INSTITUTIONAL COMPLIANCE AGREEMENT

BETWEEN THE

OFFICE OF INSPECTOR GENERAL

OF THE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

AND

UNIVERSITY OF NEVADA SCHOOL OF MEDICINE MULTISPECIALTY GROUP PRACTICE SOUTH, INC.

I. PREAMBLE

University of Nevada School of Medicine Multispecialty Group Practice South, Inc. ("UNSOM") hereby enters into this Institutional Compliance Agreement ("ICA") 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") by the following Covered Persons:

- A. UNSOM's officers, directors, and employees.
- B. Contractors engaged by UNSOM to bill/submit reimbursement claims, or responsible for the provision, marketing or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports or other requests for reimbursement for such items or services.

Contemporaneously with this ICA, UNSOM is entering into a Settlement Agreement with the United States, and this ICA is incorporated by reference into the Settlement Agreement. During the term of this ICA, the parties are expected to fully and timely comply with all of their respective obligations herein.

Prior to the execution of this ICA, UNSOM established a corporate compliance program (known as the "UNSOM Compliance Program"). The UNSOM Compliance Program includes written policies and procedures, an education and training component, mechanisms for the ongoing monitoring and auditing of UNSOM operations to assess compliance, mechanisms for employees and agents to report incidents of noncompliance

in an anonymous way, disciplinary actions for individuals violating compliance policies and procedures, and oversight of the UNSOM Compliance Program by a Corporate Compliance Officer, and a Compliance Oversight Committee and a Compliance Steering Committee (collectively "Compliance Committees"). UNSOM agrees to continue the operation of the UNSOM Compliance Program for the term of this ICA. UNSOM may modify the UNSOM Compliance Program as appropriate, but at a minimum, UNSOM shall ensure that it complies with the integrity obligations enumerated in this ICA.

II. TERM OF THE ICA

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

Sections VII, VIII, IX, X, and XI shall expire no later than 120 days from the OIG's receipt of: (1) UNSOM's final annual report; or (2) any additional materials submitted by UNSOM pursuant to a request of the OIG made prior to six years from the Effective Date, whichever is later.

III. INSTITUTIONAL COMPLIANCE OBLIGATIONS

During the term of this ICA, UNSOM hereby agrees to maintain a Compliance Program that includes the following elements:

A. <u>Compliance Officer and Compliance Committee</u>.

1. Compliance Officer. UNSOM has represented to OIG that, pursuant to the UNSOM Compliance Program, it has established the position of Director of Corporate Compliance ("Compliance Officer") and appointed an individual to serve in that capacity. 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 ICA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of UNSOM, report directly to the Dean of the School of Medicine, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Board of Directors of UNSOM, and shall be authorized to report on such matters to the Board of Directors at any time. The

Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by UNSOM as well as for any reporting obligations created under this ICA.

UNSOM shall report to the OIG, in writing, any changes in the identity or position description of the Compliance Officer, or any material actions or material changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in this ICA within 30 days of such a change.

2. Compliance Committees. UNSOM has represented to OIG that, pursuant to the UNSOM Compliance Program, it has established Compliance Committees and appointed individuals to serve on the Committees. The Compliance Officer shall chair the Compliance Committees. The Compliance Committees 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).

UNSOM shall report to the OIG, in writing, any material changes in the composition of the Compliance Committee, or any material actions or material changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this ICA within 30 days of such a change.

B. Written Standards.

- 1. Code of Conduct. UNSOM has produced to OIG a written Code of Conduct (also known as the "Compliance Handbook"). UNSOM has represented to OIG that it has distributed the Code of Conduct to various officers, directors, and employees of UNSOM who are Covered Persons. Within 120 days of the Effective Date of this ICA, UNSOM shall complete distribution of the Code of Conduct to all Covered Persons. UNSOM 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 set forth, and, at a minimum, shall continue to set forth throughout the term of this ICA, the following:
 - a. UNSOM'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. UNSOM's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program requirements and with UNSOM's own Policies and Procedures as implemented pursuant to Section III.B.2 (including the requirements of this ICA);
- c. the requirement that all of UNSOM's Covered Persons shall be expected to report to the Compliance Officer or other appropriate individual designated by UNSOM, suspected violations of any Federal health care program requirements or of UNSOM's own Policies and Procedures;
- d. the possible consequences to both UNSOM and Covered Persons of failure to comply with Federal health care program requirements and with UNSOM'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.E., and UNSOM's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to such disclosures.

To the extent not already certified, within 120 days of the Effective Date of the ICA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by UNSOM's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 60 days after becoming a Covered Person or within 120 days of the Effective Date of the ICA, whichever is later.

UNSOM shall annually review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Code of Conduct shall be distributed within 30 days of finalizing such changes. Covered Persons shall certify that they have received, read, understood and will abide by the revised Code of Conduct within 30 days of the distribution of such revisions.

