

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into between the United States of America ("United States"), acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"); and University Medical Center of Southern Nevada ("UMC") (hereafter referred to as "the Parties"), through their authorized representatives.

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. UMC provides inpatient and outpatient health care services to Medicare beneficiaries and others.

B. In connection with such services, UMC has 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. §§ 1395-1395ggg.

C. Medicare payments to a hospital for inpatient treatment rendered to a beneficiary generally are based upon the beneficiary's "principal diagnosis", as set forth by the hospital.

D. The Medicare program relies upon participating hospitals to properly indicate the principal diagnosis through the use of standard diagnosis codes.¹

E. The United States conducted an investigation into inpatient payment claims submitted to Medicare by hospitals with the principal diagnosis code of 482.89 (pneumonia due to "other specified bacteria").

F. The United States contends that it has certain civil claims against UMC under the False Claims Act, 31 U.S.C. §§ 3729-3733, and other federal statutes and/or common law doctrines for engaging in the following alleged conduct during the period from October 1, 1992 through September 30, 1997 in that UMC submitted or caused to be submitted claims to Medicare with the principal diagnosis codes of 482.89 that were not supported by the corresponding medical records (hereinafter referred to as the "Covered Conduct"). The United States alleges that, as a result of these claims, UMC received payments to which it was not entitled.

G. The United States also contends that it has certain administrative claims against

¹ International Classification of Diseases, 9th Revision, Clinical Modification ("ICD-9-CM").

UMC under the provisions for permissive exclusion from Medicare, Medicaid and other federal health care programs, 42 U.S.C. § 1320a-7(b), and the provisions for civil monetary penalties, 42 U.S.C. § 1320a-7a, and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812, for the Covered Conduct.

H. UMC has provided documents and information to the United States in response to the government's investigation of the Covered Conduct, including patient files for which claims were submitted to the Medicare Programs with the principal diagnosis code of 482.89, and UMC represents that such response has been truthful, accurate, and complete to the best of its current knowledge and belief.

I. UMC denies the contentions of the United States as set forth in paragraphs F and G above and as forth in the action captioned United States ex rel. Health Outcomes Technologies v. University Medical Center, Civil Action No. CV-S-01-538-RLH (RJJ) (UNDER SEAL), in the United States District Court for the District of Nevada.

J. To avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, the Parties reach a full and final settlement as set forth below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. UMC agrees to pay to the United States the sum of \$1,163,488 (the "Settlement Amount"), as follows: UMC agrees to make payment of the Settlement Amount less an offset of \$438,488 – which offset results from a repayment of \$438,488 made by UMC to the United States on or about January 29, 1999 – by electronic funds transfer pursuant to written instructions provided by Michael F. Hertz, Director, Commercial Litigation Branch. UMC agrees to make this electronic funds transfer in the amount of \$725,000 no later than five (5) business days after the effective date of this Agreement.

2. UMC agrees to cooperate with the United States in the administrative, civil or criminal investigation or prosecution of any person concerning the Covered Conduct, and concerning similar matters involving other hospitals and others, by providing accurate, truthful, and complete information whenever, wherever, to whomever and in whatever form the United States may reasonably request without requiring the expenditure by UMC of unreasonable time, effort, or expense. Upon reasonable notice, UMC will make reasonable efforts to facilitate access to, and encourage the cooperation of, its directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals, and will furnish to the United States, upon reasonable request, all non-privileged documents and records in its possession, custody or control relating to the Covered Conduct.

3. This agreement includes certain integrity provisions ("Integrity Provisions") that UMC has entered into with HHS that are contained in paragraph 8 below. UMC will implement its obligations under the Integrity Provisions as set forth in that paragraph.

4. UMC releases the United States, HHS, and each of their officers, agents, employees, and contractors and Relator from any and all claims, causes of action, adjustments, and set-offs of any kind arising out of or pertaining to the Covered Conduct, including the investigation of the Covered Conduct and this Agreement.

5. Subject to the exceptions in Paragraph 7 below, in consideration of the obligations of UMC set forth in this Agreement, conditioned upon UMC's timely payment in full of the Settlement Amount, and subject to paragraphs 14 and 15 below [concerning bankruptcy proceedings commenced within 91 days of the date of any payment under this Agreement,] the United States (on behalf of itself, its officers, agents, and its agencies and departments referenced above in paragraph 4), and Relator release UMC, its predecessors, successors, assigns, and affiliates and current and former board members, officers and employees from any civil or administrative monetary claim the United States has or may have 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, breach of contract and fraud, for the Covered Conduct. The United States expressly reserves any claims against any entities other than UMC and reserves any claims against any individuals except those listed herein.

6. In consideration of the obligations of UMC set forth in this Agreement, conditioned upon UMC's payment in full of the Settlement Amount, and subject to paragraphs 14 and 15 below (concerning bankruptcy proceedings commenced within 91 days of the date of any payment under this Agreement), the OIG-HHS agrees to release and refrain from instituting, directing or maintaining any administrative claim or any action seeking exclusion from Medicare, Medicaid or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against UMC under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b) (permissive exclusion), for the Covered Conduct, except as reserved in the Integrity Provisions and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude UMC or others from Medicare, Medicaid or other federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion). Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in Paragraph 7 below.

7. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including UMC) are any and all of the following:

(1) Any civil, criminal or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code);

- (2) Any criminal liability;
 - (3) Any administrative liability, including mandatory exclusion from Federal health care programs, except as explicitly otherwise stated in this Agreement;
 - (4) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
 - (5) Any claims based upon such obligations as are created by this Agreement;
 - (6) Any express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services, provided by UMC;
 - (7) Any claims based on a failure to deliver items or services billed;
- and
- (8) Any civil or administrative liability of individuals (including current or former board members, officers or employees) who receive written notification that they are the target of a criminal investigation (as defined by the United States Attorneys' manual), are indicted, charged, or convicted, or who enter into a plea agreement related to the Covered Conduct.

8. Integrity Provisions

I. PREAMBLE

UMC agrees to the following Integrity Provisions with OIG-HHS to promote compliance by its officers, employees (including employed physicians), and agents, ("Covered Persons") 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"). For the purposes of these Integrity Provisions, the definition of "Covered Persons" excludes housekeeping staff, dietary employees and, maintenance workers, construction workers, plant operations workers, grounds keeping workers, security staff and mailroom employees. In addition, for purposes of these Integrity Provisions, "Covered Contractor" is an entity (or individual) that, although not a Covered Person, either provides patient care to Federal health care program beneficiaries in UMC facilities or participates in billings or related submissions to Federal health care programs for UMC on a regular basis (i.e., more often than two weeks over a 52-week period). Prior to the execution of this Agreement, UMC established a compliance program which is described in the UMC Compliance Manual. UMC agrees to continue its operation of the compliance program for the term of these Integrity Provisions. UMC may modify its compliance program as appropriate, but at a minimum, UMC shall ensure

that it complies with the integrity obligations set forth below:

II. TERM OF THE INTEGRITY PROVISIONS

The period of the compliance obligations assumed by UMC under these Integrity Provisions shall be three (3) years from the Effective Date of this Settlement Agreement. The Effective Date of this Settlement Agreement shall be concurrent with the date of the final signature to this Settlement Agreement.

Sections VII, VIII, IX, X and XI shall expire no later than 120 days from the OIG's receipt of: (i) UMC's final annual report; or (ii) any additional materials submitted by UMC pursuant to the OIG's request, whichever is later.

III. INTEGRITY PROVISIONS

UMC hereby agrees to maintain a Compliance Program that includes the following elements:

A. Compliance Officer and Team.

1. *Compliance Officer.* Pursuant to the UMC Compliance Manual, UMC has established the position of Compliance Officer and appointed an individual to serve in that capacity. The Compliance Officer is and shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in these Integrity Provisions and with Federal health care program requirements. The Compliance Officer does and shall report directly to UMC's Chief Executive Officer, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Trustees of UMC, and shall be authorized to report on such matters to the Board of Trustees at any time. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by UMC as well as for any reporting obligations created under these Integrity Provisions.

UMC shall report to the OIG, in writing, any changes in the identity or position description 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 these Integrity Provisions, within 15 days of such a change.

2. *Compliance Committee.* Pursuant to the UMC Compliance Manual, UMC has established a Compliance Committee, referred to as the Compliance Team, and appointed individuals to serve on that Team. The Compliance Team shall, at a minimum, include the Compliance Officer and other members of senior management necessary to meet the requirements of these Integrity Provisions (e.g., senior executives of relevant departments, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair

the Compliance Team and the Team shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

UMC shall report to the OIG, in writing, any changes in the composition of the Compliance Team, or any actions or changes that would affect the Compliance Team's ability to perform the duties necessary to meet the obligations in these Integrity Provisions, within 15 days of such a change.

B. Written Standards.

1. *Compliance Handbook.* UMC has developed a written Employee Compliance Handbook ("Compliance Handbook"). To the extent not already accomplished, the Compliance Handbook shall be distributed to all Covered Persons and Covered Contractors within 90 days of the Effective Date of this Agreement. UMC shall make the promotion of, and adherence to, the Compliance Handbook an element in evaluating the performance of all employees. The Compliance Handbook, at a minimum, sets forth:

- a. UMC'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. UMC's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with UMC's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of these Integrity Provisions);
- c. the requirement that all of UMC's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by the UMC suspected violations of any Federal health care program requirements or of UMC's own Policies and Procedures;
- d. the possible consequences to both UMC and Covered Persons of failure to comply with Federal health care program requirements and with UMC's own Policies and Procedures and the failure to report such non-compliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.F, and UMC's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to such disclosures.

UMC has implemented a program to obtain an acknowledgment in writing from each Covered Person that he or she has read and reviewed the information in the Compliance Handbook; understands the contents; and understands that he or she is required to observe and abide by all rules, policies, procedures, and standards of UMC's Compliance Program. UMC shall obtain the Compliance Handbook acknowledgment from each Covered Person within 90 days of the Effective Date of these Integrity Provisions. New Covered Persons shall receive the Compliance Handbook and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days of the Effective Date of this Agreement, whichever is later.

UMC shall periodically review the Compliance Handbook to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Compliance Handbook shall be distributed within 30 days of finalizing such changes. UMC shall implement a program to insure that all Covered Persons shall certify that they have received, read, understood and will abide by the revised Compliance Handbook. To the extent applicable, within 90 days after any such revision, UMC shall obtain certification from each Department Head that the distribution and certification has been completed by each Covered Person in their Department.

2. *Policies and Procedures.* UMC has developed and implemented written Policies and Procedures regarding the operation of UMC's compliance program and its compliance with Federal health care program requirements. To the extent not already accomplished, within 90 days of the Effective Date of this Agreement, shall update such Policies and Procedures, so that, at minimum, they shall:

- a. address the subjects relating to the Compliance Handbook identified in Section III.B.1;
- b. require that all diagnosis codes submitted for claims purposes to any Federal health care program be properly supported by documentation of the physicians' diagnosis in the patient's medical record; and
- c. require that all inpatient claims with a principal diagnosis of 482.89 or 482.83 (or any successors to these codes) intended for submission to Medicare shall first be subject to pre-billing review to ensure the diagnosis code was properly assigned.

