Covered Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Covered Persons to disclose whether they are Ineligible Persons.

b. WakeMed shall screen all Covered Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.

c. WakeMed shall implement a policy requiring all Covered Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in Section III.F affects WakeMed's responsibility to refrain from (and liability for) billing Federal health care programs for items or services furnished, ordered, or prescribed by excluded persons. WakeMed understands that items or services furnished by excluded persons are not payable by Federal health care programs and that WakeMed may be liable for overpayments and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether WakeMed meets the requirements of Section III.F.

3. *Removal Requirement.* If WakeMed has actual notice that a Covered Person has become an Ineligible Person, WakeMed shall remove such Covered Person from responsibility for, or involvement with, WakeMed's business operations related to the Federal health care programs and shall remove such Covered Person from any position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Covered Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If WakeMed has actual notice that a Covered Person is charged with a criminal offense that falls within the scope of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Covered Person's employment or contract term or during the term of a physician's or other practitioner's medical staff privileges, WakeMed shall take all appropriate actions to ensure that the responsibilities of that Covered Person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings

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

H. Repayment of Overpayments

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

2. *Repayment of Overpayments*

a. If, at any time, WakeMed identifies or learns of any Overpayment, WakeMed shall repay the Overpayment to the appropriate payor (e.g., Medicare fiscal intermediary or carrier) within 60 days after identification of the Overpayment and take remedial steps within 90 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. If not yet quantified, within 60 days after identification, WakeMed 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.

b. 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.

I. Reportable Events

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

a. a substantial Overpayment;

b. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized;

c. the employment of or contracting with a Covered Person who is an Ineligible Person as defined by Section III.F.1.a; or

d. the filing of a bankruptcy petition by WakeMed.

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

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

3. *Reportable Events under Section III.I.1.a.* For Reportable Events under Section III.I.1.a, the report to OIG shall be made within 30 days of the identification of the Overpayment, and shall include:

a. a copy of the notification and repayment to the payor required in Section III.H.2;

b. a description of the steps taken by WakeMed to identify and quantify the Overpayment;

c. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

d. a description of WakeMed's actions taken to correct the Reportable Event; and

e. any further steps WakeMed plans to take to address the Reportable Event and prevent it from recurring.

Within 60 days of identification of the Overpayment, WakeMed shall provide OIG with a copy of the notification and repayment to the payor required in Section III.H.2.

4. *Reportable Events under Section III.I.1.b and c.* For Reportable Events under Section III.I.1.b and III.I.1.c, the report to OIG shall include:

a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

b. a description of WakeMed's actions taken to correct the Reportable Event;

c. any further steps WakeMed plans to take to address the Reportable Event and prevent it from recurring; and

d. if the Reportable Event has resulted in an Overpayment, a description of the steps taken by WakeMed to identify and quantify the Overpayment.

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

6. *Reportable Events Involving the Stark Law.* Notwithstanding the reporting requirements outlined above, any Reportable Event that involves only a probable violation of section 1877 of the Social Security Act, 42 U.S.C. §1395nn (the Stark Law) should be submitted by WakeMed to the Centers for Medicare & Medicaid Services (CMS) through the self-referral disclosure protocol (SRDP), with a copy to the OIG. The requirements of Section III.H.2 that require repayment to the payor of any identified Overpayment within 60 days shall not apply to any Overpayment that may result from a probable violation of only the Stark Law that is disclosed to CMS pursuant to the SRDP.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location

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

B. Purchase or Establishment of New Unit or Location

In the event that, after the Effective Date, WakeMed 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, WakeMed shall notify OIG at least 30 days prior to such purchase or the operation of the new business unit or location. This notification shall include the address of the new business unit or location, phone number, fax number, the location's Medicare and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid

program contractor to which WakeMed currently submits claims. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location

In the event that, after the Effective Date, WakeMed proposes to sell any or all of its business units or locations that are subject to this CIA, WakeMed shall notify OIG of the proposed sale at least 30 days prior to the sale of such business unit or location. This notification shall include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report

Within 150 days after the Effective Date, WakeMed shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other noncompliance job responsibilities the Compliance Officer may have;

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

3. a copy of WakeMed's Code of Conduct required by Section III.B.1;

4. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG upon request);

5. a summary of all Policies and Procedures required by Section III.B (copies of the Policies and Procedures shall be made available to OIG upon request);

6. the following information regarding each type of training required by Section III.C:

a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions; and

c. with respect to active medical staff members, the number and percentage who completed the training, the type of training and the date received, and a description of WakeMed's efforts to encourage medical staff members to complete the training.

