WMG

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

NO. _____

UNITED STATES OF AMERICA	)
	)
v.	)
	)
WAKEMED d/b/a/ WAKEMED HEALTH AND HOSPITALS	)

DEFERRED PROSECUTION AGREEMENT

WAKEMED, d/b/a WakeMed Health and Hospitals ("WakeMed"), a North Carolina Corporation, by its undersigned representatives, pursuant to authority granted by its Board of Directors, and the United States Attorney's Office for the Eastern District of North Carolina ("USAO EDNC"), hereby enter into this Deferred Prosecution Agreement (the "Agreement"). The terms and conditions of this Agreement are as follows:

Criminal Information and Acceptance of Responsibility

1. The USAO EDNC has informed WakeMed that it will file a Criminal Information, as set forth in **ATTACHMENT A**, in the United States District Court for the Eastern District of North Carolina. The Criminal Information will charge WakeMed with responsibility for a violation of Title 18, United States Code, Sections 1035 and

2, arising from employee conduct as outlined in the attached Statement of Facts. **ATTACHMENT B.** The USAO EDNC acknowledges that neither this DPA nor the Criminal Information allege that WakeMed's conduct adversely affected patient health or patient care. The conduct giving rise to this case pertains only to WakeMed's billings to the Medicare program and conduct of WakeMed employees affecting such billings.

2. WakeMed accepts and acknowledges that it is responsible for the acts of its officers, employees, and agents, as described in the Statement of Facts set forth in Attachment B. WakeMed further acknowledges and agrees that the Statement of Facts is true and accurate, and that the wrongdoing described in that document in fact occurred. WakeMed makes no other acknowledgments or admissions than those described in this document and Attachment B.

3. WakeMed agrees that in the event the USAO EDNC initiates a prosecution or civil action for breach of this Agreement, WakeMed will not contest the admissibility of the Statement of Facts in such a proceeding. WakeMed makes no other acknowledgments or admissions.

4. WakeMed and the USAO EDNC agree that, upon the filing of the Criminal Information in accordance with paragraph (1), this

Agreement shall be publicly filed in the United States District Court for the Eastern District of North Carolina.

Waiver of Speedy Trial and Statute of Limitations

5. By entry into this Agreement WakeMed expressly waives all rights to a speedy trial pursuant to the Sixth Amendment of the United States Constitution, Title 18, United States Code, Section 3161, Federal Rule of Criminal Procedure 48(b), and any applicable Local Rules of the United States District Court for the Eastern District of North Carolina, for the period that this Agreement is in effect.

6. By entry into this Agreement, WakeMed also expressly: (1) waives the statute of limitations that would have previously expired but for the execution of prior tolling agreements between the parties with respect to any alleged criminal act that is related to the facts set forth in this Agreement and in the attached Statement of Facts; and (2) waives the statute of limitations that would otherwise expire during the term of this Agreement with respect to any alleged criminal act that has previously been extended by Criminal Tolling agreements and that is related to the facts set forth in this Agreement and in the attached Statement of Facts. WakeMed represents that these waivers

are knowing and voluntary and are made in express reliance on the advice of counsel. Nothing in this Agreement shall be construed to mean that WakeMed is waiving the statute of limitations on any other matters.

Term of the Agreement

7. Absent an early termination as referenced below, this Agreement shall expire 24 months after the date of its acceptance by the Court, except that, in the event that the United States Department of Justice, including but not limited to the USAO EDNC, is conducting an ongoing investigation, prosecution or proceeding related to the facts set forth in the Statement of Facts, the provisions of Paragraphs 16-18 regarding WakeMed's cooperation shall remain in effect until such investigation, prosecution or proceeding is concluded.

8. Notwithstanding anything to the contrary in this Agreement, WakeMed may from time to time petition the USAO EDNC for an early termination of this Agreement, in which case the USAO EDNC will evaluate such requests in good faith taking into consideration WakeMed's compliance as well as any other factors it deems relevant. Neither the expiration nor early termination of either this Agreement, or any portion thereof, shall have any effect on

any other agreement or any portion thereof. WakeMed acknowledges that the USAO EDNC is under no obligation to grant an early termination or explain its reasoning thereto.

Relevant Considerations

9. The USAO EDNC enters into this Agreement based upon the individual facts and circumstances presented by this case and other relevant conduct by WakeMed. Among the facts considered were WakeMed's willingness to:

a. Acknowledge responsibility for the actions of its directors, employees, and agents, as set forth in **ATTACHMENT B**.

b. Continue to cooperate with the United States and its governmental regulatory agencies regarding the criminal investigation underlying the Criminal Information.

c. Enter into: (1) this DPA, along with the attached Statement of Facts; (2) a Settlement Agreement, dated on or about the date hereof, and in the form of **ATTACHMENT C** with the Civil Division of the USAO EDNC; and (3) a Corporate Integrity Agreement negotiated between WakeMed and the United States Department of Health and Human Services, Office of the Inspector General (HHS-OIG) that is included as **ATTACHMENT D**.

d. Employ on an on-going basis an Independent Review Organization pursuant to the terms of a Corporate Integrity Agreement negotiated directly with HHS-OIG.

Remedial Measures and Corporate Compliance Policy

10. WakeMed has taken substantial remedial measures to ensure its compliance with federal laws and regulations relative to

inpatient and outpatient billing for short hospital stays. WakeMed's efforts in this regard include, but are not limited to, the following:

a. WakeMed's Board of Directors hired Strategic Management Services, LLC ("Strategic Management") to conduct outside, independent, comprehensive annual compliance audits that evaluate the effectiveness of WakeMed's compliance program as a whole.

b. The Board voted to make the Compliance Committee a separate Board committee, rather than a subcommittee of the Audit Subcommittee, so that the Board would have focused oversight and evaluation of compliance issues.

c. Pursuant to a recommendation from Strategic Management, the Board voted to change WakeMed's compliance reporting structure so that the Chief Compliance Officer reports directly to the CEO and the Board.

d. WakeMed revised its Corporate Compliance policies, including "Billing Claims and Submission Standards," "Monitoring and Auditing of Compliance Issues," and "Self-Reporting of Errors Related to Government Reimbursement."

e. WakeMed conducted an internal review of claims for one and zero day stays and submitted cancelled claims in excess of $1.4 million dollars, approximately $1.2 million of which were processed and recouped by the Medicare contractor, to refund those dollars to the Medicare program.

f. Physicians on the staff at WakeMed provided input on and approval of changes to components of the Utilization Management plan and process.

g. WakeMed worked with outside consultants to evaluate the patient status determination process, including the

appropriate use of the InterQual "Inpatient Only List" and its relationship to Addendum E.

h. WakeMed added additional case management staff, including assigning a dedicated registered nurse case manager ("RNCM") to the Heart Center to review cardiac cases for medical necessity and appropriate billing status.

i. WakeMed implemented a process in which 100% of all zero day and one day stay claims are held for pre-billing review to evaluate medical necessity, patient status, presence of physician signature on orders, and appropriate adherence to the case management protocol process.

j. WakeMed continues to evaluate its policies, procedures, and practices, implement revisions to processes to increase compliance and billing accuracy, and monitor the effectiveness of its processes.

k. WakeMed has instituted specific practices and procedures to redress and prevent the wrongdoing described in the Statement of Facts. WakeMed has further agreed that these practices and procedures will be implemented with the oversight of an Independent Review Organization, as detailed in a Corporate Integrity Agreement between WakeMed and HHS-OIG.