2. Policies and Procedures. UNSOM has made available to OIG its written policies and procedures regarding the operation of UNSOM's compliance

program and its compliance with Federal health care program requirements ("Policies and Procedures"). UNSOM has represented to OIG that it has implemented these Policies and Procedures. UNSOM agrees to maintain the existing Policies and Procedures as well as develop additional Policies and Procedures so that, at a minimum, UNSOM's Policies and Procedures address the following:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. UNSOM's commitment to adhere to honest and accurate billing practices,
- c. 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute") and 42 U.S.C. § 1395nn (the "Stark Law"), the regulations and other guidance documents related to these statutes;
- d. requirements for billing Federal health care programs for Teaching Physician services;
- e. areas of OIG concern or risk areas outlined in OIG Model Compliance Program Guidance for Individual and Small Group Physician Practices (available through the Internet at http://oig.hhs.gov/modcomp/index.htm); and
- f. the proper documentation of services provided and other billing information as required for the submission of complete and accurate claims to the Federal health care programs, and the retention of such information in a readily retrievable form.

To the extent not already done, within 120 days of the Effective Date of the ICA, UNSOM shall make available the relevant portions of the Policies and Procedures to all Covered Persons whose functions relate 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), UNSOM 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

made available to all Covered Persons whose functions relate to those Policies and Procedures.

C. Training and Education.

During the term of this ICA, UNSOM shall continue the education and training elements of the UNSOM Compliance Program as they pertain to all Covered Persons, with the following modifications:

- 1. General Training. Within 120 days of the Effective Date of this ICA, UNSOM shall provide appropriate and adequate general training to each Covered Person. This training, at a minimum, shall:
 - a. Explain UNSOM's ICA requirements; and
 - b. Explain UNSOM's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

For the purposes of this Section III.C.1., the following UNSOM employees shall not be required to receive general training unless their job duties include direct or indirect involvement in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program: courier, network technician, non-clinical administrative assistant, receptionist, residency program administrative assistant, secretary, and non-clinical office manager.

For those Covered Persons who have already received general training that meets the requirements of Section III.C.1.b. within the six months prior to the Effective Date of this ICA, UNSOM need only provide appropriate and adequate training that meets the requirements of Section III.C.1.a.

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 120 days after the Effective Date of this ICA, whichever is later. After receiving the initial training described above, each Covered Person shall receive appropriate and adequate general training annually. This training requirement may be satisfied through the use of a computer-based training

program that adequately addresses the topics described above and where completion of such a program is verifiable.

- 2. Specific Training. Within 120 days of the Effective Date of this ICA, each Covered Person who is directly involved in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive appropriate and adequate specific training in addition to the general training required above. This specific 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 services;
 - 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;
 - f. examples of proper and improper billing practices;

This training requirement may be satisfied through the use of a computer-based training program that adequately addresses the topics described above and where completion of such a program is verifiable. Persons providing the in-person training or developing the computer-based training program must be knowledgeable about the subject area.

For the purposes of this Section III.C.2., the following UNSOM employees shall not be required to receive specific training unless their job duties include direct involvement in the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program: courier, network technician, marketing specialist, research administrative assistant, non-clinical

administrative assistant, receptionist, residency program administrative assistant, researcher, secretary, grants manager, data analyst, project director, and non-clinical office manager.

Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 120 days of the Effective Date of this ICA, whichever is later. An UNSOM employee who has completed the specific training shall monitor a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or in 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/her applicable training.

After receiving the initial training described in this Section, every Relevant Covered Person shall receive appropriate and adequate specific training annually.

3. Certification. Each individual who is required to attend training shall certify, in writing, (or in electronic form, if they have received 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 Corporate 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. <u>Review Procedures</u>.

- 1. General Description.
 - a. <u>Internal Review</u>. UNSOM shall conduct an internal review ("Claims Review") of its billing and coding practices with respect to the Medicare and Medicaid programs, which review shall comply with all of the requirements outlined in Section III.D. and in Appendix A to this ICA. The Claims Review shall be performed annually ("Annual Claims Review") and shall cover each of the one-year periods of the ICA beginning with the Effective Date of this ICA ("Reporting Period"). UNSOM shall conduct the Claims Review in accordance with Section III.D. and Appendix A to this ICA.

b. Retention of Independent Review Organization. Within 120 days of the Effective Date of this ICA, UNSOM shall retain an entity such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to review whether UNSOM has performed the Annual Claims Review for the first Reporting Period in conformance with the agreed upon procedures as described herein. Each IRO retained by UNSOM shall have expertise in the billing, coding, reporting, and other requirements of the particular section of the health care industry pertaining to this ICA and in the general requirements of the Medicare and Medicaid program(s) from which UNSOM seeks reimbursement. Each IRO shall assess, along with UNSOM, whether it can perform the IRO engagement in a professionally independent fashion taking into account any other business relationships or other engagements that may exist.

c. IRO Verification Review.