To the extent not already accomplished within 12 months prior to the Effective Date of this Agreement, the relevant portions of the Policies and Procedures shall be distributed within 90 days of the Effective Date of this Agreement to all individuals whose job functions are related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

At least annually (and more frequently if appropriate), UMC shall assess and update as necessary the Policies and Procedures. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all individuals whose job functions are related to those Policies and Procedures.

C. Training and Education.

1. *General Training.* Within 120 days of the Effective Date of this Agreement, UMC shall provide appropriate and adequate general training to each Covered Person. This training, at a minimum, shall explain UMC's:

- a. The Integrity Provisions requirements; and
- b. Compliance Program (including the Compliance Handbook and the Policies and Procedures as they pertain to general compliance issues).

This training requirement may be satisfied through the use of audio conferences or computer based training programs that adequately address the topics described above, when completion of such programs are verifiable. New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 90 days after the Effective Date of these Integrity Provisions, whichever is later. After receiving the initial training described above, each Covered Person shall receive appropriate and adequate general training annually.

2. *Coding Training.* To the extent not already accomplished within 9 months prior to the Effective Date of this Agreement, within 90 days of the Effective Date of this Agreement, each Covered Person who is involved directly or in a supervisory role in the preparation or submission of claims for items or services (including, but not limited to, coding or billing) to any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive at least four hours of coding training in addition to the general training required above. This coding training shall include a discussion of:

- a. the submission of accurate bills for services rendered to Federal health care program beneficiaries;
- b. policies, procedures and other requirements applicable to the documentation of medical records;
- c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
- d. applicable reimbursement statutes, regulations, and program requirements and directives;

- e. the legal sanctions for improper billings; and
- f. examples of proper and improper billing practices.

This training requirement may be satisfied through the use of audio conferences or computer based training programs that adequately address the topics described above, when completion of such programs are verifiable. Persons providing the coding training must be knowledgeable about the subject area.

Relevant Covered Persons shall receive this coding training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 90 days of the Effective Date of these Integrity Provisions, whichever is later. A UMC employee who has completed the coding training shall review a new Relevant Covered Person's work, to the extent that the work relates to the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes his or her applicable training.

After receiving the initial training described in this Section, every Relevant Covered Person shall receive at least two hours of coding training annually.

3. *Certification.* Each individual who is required to attend training shall certify, in writing (or in electronic form, for computer-based training), 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 his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Covered Contractor Requirements.

Within 120 days of the Effective Date of these Integrity Provisions, UMC shall use its best practicable efforts to obtain written documentation from each Covered Contractor showing:

1. *Compliance Handbook.* That the Covered Contractor has received and read UMC's Compliance Handbook and that the Covered Contractor understands that UMC's Compliance Handbook applies to the Covered Contractors.

2. *Policies and Procedures.* That the Covered Contractor has received and read UMC's Policies and Procedures, applicable to the job functions for which the Covered Contractor has been engaged.

3. *Confidential Disclosure Program.* That the Covered Contractor has received notice of and education on the appropriate use of the Confidential Disclosure Program.

4. *General and Coding Training.* That UMC has made General Training available to each Covered Contractor. That UMC has made Coding Training available to each Covered Contractor who is involved directly or in a supervisory role in the preparation or submission of claims for items or services (including, but not limited to, coding or billing) to any Federal health care program .

UMC shall use its best practicable efforts to obtain the written documentation requested in this Section III.C from each new Covered Contractor within 30 days after commencing work for UMC or within 120 days of the Effective Date of these Integrity Provisions, whichever is later.

The Compliance Officer (or his or her designee) shall retain: (1) the written documentation from each Covered Contractor; (2) a list of Covered Contractor who receives General Training; and (3) a list of each Covered Contractor who receives Coding Training. These shall be made available to OIG, upon request.

E. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 120 days of the Effective Date of these Integrity Provisions, UMC shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter “Independent Review Organization” or “IRO”), to perform reviews to assist UMC in assessing and evaluating its billing and coding practices and certain compliance obligations pursuant to these Integrity Provisions and the Settlement Agreement. Each IRO retained by UMC shall have expertise in the billing, coding, reporting and other requirements relating to hospital operations and in the general requirements of the Federal health care program(s). Each IRO shall assess, along with UMC, whether it can perform the IRO review in a professionally independent fashion taking into account any other business relationships or other engagements that may exist. The IRO(s) review shall address and analyze UMC’s billing and coding to the Federal health care programs (“Claims Review”) and shall analyze whether UMC sought payment for certain unallowable costs (“Unallowable Cost Review”).

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the Integrity Provisions beginning with the Effective Date of this Agreement. The IRO(s) shall perform all components of each annual Claims Review except, subject to approval from OIG and subject to the conditions set forth in section III.D.8, after the first annual Claims Review period, UMC may elect to conduct an internal billing review for Claims Review periods 2 and 3.

c. Frequency of Unallowable Cost Review. The Unallowable Cost Review shall be performed by the IRO for the first one-year reporting period beginning with the Effective Date of these Integrity Provisions.

