INSTITUTIONAL COMPLIANCE AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
RUSH PRESBYTERIAN - ST. LUKE'S MEDICAL CENTER ON BEHALF OF
THE UNIVERSITY TRANSPLANT MEDICAL SERVICE PLAN

I. PREAMBLE

Rush Presbyterian - St. Luke's Medical Center ("Rush") on behalf of the University Transplant Medical Service Plan (the "UT MSP") 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 by the UT MSP's physicians, officers, directors, employees, contractors, agents, third parties engaged to bill or submit reimbursement claims, and all other individuals within the UT MSP 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 ("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"). Contemporaneously with this ICA, Rush is entering into a Settlement Agreement with the United States, and this ICA is incorporated by reference into the Settlement Agreement.

For purposes of this ICA, Covered Persons shall not include any officers, directors, employees, or physicians of Rush who do not report to the Director of the UT MSP. Covered Persons shall also not include legal counsel for UT MSP or Rush.

Prior to the execution of this ICA, Rush voluntarily established its own corporate compliance program (known as the "Rush Compliance Program") that applies to all Rush departments and Medical Service Plans, including the UT MSP. The Rush Compliance Program provides for written policies and procedures, an education and training component, mechanisms for the ongoing review of Rush 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 Rush Compliance Program by a Corporate Compliance Committee and a Chief Compliance Officer who have direct access to the President of Rush and the Board of Trustees. Rush agrees to continue the operation of the Rush Compliance Program for the term of this ICA. Rush may modify the Rush Compliance Program as appropriate, but at a minimum, Rush shall ensure that it complies with the integrity obligations for the UT MSP that are enumerated in this ICA.

II. TERM OF THE ICA

The period of the compliance obligations assumed by the UT MSP under this ICA shall be three (3) 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 remain in effect until OIG has completed its review of the final annual report and any additional materials submitted by the UT MSP pursuant to OIG's request.

III. CORPORATE INTEGRITY OBLIGATIONS

The UT MSP hereby agrees to maintain and/or establish a Compliance Program that includes the following elements:

A. Compliance Officer and Committee.

1. *Chief Compliance Officer.* Rush has represented to OIG that, pursuant to the Rush Compliance Program, it has established the position of Chief Compliance Officer and appointed an individual to serve in that capacity. As part of her duties, the Chief Compliance Officer shall continuously be charged with the responsibility for all activities of the UT MSP in furtherance of the integrity obligations assumed in this ICA, including the day-to-day compliance activities engaged in by the UT MSP, developing and implementing policies, procedures, and practices designed to ensure compliance by UT MSP with the requirements set forth in this ICA and with Federal health care program requirements, and complying with any reporting obligations created under this ICA. Accordingly, for the term of this ICA, Rush shall formally maintain the appointment of an individual to serve as the Chief Compliance Officer as set forth in Rush's Board of Trustees Resolution to Establish Position of Chief Compliance Officer.

The Chief Compliance Officer shall make regular reports to the Board of Trustees on at least a quarterly basis, and shall be authorized to report on compliance matters affecting the UT MSP to the Board of Trustees at any time.

Any changes in the identity or position description of the Chief Compliance Officer, or any actions or changes that would affect the Chief Compliance Officer's ability to perform the duties necessary to meet the obligations in this ICA, must be reported to OIG, in writing, within 15 days of such a change.

2. *Compliance Committee.* Rush has represented to OIG that, pursuant to the Rush Compliance Program, it has established a Corporate Compliance Committee and appointed individuals to serve on that Committee. Rush has also represented to OIG that the Chief Compliance Officer chairs the Corporate Compliance Committee. The Corporate Compliance Committee shall support the Chief Compliance Officer in fulfilling his/her responsibilities with respect to this ICA.

Any actions or changes that would affect the Corporate Compliance Committee's ability to perform the duties necessary to meet the obligations in this ICA, must be reported to OIG, in writing, within 15 days of such a change.