- i. The IRO shall randomly select twenty (20) percent of the records included in the UNSOM Annual Claims Review for the first Reporting Period and independently verify the accuracy of the claims submitted to the Medicare and Medicaid programs for reimbursement ("Verification Review").
- ii. After the first Reporting Period, UNSOM shall not be required to retain the IRO for subsequent Reporting Periods, unless the OIG, in its sole discretion, reasonably determines that UNSOM's Annual Claims Review for the first Reporting Period does not satisfactorily establish the adequacy of UNSOM's auditing practices in conformance with the agreed upon procedures described herein. The OIG shall timely notify UNSOM in writing of its determination not to suspend the IRO Verification Review for a subsequent Reporting Period, and to reinstate the IRO

Verification Review for the upcoming Reporting Period.

As part of UNSOM's Annual Report, as applicable, the IRO shall submit a report that verifies that the requirements outlined in Section III.D. and in Appendix A to this ICA have been satisfied and shall report the results, sampling unit by sampling unit, of any Verification Review performed.

d. <u>Retention of Records</u>. During the term of this ICA, UNSOM and the IRO(s) shall retain and make available to the OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (including those exchanged between the IRO and UNSOM) related to the Claims Review.

2. Claims Review.

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

- a. <u>Discovery Sample</u>. UNSOM shall randomly select and review a sample of 50 Medicare and Medicaid Paid Claims submitted by or on behalf of UNSOM. The Paid Claims shall be reviewed based on the supporting documentation available at UNSOM or under UNSOM's control and applicable billing and coding regulations and guidance to determine whether the claim submitted was correctly coded, submitted, and reimbursed.
 - i. Results of Discovery Sample. If the Reportable Error Rate (as defined in Appendix A) for a Discovery Sample is less than 5%, no further audit work is required by UNSOM for that Reporting Period. (Note: The threshold listed above does not imply that this is an acceptable error rate. Accordingly, UNSOM should, as appropriate, further analyze any errors

identified in the Discovery Sample. UNSOM 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 a Discovery Sample indicates that the Reportable Error Rate is 5% or greater, UNSOM shall perform a Full Sample as described below.
- b. Full Sample. If necessary, as determined by procedures set forth in Sections III.D.2.a, UNSOM shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A to this ICA. The Full Sample shall be designed to (i) estimate the actual Claims Review Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (ii) conform with the then applicable Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at UNSOM or under UNSOM'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, UNSOM 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 UNSOM 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. <u>Systems Review</u>. If UNSOM's Discovery Sample identifies a Reportable Error Rate of 5% or greater, UNSOM shall also conduct

- a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in a Claims Review Overpayment, UNSOM shall 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 Claims Review Overpayments. The UNSOM Audit Department shall provide the UNSOM Compliance Officer any observations and recommendations on suggested improvements to the system(s) and the process(es) that generated the claim.
- d. Repayment of Identified Claims Review Overpayments. In accordance with Section III.H.1, UNSOM shall repay within 30 days any Claims Review Overpayment(s) identified in the Discovery Sample and/or the Full Sample (if applicable), regardless of the Reportable Error Rate, to the appropriate payor and in accordance with payor refund policies. UNSOM shall make available to the OIG upon request any and all documentation that reflects the refund of the Claims Review Overpayment(s) to the payor and the associated documentation.
- 3. Claims Review Report. UNSOM 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 to this ICA.
- 4. Validation Review. In the event the OIG has reason to believe that:

 (a) UNSOM's Annual Claims Review fails to conform to the requirements of this ICA; or (b) UNSOM's and/or the IRO's findings or Annual Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review of the documentation, materials, and information directly reviewed in or relevant to the Annual Claims Review or IRO Verification Review to determine whether the Annual Claims Review or the IRO Verification Review complied with the requirements of the ICA and/or whether the findings of the Annual Claims Review results are inaccurate ("Validation Review"). UNSOM agrees to pay for the reasonable cost of any such Validation Review performed by the

OIG or any of its designated agents so long as it is initiated within one year after the OIG's receipt of the UNSOM's Annual Claims Review or IRO Verification Review in question. However, if additional information becomes available that was otherwise not available at the time the Annual Claims Review or IRO Verification Review in question was submitted, OIG shall have the right to conduct a Validation Review of any such implicated Reviews at the expense of UNSOM as described above.

Prior to initiating a Validation Review, the OIG shall notify UNSOM of its intent to do so and provide a written explanation of why the OIG believes such a Validation Review is necessary and an estimate of the cost of such Validation Review. Prior to initiating a Validation Review, UNSOM and the OIG shall meet to discuss the results of the Annual Claims Review or IRO Verification Review submissions or findings in question; address the concerns raised by the OIG; present any additional or relevant information to clarify the results of the Annual Claims Review or IRO Verification Review; or to correct the inaccuracy of the Annual Claims Review or IRO Verification Review in question; and/or propose alternatives to the proposed Validation Review. UNSOM agrees to provide any additional relevant information as may reasonably be requested by the OIG under this section in an expedited manner. The OIG will attempt in good faith to resolve the Annual Claims Review or IRO Verification Review with UNSOM 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.

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

E. <u>Disclosure Program.</u>

UNSOM has represented to OIG that it has established a confidential 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 UNSOM'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. UNSOM shall maintain the disclosure program for the term of this ICA. UNSOM shall appropriately publicize the existence of the disclosure program (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 his/her designee) shall use his best efforts to gather all relevant information from the disclosing individual. The Compliance Officer (or his/her designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to obtain all of the information necessary to determine whether a further review should be conducted. For any disclosure related to a Federal health care program or abuse or neglect of patients 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, UNSOM 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/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.