A copy of all training materials and the documentation supporting this information shall be made available to OIG upon request.

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

8. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; (c) information to demonstrate that the IRO has the qualifications outlined in Appendix A to this CIA; (d) a summary and description of any and all current and prior engagements and agreements between WakeMed and the IRO; and (e) a certification from the IRO regarding its professional independence and objectivity with respect to WakeMed;

9. a description of the process by which WakeMed fulfills the requirements of Section III.F regarding Ineligible Persons;

10. a list of all of WakeMed'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 and state Medicaid program provider number and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which WakeMed currently submits claims;

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

12. the certifications required by Section V.C.

B. Annual Reports

WakeMed shall submit to OIG annually a report with respect to the status of, and findings regarding, WakeMed's compliance activities for each of the five Reporting Periods (Annual Report). Each Annual Report shall include, at a minimum:

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

2. the Board of Directors Compliance Committee resolution required by Section III.A.3;

3. a summary of any changes or amendments to WakeMed's Code of Conduct required by Section III.B.1 and the reason for such changes, along with a copy of the revised Code of Conduct;

4. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be made available to OIG upon request);

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

6. the following information regarding each type of training required by Section III.C:

   a. a description of the initial and annual training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;

   b. the number of individuals required to complete the initial and annual training, the percentage of individuals who actually completed the initial and annual training, and an explanation of any exceptions;

   c. with respect to active medical staff members, the number and percentage who completed the training, the type of training and the date received, and a description of

WakeMed's efforts to encourage medical staff members to complete the training; and

d. a statement that all Relevant Care Management Covered Persons have obtained and properly maintained the licensure and certifications required by Section III.C.2, and an explanation of any exceptions.

A copy of all training materials and the documentation to support this information shall be made available to OIG upon request.

7. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter;

8. WakeMed's response to the reports prepared pursuant to Section III.D, along with corrective action plan(s) related to any issues raised by the reports;

9. a summary and description of any and all current and prior engagements and agreements between WakeMed and the IRO (if different from what was submitted as part of the Implementation Report);

10. a certification from the IRO regarding its professional independence and objectivity with respect to WakeMed;

11. a summary of Reportable Events (as defined in Section III.I) identified during the Reporting Period and the status of any corrective action relating to all such Reportable Events;

12. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: 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;

13. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs (the complete disclosure log shall be made available to OIG upon request);

14. any changes to the process by which WakeMed fulfills the requirements of Section III.F regarding Ineligible Persons;

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

16. a description of all changes to the most recently provided list of WakeMed's locations (including addresses) as required by Section V.A.10; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Medicare and state Medicaid program provider number(s) and/or supplier number(s); and the name and address of each Medicare and state Medicaid program contractor to which WakeMed currently submits claims; and

17. the certifications required by Section V.C.

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 each Annual Report shall include a certification by the Compliance Officer that:

1. to the best of his or her knowledge, except as otherwise described in the report, WakeMed is in compliance with all of the requirements of this CIA;

2. he or she has reviewed the report and has made reasonable inquiry regarding its content and believes that the information in the report is accurate and truthful; and

3. to the best of his or her knowledge, WakeMed has complied with its obligations under the Settlement Agreement: (a) 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; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs.

D. Designation of Information

WakeMed 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. WakeMed shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

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

WakeMed:

Compliance Officer
WakeMed Health and Hospitals
3000 New Bern Avenue
Raleigh, NC 27610
(919) 350-8241
(919) 350-7725
pholloway@wakemed.org

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. Upon request by OIG, WakeMed may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), in addition to a paper copy.