B. Written Standards.

1. *Rush Compliance Manual.* Rush has represented to OIG that, pursuant to the Rush Compliance Program, it has drafted the Rush Compliance Manual containing information on Rush's compliance policies, along with specific rules and regulations. To the extent not already accomplished, Rush shall finalize the Rush Compliance Manual and distribute it to all Covered Persons within 120 days of the effective date of this ICA. Rush shall make the promotion of, and adherence to, the compliance policies outlined in the Rush Compliance Manual an element in evaluating the performance of all Covered Persons. The Rush Compliance Manual shall, at a minimum, set forth:

a. Rush'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. Rush's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program

requirements, and with Rush's and the UT MSP's Compliance Policy Manuals;

c. the requirement that all of the UT MSP's Covered Persons shall be expected to report to the Chief Compliance Officer or other individual designated by Rush suspected violations of any Federal health care program requirements or of Rush's or the UT MSP's Compliance Policy Manuals;

d. the possible consequences to Rush, the UT MSP, and Covered Persons of failure to comply with all Federal health care program requirements and with Rush's or the UT MSP's Compliance Policy Manuals, or of failure to report such non-compliance; and

e. the right of all individuals to use the Confidential Disclosure Program described in Section III.E, and Rush's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

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 Rush's Compliance Manual. New Covered Persons shall receive the Rush Compliance Manual within 30 days after becoming a Covered Person 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.

Rush shall annually review the Rush Compliance Manual to determine if revisions are appropriate and shall make any necessary revisions based on such a review. Any such revised Rush Compliance Manual shall be distributed to Covered Persons within 30 days of finalizing such changes. All Covered Persons shall certify that they have received, read, understood and will abide by the revised Rush Compliance Manual within 60 days of the finalization of such revisions.

2. *Rush Compliance Policy Manual.* Rush has represented to OIG that, pursuant to the Rush Compliance Program, it has drafted the Rush Compliance Policy Manual containing Rush's full compliance policies. To the extent not already accomplished, Rush shall finalize the Rush Compliance Policy Manual within 120 days of the effective date of this ICA. At a minimum, the Rush Compliance Policy Manual

shall address the subjects relating to the Rush Compliance Manual identified in Section III.B.1.

A copy of the final Rush Compliance Policy Manual shall be submitted to OIG with Rush's Implementation Report.

To the extent not already accomplished, the Rush Compliance Policy Manual shall be made available to all Covered Persons within 120 days of the effective date of the ICA. Appropriate and knowledgeable staff shall be available to explain the Rush Compliance Policy Manual.

At least annually (and more frequently if appropriate), Rush shall assess and update as necessary the Rush Compliance Policy Manual. Within 30 days of the effective date of any revisions, the relevant portions of any such revised Rush Compliance Policy Manual shall be made available to all Covered Persons.

3. *UT MSP Compliance Policy Manual.* Rush has represented to OIG that, pursuant to the Rush Compliance Program, the UT MSP must prepare a Compliance Policy Manual to supplement Rush's Compliance Policy Manual. The UT MSP shall prepare the UT MSP Compliance Policy Manual within 120 days of the effective date of this ICA. At a minimum, the UT MSP Compliance Policy Manual shall address:

a. the subjects relating to the Rush Compliance Manual identified in Section III.B.1;

b. "incident to" billing by physicians for services provided by ancillary providers;

c. coding and upcoding;

d. discipline for physicians, whether employed or non-employed, associated with the UT MSP who violate any of the Rush or UT MSP compliance policies; and

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

A copy of the UT MSP Compliance Policy Manual shall be submitted to OIG with Rush's Implementation Report.

The UT MSP Compliance Policy Manual shall be made available to all Covered Persons within 120 days of the effective date of the ICA. Appropriate and knowledgeable staff shall be available to explain the UT MSP Compliance Policy Manual.

At least annually (and more frequently if appropriate), the UT MSP shall assess and update as necessary the UT MSP Compliance Policy Manual. Within 30 days of the effective date of any revisions, the relevant portions of any such revised UT MSP Compliance Policy Manual shall be made available to all Covered Persons.

C. Education and Training.

Rush and the UT MSP shall continue the education and training as set forth in the Rush Compliance Program as it pertains to all Covered Persons. Education and training for Covered Persons shall have at least two components: Basic annual training on Rush's and the UT MSP's compliance programs and specific training for those Covered Persons whose job functions require understanding of particular compliance policies.

1. *General Training.* Within 120 days of the effective date of this ICA, the UT MSP shall provide at least two (2) hours of general training to each Covered Person. This training shall explain:

a. The existence and requirements of the ICA; and

b. The Rush and UT MSP compliance programs (including the Rush Compliance Manual, Rush Compliance Policy Manual, and the UT MSP Compliance Policy Manual as they pertain to general compliance issues).

All training materials shall be made available to OIG, upon request.

For those Covered Persons who have received general/overview training as part of the Rush Compliance Program within the one year period prior to the effective date of this ICA, the general training need only explain the existence and requirements of the

ICA and any changes to the Rush and UT MSP compliance programs since the date they were trained.