F. <u>Ineligible Persons</u>.

1. Definition. For purposes of this ICA, 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. UNSOM shall not knowingly hire as employees, or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, UNSOM shall screen all prospective employees and prospective contractors prior to engaging their services 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) UNSOM to refrain from billing Federal health care programs for services of the Ineligible Person.
- 3. Review and Removal Requirement. To the extent not already performed within the 12 months prior to the Effective Date of this ICA, within 120 days of the Effective Date of this ICA, UNSOM shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, UNSOM shall review its list of current employees and contractors against the Exclusion Lists annually in accordance with its standard review procedures. In addition, UNSOM shall require employees and contractors to disclose immediately any debarment, exclusion, or other event that makes the employee an Ineligible Person.

If UNSOM has actual notice that an employee or contractor has become an Ineligible Person, UNSOM shall remove such person from responsibility for, or involvement with, UNSOM'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 UNSOM 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, UNSOM 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.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days of discovery, UNSOM shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to UNSOM and conducted or brought by a governmental entity or its agents involving an allegation that UNSOM has committed a crime or has engaged in fraudulent activities relating to Federal health care programs. 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. UNSOM 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.

H. Reporting.

1. Overpayments.

- a. *Definition of Overpayments*. For purposes of this ICA, an "Overpayment" shall mean the amount of money UNSOM has received in excess of the amount due and payable under any Federal health care program requirements. UNSOM may not subtract any underpayments for purposes of determining the amount of relevant Overpayments for ICA reports except for the purposes of calculating the Reportable Error Rate as set forth in Appendix A.
- b. Reporting of Overpayments. If, at any time, UNSOM identifies or learns of any Overpayments, UNSOM 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, UNSOM 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, UNSOM 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 for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Appendix B to this ICA. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Material Deficiencies.

- a. Definition of Material Deficiency. For purposes of this ICA, 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 UNSOM determines through any means that there is a Material Deficiency, UNSOM 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.H.1, and shall include the payor's name and address, and, to the extent available:
 - (A) all of the information on the Overpayment Refund Form;
 - (B) the 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;

If the information required in Section H.2.b.i.(A)-(C) is not available at the same time as the notification to the payor required in Section III.H.1 because the overpayment has not yet been quantified, UNSOM shall report the information to the OIG when the overpayment is quantified, as per the schedule established pursuant to Section H.1.b.;

- 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 UNSOM's actions taken to correct the Material Deficiency; and
- iv. any further steps UNSOM plans to take to address the Material Deficiency and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date of this ICA, UNSOM changes locations or sells, closes, purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, UNSOM shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of change of location, sale, closure, purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Medicare UNSOM number(s) (if any), and the corresponding contractor's name and address that has issued each Medicare UNSOM number. All Covered Persons at such locations shall be subject to the applicable requirements in this ICA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION CERTIFICATION AND ANNUAL REPORTS

A. <u>Implementation Certification</u>. Within 150 days after the Effective Date of this ICA, UNSOM's Compliance Officer shall be available to the OIG to summarize the status of UNSOM's implementation of the requirements of this ICA. The UNSOM Compliance Officer shall also submit a written certification to the OIG summarizing the status of its implementation of the requirements of this ICA. The documentation supporting this certification shall be available to OIG, upon request. The Compliance officer shall certify that:

- 1. all positions and committees specified in Section III.A. have been filled;
- 2. all training required by Section III.C. were held and all related certifications and documentation required in Section III.C. are in the possession of the UNSOM Compliance Officer;
- 3. the Policies and Procedures required by Section III.B. have been developed, are being implemented, and have been made available to all appropriate Covered Persons;
- 4. all Covered Persons have completed the Code of Conduct certification required by Section III.B.1.;

- 5. all Covered Persons and/or Relevant Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C.;
- 6. the Disclosure Program is being conducted according to the requirements of Section III.E.;
- 7. the Ineligible Persons screening as required by Section III.F. has been completed; and
- 8. the certification required by Section V.C.
- B. <u>Annual Reports</u>. UNSOM shall submit to OIG Annual Reports with respect to the status of, and findings regarding, UNSOM's compliance activities for each of the five one-year periods beginning on the Effective Date of the ICA. (The one-year period covered by each Annual Report shall be referred to as "the Reporting Period").