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

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

X. BREACH AND DEFAULT PROVISIONS

WakeMed 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, WakeMed and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day WakeMed fails to establish and implement any of the following obligations as described in Section III:

a. a Compliance Officer;

b. a Compliance Committee;

c. the Board of Directors compliance obligations;

d. a written Code of Conduct;

e. written Policies and Procedures;

f. the training of Covered Persons, Relevant Billing Covered Persons, Relevant Clinical Covered Persons, Relevant Care Management Covered Persons and Board Members;

g. a Disclosure Program;

h. Ineligible Persons screening and removal requirements;

i. notification of Government investigations or legal proceedings; and

j. reporting of Reportable Events.

2. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day WakeMed fails to engage and use an IRO, as required in Section III.D, Appendix A, and Appendix B.

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

4. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day WakeMed fails to submit any Inpatient Medical Necessity and Appropriateness Review Report, Unallowable Cost Review Report, or Systems Review Report in accordance with the requirements of Section III.D and Appendix B.

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

6. A Stipulated Penalty of $5,000 for each false certification submitted by or on behalf of WakeMed as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of $1,000 for each day WakeMed fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to WakeMed stating the specific grounds for its determination that WakeMed has failed to comply fully and adequately with the CIA obligation(s) at issue and steps WakeMed shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after WakeMed receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1- 6 of this Section.

B. Timely Written Requests for Extensions

WakeMed 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 WakeMed 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 WakeMed 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 WakeMed 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 WakeMed of: (a) WakeMed's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties. (This notification shall be referred to as the "Demand Letter.")

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, WakeMed 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 WakeMed elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until WakeMed 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 electronic funds transfer to an account specified by OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that WakeMed 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 repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;

b. a failure by WakeMed to report a Reportable Event, take corrective action, and make the appropriate refunds, as required in Section III.I;

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 engage and use an IRO in accordance with Section III.D, Appendix A, and Appendix B.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by WakeMed constitutes an independent basis for WakeMed's exclusion from participation in the Federal health care programs. Upon a determination by OIG that WakeMed has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify WakeMed of: (a) WakeMed's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion. (This notification shall be referred to as the "Notice of Material Breach and Intent to Exclude.")

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

4. *Exclusion Letter.* If, at the conclusion of the 30 day period, WakeMed fails to satisfy the requirements of Section X.D.3, OIG may exclude WakeMed from participation in the Federal health care programs. OIG shall notify WakeMed in writing of its determination to exclude WakeMed. (This letter shall be referred to 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 WakeMed's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, WakeMed may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to WakeMed 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, WakeMed 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 Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether WakeMed was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. WakeMed 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 WakeMed to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless WakeMed requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

a. whether WakeMed 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) WakeMed had

begun to take action to cure the material breach within that period; (ii) WakeMed has pursued and is pursuing such action with due diligence; and (iii) WakeMed provided to OIG within that period a reasonable timetable for curing the material breach and WakeMed 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 WakeMed, only after a DAB decision in favor of OIG. WakeMed's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude WakeMed 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 WakeMed 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. WakeMed 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 WakeMed, WakeMed 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

WakeMed and OIG agree as follows:

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

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

C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA.

D. OIG may agree to a suspension of WakeMed's obligations under this CIA based on a certification by WakeMed that it is no longer providing health care items or services that will be billed to any Federal health care program and that it does not have any ownership or control interest, as defined in 42 U.S.C. §1320a-3, in any entity that bills any Federal health care program. If WakeMed is relieved of its CIA obligations, WakeMed

will be required to notify OIG in writing at least 30 days in advance if WakeMed plans to resume providing health care items or services that are billed to any Federal health care program or to obtain an ownership or control interest in any entity that bills any Federal health care program. At such time, OIG shall evaluate whether the CIA will be reactivated or modified.

E. The undersigned WakeMed 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.

F. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.