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 this ICA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least one hour of general training annually.

Rush and UT MSP shall be obligated to provide general training to personnel of UT MSP contractors which qualify as Covered Persons who: (1) are directly involved in the delivery of patient care items or services by UT MSP; (2) are directly involved in the preparation or submission of claims for reimbursement from any Federal health care program by UT MSP; or (3) are the principal contacts between Rush and/or the UT MSP and the contractor (hereinafter referred to as "Relevant Contractor Personnel").

2. *Specific Training*. Within 150 days of the effective date of this ICA, each Covered Person shall receive at least six (6) hours of specific training in addition to the general training required above. This specific training shall include:

a. The topics for each Covered Person to be covered pursuant to the Compliance Training Plan for 2001 (Appendix C) and the Training Grid July 2000 (Appendix D).

b. The following additional topics that were not checked on the training grid:

i. for Covered Persons who are lab staff: Coding and Upcoding;

ii. for Covered Persons who are MSP Practice Administrators: Basic Billing Primer, Physician Orders, and E/M Documentation;

iii. for Covered Persons who are Office Managers: Billing for Non-Patient Services, Basic Billing Primer, Physician Orders, and E/M Documentation;

iv. for Covered Persons who are Office Staff: Accurate Books and Records, Waiver of Co-Pays & Deductibles, Basic Billing Primer, Medical Necessity, Bundling and Unbundling, Coding and Upcoding, Billing for Services Not Rendered, Teaching Physicians, Physician Consultations, Incident to Physicians;

v. for Covered Persons who are Billers or Coders: Accurate Books and Records, Professional Courtesy, Waiver of Co-Pays and Deductibles, Teaching Physicians, Physician Orders, and E/M Documentation;

vi. for Covered Persons who are third parties engaged to bill/submit reimbursement claims on behalf of UT MSP: all topics checked on the Training Grid July 2000 for Billers plus Accurate Books and Records, Professional Courtesy, Waiver of Co-Pays and Deductibles, Teaching Physicians, Physician Orders, and E/M Documentation;

vii. for Covered Persons who are Non-employed Physicians: all topics checked on the Training Grid July 2000 for Employed Physicians; and

viii. For Covered Persons who are Registered Nurses: Medical Necessity, Coding and Upcoding, Clinical Documentation, and Basic Billing Primer.

All training materials shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the subject areas.

For those Covered Persons, if any, who have received specific training that meets the requirements of this Section as part of the Rush Compliance Program within the one year period prior to the effective date of this ICA, OIG shall credit that training for purposes of satisfying the specific training requirement for the first year of this ICA.

All Covered Persons shall receive this training within 60 days of the beginning of their employment or becoming Covered Persons or within 120 days of the effective date of this ICA, whichever is later. A UT MSP employee who has completed the specific

training shall review a new Covered Person's work, until such time as the new Covered Person completes applicable training.

After receiving the initial training described in this Section, every Covered Person shall receive at least four (4) hours of specific training annually.

Rush and UT MSP shall be obligated to provide specific training to Relevant Contractor Personnel of UT MSP contractors which qualify as Covered Persons.

3. *Certification.* Each individual who is required to attend training shall certify, in writing, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Chief 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. Review Procedures.

1. *Rush University Transplant Follow-Up Audit.* Rush and the UT MSP have represented to OIG that as of February, 2000, the Rush Corporate Compliance Committee has adopted a Follow-Up Audit Proposal for the UT MSP (Appendix E). Rush and the UT MSP shall continue to implement the Follow-Up Audit as set forth in Appendix E for the term of this ICA.

2. *General Description.*

a. Retention of Independent Review Organization. Within 120 days of the effective date of this ICA, the UT MSP shall retain an entity (or entities), such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform review engagements to assist the UT MSP in evaluating its billing and coding practices and its compliance obligations pursuant to this ICA and the Settlement Agreement. Each Independent Review Organization retained by the UT MSP shall have competency in the billing, coding, reporting and other requirements related to the care of transplant patients in particular and in the general requirements of the Federal health care program(s) from which the UT MSP seeks reimbursement.

b. Types of Engagements. The Independent Review Organization(s) shall conduct two separate engagements. The separate engagements may be conducted by more than one IRO. One engagement shall address the UT MSP's billing and coding to the Federal health care programs ("Billing Engagement"). The second engagement shall address the UT MSP's compliance with the obligations assumed under this ICA and the Settlement Agreement ("Compliance Engagement").

c. Frequency of Billing and Compliance Engagements. The Billing Engagement shall be performed annually and shall cover each of the one-year periods beginning with the effective date of this ICA. The IRO(s) shall perform all components of each annual Billing Engagement except, subject to approval from OIG and subject to the conditions set forth in Section III.D.5, after the first annual Billing Engagement period, the UT MSP may elect to engage Rush's Internal Audit Department to conduct a Billing Engagement for Billing Engagement periods 2 and 3. The Compliance Engagement shall be performed by the IRO for the first one-year period beginning with the effective date of this ICA.