Each Annual Report shall include:

- 1. any changes in the identity, position description, or other noncompliance job responsibilities of the Compliance Officer, any material actions or material changes that would affect the Compliance Officer's ability to perform the duties necessary to meet the obligations in the ICA, and any change in the membership of the Compliance Committees described in Section III.A.;
- 2. a certification by the Compliance Officer that:
 - a. all Covered Persons have completed any Code of Conduct certifications required by Section III.B.1.;
 - b. all Covered Persons and/or Relevant Covered Persons have completed the applicable training and executed the certification(s) required by Section III.C.;
 - c. UNSOM 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);
- 4. a description of all training required by Section III.C. 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, a schedule of when the training sessions were held, and the other information required by that Section. UNSOM shall also make copies of all training materials available to the OIG upon request;
- 5. a complete copy of all reports prepared pursuant to the review requirements of Section III.D., including a copy of the methodology used;
- 6. UNSOM's response and corrective action plan(s) related to any issues raised by the Annual Claims Reviews or IRO Verification Review, if any;
- 7. as applicable, a certification from the IRO regarding its professional independence from UNSOM;
- 8. a summary of Material Deficiencies (as defined in Section III.H.) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;
- 9. 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: 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;

- 10. a summary of the disclosures in the disclosure log required by Section III.E. that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;
- 11. a description of any personnel actions (other than hiring) taken by UNSOM as a result of the obligations in Section III.F., and the name, title, and responsibilities of any person that falls within the ambit of Section III.F.4., and the actions taken in response to the obligations set forth in that Section;
- 12. 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;
- 13. a description of all changes to the most recently provided list (as updated) of UNSOM's locations (including locations and mailing addresses) as required by Section IV., 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
- 14. the certification required by Section V.C.

The first Annual Report shall be received by the 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. <u>Certifications</u>. The Implementation Certification and Annual Reports shall include a certification by the Corporate Compliance Officer that: (1) except as otherwise described in the applicable report, UNSOM is in compliance with all of the requirements of this ICA, to the best of his or her knowledge; and (2) the Corporate Compliance Officer has reviewed the Implementation Certification or Annual Report, as applicable, and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.
- D. <u>Designation of Information</u>. UNSOM 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. UNSOM 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 this ICA, all notifications and reports required under this ICA shall be submitted to the following entities:

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
Phone: 202.619.2078

Fax: 202.2

202.205.0604

UNSOM:

Jeffrey W. Wyatt Assistant Dean for Administration Chief Business Officer University of Nevada School of Medicine 2040 W. Charleston Blvd., Suite 400 Las Vegas, NV 89102

Phone:

702.671.2240

Fax:

702.671.2277

Unless otherwise specified, all notifications and reports required by this ICA 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 this ICA, 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 UNSOM's relevant books, records, and other documents and supporting materials and/or conduct on-site reviews of any of UNSOM's locations for the purpose of verifying and evaluating: (a) UNSOM's compliance with the terms of this ICA; and (b) UNSOM's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by UNSOM to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. UNSOM shall have the right to have representatives present at the time of an on-site review. Nothing in this ICA requires UNSOM to provide the OIG or its duly authorized representative(s) or agents with any legally-privileged documents nor shall this ICA be construed as constituting a present or future waiver by UNSOM of any legal privileges. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of UNSOM'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. UNSOM agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. UNSOM's employees may elect to be interviewed with

or without a representative of UNSOM present, and with or without legal counsel present.

VIII. DOCUMENT AND RECORD RETENTION

UNSOM shall maintain for inspection all relevant documents and records relating to reimbursement from the Federal health care programs as required by such Federal health care programs, and shall maintain for inspection all relevant documents and records relating to compliance with this ICA, for six years from the Effective Date of this ICA (or longer if otherwise required by law).

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 UNSOM prior to any release by OIG of information submitted by UNSOM pursuant to its obligations under this ICA and identified upon submission by UNSOM as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, UNSOM shall have the rights set forth at 45 C.F.R. § 5.65(d). UNSOM 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

- A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, UNSOM and OIG hereby agree that failure to comply with certain obligations set forth in this ICA 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 UNSOM fails to have in place any of the following obligations described in Section III:
 - a. a Compliance Officer;
 - b. a Compliance Committee;

- c. written Code of Conduct;
- d. written Policies and Procedures;
- e. a requirement that Covered Persons and Relevant Covered Persons be trained, as applicable; 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 UNSOM fails to retain an IRO, as required in Section III.D.
- 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 UNSOM fails to meet any of the deadlines (or any extensions approved pursuant to Section X.B.), for the submission of the Implementation Certification or the Annual Reports to OIG.
- 4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date the failure to comply began) for each day UNSOM employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, UNSOM'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 (the Stipulated Penalty described in this paragraph shall not be applicable for any time period during which UNSOM can demonstrate that it did not discover the person's exclusion or other ineligibility after making a reasonable inquiry (as described in Section III.F.) as to the status of the person).
- 5. A Stipulated Penalty of \$1,500 for each day UNSOM fails to grant access to the information or documentation as required in Section VII of this ICA. (This Stipulated Penalty shall begin to accrue on the date UNSOM fails to grant access.)
- 6. A Stipulated Penalty of \$1,000 for each day UNSOM fails to comply fully and adequately with any obligation of this ICA not otherwise described above. In its notice to UNSOM, OIG shall state the specific grounds for its determination that

UNSOM has failed to comply fully and adequately with the ICA obligation(s) at issue and steps UNSOM must take to comply with the ICA. (This Stipulated Penalty shall begin to accrue 10 days after the UNSOM 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 1-4 of this Section.