ON BEHALF OF WAKEMED

/William K. Atkinson, II/ 12/18/12

Dr. William K. Atkinson, II
President & Chief Executive Officer
WakeMed

DATE

/Maureen Demarest Murray/ 12/18/12

Maureen Demarest Murray
Steven W. Petersen
Smith Moore Leatherwood LLP
Counsel for WakeMed

DATE

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

/Robert K. DeConti/ — 12/19/12

ROBERT K. DECONTI
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

DATE

/Sandra Jean Sands/ — 12/18/2012

SANDRA JEAN SANDS
Senior Counsel
Office of Inspector General
U.S. Department of Health and Human Services

DATE

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

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

A. IRO Engagement

1. WakeMed shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives the information identified in Section V.A.8 of the CIA or any additional information submitted by WakeMed in response to a request by OIG, whichever is later, OIG will notify WakeMed if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, WakeMed may continue to engage the IRO.

2. If WakeMed engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, WakeMed shall submit the information identified in Section V.A.8 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives this information or any additional information submitted by WakeMed at the request of OIG, whichever is later, OIG will notify WakeMed if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, WakeMed may continue to engage the IRO.

B. IRO Qualifications

The IRO shall:

1. assign individuals to conduct the Inpatient Medical Necessity and Appropriateness Review, Unallowable Cost Review, and Systems Review engagement who have expertise in billing, coding, reporting, and other requirements governing inpatient admissions of patients covered by Medicare, and other requirements applicable to WakeMed and in the general requirements of the Federal health care program(s) from which WakeMed seeks reimbursement;

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

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

4. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis; and

5. assign individuals to conduct the Systems Review who have a nationally recognized history of doing such reviews.

C. IRO Responsibilities

The IRO shall:

1. perform each Inpatient Medical Necessity and Appropriateness Review, Systems Review and Unallowable Cost review, in accordance with the specific requirements of the CIA;

2. follow all applicable Medicare rules and reimbursement guidelines in making assessments in the Inpatient Medical Necessity and Appropriateness Review and Systems Review;

3. if in doubt of the application of a particular Medicare policy or regulation, request clarification from the appropriate authority (e.g., fiscal intermediary or carrier);

4. respond to all OIG inquires in a prompt, objective, and factual manner; and

5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity

The IRO must perform the Inpatient Medical Necessity and Appropriateness Review, the Unallowable Cost Review, and the Systems Review in a professionally independent and objective fashion, as defined in the most recent Government Auditing Standards issued by the United States Government Accountability Office.

E. IRO Removal/Termination

1. *Provider and IRO.* If WakeMed terminates its IRO or if the IRO withdraws from the engagement during the term of the CIA, WakeMed must submit a notice explaining its reasons for termination or the reason for withdrawal to OIG no later than 30 days after termination or withdrawal. WakeMed must engage a new IRO in accordance with Paragraph A of this Appendix and within 60 days of termination or withdrawal of the IRO.

2. *OIG Removal of IRO.* In the event OIG has reason to believe the IRO does not possess the qualifications described in Paragraph B, is not independent and objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require WakeMed to engage a new IRO in accordance with Paragraph A of this Appendix. WakeMed must engage a new IRO within 60 days of termination of the prior IRO or at least 60 days prior to the end of the current Reporting Period, whichever is earlier.

Prior to requiring WakeMed to engage a new IRO, OIG shall notify WakeMed of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, WakeMed may present additional information regarding the IRO's qualifications, independence or performance of its responsibilities. OIG will attempt in good faith to resolve any differences regarding the IRO with WakeMed prior to requiring WakeMed to terminate the IRO. However, the final determination as to whether or not to require WakeMed to engage a new IRO shall be made at the sole discretion of OIG.

APPENDIX B

INPATIENT MEDICAL NECESSITY AND APPROPRIATENESS REVIEW AND SYSTEMS REVIEW

A. Inpatient Medical Necessity and Appropriateness Review. The IRO shall perform the Inpatient Medical Necessity and Appropriateness Review annually to cover each of the five Reporting Periods. The IRO shall perform all components of each Inpatient Medical Necessity and Appropriateness Review. The Inpatient Medical Necessity and Appropriateness Review shall consist of all the following: The IRO shall evaluate and analyze WakeMed's inpatient admissions, relevant length of stays (as identified in Section A.1.b. of Appendix B), associated billing, and claims submission to Medicare and the reimbursement received, and determine if such admissions and lengths of stays were medically necessary and appropriate under the applicable Medicare rules and regulations governing inpatient admission, treatment, discharge, billing, and reimbursement (Inpatient Medical Necessity and Appropriateness Review).