Ongoing Compliance and Monitoring Obligations

11. WakeMed shall maintain and continue to implement all aspects of its existing compliance program relevant to the matters addressed by this Agreement and attached Statement of Facts throughout the term of this Agreement, subject to WakeMed's ability, with the Government's consent, to modify or supplement the relevant elements of such program to improve its effectiveness.

12. Throughout the term of this Agreement, WakeMed agrees to produce and provide, through the Independent Review Organization, to HHS-OIG and the USAO EDNC, a report of its compliance programs with regard to the matters addressed by this Agreement and attached Statement of Facts as well as any violations of this Agreement or laws and regulations pertaining to the billing of zero or one-day hospital stays as inpatient stays, in the manner and frequency dictated by the Corporate Integrity Agreement. From time to time, HHS-OIG and the USAO EDNC may require supplements to such reports. WakeMed agrees to provide such supplemental reports in a timely fashion and to take remedial action as to any violations or deficiencies discovered.

13. WakeMed agrees that for the duration of this Agreement it will retain and pay the Independent Review Organization referenced above for the purpose of monitoring WakeMed's compliance with this Agreement and law and regulations pertaining to the billing of zero and one-day hospital stays as inpatient hospital stays, as required by the Corporate Integrity Agreement between WakeMed and HHS-OIG that is attached as **ATTACHMENT D**. Such Monitor shall be selected in accordance with the terms of the Corporate Integrity Agreement, and shall have the qualifications and duties

set forth therein. Specifically, the Independent Review Organization shall:

a. Have access to all aspects of WakeMed's patient access, case management, denial management, and billing operations at WakeMed's Raleigh Campus. Such access shall include the ability to interview, with or without others present at the Monitor's discretion, any and all employees, officers and directors and to review any and all documentation or data, in whatever form. However, nothing in this clause shall be interpreted in such a manner as to interfere with any individual's right or WakeMed's right to be represented by counsel during such an interview;

b. Be required to judge the effectiveness of WakeMed's compliance with regards to billing of zero and one-day stay hospital stays and record in writing and address all failures and deficiencies and make recommendations for improvement;

c. Be required, pursuant to the schedule established in the Corporate Integrity Agreement and at least 45 calendar days prior to the scheduled expiration of this Agreement, to prepare a comprehensive written report as to all observations, findings, and recommendations relative to WakeMed's inpatient/outpatient admission, case management, and billing compliance with regards to zero and one-day hospitalization stays; and

d. Be responsive to any and all inquiries by the United States and the regulatory agencies in the interim between the issuance of written reports.

14. The Independent Review Organization need not be given access to such portions of WakeMed's internal documentation, data and communications which are protected by the attorney-client or work-product privilege. However, the assertion of any such

privilege shall be noted in the Monitor's written reports and the Monitor's own communications and recommendations shall not be deemed subject to such privileges.

15. The Independent Review Organization's report may be distributed to any governmental agency deemed appropriate by the USAO and/or the United States Department of Health and Human Services. Absent the necessity of litigation concerning an alleged breach of this Agreement, a Corporate Integrity Agreement, or a Court Order, the Government will treat the Monitor's reports as "confidential commercial information" as that term is used in the Freedom of Information Act, as amended, 5 U.S.C. § 552, 22 C.F.R. Part 171.

Continuing Cooperation & Avoidance of Criminal Conduct

16. WakeMed agrees that its continuing cooperation during the term of this Agreement shall include, but shall not be limited to, the following:

a. Not engaging in or attempting to engage in any felonious criminal conduct.

b. Making available WakeMed officers and employees and imposing no impediment to the availability of former officers and employees, to provide information and/or testimony at all reasonable times as requested by the United States, including sworn testimony before a federal grand jury or in federal trials, as well as interviews with federal law enforcement authorities. However, it is

understood that the United States will not enforce this clause in such a manner as to interfere with any such individual's right to be represented by counsel.

c. Providing testimony, certifications, and other information deemed necessary by the United States or a court to identify or establish the original location, authenticity, or other evidentiary foundation necessary to admit into evidence documents in any criminal proceeding, as requested by the USAO EDNC.

d. WakeMed agrees, if requested by the United States during the term of this Agreement, to call a meeting, on a date and place mutually agreed upon by WakeMed and the United States, of management and other WakeMed employees identified by the USAO EDNC for the purpose of communicating the goals and expected effect of this Agreement.

17. WakeMed acknowledges and understands that its prior, ongoing, and future cooperation are important factors in the decision of the USAO EDNC to enter into this Agreement, and WakeMed agrees to continue to cooperate fully with the United States and with any other governmental agency designated by the United States, regarding any issue about which WakeMed has knowledge or information.

18. WakeMed acknowledges and understands that the provisions of this Agreement, including Paragraphs 16, 17, and 24, do not provide any protection against prosecution of any present or former director, officer, or employee of WakeMed for any violations

committed by them individually, even if such violations accrued only to the financial benefit of WakeMed.

Public Statements by WakeMed

19. WakeMed agrees that it will cause its present and future attorneys, directors, managers and officers not to make any public statement (i.e. press release, press conference, response to analysts, press reports, press inquiries or other similar statements) contradicting: (1) its responsibility for the conduct of its directors, officers, employees, and agents, or (2) any aspect of the Statement of Facts. Any such contradictory public statement may, in the sole discretion of the United States, be deemed a breach of this Agreement. The United States will in good faith consider whether to permit a retraction or correction by WakeMed of such an offending statement or other remedial action to cure such a breach. The United States will notify WakeMed of its decision as to whether it will permit such a cure within 30 days of learning of the breach. For the avoidance of doubt, this paragraph is not intended to apply to any statement (a) by any attorney, director, manager or officer of WakeMed who had been, but, on the date of this Agreement, was no longer employed or retained by WakeMed, or (b) made in connection with any subpoena, discovery

request, testimony, interview or other formal questioning in connection with any criminal or civil proceeding.

Conditional Release from Criminal Liability

20. In return for the full and truthful cooperation of WakeMed as described above, and WakeMed's compliance with the other terms and conditions of this Agreement, the USAO-EDNC agrees, subject to Paragraphs 22 through 26, below, not to: (i) bring any criminal case against WakeMed related in whole or in part to a violation of Title 18, United States Code, Sections 1035 and 2 arising from the unauthorized admission of patients as inpatients and unauthorized marking of physician orders to reflect inpatient admissions, or based on any such conduct that may have occurred prior to the date of this Agreement, except as set forth in Paragraph 1; (ii) use any information related to the conduct described in the Criminal Information or the Statement of Facts against WakeMed in any criminal or civil proceeding; or (iii) seek to revoke WakeMed's privileges as a Medicare provider based upon the conduct described in the Criminal Information and the Statement of Facts.

21. If the Court does not accept this Agreement, the parties will revert to their pre-Agreement positions and may proceed as

each deems appropriate, and nothing herein shall be used against any party hereto or otherwise be admissible in any criminal or civil proceeding based in whole or part on the conduct described in the Criminal Information or the Statement of Facts.