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

3. *Billing Engagement.* The Billing Engagement shall be composed of two separate reviews, a "Claims Review" and a "Systems Review." The Claims Review and corresponding Claims Review Report are discussed in detail in Appendix A to this ICA, which is incorporated by reference.

a. Claims Review. The IRO shall perform a Claims Review to identify any overpayments through an appraisal of Paid Claims submitted by the UT MSP to the Medicare program. The Claims Review shall be performed in accordance with the procedures set forth in Appendix A to this ICA.

b. Claims Review Report. The IRO shall prepare a report based upon each Claims Review performed ("Claims Review Report"). The Claims Review Report shall be created in accordance with the procedures set forth in Appendix A to this ICA.

c. Systems Review. The IRO shall review the UT MSP's billing and coding systems and/or operations (the "Systems Review"). The Systems Review shall consist of a thorough review of the following:

i. the UT MSP's billing systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the operation of the billing system, safeguards to ensure proper claim submission and billing, and procedures to correct inaccurate billing); and

ii. the UT MSP's coding systems and/or operations relating to claims submitted to all Federal health care programs (including, but not limited to, the process by which claims are coded, safeguards to ensure proper coding, and procedures to correct inaccurate coding).

d. Systems Review Report. The IRO shall prepare a report based upon each Systems Review performed ("Systems Review Report"). The Systems Review Report shall include the IRO's findings and supporting rationale regarding:

i. the strengths and weaknesses in the UT MSP's billing systems and/or operations;

ii. the strengths and weaknesses in the UT MSP's coding systems and/or operations; and

iii. any recommendations the IRO may have to improve any of these systems, operations, and processes.

4. *Compliance Engagement.*

a. Compliance Review. The IRO shall conduct a review of the UT MSP's compliance activities ("Compliance Review"). The Compliance Review shall consist of a review of the UT MSP's compliance with certain provisions of the Settlement Agreement.

i. Unallowable Costs Review. The IRO shall determine whether Rush and the UT MSP have complied with their obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and their 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 Rush and the UT MSP or any of their 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 of the Settlement Agreement, as well as from previous years.

b. Compliance Review Report. The IRO shall prepare a report based upon the Compliance Review performed (the "Compliance Review Report"). The Compliance Review Report shall include:

i. the IRO's findings and supporting rationale regarding whether Rush and the UT MSP have complied with their obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and their obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor

4. *Validation Review.* In the event the OIG has reason to believe that: (a) the UT MSP's Billing or Compliance Engagement fails to conform to the requirements of this ICA; or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Billing and Compliance Engagement comply with the requirements of the ICA and/or the findings or Claims Review results are inaccurate. The UT MSP 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 the final annual report (as described in Section II) is received by the OIG.

5. *Internal Billing Review Option.*

a. Subject to approval from OIG and subject to the conditions set forth below, after the IRO has completed the Billing Engagement for the first Billing Engagement Period, the UT MSP may, at its option, engage Rush's Internal Audit Department to conduct an Internal Billing Review in lieu of engaging an IRO for Billing Engagement Periods 2 and 3. If the UT MSP chooses to exercise the Internal Billing Review Option, the results shall be validated by an IRO and shall comply with all of the requirements outlined herein and in Section III.D.2 above.

b. Prior to exercising the Internal Billing Review Option, Rush and the UT MSP agree: i) to develop and adopt a written formal audit workplan for the UT MSP consistent with the terms of the ICA and in conjunction with the IRO; ii) to devote sufficient resources and staff to enable it to implement the audit workplan; and iii) that Rush's Internal Audit Department shall assign persons to the Internal Billing Review who are qualified and experienced in accepted auditing and control processes, and who possess expertise in billing, coding, and Medicare program requirements. In addition, Rush and the UT MSP agree that the persons assigned to implement the Internal Billing Review 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 submission.