1. *Definitions*. For the purposes of the Inpatient Medical Necessity and Appropriateness Review, the following definitions shall be used:

a. Overpayment: The amount of money WakeMed has received in excess of the amount due and payable under any Federal health care program requirements.

b. Inpatient Admission Paid Claim: A claim submitted by WakeMed and for which WakeMed has received reimbursement from the Medicare program, limited to the following categories of claims/patients:

i. "Zero-day" inpatient admissions (i.e., claims bearing the same calendar date for both the admission and discharge date) (Zero-Day Stays); and

ii. "One-day" inpatient admissions (i.e., claims bearing an admission date followed by a discharge date one day later) (One-Day Stays).

c. Population: The Population shall be defined as all Inpatient Admission Paid Claims during the 12-month period covered by the Inpatient Medical Necessity and Appropriateness Review.

d. Error Rate: The Error Rate shall be the percentage of net Overpayments identified in the sample. The net Overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross Overpayments identified in the sample. (Note: Any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample shall be included as part of the net Overpayment calculation.)

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

e. Case Management Protocol: The case management/utilization protocol used by WakeMed in determining whether Medicare patients are treated at WakeMed on an inpatient, outpatient, or observation basis.

2. *Discovery Sample.* The IRO shall randomly select and review a sample of 50 Paid Claims (Discovery Sample). The Paid Claims shall be reviewed based on the supporting documentation available at WakeMed's office or under WakeMed's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed as an inpatient admission or whether the claim should have been billed to Medicare on an outpatient basis.

If the Error Rate (as defined above) for the Discovery Sample is less than 5%, no additional sampling is required. (Note: The guidelines listed above do not imply that this is an acceptable error rate. Accordingly, WakeMed should, as appropriate, further analyze any errors identified in the Discovery Sample. WakeMed recognizes that OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Inpatient Admission Paid Claims included, or errors identified, in the Discovery Sample or any other segment of the universe.)

3. *Full Sample.* If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall select an additional sample of Inpatient Admission Paid Claims (Full Sample) using commonly accepted sampling methods. The Full Sample shall be designed to: (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate;

and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Inpatient Admission Paid Claims selected for the Full Sample shall be reviewed based on supporting documentation available at WakeMed or under WakeMed's control and applicable billing and coding regulations and guidance to determine whether the claim was correctly coded, submitted, and reimbursed. For purposes of calculating the size of the Full Sample, the Discovery Sample may serve as the probe sample, if statistically appropriate. Additionally, the IRO may use the Inpatient Admission Paid Claims sampled as part of the Discovery Sample, and the corresponding findings for those Inpatient Admission Paid Claims, as part of its Full Sample, if: (1) statistically appropriate and (2) the IRO selects the Full Sample Inpatient Admission Paid Claims using the seed number generated by the Discovery Sample. OIG, in its sole discretion, may refer the findings of the Full Sample (and any related workpapers) received from WakeMed to the appropriate Federal health care program payor, including the Medicare contractor (e.g., Medicare Administrative Contractor or DMERC), for appropriate follow-up by that payor.

4. *Other Requirements*

a. Supplemental Materials. The IRO shall request all documentation and materials required for its review of the Inpatient Admission Paid Claims selected as part of the Discovery Sample or Full Sample (if applicable), and WakeMed shall furnish such documentation and materials to the IRO prior to the IRO initiating its review of the Discovery Sample or Full Sample (if applicable). If the IRO accepts any supplemental documentation or materials from WakeMed after the IRO has completed its initial review of the Discovery Sample or Full Sample (if applicable) (Supplemental Materials), the IRO shall identify in the Inpatient Medical Necessity and Appropriateness Review Report the Supplemental Materials, the date the Supplemental Materials were accepted, and the relative weight the IRO gave to the Supplemental Materials in its review. In addition, the IRO shall include a narrative in the Report describing the process by which the Supplemental Materials were accepted and the IRO's reasons for accepting the Supplemental Materials.