Breach of the Agreement

22. Should the USAO EDNC determine that, during the term of this Agreement, WakeMed knowingly and materially breached this Agreement, including committing any felonious criminal conduct as referenced in Paragraph 16(a), WakeMed shall, in the discretion of the United States, thereafter be subject to prosecution for any federal crimes of which the United States has knowledge, including crimes relating to the matters set forth in the Statement of Facts and which are set forth in the Criminal Information filed in conjunction with this Agreement. If such prosecution results in an obligation by WakeMed to pay any fines, penalties or other similar payments for conduct attributed to WakeMed and taking place prior to the date of this Agreement, then WakeMed shall receive a credit against such fines, penalties or other similar payments in an amount equal to the aggregate payments made pursuant to this Agreement.

23. Should the United States determine that, during the term of this Agreement, WakeMed knowingly and materially breached this Agreement, including committing any felonious criminal conduct as referenced in Paragraph 16(a), the USAO EDNC shall provide written notice to WakeMed of the alleged breach and extend to WakeMed a 30-day window of opportunity within which to make a presentation to the United States to demonstrate that no breach occurred, or, to the extent applicable, that the breach was not material or knowingly committed, or that WakeMed should for other reasons be permitted to cure such breach with specified remedial action. The parties further understand and agree that the determination whether WakeMed has breached this Agreement rests solely in the discretion of the United States, and the exercise of such discretion by the United States under this Paragraph is not subject to review in any court or tribunal outside the Department of Justice. In the event of a breach of this Agreement that results in a prosecution of WakeMed, such prosecution may be premised upon any information provided by or on behalf of WakeMed to the United States at any time, unless otherwise agreed when the information was provided.

24. WakeMed and the USAO EDNC agree that any prosecution that is related to the facts set forth in this Agreement and the

attached Statement of Facts and that is not time-barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against WakeMed, notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the expiration of the Term. By signing this Agreement, WakeMed agrees that the statute of limitations with respect to any prosecution that is not time barred on the date of this Agreement shall be tolled for the Term of this Agreement.

25. WakeMed expressly acknowledges and incorporates by reference the previous Criminal Tolling Agreements between WakeMed and the USAO-EDNC.

26. WakeMed waives all defenses based on the statute of limitations, any claim of preindictment delay, and any speedy trial claim with respect to such prosecution or action, except to the extent that such defenses existed as of the date of the signing of this Agreement or may arise after the conclusion of the tolling period described in the Paragraphs 24 and 25.

Dismissal of Criminal Information

27. The United States agrees that if WakeMed has complied in all material respects with this Agreement, the United States will not continue a criminal prosecution against WakeMed described in

Paragraph 1 and, within 30 days of the expiration or early termination of this Agreement, will move to dismiss with prejudice the Criminal Information filed pursuant to Paragraph 1.

Sale or Merger of WakeMed

28. WakeMed agrees that, if it sells or merges all or substantially all of its business operations as they exist as of the date of this Agreement to or into a single purchaser or group of affiliated purchasers during the term of this Agreement, it shall include in any contract for sale or merger a provision binding the purchaser/successor to conform to the obligations described in this Agreement. This provision shall not be construed, however, to expand the scope of the DPA to facilities other than the WakeMed Raleigh Campus.

Limitation on Binding Effect of Agreement

29. It is understood that this Agreement is limited to WakeMed, and to the extent provided herein, its affiliates and subsidiaries, and the United States on behalf of the U.S. Department of Justice, and does not bind other federal, state or local authorities. However, the USAO EDNC will bring this Agreement, the cooperation of WakeMed, and its compliance with its other obligations under this Agreement to the attention of other prosecuting offices and/or regulatory authorities, if requested to

do so. As used in this agreement, the terms "United States" and "Government" mean the USAO EDNC and for the purposes of paragraphs 6-8, 10 and 22 of this Agreement the United States Department of Health and Human Services.

Complete Agreement

30. This Agreement, which is conditioned on WakeMed's entry into the separate Civil Settlement Agreement and the Corporate Integrity Agreement that are attachments hereto, constitutes the full and complete agreement between WakeMed and the Government with respect to the resolution of the criminal investigation of this matter. No additional promises, agreements, or conditions have been entered into with respect to the resolution of the criminal investigation other than those set forth in this Agreement, and none will be entered into unless in writing and signed by the USAO EDNC, counsel authorized to represent WakeMed, and a duly authorized representative of WakeMed. It is understood that the Government may permit exceptions to or excuse particular requirements set forth in this Agreement at the written request of WakeMed, but any such permission shall be in writing and will not otherwise impact the validity of the Agreement. Nothing in this agreement will supersede or control the provisions of the

Settlement Agreement entered into between WakeMed and the Civil Division of the United States Department of Justice or the Corporate Integrity Agreement between WakeMed and HHS-OIG.

AGREED:

FOR WAKEMED HEALTH AND HOSPITALS

12/18/12

WILLIAM K. ATKINSON, II
President and Chief Executive Officer
WakeMed Health and Hospitals

STEPHEN W. PETERSEN
MAUREEN D. MURRAY
Counsel for WakeMed Health and Hospitals

FOR THE UNITED STATES

THOMAS G. WALKER
United States Attorney
Eastern District of North Carolina

ROBERT J. HIGDON, Jr.
Chief, Criminal Division
Eastern District of North Carolina

WILLIAM M. GILMORE
Assistant U.S. Attorney, EDNC
Criminal Division, Economic Crimes
Eastern District of North Carolina

On this 19th day of December, 2012.

CERTIFICATE OF COUNSEL

I am counsel for WakeMed in the matter covered by the Deferred Prosecution Agreement (the "Agreement") entered into between WakeMed and the United States Attorney's Office for the Eastern District of North Carolina (the "USAO EDNC"). In connection with such representation, I have examined relevant WakeMed documents and have discussed the terms of the Agreement with the Board of Directors of WakeMed. Further, I have carefully reviewed the terms of the Agreement with the Board of Directors of WakeMed and the Vice-President, Legal Services for WakeMed. I have fully advised them of the rights of WakeMed, of possible defenses, and of the consequences of entering into the Agreement. To the best of my knowledge, the decision of WakeMed to enter into the Agreement, based on the authorization of the Board of Directors of WakeMed, is an informed and voluntary one.

Stephen W. Petersen

STEPHEN W. PETERSEN
Counsel for WakeMed Health and Hospitals

On this 6th day of December, 2012.

ATTACHMENT A: CRIMINAL INFORMATION

WMG

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

NO._____

UNITED STATES OF AMERICA	)	
	)	
v.	)	INFORMATION
	)	
WAKEMED d/b/a WAKEMED HEALTH AND HOSPITALS	)	

The United States Attorney charges that:

INTRODUCTION

At all times material to this Information:

1. WAKEMED, doing business as WAKEMED HEALTH AND HOSPITALS (hereinafter "WAKEMED") was a business operating acute care hospitals in Wake County, within the Eastern District of North Carolina.

2. Between the years 2000 and 2008, WAKEMED regularly billed the Government under Medicare parts "A" and "B" for services rendered to Medicare beneficiaries at WAKEMED's Raleigh Campus (hereinafter "WakeMed Raleigh"), located at 3000 New Bern Avenue in Raleigh.

3. Under Medicare rules and regulations, detailed herein, bills submitted to the Government under part "A" pertain to services rendered to "inpatients," while bills submitted under part "B" pertain to services rendered to "outpatients."