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

2. *Claims Review*. The Claims Review shall include a Discovery Sample and, if necessary, a Full Sample. The applicable definitions, procedures, and reporting requirements are outlined in Appendix A to the Integrity Provisions, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Paid Claims submitted by or on behalf of UMC. The Paid Claims shall be reviewed based on the supporting documentation available at UMC or under UMC's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted and reimbursed.

i. If the Error Rate (as defined in Appendix A) for the Discovery Sample is less than 5%, no additional sampling is required, nor is the Systems Review required. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, UMC should, as appropriate, further analyze any errors identified in the Discovery Sample. UMC recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

ii. If the Discovery Sample indicates that the Error Rate is 5% or greater, the IRO shall perform a Full Sample and a Systems Review, as described below.

b. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should 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 Paid Claims shall be reviewed based on supporting documentation available at UMC or under UMC's control and applicable billing and coding regulations and guidance to determine

whether the claim submitted 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, UMC may use the Items sampled as part of the Discovery Sample, and the corresponding findings for those 50 Items, as part of its Full Sample. The OIG, in its full discretion, may refer the findings of the Full Sample (and any related workpapers) received from UMC to the appropriate Federal health care program payor, including the Medicare contractor (e.g., carrier, fiscal intermediary, or DMERC), for appropriate follow-up by that payor.

c. Systems Review. If UMC's Discovery Sample identifies an Error Rate of 5% or greater, UMC's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es), that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to UMC observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.

d. Repayment of Identified Overpayments. In accordance with Section III.I.1 of the Integrity Provisions, UMC agrees to 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. UMC agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor and the associated documentation.

3. *Claims Review Report*. The IRO shall prepare a report based upon the Claims Review performed (the "Claims Review Report"). Information to be included in the Claims Review Report is detailed in Appendix A.

4. *Unallowable Cost Review*. The IRO shall conduct a review of UMC's compliance with the unallowable cost provisions of this Agreement.

a. The IRO shall determine whether UMC has complied with its obligations not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in this Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from the United States, or any State Medicaid program. This unallowable cost analysis shall include, but not be limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by UMC or any of its subsidiaries, and to 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. 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. The Unallowable Cost Review Report shall include:

a. the IRO's findings and supporting rationale regarding the Unallowable Costs Review and whether UMC has complied with its obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in this 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 the OIG has reason to believe that: (a) UMC's Claims Review or Unallowable Cost Review fails to conform to the requirements of these Integrity Provisions; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Unallowable Cost Review complied with the requirements of the Integrity Provisions and/or the findings or Claims Review results are inaccurate ("Validation Review"). UMC agrees to pay for the reasonable cost of any such review performed by the OIG or any of its designated agents so long as it is initiated before one year after UMC's final submission (as described in Section II) is received by the OIG.

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

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

8. *Internal Billing Review Option.* Subject to approval from OIG and subject to the conditions set forth below, after the first complete Claims Review period in which the IRO has performed the Claims Review as required in section III.D.2, UMC may, at its option, conduct an internal review of its billings to the Federal health care programs for Claims Review periods 2 and

3 in lieu of having the IRO conduct the Claims Review. This internal review shall comply with all of the requirements outlined herein and in section III.D.2 above.

Prior to conducting its internal billing review, UMC agrees: i) to develop and adopt a written formal internal audit work plan consistent with the terms of these Integrity Provisions; ii) to devote sufficient resources and staff to enable it to accomplish an internal billing review based on its internal work plan; and iii) that its internal billing review staff shall at all times include persons qualified and experienced in accepted auditing and control processes, who possess expertise in billing, coding and Medicare program requirements. In addition, UMC agrees that its internal billing review staff shall not include persons who were involved in the submission of bills or claims to the Medicare programs during the period to be audited and shall not include persons who are presently involved in such submissions.

If, in its sole discretion, OIG determines that such internal review satisfactorily establishes the adequacy of UMC's billing and compliance practices pursuant to these Integrity Provisions, the OIG will allow UMC to perform an internal review in lieu of the IRO conducting the Claims review for the year following the receipt of a satisfactory Claims Review report from the IRO. Consistent with the requirements of section III.D.2, the internal billing review shall include a Claims Review and the required respective reports of UMC's findings.

In the event UMC is unable to satisfactorily implement an audit work plan, devote sufficient resources and appropriate qualified staff, or conduct a satisfactory internal review, UMC agrees, at OIG's discretion, to engage the IRO to complete all remaining Claims Review requirements under the Integrity Provisions. To the extent that OIG permits UMC to perform internal billing reviews, UMC shall submit all the information required in section III.D.2 as well as the results of the IRO's verification. If UMC decides not to exercise its internal review option, the requirements of the IRO Claims Review shall remain in effect for the term of these Integrity Provisions.

F. Disclosure Program.

UMC has established and will maintain for the term of these Integrity Provisions 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 UMC'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. UMC 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 non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality will 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, UMC shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or his or her designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not), the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be available to OIG, upon request. Nothing in this Section will, however, be construed as a waiver of UMC's attorney-client privilege or attorney work product privilege. Notwithstanding that fact, the existence of any such privilege shall not be used by UMC to avoid its obligations to comply with the provisions of these Integrity Provisions.

G. Ineligible Persons.

1. *Definition.* For purposes of these Integrity Provisions, an "Ineligible Person" shall be any individual or entity who: (a) is currently excluded, debarred or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or non-procurement programs; or (b) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred or otherwise declared ineligible.

2. *Screening Requirements.* UMC shall not hire as an employee, engage as a contractor, or grant staff privileges to, any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, UMC shall screen all prospective employees and prospective contractors prior to engaging their services and screen physicians prior to granting staff privileges by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) appropriately querying the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>) and the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>) (these lists will hereinafter be referred to as the "Exclusion Lists"). Nothing in this Section affects the responsibility of (or liability for) UMC to refrain from billing Federal health care programs for services of the Ineligible Person.