b. Inpatient Admission Paid Claims without Supporting Documentation. Any Inpatient Admission Paid Claim for which WakeMed cannot produce documentation sufficient

to support the Inpatient Admission Paid Claim shall be considered an error and the total reimbursement received by WakeMed for such Inpatient Admission Paid Claim shall be deemed an Overpayment. Replacement sampling for Inpatient Admission Paid Claims with missing documentation is not permitted.

c. Use of First Samples Drawn. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Inpatient Admission Paid Claims selected in each first sample shall be used (i.e., it is not permissible to generate more than one list of random samples and then select one for use with the Discovery Sample or Full Sample).

5. *Credentials.* The IRO shall provide the names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Inpatient Medical Necessity and Appropriateness Review and (2) performed the Inpatient Medical Necessity and Appropriateness Review.

6. *Repayment of Identified Overpayments.* WakeMed shall repay within 30 days any Overpayment(s) identified in the Discovery Sample or the Full Sample (if applicable), regardless of the Error Rate, to the appropriate payor and in accordance with payor refund policies. WakeMed shall make available to OIG all documentation that reflects the refund of the Overpayment(s) to the payor.

B. Inpatient Medical Necessity and Appropriateness Review Report. The IRO shall prepare an Inpatient Medical Necessity and Appropriateness Review Report as described in this Appendix for each Inpatient Admissions Paid Claims Review performed. The following information shall be included in the Inpatient Medical Necessity and Appropriateness Review Report for each Discovery Sample and Full Sample (if applicable).

1. *Inpatient Medical Necessity and Appropriateness Review Methodology*

a. Inpatient Medical Necessity and Appropriateness Review Population. A description of the Population subject to the Inpatient Medical Necessity and Appropriateness Review.

b. Inpatient Medical Necessity and Appropriateness Review Objective. A clear statement of the objective intended to be

achieved by the Inpatient Medical Necessity and Appropriateness Review.

c. Source of Data. A description of the specific documentation relied upon by the IRO when performing the Inpatient Medical Necessity and Appropriateness Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies (including title and policy number), CMS program memoranda (including title and issuance number), CMS manual provisions, North Carolina Quality Improvement Organization manuals, Medicare Administrative Contractor manual, bulletins or Local Coverage Decisions (including issue and date), other policies, regulations, or directives).

d. Review Protocol. A narrative description of how the Inpatient Medical Necessity and Appropriateness Review was conducted and what was evaluated.

e. Supplemental Materials. A description of any Supplemental Materials as required by A.5.a., above.

2. *Statistical Sampling Documentation*

a. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used by the IRO.

b. A copy of the statistical software printout(s) estimating how many Inpatient Admission Paid Claims are to be included in the Full Sample, if applicable.

c. A description or identification of the statistical sampling software package used to select the sample and determine the Full Sample size, if applicable.

3. *Inpatient Medical Necessity and Appropriateness Review Findings*

a. Narrative Results

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

description, of the personnel involved in coding and billing.

ii. A narrative explanation of the IRO's findings and supporting rationale (including reasons for errors, patterns noted, etc.) regarding the Inpatient Medical Necessity and Appropriateness Review, including the results of the Discovery Sample, and the results of the Full Sample (if any).

b. Quantitative Results

i. Total number and percentage of instances in which the IRO determined that the Inpatient Admission Paid Claims submitted by WakeMed (Claim Submitted) differed from what should have been the correct claim (Correct Claim), regardless of the effect on the payment.

ii. Total number and percentage of instances in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to WakeMed.

iii. Total dollar amount of all Overpayments in the sample.

iv. Total dollar amount of Inpatient Admission Paid Claims included in the sample and the net Overpayment associated with the sample.

v. Error Rate in the sample.

vi. A spreadsheet of the Inpatient Medical Necessity and Appropriateness Review results that includes the following information for each Inpatient Admission Paid Claim: Federal health care program billed, beneficiary health insurance claim number, date of service, code submitted (e.g., DRG, CPT code, etc.), code reimbursed, allowed amount reimbursed by payor, correct level of care (as determined by the IRO), correct code (as determined by the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount.

c. Recommendations. The IRO's report shall include any recommendations for improvements to WakeMed's billing and coding system based on the findings of the Inpatient Medical Necessity and Appropriateness Review.