4. With respect to routine cardiac surgeries, procedures,

and treatments (referred to collectively herein as "treatments"), Medicare generally pays a higher rate of reimbursement to hospitals for services rendered to "inpatients" as opposed to "outpatients."

5. WakeMed Raleigh utilized various facilities to provide cardiac services to both "inpatients" and "outpatients." A core facility for the provision of cardiac services at WakeMed Raleigh was the "Heart Center Observation Area" (hereinafter "HCOA"). The HCOA contained 41 observation beds and was designed to facilitate a high volume of cardiac treatments. The HCOA did not possess any licensed "inpatient" beds. According to WakeMed's solicitations, "Most patients are discharged from [the HCOA] on the same day as their procedure."

6. In many instances, patients who received cardiac treatments at WakeMed Raleigh's HCOA and other units did not require, nor did they receive, an overnight stay in a hospital bed as an inpatient. Likewise, the admitting physicians at no time intended for the patients to remain in a hospital bed overnight as an inpatient. Nevertheless, WakeMed billed Medicare for these patients as inpatients rather than outpatients and, as such, received a higher reimbursement from Medicare.

7. This Information pertains to certain criminal admissions practices at WakeMed Raleigh Campus conducted by and under the direction of its Director of Patient Access, for which WakeMed is criminally liable. As a result of the admission practices,

detailed herein, WakeMed systematically billed Medicare for numerous inpatient hospital stays that were, in fact, outpatient treatments for which the patient neither required, nor received, an overnight stay in the hospital as an inpatient. These practices resulted in several million dollars in overpayments to WakeMed.

STATUTORY AND REGULATORY BACKGROUND

8. Medicare was a federally funded, national health care benefit program administered through the United States Department of Health and Human Services (HHS). Medicare provided benefits for the elderly, certain disabled people, and persons with permanent kidney failure.

9. Medicare had several components, including part "A," and part "B,". Medicare part "A" generally pertained to covered services rendered to Medicare beneficiaries by hospitals in the inpatient setting. With respect to this case, Medicare part "B" generally pertained to covered services rendered to Medicare beneficiaries by a hospital or by physicians at the hospital, in the outpatient setting.

10. Under Medicare, hospitals were reimbursed at different rates depending upon whether the physician of record ordered that a patient receive services at the hospital as an "inpatient" or as an "outpatient." Inpatients are generally expected by policymakers to require a greater expenditure of hospital resources due to the heightened degree of patient care and longer expected length of

stay needed to treat the patient. Outpatients are generally expected to require a lesser expenditure of resources. Consequently, hospital claims billed to Medicare for services rendered to inpatients are generally reimbursed at a higher rate than claims for services rendered to outpatients.

11. Medicare defined an "inpatient" as a person who was admitted to a hospital for bed occupancy for the purposes of receiving inpatient hospital services. Generally, a patient was considered an inpatient if formally admitted as inpatient with the expectation that he or she would remain at least overnight and occupy a bed. If, after admission, it was determined that the patient could be discharged or transferred to another facility without actually occupying a bed, this fact alone would not change the patient's status as an inpatient for the purposes of Medicare. When patients with known diagnoses entered a hospital for a specific minor surgical procedure or other treatment that was expected to keep them in the hospital for only a few hours (less than 24), they were considered "outpatients" by Medicare, regardless of the hour they came to the hospital, whether they used a bed, and whether they remained in the hospital past midnight.

12. Medicare defined an "outpatient" as a person who was not admitted by the hospital as an inpatient, but was registered on the hospital records as an outpatient and received services from the hospital. Medicare further provided that where the hospital used

the category "day patient," i.e. an individual who received hospital services during the day and was not expected to be lodged in the hospital at midnight, the individual was considered an outpatient.

13. According to Medicare, the physician or other practitioner responsible for a patient's care at the hospital was responsible for deciding whether the patient should be admitted as an "inpatient." Medicare instructed physicians to use a "24-hour period" as a benchmark. Medicare further instructed that physicians should order admission for patients who were expected to need hospital care for 24 hours or more, and treat all other patients on an "outpatient" basis.

ALLEGATIONS CONCERNING ADMISSIONS PRACTICES

14. Various physician practices doing business with WakeMed contacted WakeMed to schedule patients for routine, non-emergency cardiac treatments at WakeMed Raleigh.

15. Prior to the date of treatment, physician practices provided certain preliminary documentation to WakeMed's "pre-admission" or "patient access" nurses (hereinafter "Patient Access Staff"). WakeMed's Patient Access Staff was charged to, among other things, obtain patient demographic information, obtain payment and insurance information, and designate the patient's "admission status" on the hospital's mainframe database.

16. After reviewing documentation to determine whether a

patient's visit would be paid for by Medicare, as opposed to private insurance, the Patient Access Staff initiated an electronic medical record for the patient encounter by opening the new record as either an "inpatient" or "outpatient." The Patient Access Staff applied different standards for the admission of Medicare patients, as opposed to private insurance patients, for this initial determination of status.

17. In many cases, the preliminary documentation provided to the Patient Access Staff by the referring physician practice included a specific, written order designating the patient as an "outpatient." In other instances, the preliminary documentation did not include a specific order indicating the patient's admission status. Regardless, in each and every claim billed to Medicare at issue in this Information, prior to the patient's arrival to WakeMed Raleigh, WakeMed did not receive a written order from a physician indicating that the patient was to be admitted as an "inpatient."

18. In many instances, even when the Patient Access Staff at WakeMed Raleigh was in possession of a written order from a physician indicating that a patient was to be admitted as an "outpatient," the Patient Access Staff admitted the patient as an "inpatient." The Patient Access Staff was instructed to, and did in fact, ignore physician designations of status as "outpatient" on written orders (this conduct being referred to herein as "Ignoring

Orders"). Likewise, the nurses of the Patient Access Staff were not instructed to, nor did they consult with the referring physician prior to admitting patients as "inpatients" on WakeMed's electronic database in contravention of a written order (this conduct being referred to herein as "Failing to Consult").

19. As a result of the foregoing conduct of Ignoring Orders and Failing to Consult, the intentions and expectations of the referring physician regarding the patient's length of stay at WakeMed Raleigh were ignored and circumvented. False status designations flowed through to WakeMed's coding and billing departments, who relied upon the false electronic entries, and methodically billed the visits as inpatient hospital stays despite the fact that the patients were neither expected to, nor did they, remain in the hospital overnight as an inpatient. Consequently, Medicare paid WakeMed substantially more money on the claims than it would otherwise have paid.

20. Some physicians who routinely performed cardiac treatments at WakeMed Raleigh's HCOA did not provide an order to WakeMed's Patient Access Staff to admit their patients as "inpatients" prior to performing the treatment. These physicians would generally schedule the treatment, perform the treatment, and then determine whether the patient would need to be admitted for an overnight stay, or discharged to home. Absent complications following the procedure, these physicians frequently wrote orders

designating patients as "outpatients", along with orders to discharge the patient to their home after a brief recovery period of a few hours. The physicians at no time intended for these patients to remain in a hospital bed overnight as an inpatient.