3. *Review and Removal Requirement.* To the extent not already accomplished within 6 months prior to the Effective Date of this Agreement, UMC shall review its list of current employees, contractors, and physicians with staff privileges against the Exclusion Lists within 120 days of the Effective Date of this Agreement. Thereafter, UMC shall review its list of current employees, contractors, and physicians with staff privileges against the Exclusion Lists annually. In addition, UMC shall require employees and contractors to disclose immediately any debarment, exclusion, or other event that makes the employee an Ineligible Person.

If UMC has actual notice that an employee, contractor, or physician with staff privileges has become an Ineligible Person, UMC shall remove such person from responsibility for, or involvement with, UMC's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If UMC has actual notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract term, the UMC shall take all appropriate actions to ensure that the responsibilities of that employee or contractor have not and shall not adversely affect the quality of care rendered to any beneficiary, patient or resident, or the accuracy of any claims submitted to any Federal health care program.

5. *Physicians with Staff Privileges.* Prior to granting staff privileges to a physician after the Effective Date of this CIA, Hospital shall screen in the manner described in section III.G.2 above to determine if the physician is an Ineligible Person. Furthermore, Hospital shall review its list of physicians with privileges against the Exclusion Lists within 90 days of the Effective Date of this CIA and at least semi-annually thereafter. If a physician with privileges is an Ineligible Person, Hospital shall ensure that the physician does not provide, order, or prescribe any items or services payable in whole or in part by any Federal health care program. In addition to any other appropriate measures, Hospital shall ensure that any physician who is an Ineligible Person is not "on call" at Hospital.

H. Notification of Government Investigation or Legal Proceedings.

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

I. Reporting.

1. *Overpayments.*

a. Definition of Overpayments. For purposes of these Integrity Provisions, an “overpayment” shall mean the amount of money UMC has received in excess of the amount due and payable under any Federal health care program requirements.

b. Reporting of Overpayments. If, at any time, UMC identifies or learns of any overpayments, UMC shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of identification of the overpayment and take remedial steps within 60 days of identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the overpayments from recurring. Also, within 30 days of identification of the overpayment, UMC shall repay the overpayment to the appropriate payor to the extent such overpayment has been quantified. If not yet quantified, within 30 days of identification, UMC 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 should be done in accordance with the payor’s policies and applicable law, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to these Integrity Provisions. Notwithstanding the above, notification and repayment of any overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. *Material Deficiencies.*

a. Definition of Material Deficiency. For purposes of these Integrity Provisions, a “Material Deficiency” means anything that involves:

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

A Material Deficiency may be the result of an isolated event or a series of occurrences.

b. Reporting of Material Deficiencies. If UMC determines through any means that there is a Material Deficiency, UMC shall notify OIG, in writing, within 30 days of making the determination that the Material Deficiency exists. The report to the OIG shall include the following information:

- (i) If the Material Deficiency results in an overpayment, the report to the OIG shall be made at the same time as the notification to the payor required in Section III.I.1, and shall include all of the information on the Overpayment Refund Form, as well as:
 - (B) the payor's name, address, and contact person to whom the overpayment was sent; and
 - (C) the date of the check and identification number (or electronic transaction number) by which the overpayment was repaid/refunded;
- (ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;
- (iii) a description of UMC's actions taken to correct the Material Deficiency; and
- (iv) any further steps UMC plans to take to address the Material Deficiency and prevent it from recurring.

IV. NEW FACILITIES OR LOCATIONS

In the event that, after the Effective Date of this Agreement, UMC changes locations, sells, or closes any facility or location, or purchases or establishes new facility or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, UMC shall notify OIG of this fact as soon as possible, but no later than within 60 days of the date of change of location, sale, closure, purchase or establishment. This notification shall include the affected location(s), phone number, fax number, Medicare provider number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare provider number. All Covered Persons at new facilities and locations shall be subject to the applicable requirements in these Integrity Provisions (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the Effective Date of these Integrity Provisions, UMC shall submit a written report to OIG summarizing the status of its implementation of the requirements of these Integrity Provisions. This Implementation Report shall include:

1. the name, address, phone number, and position description of the Compliance Officer required by Section III.A, and a summary of other non-compliance job responsibilities of the Compliance Officer;
2. the names and positions of the members of the Compliance Team required by Section III.A;
3. a copy of UMC's Compliance Handbook required by Section III.B.1;
4. a copy of all compliance-related Policies and Procedures required by Section III.B.2 and a summary of all other Policies and Procedures required by Section III.B.2;
5. a copy of all training materials used for the training required by Section III.C, a description of such training, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;
6. a certification by the Compliance Officer that:
 - a. the Policies and Procedures required by Section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;
 - b. all Covered Persons have completed the Compliance Handbook acknowledgment required by Section III.B.1, as evidenced by the certifications from the Department Heads; and
 - c. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C.;

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

7. a description of the Disclosure Program required by Section III.F;
8. the identity of the IRO(s), a summary/description of all engagements between UMC and the IRO, including, but not limited to, any outside financial audits,

compliance program engagements, or reimbursement consulting, and the proposed start and completion dates of the first annual review;

9. a certification from the IRO regarding its professional independence from the UMC;
10. a summary of personnel actions (other than hiring) taken pursuant to Section III.G;
11. a list of all of UMC's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare provider identification number(s) and the name and address of the Medicare contractor to which UMC currently submits claims;
12. a description of UMC's organizational structure, including identification of any parent and sister entities, subsidiaries and their respective lines of business (as applicable); and
13. the certification required by Section V.C.