B. Timely Written Requests for Extensions. UNSOM 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 ICA for good faith consideration by the OIG. 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 UNSOM fails to meet the revised deadline set by OIG nor shall UNSOM be in breach of the ICA. 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 UNSOM 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 UNSOM 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 UNSOM in writing of: (a) UNSOM's failure to comply, including such information required by Section X.A.6., as applicable; 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, UNSOM 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 UNSOM elects to request an ALJ hearing, the Stipulated Penalties resulting from Section X.A.1-5 shall

continue to accrue until UNSOM cures, to OIG's satisfaction, the alleged breach in dispute. Stipulated Penalties resulting from Section X.A.6. shall be tolled until such time as the final decision is rendered in accordance with Section X.E.2. If the ALJ should agree with and find in favor of UNSOM, no Stipulated Penalties shall be due. 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 ICA 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 UNSOM has materially breached this ICA, 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 ICA

- 1. Definition of Material Breach. A material breach of this ICA means:
 - a. a failure by UNSOM to report a Material Deficiency, take corrective action and make the appropriate refunds, as required in Section III.H;
 - b. a repeated and/or flagrant violation of the obligations under this ICA, 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.D.

- 2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this ICA by UNSOM constitutes an independent basis for UNSOM's exclusion from participation in the Federal health care programs. Upon a determination by OIG that UNSOM has materially breached this ICA and that exclusion should be imposed, OIG shall notify UNSOM in writing of: (a) UNSOM's material breach and the specific nature of the 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. UNSOM 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. UNSOM is in compliance with the obligations of the ICA 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) UNSOM has begun to take action to cure the material breach; (ii) UNSOM is pursuing such action with due diligence; and (iii) UNSOM has provided to OIG a reasonable timetable for curing the material breach.
- 4. Exclusion Letter. If at the conclusion of the 30-day period, UNSOM fails to satisfy the requirements of Section X.D.3, OIG may exclude UNSOM from participation in the Federal health care programs. OIG will notify UNSOM in writing of its determination to exclude UNSOM (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 in accordance with the requirements of such programs. Reinstatement to Federal health care program participation is not automatic. If at the end of the period of exclusion, UNSOM wishes to apply for reinstatement to Federal health care programs, UNSOM must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. <u>Dispute Resolution</u>

- 1. Review Rights. Upon OIG's delivery to UNSOM of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this ICA, UNSOM 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 ICA. 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, by 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 this ICA shall be: (a) whether UNSOM was in compliance with the obligations of this ICA for which the OIG demands payment; (b) whether UNSOM failed to cure; (c) whether the alleged non-compliance could have been cured within the 10-day period or such period agreed to in writing by UNSOM and OIG; and (d) the period of noncompliance. OIG shall have the burden of going forward and the burden of persuasion with respect to the issue of whether UNSOM was out of compliance (for Stipulated Penalties) or in material breach (for exclusion) and with respect to the period of noncompliance or material breach. UNSOM shall bear the burden of going forward and the burden of persuasion with respect to the issue of whether, during the specified period, UNSOM cured the alleged noncompliance or material breach, and with respect to the issue of whether the alleged noncompliance or material breach could have been cured during the specified period. The burden of persuasion will be judged by a preponderance of the evidence. 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 this ICA and orders UNSOM to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless UNSOM requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

- 3. *Exclusion Review*. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this ICA shall be:
 - a. whether UNSOM was in material breach of this ICA as set forth in the Exclusion Letter;
 - b. whether such material 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, and that:
 - i. UNSOM had begun to take action to cure the material breach within that period;
 - ii. UNSOM has pursued and is pursuing such action with due diligence; and
 - iii. UNSOM provided to OIG within that period a reasonable timetable for curing the material breach and UNSOM 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 UNSOM, only after a DAB decision in favor of OIG. UNSOM's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude UNSOM 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 UNSOM 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. UNSOM 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 UNSOM, UNSOM will be reinstated effective on the date of the original exclusion.

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

XI. EFFECTIVE AND BINDING AGREEMENT

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

- A. This ICA shall be binding on the successors, assigns, and transferees of UNSOM;
 - B. This ICA shall become final and binding on the date the final signature is obtained on the ICA;
 - C. Any modifications to this ICA shall be made with the prior written consent of the parties to this ICA;
 - D. OIG may agree to a suspension of UNSOM's obligations under the ICA in the event of UNSOM's cessation of participation in Federal health care programs. If UNSOM withdraws from participation in Federal health care programs and is relieved from its ICA obligations by the OIG, UNSOM agrees to notify OIG 30 days in advance of UNSOM'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 ICA should be reactivated or modified.
 - E. By their signatures, the President of UNSOM represents and warrants that he is the corporate officer with delegated authority to execute this ICA on behalf of UNSOM and the Compliance Officer represents and warrants that he is authorized to carry out the ICA obligations set forth herein on behalf of UNSOM. The undersigned OIG signatory represents that he is signing this ICA in his official capacity and that he is authorized to execute this ICA.