21. In many of these cases, despite the lack of a written "inpatient" order from the referring physician, WakeMed Raleigh's Patient Access Staff would electronically admit the cardiac patients as "inpatients" on the mainframe database at the time of registration (this conduct being referred to herein as "Admitting Without Orders"). After electronically admitting the patients, the Patient Access Staff then printed a copy of the referring physican's standard orders for routine cardiac procedures. Without any instruction, authorization, or consultation with the referring physician, the Patient Access Staff then marked the box on the orders reflecting that the physician had ordered the patient to be admitted as an "inpatient," when in fact no such order had been given (the conduct being referred to herein as "Fabricating Inpatient Orders").

22. As a result of the foregoing conduct of Admitting Without Orders and Fabricating Inpatient Orders, the intentions and expectations of the referring physician regarding the patient's length of stay at WakeMed Raleigh were ignored and circumvented. False electronic status designations and falsely-marked standard physician orders flowed through to WakeMed's coding and billing

departments who relied upon them, and methodically billed the visits as inpatient hospital stays despite the fact that the patients were neither expected to, nor did they, remain in the hospital overnight as an inpatient. Consequently, Medicare paid WakeMed substantially more money on the claims than it would otherwise have paid.

23. WakeMed Raleigh's Director of Patient Access ("DPA") oversaw and was responsible for the actions of the Patient Access Staff. The DPA was knowledgeable of Medicare rules and regulations defining inpatients and outpatients, and the materiality of the intent of the physician (documented in the form of a written physician order) to the status determination. In fact, the DPA was obligated to ensure that WakeMed Raleigh's patient access policies and procedures were sufficient to ensure compliance with Medicare rules and regulations. Furthermore, the DPA was obligated to ensure that all Patient Access Staff complied with WakeMed's rules and regulations, and otherwise conformed their actions to the law.

24. WakeMed Raleigh's DPA was aware that Medicare paid WakeMed substantially more money for cardiac procedures performed and billed as "inpatient" procedures as opposed to "outpatient" procedures.

25. WakeMed's DPA was also aware that the Patient Access Staff was Ignoring Orders, Failing to Consult, Admitting Without

Orders, and Fabricating Inpatient Orders, as those terms are defined herein. These actions undertaken by the Patient Access Staff, at the direction of the DPA, violated WakeMed's own policies and procedures governing the role of the Patient Access Department, and the authentication of physician orders. The DPA was aware that the inpatient classifications on WakeMed's mainframe database, and the physician orders marked as inpatient without prior consultation or consent from physicians, would be relied upon by subsequent departments at WakeMed, including but not limited to the coding and billing departments. Notwithstanding, the DPA authorized and in fact trained Patient Access Staff to carry on the aforementioned practices.

26. The foregoing actions of the DPA and her staff caused Medicare to overpay WakeMed several million dollars for outpatient hospital treatments that were documented and billed as inpatient hospital stays.

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COUNT ONE

False Statements In Connection With Medicare Benefits & Aiding and Abetting 18 U.S.C. 1035 & 2

27. Paragraphs 1 through 26 of this Information are re-alleged and incorporated by reference as though fully set forth herein.

28. Beginning at a time unknown, but no earlier than January of 2001, and continuing to a time unknown, but no later than January 2008, in the Eastern District of North Carolina, WAKEMED HEALTH AND HOSPITALS, by and through its Director of Patient Access, did, in a matter involving a health care benefit program, knowingly and willfully make, and cause to be made: (1) materially false and fictitious statements and representations, and (2) materially false writings and documents; knowing the same to contain materially false and fictitious statements and entries, in connection with the delivery of and payment for health care benefits, items, and services.

All in violation of Title 18, United States Code, Sections 1035 and 2.

THOMAS G. WALKER
United States Attorney

By: WILLIAM M. GILMORE
Assistant United States Attorney
Criminal Division

ATTACHMENT B: STATEMENT OF FACTS

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

UNITED STATES OF AMERICA	)	
	)	
v.	)	**STATEMENT OF FACTS**
	)	
WAKEMED HEALTH AND HOSPITALS	)	

I. INTRODUCTION

This Statement of Facts is incorporated by reference as part of the Deferred Prosecution Agreement (the "Agreement") between WAKEMED, a North Carolina Corporation ("WakeMed"), and the United States Attorney's Office for the Eastern District of North Carolina ("USAO EDNC") (hereinafter the "Parties"). The Parties hereby agree and stipulate that the following information is true and accurate. As set forth in Paragraph 2 of the Agreement, WakeMed admits that the conduct described herein occurred, and acknowledges that it is responsible for the acts of its officers, employees, and agents. Should the USAO EDNC proceed with the prosecution that is deferred by the Agreement or any related civil action, WakeMed agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding. If this matter were to proceed to trial, the United States would prove

beyond a reasonable doubt, by admissible evidence, the facts alleged in this Statement of Facts. This evidence would establish the following:

II. STATUTORY AND REGULATORY BACKGROUND

1. Medicare was a federally funded, national health care benefit program administered through the United States Department of Health and Human Services (HHS). Medicare provided benefits for the elderly, certain disabled people, and persons with permanent kidney failure.

2. Medicare had several components, including part "A" and part "B". Medicare part "A" generally pertained to covered services rendered to Medicare beneficiaries by hospitals in the "inpatient" setting. With respect to this case, Medicare part "B" generally pertained to covered services rendered to Medicare beneficiaries by a hospital or by physicians at the hospital in the "outpatient" setting.

3. Under Medicare, hospitals were reimbursed at different rates depending upon whether the physician of record or other practitioner responsible for a patient's care at the hospital ordered that a patient receive services at the hospital as an "inpatient" or as an "outpatient." Inpatients are generally

expected by policymakers to require a greater expenditure of hospital resources due to the heightened degree of patient care and longer expected length of stay needed to treat the patient. Outpatients are generally expected to require a lesser expenditure of resources. Consequently, hospital claims billed to Medicare for services rendered to inpatients are generally reimbursed at a higher rate than claims for services rendered to outpatients.

4. Medicare defined an "inpatient" as a person who was admitted to a hospital for bed occupancy for the purpose of receiving inpatient hospital services. Generally, a patient was considered an inpatient if formally admitted as inpatient with the expectation that he or she would remain at least overnight and occupy a bed. If, after admission, it was determined that the patient could be discharged or transferred to another facility without actually occupying a bed, this fact alone would not change the patient's status as an inpatient for the purposes of Medicare. When patients with known diagnoses entered a hospital for a specific minor surgical procedure or other treatment that was expected to keep them in the hospital for only a few hours (less than 24), they were generally considered "outpatients" by Medicare

regardless of the hour they came to the hospital, whether they used a bed, and whether they remained in the hospital past midnight.

5. Medicare defined an "outpatient" as a person who was not admitted by the hospital as an inpatient, but was registered on the hospital records as an outpatient and received services from the hospital. Medicare further provided that where the hospital used the category "day patient," i.e. an individual who received hospital services during the day and was not expected to be lodged in the hospital at midnight, the individual was considered an outpatient.

6. According to Medicare, the physician or other practitioner responsible for a patient's care at the hospital was responsible for deciding whether the patient should be admitted as an "inpatient." Medicare instructed physicians to use, among other things, a "24-hour period" as a benchmark when determining inpatient billing status. Medicare further instructed that physicians should order admission for patients who were expected to need hospital care for 24 hours or more, and treat all other patients on an "outpatient" basis.

III. BACKGROUND ON WAKEMED HEALTH AND HOSPITALS

7. WakeMed is a business consisting of acute care hospitals, outpatient diagnostic and rehabilitation centers, skilled nursing facilities, freestanding emergency departments, and medical parks. WakeMed, through its system of facilities, treats patients from a broad geographic area within the Eastern District of North Carolina.