B. Annual Reports. UMC shall submit to OIG Annual Reports with respect to the status of, and findings regarding, UMC's compliance activities for each of the three one-year periods beginning on the Effective Date of the Agreement. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

1. any change in the identity, position description, or other non-compliance job responsibilities of the Compliance Officer and any change in the membership of the Compliance Team described in Section III.A;
2. a certification by the Compliance Officer that:
 - a. all Covered Persons have completed any Compliance Handbook certifications required by Section III.B.1;
 - b. all Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C;
 - c. UMC has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such

denials of claims; (ii) not to charge to or otherwise seek payment from Federal or State payors for unallowable costs (as defined in the Settlement Agreement); and (iii) to identify and adjust any past charges or claims for unallowable costs;

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

3. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B and the reasons for such changes (e.g., change in contractor policy) and copies of any compliance-related Policies and Procedures;
4. a copy of all training materials used for the training required by Section III.C (to the extent it has not already been provided as part of the Implementation Report or otherwise), a description of such training conducted during the Reporting Period, including a description of the targeted audiences, length of sessions, which sessions were mandatory and for whom, percentage of attendance, and a schedule of when the training sessions were held;
5. a report of the percentage of Covered Contractors who: (1) returned written certifications in accordance with Section III.D, (2) received General Training; and (3) received Coding Training;
6. a complete copy of all non-privileged reports prepared pursuant to the IRO's billing and compliance engagements, including a copy of the methodology used, along with a copy of the IRO's engagement letter;
7. UMC's response and corrective action plan(s) related to any issues raised by the IRO(s);
8. a revised summary/description of all engagements between UMC and the IRO, including, but not limited to, any outside financial audits, compliance program engagements, or reimbursement consulting, if different from what was submitted as part of the Implementation Report;
9. a certification from the IRO regarding its professional independence from UMC;
10. a summary of Material Deficiencies (as defined in Section III.I) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

11. a report of the aggregate overpayments that have been returned to the Federal health care programs. Overpayment amounts should be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each applicable state separately) 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;
12. a summary of the disclosures in the disclosure log required by Section III.F that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;
13. a description of any personnel actions (other than hiring) taken by UMC as a result of the obligations in Section III.G, and the name, title, and responsibilities of any person that falls within the ambit of Section III.G.4, and the actions taken in response to the obligations set forth in that Section;
14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.H. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
15. a description of all changes to the most recently provided list (as updated) of UMC's locations (including locations and mailing addresses) as required by Section V.A.11, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number; and
16. the certification required by Section V.C.

The first Annual Report shall be received by the OIG no later than 90 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

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

D. Designation of Information: UMC 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. UMC 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 of these Integrity Provisions, all notifications and reports required under these Integrity Provisions shall be submitted to the following entities:

If to OIG:

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

If to UMC:

Trudy Mattson
Compliance Officer
University Medical Center of Southern Nevada
1800 W. Charleston Blvd.
Las Vegas, NV 89102
Telephone: (702) 383-2529

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

VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS

During the term of the Integrity Provisions, 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 UMC's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of UMC's locations for the purpose of verifying and evaluating: (a) UMC's compliance with the terms of these Integrity Provisions; and (b) UMC's compliance with the

requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by UMC to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. UMC shall have the right to have representatives present at the time of any on-site review. Nothing in these Integrity Provisions requires UMC to provide to the OIG or its duly authorized representative(s) or agents any legally-privileged documents nor shall these Integrity Provisions be construed as constituting a present or future waiver by UMC of any legal privileges. Notwithstanding that fact, the existence of any such privilege shall not be used by UMC to avoid its obligations to comply with the provisions of these Integrity Provisions. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of UMC'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. UMC agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. UMC's employees may elect to be interviewed with or without a representative of UMC and/or legal counsel present.

VIII. DOCUMENT AND RECORD RETENTION

UMC shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with these Integrity Provisions, for four (4) years (or longer if otherwise required by law). Electronic or other images of documents shall satisfy this requirement.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify UMC prior to any release by OIG of information submitted by UMC pursuant to its obligations under these Integrity Provisions and identified upon submission by UMC as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, UMC shall have the rights set forth at 45 C.F.R. § 5.65(d). UMC shall refrain from identifying any information as exempt from release if that information does not meet the criteria for exemption from disclosure under FOIA.

X. BREACH AND DEFAULT PROVISIONS

UMC is expected to fully and timely comply with all of its Integrity Provisions obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, UMC and OIG hereby agree that failure to comply with certain obligations set forth in these Integrity Provisions 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 UMC fails to have in place any of the obligations described in Section III of these Integrity Provisions:

- a. a Compliance Officer;
- b. a Compliance Team;
- c. a written Compliance Handbook;
- d. written Policies and Procedures;
- e. a requirement that Covered Persons be trained; and
- f. a Disclosure Program.

2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day UMC fails to retain an IRO, as required in Section III.E.

3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day UMC fails to meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG.

4. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day UMC employs, contracts with, or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, UMC's business operations related to the Federal health care programs; or (ii) is in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds (if the Ineligible Person is a physician with staff privileges at UMC, then the Stipulated Penalty shall accrue for each day that the Ineligible Person provided, ordered, or prescribed any items or services at Hospital that were payable in whole or in part by any Federal health care program) (the Stipulated Penalty described in this paragraph shall not be demanded for any time period during which UMC can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.G) as to the status of the person).