ON BEHALF OF UNSOM

1 Cluber	2.27.02
Robert H. Miller, M.D.	DATE
President	
University of Nevada School of Medicine	
Multispecialty Group Practice South, Inc.	
Jeffrey W. Wyatt Chief Business Officer University of Nevada School of Medicine Multispecialty Group Practice South, Inc. Approved as to form:	3/27/02 DATE
Lisa Char	2/20/02
Lisa Chase	DATE
The Law Offices of Lisa Chase, P.C.	

Counsel for University of Nevada School of Medicine

Multispecialty Group Practice South, Inc.

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

3/5/02 DATE

LEWIS MORRIS

Assistant Inspector General for Legal Affairs

Office of Inspector General

U. S. Department of Health and Human Services

APPENDIX A

A. Claims Review.

- 1. **Definitions**. For the purposes of the Claims Review, the following definitions shall be used:
 - a. <u>Claims Review Overpayment:</u> The amount of money UNSOM has received in excess of the amount due and payable under the Medicare and Medicaid program requirements.
 - b. <u>Item</u>: Any discrete unit that can be sampled (<u>e.g.</u>, code, line item, beneficiary, patient encounter, etc.).
 - c. <u>Paid Claim</u>: A code or line item submitted by UNSOM and for which UNSOM has received reimbursement from any Federal health care program.
 - d. <u>Population</u>: All Items for which UNSOM has submitted a code or line item and for which UNSOM has received reimbursement from the Medicare or Medicaid program (<u>i.e.</u>, a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.
 - e. <u>Reportable Error Rate</u>: The Reportable Error Rate shall be the Net Financial Error Rate, as defined below, identified in the Discovery and Full Samples.
 - i. For the first year as well as any subsequent years requiring an IRO Verification Review, if any, the Net Financial Error Rate shall be calculated by subtracting any underpayments from any Claims Review Overpayments ("Net Overpayment") and dividing the Net Overpayment by the total dollar amount associated with the Items in the sample. In addition (i) all payment errors identified by UNSOM and not verified by the IRO; (ii) all payment errors identified by UNSOM and verified by the IRO; and (iii) all payment errors

identified by the IRO and not identified by UNSOM shall be included among the Net Overpayment calculation.

ii. For each year not requiring an IRO Verification Review, if any, the Net Financial Error Rate shall be calculated by subtracting any underpayments from any Claims Review Overpayments ("Net Overpayment") and dividing the Net Overpayment by the total dollar amount associated with the Items in the sample.

2. Other Requirements.

- a. <u>Paid Claims without Supporting Documentation</u>. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which UNSOM cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by UNSOM for such Paid Claim shall be deemed a Claims Review Overpayment. Replacement sampling for Paid Claims with missing documentation shall not be permitted.
- b. <u>Use of First Samples Drawn</u>. For the purposes of all samples (Discovery Sample(s) and Full Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in each first sample (or first sample for each strata, if applicable) shall be used. In other words, 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.
- **B.** <u>Claims Review Report.</u> The following information shall be included in each Claims Review Report for each Discovery Sample and Full Sample (if applicable):

1. Claims Review Methodology

a. <u>Sampling Unit</u>. A description of the Item as that term is utilized for the Claims Review. For purposes of this Claims Review, the term "Item" may refer to any discrete unit that can be sampled (<u>e.g.</u>, claim, line item, beneficiary, patient encounter, etc.).

- b. <u>Claims Review Population</u>. A description of the Population subject to the Claims Review.
- c. <u>Claims Review Objective</u>. A clear statement of the objective intended to be achieved by the Claims Review.
- d. <u>Sampling Frame</u>: A description of the sampling frame, which is the totality of Items from which the Discovery Sample and, if any, Full Sample has been selected and an explanation of the methodology used to identify the sampling frame. In most circumstances, the sampling frame will be identical to the Population.
- e. <u>Source of Data</u>: A description of the specific documentation relied upon by UNSOM when performing the Claims Review and by the IRO when performing the IRO Verification Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, specific local medical review policies and the contractors that issued such policies, title and transmittal number of CMS program memoranda, specific cites in the Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).
- f. <u>Review Protocol</u>: A narrative description of how the Claims Review was conducted and what was evaluated.

2. Claims Review Findings

- a. A description of UNSOM's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.
- b. UNSOM's and/or IRO's findings, supporting rationale, and a summary of such findings and rationale regarding the Claims Review and the IRO Verification Review, respectively, including the results of the Discovery Sample and the results of the Full Sample (if any) with the gross Claims Review Overpayment amount, the gross

underpayment amount, the Net Overpayment amount, and the Reportable Error Rate for each sample. Note: for the purpose of this reporting, any potential cost settlements or other supplemental payments shall not be included in the Net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the Net Overpayment calculation.

c. UNSOM's finding and recommendations concerning the Systems Review, if any.

3. Statistical Sampling Documentation

- a. The number of Items appraised in the Discovery Sample and, if applicable, in the Full Sample.
- b. A copy of the printout of the random numbers generated by the "Random Numbers" function of the statistical sampling software used.
- c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample.
- d. A description or identification of the statistical sampling software package used to conduct the sampling.