8. At the time WakeMed was founded in 1961, it was owned by Wake County. WakeMed first became a certified Medicare provider in June of 1966. In 1997, WakeMed became a private, not-for-profit health care provider.

9. WakeMed is presently Wake County's only Level I trauma center, inpatient rehabilitation hospital, dedicated pediatric inpatient unit, children's emergency department, Level IV intensive care nursery, and air ambulance program, and one of only two primary stroke centers.

10. WakeMed regularly treats a high volume of patients. For example, during the 2010 fiscal year, WakeMed treated 575,369 patients, of which 111,056 were Medicare beneficiaries. During this same period, WakeMed also treated 131,496 Medicaid patients.

11. WakeMed regularly provides services to the uninsured and indigent, resulting in a large amount of services for which WakeMed is not compensated. For example, in 2009, WakeMed was found by a state regulatory agency to have provided $62,314,585 in uncompensated care.

12. WakeMed, both directly and through the WakeMed Faculty Physicians, is Wake County's largest private employer. In fiscal year 2010, WakeMed employed approximately 7,607 employees. During this same period, WakeMed also provided volunteer work opportunities to more than 1,000 volunteers, and had 1,200 credentialed physicians on staff. WakeMed's gross wages to its employees during the 2010 fiscal year amounted to more than $396 Million.

13. During its 50 years of operation, no facility in the WakeMed system has ever had its Medicare provider agreement terminated, been subject to civil monetary penalties, or had any other Medicare sanctions imposed.

IV. WAKEMED'S KNOWLEDGE OF OBLIGATIONS CONCERNING STATUTES, REGULATIONS, AND MANUALS REGARDING MEDICARE CLAIMS

14. WakeMed was at all times aware of, and had access to, the relevant regulations, policies and manuals governing claims for

inpatient services which were billed to Medicare.

15. WakeMed acknowledges and admits that it was at all times bound by said regulations, codes, polices, and manuals, and any and all definitions contained within the same, governing the admission of and billing for patients receiving services billed to Medicare.

16. WakeMed, through its employees and agents, has received training and education relating to appropriate billing to Medicare of "short" hospital stays.

17. In June of 2000, WakeMed's Quality Improvement Organization (QIO), The Carolinas Center for Medical Excellence (CCME), presented a program to North Carolina hospital providers relating to improper billings. Some WakeMed personnel served on the panel of speakers for the conference. The QIO's written material from its presentation stated that "One of the responsibilities of a hospital under agreement with Medicare is to monitor the necessity of inpatient admission. It is the attending physician's decision to determine the appropriate level of care setting for the patient (i.e. outpatient observation versus inpatient)."

18. Later, WakeMed's QIO provided WakeMed with a 2005 Compliance Workbook through the government sponsored Hospital

Payment Monitoring Program (HPMP) that provided extensive guidance and instructions to hospitals related to unnecessary admissions and that addressed billing for "short" hospital stays. The HPMP Compliance Workbook indicated at various locations that the physician was responsible for the admission of the patient.

19. WakeMed was never instructed by its QIO that it was permissible under Medicare rules and regulations to admit patients as inpatients without a valid order from the physician of record.

V. ORIGIN OF INVESTIGATION

20. Cahaba Safeguard Administrators, LLC (Cahaba) was retained by the Government as a Program Safeguard Contractor (PSC). Cahaba was charged to identify possible areas of fraud and abuse relating to Medicare Part A claims.

21. In 2007, Cahaba performed a proactive data analysis concerning Medicare Part A providers in North Carolina to identify those having a high number of claims for inpatient hospital stays lasting less than one day.

22. Cahaba discovered that in many instances, providers billed claims in a diagnostic related group (DRG) that had an expected length of stay of two or more days when, in fact, the patients did not stay in the hospital for even one day. WakeMed

was identified as the North Carolina provider with the largest percentage of these "zero-day stay" billings. Additionally, WakeMed was found to be the seventh highest in the United States for zero-day stays during this time period.

23. As a result of these findings, Cahaba initiated an audit of WakeMed's Medicare billings for zero-day stays. Cahaba obtained a sampling of zero-day stay records from WakeMed from the period between October 1, 2003 and September 30, 2006. Upon review of those records, Cahaba discovered that in most instances, the patients visited the hospital for a scheduled cardiac procedure and were discharged home on the same day as the procedure. Additionally, WakeMed billed inpatient services when in fact the attending physicians had not ordered that the patients be admitted as an inpatient and the patients were never assigned to or occupied an inpatient bed.

24. On November 30, 2007, Cahaba personnel visited WakeMed's Campus to have WakeMed's staff explain their processes for admission, coding, and billing of medical services billed to Medicare. The purpose of the visit was to determine why a large number of hospital visits for planned outpatient procedures were billed as inpatient hospital stays. The visit was conducted by a

Cahaba benefit integrity investigator and benefit integrity nurse.

25. During Cahaba's visit to WakeMed's Campus, a representative of WakeMed's "Denial Management Team" and her supervisor, WakeMed's Director of Patient Access, told the Cahaba investigators that, under WakeMed's policies and procedures, the physician's order determined if the patient status at WakeMed was inpatient or outpatient. The Director of Patient Access and her subordinate further advised the Cahaba investigators that for scheduled procedures, the attending physician's office would call WakeMed and advise of the patient status (inpatient or outpatient), and that if the status changed later, it had to be done through a physician's order.

26. In connection with the Cahaba audit, WakeMed's Director of Patient Access provided Cahaba a copy of a document entitled "Scope of Service" which detailed the role of the Patient Access Department at WakeMed. Per the Scope of Service, the Patient Access staff, "obtains physician orders for pre-scheduled patients," "dialogues with physician/office staff to obtain clinical information," and "use[es] clinical data and admission criteria to place patients in an appropriate care setting and at the proper level of care." The Scope of Service was approved by

the Director of Patient Access, and further identified the Director of Patient Access as being responsible for the actions of the Patient Access Staff.

27. WakeMed also provided Cahaba a copy of certain official WakeMed policies and procedures for the registration and status designation of patients receiving scheduled procedures. Each of these procedures, which were approved by and under the supervision of the Director of Patient Access, required WakeMed employees to utilize the physician's order as an integral part of the admission process and status determination for the patient as either an inpatient or an outpatient.

28. Cahaba was unable to reconcile WakeMed's statements regarding its admission and billing procedures with the medical records and other data obtained from WakeMed and physician practices relating to the sample of patients at issue. Cahaba found that, in many instances, WakeMed had admitted and billed hospital visits as inpatients when there was not any order from the physician directing the inpatient admission of the patient. To the contrary, the orders often directed that the patients be designated as outpatients. Additionally, Cahaba found that in many cases, WakeMed had billed patient visits as inpatient stays when the

physician billed his services as outpatient procedures. Based upon these discrepancies, Cahaba referred the case to the United States Department of Health and Human Services, Office of the Inspector General (HHS-OIG), for further inquiry.

29. HHS-OIG, with the assistance of the United States Attorney's Office, subpoenaed various additional medical records from WakeMed. HHS-OIG also requested that WakeMed produce numerous employees to be interviewed regarding WakeMed's procedures affecting the billing of patient encounters at WakeMed as either inpatient or outpatient. WakeMed produced records and made witnesses available to HHS-OIG as requested.