5. A Stipulated Penalty of \$1,500 for each day UMC fails to grant access to the information or documentation as required in Section VII of these Integrity Provisions. (This Stipulated Penalty shall begin to accrue on the date UMC fails to grant access.)

6. A Stipulated Penalty of \$1,000 for each day UMC fails to comply fully and adequately with any obligation of these Integrity Provisions. In its notice to UMC, OIG shall state the specific grounds for its determination that UMC has failed to comply fully and adequately with the Integrity Provisions obligation(s) at issue and steps the UMC must take to comply with the Integrity Provisions. (This Stipulated Penalty shall begin to accrue 10 days after UMC receives notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this paragraph shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under Paragraphs 1-5 of this Section.

B. Timely Written Requests for Extensions. UMC 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 these Integrity Provisions which the OIG will consider in good faith and not unreasonably deny. 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 UMC 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 UMC 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 UMC 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 UMC of: (a) UMC's failure to comply; and (b) the OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is hereinafter referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days of the receipt of the Demand Letter, UMC 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 UMC elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until UMC 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 the Integrity Provisions and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that UMC has materially breached these Integrity Provisions, 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 these Integrity Provisions

1. *Definition of Material Breach.* A material breach of these Integrity Provisions means:

- a. a failure by UMC to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in Section III.I;
- b. a repeated or flagrant violation of the obligations under these Integrity Provisions, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to retain and use an Independent Review Organization in accordance with Section III.E.

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

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, UMC fails to satisfy the requirements of Section X.D.3, OIG may exclude UMC from participation in the Federal health care programs. OIG will notify UMC in writing of its determination to exclude UMC (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of the

Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, UMC wishes to apply for reinstatement, UMC must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to UMC of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under these Integrity Provisions, UMC 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 these Integrity Provisions. 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 of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under these Integrity Provisions shall be: (a) whether UMC was in full and timely compliance with the obligations of these Integrity Provisions for which the OIG demands payment; and (b) the period of noncompliance. UMC shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. The 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 these Integrity Provisions and orders UMC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless UMC requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

- a. whether UMC was in material breach of these Integrity Provisions;
- 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) UMC had begun to take action to cure the material breach within that period;
 - (ii) UMC has pursued and is pursuing such action with due diligence; and
 - (iii) UMC provided to OIG within that period a reasonable timetable for curing the material breach and UMC 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 the UMC, only after a DAB decision in favor of OIG. UMC's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude UMC upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that UMC 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. UMC agrees to 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 UMC, UMC will be reinstated effective on the date of the original exclusion.

XI. EFFECTIVE AND BINDING AGREEMENT

Consistent with the provisions in the Settlement Agreement pursuant to which these Integrity Provisions is entered, and into which these Integrity Provisions is incorporated, UMC and OIG agree as follows:

- A. These Integrity Provisions shall be binding on the successors, assigns, and transferees of UMC;
- B. These Integrity Provisions shall become final and binding on the date the final signature is obtained on the Integrity Provisions;
- C. Any modifications to these Integrity Provisions shall be made with the prior written consent of the parties to these Integrity Provisions;
- D. OIG may agree to a suspension of UMC's obligations under the Integrity Provisions in the event of UMC's cessation of participation in Federal health care programs. If UMC withdraws from participation in Federal health care programs and is relieved from its Integrity Provisions obligations by the OIG, UMC agrees to notify OIG 30 days in advance of UMC's intent to reapply as a participating provider or supplier

with the Federal health care programs. Upon receipt of such notification, OIG will evaluate whether the Integrity Provisions should be reactivated or modified.

- E. The undersigned UMC signatories represent and warrant that they are authorized to execute these Integrity Provisions. The undersigned OIG signatory represents that he is signing these Integrity Provisions in his official capacity and that he is authorized to execute these Integrity Provisions.

9. UMC waives and will not assert any defenses it may have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on a contention that, under the Double Jeopardy or Excessive Fines Clause of the United States Constitution, this settlement bars a remedy sought in such criminal prosecution or administrative action. UMC agrees that this settlement is not punitive in purpose or effect. 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.

10. The Settlement Amount will not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or any State payor, related to the Covered Conduct; and UMC 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 any such denials of claims.

11. UMC agrees to the following:

(a) Unallowable Costs Defined: that all costs (as defined in the Federal Acquisition Regulations (FAR) § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of UMC, its present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "unallowable costs":

- (1) the matters covered by this Agreement,
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement,
- (3) UMC's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees),
- (4) the negotiation and performance of this Agreement,

(5) the payment UMC makes to the United States pursuant to this Agreement and any payments that UMC may make to relators, including costs and attorneys fees, and

(6) the negotiation of, and obligations undertaken pursuant to the Integrity Provisions to:

(i) Retain an independent review organization to perform annual reviews as described in the Integrity Provisions; and

(ii) prepare and submit reports to the OIG-HHS,

are unallowable costs on Government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP).

(All costs described or set forth in this Paragraph 16(a) are hereafter, "unallowable costs").

(b) Future Treatment of Unallowable Costs: These unallowable costs will be separately determined and accounted for in non-reimbursable cost centers by UMC, and UMC will 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 UMC or any of its subsidiaries to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

(c) Treatment of Unallowable Costs Previously Submitted for Payment: UMC further agrees that within 120 days of the effective date of this Agreement it will identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid, VA 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 UMC or any of its subsidiaries or affiliates, and will 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. UMC agrees that the United States, at a minimum, will be entitled to recoup from UMC 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 UMC or any of its subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on UMC or any of its subsidiaries' cost reports, cost statements, or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the unallowable costs described in this Paragraph.