C. *Systems Review*. WakeMed's IRO shall also conduct a Systems Review for each year the Error Rate of the Discovery Sample is 5% or greater. Regardless of Error Rate in years one, two and four of the CIA, the IRO shall conduct a Systems Review. The Systems Review shall consist of the following:

1. *Systems Review Content*

a. a review of WakeMed's Patient Access, Care Management, Case Management, Denial Department, Utilization Review, billing and coding systems and processes relating to claims submitted to Federal health care programs (including, but not limited to, the operation of the billing system, the process by which claims are coded, safeguards to ensure proper coding, claims submission and billing; and procedures to identify and correct patient level of care (inpatient versus observation or outpatient), procedures to identify and correct inaccurate coding and billing);

b. for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO shall review the system(s) and process(es) that generated the claim and identify any problems or weaknesses that may have resulted in the identified Overpayments. This review shall include periodic interviews of staff within the Patient Access, Case Management, Care Management, Denial Management, Utilization Review, and other Departments (as appropriate), to confirm that it is the physician or other practitioner responsible for a patient's care at WakeMed that determines whether a patient is admitted, as required by Medicare Benefit Policy Manual Chapter 1.10. These interviews shall be conducted to specifically confirm: (1) WakeMed staff require the physician to complete, give, and authenticate an order that states, "inpatient," "admit to [inpatient unit]," or other similar language reflecting the physician's intent that a patient be admitted to WakeMed as an inpatient prior to classifying any patient as an

inpatient; (2) WakeMed staff follow supported and properly authenticated orders regarding admission status from the physician responsible for the patient's care at the hospital; (3) WakeMed staff (i) consult the physician responsible for the patient's care at the hospital when the admission status designated by the physician on the order is not supported, (ii) obtain a supported and properly authenticated order from the physician, and (iii) follow the supported and properly authenticated order; (4) WakedMed staff does not execute or change orders for inpatient admission without proper authentication or consent from the physician or appropriate implementation of the physician review process outlined in WakeMed's Utilization Management Plan, as required by 42 C.F.R. § 482.30. The IRO shall provide its observations and recommendations on suggested improvements to the system(s) and process(es) that generated the claim.

2. *Systems Review Findings*. The IRO shall prepare a Systems Review Report based on the Systems Review performed that shall include the IRO's observations, findings, and recommendations regarding:

a. the strengths and weaknesses in WakeMed's Patient Access, Case Management, Care Management, Denial Management, and Utilization Review systems and processes;

b. the strengths and weaknesses in WakeMed's billing systems and processes;

c. the strengths and weaknesses in WakeMed's coding systems and processes; and

d. the strengths and weaknesses in WakeMed's systems and processes for categorizing inpatient, outpatient, and observation including, but not limited to processes within the Patient Access, Case Management, Care Management, Denial Management, Utilization Review, Coding, and Billing Departments;

e. possible improvements to WakeMed's Patient Access, Case Management, Care Management, Denial Management, Utilization Review, Utilization Review,

billing and coding systems and processes to address the specific problems or weaknesses that resulted in the identified Overpayments; and

f. a discussion of findings from interviews of staff members involved in patient access, case management, care management, denial management, billing, and coding functions, to determine whether appropriate communication with physicians concerning each physician's intent with respect to admission status (as documented in the form of properly authenticated orders) was followed. Findings should expressly identify what effect if any the adherence to, or deviation from, WakeMed's policies and procedures had upon the review finding.

3. *Credentials.* The IRO shall provide the names and credentials of the individuals who: (1) designed the procedures and methodology utilized for the Systems Review and (2) performed the Systems Review.