30. HHS-OIG conducted numerous interviews of WakeMed employees with the assistance of the USAO-EDNC.

31. The statements contained in the following section are stipulated facts which were discovered through the course of those investigations.

VI. FINDINGS CONCERNING WAKEMED'S ADMISSION PRACTICES

32. Between the years 2000 and 2008, WakeMed regularly billed the Government under Medicare parts "A" and "B" for services rendered to Medicare beneficiaries at WakeMed's Raleigh Campus (hereinafter "WakeMed Raleigh"), located at 3000 New Bern Avenue in

Raleigh. A large number of these billings pertained to short hospital stays in which a patient visited WakeMed for a planned procedure, successfully received the procedure, and was discharged home the same day without staying in an inpatient bed overnight.

33. Many of the procedures performed in connection with these short stay billings at WakeMed Raleigh were routine, non-emergency cardiac treatments, and were performed at a facility known as the Wake Heart Center. The Wake Heart Center was built in 1998 and housed various physician practices whose patients were frequently treated at one of the Heart Center's eight cardiac catheterization labs and two electrophysiology labs.

34. WakeMed engaged in various practices that caused WakeMed to bill the Government under Part "A" for inpatient services when WakeMed did not possess an order supporting that billing status. These practices[1] occurred in various departments at WakeMed, including WakeMed's Patient Access Department, Case Management Department, and Coding departments. While the practices

[1] None of the practices, described in detail herein, had any impact upon the actual patient care received by WakeMed's patients. In fact, for all of the patient encounters that were the subject of the investigation, the billing status of the patient (i.e., outpatient or inpatient) did not affect or change the care the patients received.

predominately impacted the admission status of and billing for cardiac patients treated at the Wake Heart Center, other units were also affected to a lesser degree.

35. With respect to the claims under investigation, prior to the date of treatment for planned procedures, physician practices provided certain preliminary documentation to WakeMed's "pre-admission" or "patient access" nurses (hereinafter "Patient Access Staff"). WakeMed's Patient Access Staff was charged to, among other things, obtain physician orders, obtain patient demographic information, obtain payment and insurance information, and enter the patient's "admission status" on the hospital's mainframe database.

36. The Patient Access Staff applied different standards for the admission of Medicare patients, as opposed to private insurance patients, for this initial determination of status. After reviewing documentation to determine whether a patient's visit would be paid for by Medicare, the Patient Access Staff initiated an electronic medical record for the patient encounter.

37. To create the electronic medical record, WakeMed's Patient Access staff entered the patient demographic and procedural information into its mainframe computer. WakeMed utilized a

commercially available software program that required the Patient Access Staff to select a patient status at the initiation of the medical record. The software did not provide a mechanism to put off or place on hold the designation of the patient as an inpatient or outpatient.

38. Most of the claims under investigation involved patients referred to WakeMed by two different physician group practices. Between these two practices, one practice typically provided written physician orders designating the patient's admission status prior to admission. The second physician practice typically did not provide written physician orders designating the patient's admission status prior to admission.

39. Despite the existence, in some instances, of written physician orders designating the patient's admission status as inpatient or outpatient, the Patient Access Staff did not always follow the status ordered by the physician. Instead, the Patient Access Staff admitted patients as inpatients or outpatients according to a list disseminated by the Director of Patient Access that was derived in part from Addendum E and InterQual.[2] The

[2] Addendum E, as discussed herein, was a set of procedures for which Medicare would only issue payment when rendered in the "inpatient" setting. InterQual was a proprietary product created

Patient Access Staff also did not, in all cases, and was not required by its supervisor, to contact physicians prior to registering patients as inpatients, even when the status assigned by the Patient Access Staff directly conflicted with a physician's order. As a result, patients were routinely admitted to the hospital as inpatients without, or in contravention of, physician orders.

40. In other cases, patients referred to WakeMed by a second practice were admitted as inpatients by WakeMed's Patient Access Staff even though the physician had not ordered the admission of the patient. The Patient Access Staff utilized the same list, described above, to determine whether the patient would be classified on WakeMed's mainframe computer as an inpatient or outpatient.

41. In many of these cases, after electronically designating the patients as inpatients, the Patient Access Staff then printed a copy of the referring physician's standard orders for routine cardiac procedures. Without any further instruction,

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by McKesson Corporation that, among other things, identified procedures which it deemed to be appropriate for the inpatient hospital setting. Medicare did not sanction the use of InterQual as a means of superseding a physician's order.

authorization, or consultation with the referring physician, the Patient Access Staff then marked the box on the physician's orders reflecting an inpatient admission when, in fact, no such order had been given. The Patient Access Staff was not required to, nor did they, consult with the physicians before marking the orders to reflect an "inpatient" admission. These actions violated WakeMed's written policies and procedures governing the initiation and execution of standing orders, and the pre-admission and pre-registration of Medicare patients.

42. WakeMed Raleigh had supervisors who were responsible for the actions of the Patient Access Staff. The supervisors were knowledgeable of Medicare rules and regulations defining inpatients and outpatients, and the importance of the intent of the physician to the status determination. WakeMed Raleigh's supervisors were obligated to ensure that WakeMed Raleigh's patient access policies and procedures were sufficient to ensure compliance with Medicare rules and regulations. These supervisors were obligated to ensure that all Patient Access Staff complied with WakeMed's rules and regulations, and otherwise conformed their actions to the law.

VIII. REMEDIAL MEASURES

43. Following the Cahaba audit and subsequent investigations, the USAO-EDNC has learned of various remedial measures undertaken by WakeMed as a result of the facts discovered through the investigation. These remedial measures include, but are not limited to, those set forth in this Section.

44. After the Cahaba audits and inquiries, but before receiving additional subpoenas from the Department of Justice, WakeMed conducted an internal review of claims for one and zero day stays and attempted to refund approximately $1.4 million to the Medicare program. Of this amount, $1.2 million was actually processed and recouped by the Medicare contractor.

45. Following the November 2007 and January 2008 Cahaba audits, WakeMed took steps to evaluate, revise, and improve its Corporate Compliance Program to address the risk of compliance issues arising from the evaluation and determination of patient status for Medicare billing purposes.

46. In 2008, the WakeMed Board of Directors hired Strategic Management Services, LLC ("Strategic Management") to conduct outside, independent, comprehensive annual compliance audits.

47. The WakeMed Board voted to make the Compliance Committee a separate Board committee, rather than a subcommittee of the Audit Subcommittee, so that the Board would have focused oversight and evaluation of compliance issues.

48. Prior the USAO-EDNC investigation, WakeMed's Director of Corporate Compliance reported to WakeMed's Senior Vice President of Finance. Pursuant to a recommendation from Strategic Management, the Board voted to change the compliance reporting structure so that the Chief Compliance Officer reports directly to the CEO and the Board.

49. WakeMed revised its Corporate Compliance policies, including "Billing Claims and Submission Standards," "Monitoring and Auditing of Compliance Issues," and "Self-Reporting of Errors Related to Government Reimbursement."

50. Physicians on the staff at WakeMed provided input on and approval of changes to components of the Utilization Management plan and process.

51. WakeMed worked with outside consultants to evaluate the patient status determination process, including the appropriate use of the InterQual "Inpatient Only List" and its relationship to Addendum E.