12. This Agreement is intended to be for the benefit of the Parties only, and by this instrument the Parties do not release any claims against any other person or entity, except to the extent provided for herein.

13. UMC agrees that it will not seek any additional payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents or sponsors. UMC waives any causes of action against these beneficiaries or their parents or sponsors based upon the claims for payment covered by this Agreement.

14. UMC warrants that it has reviewed its financial situation and that, to its knowledge, it currently is solvent within the meaning of 11 U.S.C. § 547(b)(3) and 548(a)(1)(A)(ii)(I), and will remain solvent following payment to the United States of the Settlement Amount. Further, the parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants and obligations set forth constitute a contemporaneous exchange for new value given to UMC, within the meaning of 11 U.S.C. § 547(c)(1), and (b) conclude that these mutual promises, covenants and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended and do, in fact, represent a reasonably equivalent exchange of value which is not intended to hinder, delay, or defraud any entity to which UMC was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

15. If, within 91 days of the effective date of this Agreement, UMC commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (a) seeking to have any order for relief of UMC's debts, or seeking to adjudicate UMC as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for UMC or for all or any substantial part of UMC's assets, UMC agrees as follows:

a. UMC's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547, and UMC will not argue or otherwise take the position in any such case, proceeding, or action that: (i) UMC's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) UMC was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to UMC.

b. If UMC's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action, or proceeding against UMC for the claims that would otherwise be covered by the releases provided in Paragraphs 5 and 6 above. UMC agrees that (i) any such claims, actions, or proceedings brought by the United States (including any proceedings to exclude UMC from participation in Medicare, Medicaid, or other Federal health care

programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that UMC will not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) UMC will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought by the United States within 30 calendar days of written notification to UMC that the releases have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the effective date of settlement; and (iii) the United States has a valid claim against UMC in the amount of \$2,500,000 for claims that were submitted between October 1, 1992 and September 30, 1997, plus interest. The United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

c. UMC acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.

16. After this Agreement is executed and the Settlement Amount is received by the United States, the United States and Relator will notify the Court that the parties stipulate and request that this case (United States ex rel. Health Outcomes Technologies v. University Medical Center, CV-S-01-538-RLH (RJJ) (D. Nev.) be dismissed with prejudice.

17. By this Agreement, the Relator and Relator's Counsel will release and will be deemed to release UMC from any claim that the Relator, and/or Relator's Counsel may have under 31 U.S.C. § 3730(d) to pay Relator's or Relator's Counsel attorneys' fees, expenses and costs.

18. Conditioned on UMC's payment in full of the Settlement Amount, Relator shall receive from the United States a payment totaling 14% of the Settlement Amount to equal \$162,888.32. The United States shall pay Relator this amount within a reasonable time after receipt by the United States from UMC of the Settlement Amount. It is expressly understood and agreed that the United States in no way promises or guarantees nor is liable to Relator for the collection or payment of any funds pursuant to this Agreement or the payment of any funds pursuant to this Agreement or the payment of any Relator's share payments except as provided herein for funds actually collected and received by the United States.

19. On receipt of the payments described in Paragraph 17 above, Relator will release and will be deemed to have released and forever discharged the United States, its officers, agents, and employees from any liability arising from the filing of the Complaint as against UMC including any claim pursuant to 31 U.S.C. § 3730(d) to a share of any settlement proceeds received from UMC, and in full satisfaction and settlement of claims under this Agreement.

20. Each party to this Agreement will bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

21. UMC represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

22. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the United States District Court for the District of Nevada, except that disputes arising under the Integrity Provisions shall be resolved exclusively under the dispute resolution provisions set forth in those provisions.

23. This Agreement, including the Integrity Provisions, constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties, except that only UMC and OIG-HHS must agree in writing to modification of the Integrity Provisions contained in paragraph 8.

24. All parties consent to the United States' and UMC's disclosure of this Agreement, and information about this Agreement, to the public.

25. The undersigned individuals signing this Agreement on behalf of UMC represent and warrant that they are authorized to execute this Agreement on behalf of that entity. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

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

27. This Agreement is binding on successors, transferees, and assigns.


28. This Agreement is effective on the date of signature of the last signatory to the

Agreement.

THE UNITED STATES OF AMERICA

DATED: 7/17/02

As to Section I; Section II
Paras. A-J; and Section III
Paras. 1- 7 and 9-28 only.

BY: 

LAWRENCE A. CASPER
Attorney
U.S. Department of Justice
Commercial Litigation Branch
Civil Division

DATED: _____

BY: _____

LEWIS MORRIS
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

Agreement.

THE UNITED STATES OF AMERICA

DATED: _____

As to Section I; Section II
Paras. A-J; and Section III
Paras. 1- 7 and 9-28 only.

BY: _____

LAWRENCE A. CASPER
Attorney
U.S. Department of Justice
Commercial Litigation Branch
Civil Division

DATED: 4/16/02

BY: _____

LEWIS MORRIS
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

UNIVERSITY MEDICAL CENTER OF SOUTHERN NEVADA

DATED: 4/18/02

BY: WR Hale
WILLIAM R. HALE
Chief Executive Officer
University Medical Center of
Southern Nevada

DATED: 4/16/02

BY: Charles B. Oppenheim
CHARLES B. OPPENHEIM
Foley & Lardner

RELATOR, HEALTH OUTCOMES TECHNOLOGIES

DATED: 4-17-02

BY: Michael Holston /mlt
MICHAEL HOLSTON
DRINKER, BIDDLE & REATH
Attorneys for Relator,
Health Outcomes Technologies