4. Claims Review Results

- a. Total number and percentage of instances (based on UNSOM's internal Claims Review, if applicable) in which UNSOM determined that the Paid Claims submitted ("Claims Submitted") differed from what should have been the correct claim ("Correct Claim"), regardless of the effect on the payment.
- b. Total number and percentage of instances (based on UNSOM's internal Claims Review, if applicable) in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in a Claims Review Overpayment to UNSOM.

- c. Based on UNSOM's Claims Review or the IRO's Verification Review, total dollar amount of paid Items included in the sample and the Net Overpayment associated with the sample.
- d. For each Discovery and Full Sample performed by UNSOM and verified by the IRO: (i) the number of Items the IRO verified; (ii) the number of instances in which the IRO disagreed with UNSOM's payment determinations; and (iii) the dollars associated with the difference between the IRO's and UNSOM's payment determinations.
- e. Reportable Error Rate in each Discovery and/or Full Sample, as defined in Section A.1.e of this Appendix.
- f. A spreadsheet of the Claims Review results that includes the following information for each Paid Claim appraised: Federal health care program billed, beneficiary health insurance claim number, date of service, procedure code submitted, procedure code reimbursed, allowed amount reimbursed by payor, correct procedure code (as determined by UNSOM's Claims Review), correct procedure code (as determined by the IRO Verification Review), correct allowed amount (as determined by UNSOM's Claims Review), correct allowed amount (as determined by the IRO Verification Review), dollar difference between allowed amount reimbursed by payor and the correct allowed amount (determined by UNSOM's Claims Review); and dollar difference between allowed amount reimbursed by payor and the correct allowed amount (determined by the IRO Verification Review).
- 5. **Systems Review Report.** Observations and recommendations on possible improvements to the system(s) and process(es) that generated the Claims Review Overpayment(s) in the sample Population.
- 6. **Credentials.** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; (2) performed the Claims Review; and (3) performed the verification review, if applicable.

Attachment 1

Claim Review Results

		 	 	 	 	 	
Dollar Difference between Amt Reimbursed and Correct Allowed Amt							
Correct Allowed Amt Reimbursed (IRO determined)							
Correct Procedure Code (IRO determined)							0
Allowed Amount Reimbursed							
Procedure Code Reimbursed							
Procedure Code Submitted							
Date of Service							
Bene HIC #							
Federal Health Care Program Billed							

attachment1.november2001.wpd

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR						
Date:	D					
Contractor Deposit Control #	Date of Depos	31t:		Ī		
Contractor Contact Name:		Phone #				
Contractor Address:						
Contractor Fax:						
TO PE CO	OMPLETED BY PROVIDER/P.	UVSICIAN/SI	DDI IFD			
Please complete and forward to	Medicare Contractor This form	or a similar doc	ument containing th	he following		
information, should accompany	Medicare Contractor. This form, every voluntary refund so that rec	eipt of check is p	properly recorded o	and applied.		
LADDDECC	PLIERNAME					
ADDRESS	PLIER #CHI	CCV NUIMDED	11			
PROVIDER/PHYSICIAN/SUP	PLIER #CHI	ECK NUMBER:	#			
CONTACT PERSON:	CONTACT PERSON: PHONE #AMOUNT OF CHECK \$ CHECK DATE					
AMOUNT OF CITECIX #	CHECK DATE					
	REFUND INFORMAT	TION				
For each Claim, provide the fo		<u> </u>				
Patient Name	HJ	IC#				
Medicare Claim Number	HI Claim Amo ment: (Select reason code fro	ount Refunded \$)			
Reason Code for Claim Adjustn	nent: (Select reason code from	om list below. U	Jse one reaso			
n per claim)						
(Please list <u>all</u>	claim numbers involved. Attach	separate sheet,	if necessary)			
Note: If Specific Patient/HIC/C please indicate meth overpayment:	Claim #/Claim Amount data not ava odology and formula used t	tilable for all cla to determine	ims due to Statistice amount and re	al Sampling, ason for		
For Institutional Facilities On	dy:			-		
Cost Report Year(s)	e involved, provide a breakdown b					
		y amount and co	orresponding cost i	report year.)		
For OIG Reporting Requirem		- -	~ .			
	rity Agreement with OIG?	Yes	No			
Reason Codes:						
Billing/Clerical Error 01 - Corrected Date of Service	MSP/Other Payer Involvement 08 - MSP Group Health Plan Insurance	Miscellaneous	Do assume am to tion			
02 - Duplicate	09 - MSP No Fault Insurance	13 - Insumiciem I	led in an HMO			
03 - Corrected CPT Code	09 - MSP No Fault Insurance 10 - MSP Liability Insurance 11 - MSP, Workers Comp.(Including	15 - Services Not	Rendered			
04 - Not Our Patient(s) 05 - Modifier Added/Removed	11 - MSP, Workers Comp.(Including	16 - Medical Nec	essity			
05 - Modifier Added/Removed	Black Lung	17 - Other (Please	e Specify)			
06 - Billed in Error	12 - Veterans Administration	y - 100A				
07 - Corrected CPT Code						