52. WakeMed added additional case management staff, including assigning a dedicated registered nurse case manager ("RNCM") to the Heart Center to review cardiac cases for medical necessity and appropriate billing status.

53. WakeMed implemented a process in which 100% of all zero day and one day stay claims are held for pre-billing review to evaluate medical necessity, patient status, presence of physician signature on orders, and appropriate adherence to the case management protocol process.

54. WakeMed adopted and implemented specific policies and procedures to ensure that physician orders to either admit a patient, or not admit a patient, are followed. WakeMed further adopted polices to ensure that, where appropriate, WakeMed employees have appropriate dialogue with physicians concerning patient admission status. WakeMed further consented and agreed to ongoing monitoring by a third party to ensure compliance with the foregoing policies and procedures.

55. WakeMed continues to evaluate its policies, procedures, and practices, implement revisions to processes to increase compliance and billing accuracy, and monitor the effectiveness of its processes.

ATTACHMENT C: CIVIL SETTLEMENT AGREEMENT

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the United States Department of Health and Human Services ("HHS") (collectively the "United States"), and WakeMed d/b/a WakeMed Health and Hospitals ("WakeMed"), (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Defendant WakeMed is a corporation that owns and operates two hospitals, WakeMed Raleigh Campus and WakeMed Cary Hospital that provide medical services in Wake County, North Carolina.

C. The United States contends that WakeMed submitted or caused to be submitted claims for payment to the Medicare Program (Medicare), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1.

D. The United States contends that it has certain civil claims against WakeMed arising from false claims to Medicare for short-term inpatient hospital admissions that were billed incorrectly as "zero-day" admissions (where the bill showed admission and discharge on the same calendar day) when the claims should have been submitted for outpatient/observation visits during the period from October 1, 2003 through August 31, 2010, for WakeMed's Raleigh and Cary hospital facilities. That conduct is referred to below as the Covered Conduct.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. WakeMed and the United States agree to settle the Covered Conduct described in paragraph D above for a total payment of $ 8 million ("Settlement Amount"). Payment shall consist of the following: WakeMed shall pay $6,775,419.58 to the United States within five (5) business days via wire transfer per written payment instructions, which will be provided by the United States Attorney's Office for Eastern District of North Carolina, no later than 5 days after the Effective Date of this Agreement. WakeMed will be credited $1,224,580.42 toward the settlement amount for amounts that WakeMed has paid to the Medicare program for certain claims that fall within the Covered Conduct.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon WakeMed's full payment of the Settlement Amount, the United States releases WakeMed, together with its current and former: parent corporations; direct and indirect subsidiaries; brother or sister corporations; divisions; owners; and affiliates; officers and directors of the Board of Directors of WakeMed, and the successors and assigns of any of them, from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. In consideration of the obligations of WakeMed in this Agreement and the Corporate Integrity Agreement (CIA), entered into between the OIG-HHS and WakeMed, and

conditioned upon WakeMed's full payment of the Settlement Amount, the OIG-HHS agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against WakeMed under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 4 (concerning excluded claims), below, and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude WakeMed from Medicare, Medicaid, and other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 4, below.

4. Notwithstanding the release given in paragraph 2 of this Agreement, or any other term of this Agreement, and except as conditionally released in a related Deferred Prosecution Agreement ("DPA") with the U.S. Attorney for the Eastern District of North Carolina, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon obligations created by this Agreement;

f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;

g. Any liability for failure to deliver goods or services due;

h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

i. Any liability of individuals (including current or former directors, officers, employees, or agents of WakeMed) who receive written notification that they are the target of a criminal investigation (as defined in the United States Attorneys' Manual), are indicted or charged, or who enter into a plea agreement, related to the Covered Conduct.

5. WakeMed waives and shall not assert any defenses WakeMed may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

6. WakeMed fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and

expenses of every kind and however denominated) that WakeMed has asserted, could have asserted, or may assert in the future against the United States, and its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

7. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld as of the Effective Date of this Settlement Agreement from payment by any Medicare carrier or intermediary or any state payer related to the Covered Conduct; and WakeMed agrees not to resubmit to any Medicare carrier or intermediary or any state payer any previously denied claims related to the Covered Conduct, and agrees not to appeal and to withdraw any appeals of any such denials of claims.

8. WakeMed agrees to the following:

(a) Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of WakeMed, its present or former officers, directors, employees, and agents in connection with:

(1) the matters covered by this Agreement and the related Deferred Prosecution Agreement;

(2) the United States' audit(s) and civil and criminal investigation(s) of the matters covered by this Agreement;

(3) WakeMed's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and criminal

investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);

(4) the negotiation and performance of this Agreement and the Deferred Prosecution Agreement;

(5) the payment WakeMed makes to the United States pursuant to this Agreement; and

(6) the negotiation of, and obligations undertaken pursuant to the CIA to: (i) retain an independent review organization to perform annual reviews as described in Section III of the CIA; and (ii) prepare and submit reports to the OIG-HHS, are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs). However, nothing in this paragraph 8(a)(6) that may apply to the obligations undertaken pursuant to the CIA affects the status of costs that are not allowable based on any other authority applicable to WakeMed.

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for in nonreimbursable cost centers by WakeMed, and WakeMed shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request

submitted by WakeMed or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: WakeMed further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by WakeMed or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. WakeMed agrees that the United States, at a minimum, shall be entitled to recoup from WakeMed any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by WakeMed or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on WakeMed or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine WakeMed's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

9. WakeMed agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, WakeMed shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. WakeMed further agrees within a reasonable time to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

10. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in this Agreement, such as in Paragraphs 2 (release) above and 11 (waiver for beneficiaries), below and as stated in the related Deferred Prosecution Agreement.

11. WakeMed agrees that it shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

12. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

13. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

14. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Eastern District of North Carolina. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against either Party for that reason in any subsequent dispute.

15. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

16. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

17. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

18. This Agreement is binding on WakeMed's successors, transferees, heirs, and assigns.

19. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public. WakeMed may also disclose this Agreement to the public if desired and after the United States' first disclosure.

20. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 12-18-12

THOMAS G. WALKER
United States Attorney

BY: Neal Fowler
NEAL I. FOWLER
Assistant United States Attorney
Eastern District of North Carolina

DATED: _____

BY: _____
ROBERT K. DeCONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health
and Human Services

THE UNITED STATES OF AMERICA

DATED:_____

THOMAS G. WALKER
United States Attorney

BY:_____
NEAL I. FOWLER
Assistant United States Attorney
Eastern District of North Carolina

DATED: 12/19/12

BY: Robert K. DeConti
ROBERT K. DeCONTI
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health
and Human Services

WAKEMED

DATED: 12/18/12

BY: _____
DR. WILLIAM K. ATKINSON, Ph.D.
President and Chief Executive Officer
WakeMed

APPROVED AS TO FORM:

DATED: 12-18-12

BY: _____
MAUREEN DEMAREST MURRAY
STEPHEN W. PETERSEN
Smith Moore Leatherwood LLP
Counsel for WakeMed

ATTACHMENT D: CORPORATE INTEGRITY AGREEMENT

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

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

12/18/12
DATE

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

12-18-12
DATE

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

Robert K. DeConti

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

12/19/12

DATE

Sandra Jean Sands

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

12/18/2012

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.