c. Consistent with the requirements of Section III.D.2, the Internal Billing Review shall include a Claims Review, a Systems Review,

and the required respective reports of findings. The Internal Billing Review shall also include a report from an IRO that verifies that the requirements of Section III.D.2 have been satisfied. As part of any such verification performed by an IRO under this ICA, the IRO shall conduct a review of at least 20% of the claims reviewed by Rush's Internal Audit Department in each year. If, in its sole discretion, OIG determines that the Internal Billing Review satisfactorily establishes the adequacy of the UT MSP's billing and compliance practices pursuant to this ICA during Billing Engagement Period 2, OIG will allow the UT MSP to engage Rush's Internal Audit Department in lieu of engaging an IRO for Billing Engagement Period 3.

d. In the event that OIG determines, in its sole discretion, that the UT MSP is unable to satisfactorily implement the audit workplan, devote sufficient resources or appropriate qualified staff, or conduct the Internal Billing Review, the UT MSP agrees to engage an IRO to complete all remaining Billing Engagement requirements under this ICA. To the extent that OIG permits the UT MSP to perform Internal Billing Reviews, the UT MSP shall submit all information required in Section III.D.2 as well as the results of the IRO's verification. If the UT MSP decides not to exercise its Internal Billing Review Option, the requirements applicable to engagement of an IRO to perform the Billing and Compliance Engagements shall remain in effect for the term of this ICA.

E. Confidential Disclosure Program.

Rush has represented to OIG that it has established and will continue to maintain a confidential disclosure program that includes, but is not limited to, its toll free telephone hotline. This confidential disclosure program will continue to enable individuals to disclose, to the Chief Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with the UT MSP's policies, 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. ("Potential UT MSP Compliance Issues") Rush and the UT MSP shall continue to publicize the existence of the confidential disclosure mechanism (e.g.,

via periodic e-mails to employees or by posting the information in prominent common areas).

The Confidential Disclosure Program shall emphasize a non-retribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communications. Upon receipt of a disclosure of a Potential UT MSP Compliance Issue, the Chief Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Chief Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure of a Potential UT MSP Compliance Issue 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 of a Potential UT MSP Compliance Issue 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, Rush and the UT MSP shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

The Chief Compliance Officer (or his or her designee) shall maintain a confidential disclosure log, which shall include a record and summary of each disclosure received of a Potential UT MSP Compliance Issue, the status of the respective internal reviews associated with Potential UT MSP Compliance Issues, and any corrective action taken in response to the internal reviews. The confidential disclosure log of Potential UT MSP Compliance Issues shall be available to OIG, upon request.

F. Ineligible Persons.

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 related to the provision of health care items or services, but has not yet been excluded, debarred or otherwise declared ineligible.

2. *Screening Requirements.* The UT MSP shall not hire or engage as contractors or grant staff privileges to any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, the UT MSP shall screen all prospective employees and prospective contractors prior to engaging their services and screen UT MSP physicians prior to granting staff privileges by: (a) requiring applicants to disclose

whether they are Ineligible Persons; and (b) reviewing 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://www.hhs.gov/oig) (these lists will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement.* Within 120 days of the effective date of this ICA, the UT MSP shall review its lists of current employees, contractors and UT MSP physicians with staff privileges against the Exclusion Lists. Thereafter, the UT MSP shall review the lists quarterly. In addition, the UT MSP shall require UT MSP employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If the UT MSP has notice that a UT MSP employee, contractor or physician with staff privileges has become an Ineligible Person, then the UT MSP shall remove such person from responsibility for, or involvement with, the UT MSP'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 the UT MSP has notice that a UT MSP 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, the UT MSP 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, the UT MSP shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that the UT MSP 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. The UT MSP 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 the UT MSP has received in excess of the amount due and payable under any Federal health care program requirements. The UT MSP may not subtract any underpayments for purposes of determining the amount of relevant "overpayments."

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

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 potential 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 the UT MSP determines that there is a Material Deficiency within the UT MSP billing system, the UT MSP 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 all of the information on the Overpayment Refund Form, as well as:

(A) the payor's name, address, and contact person to whom the overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid/refunded;

(ii) a complete description of the Material Deficiency, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

(iii) a description of the UT MSP's actions taken to correct the Material Deficiency; and

(iv) any further steps the UT MSP 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, the UT MSP changes locations or purchases or establishes new business units related to the furnishing of items or services that may be reimbursed by Federal health care programs, the UT MSP shall notify OIG of this fact as soon as possible, but no later than within 30 days of the date of

change of location, purchase or establishment. This notification shall include the location of the new operation(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 such locations shall be subject to the applicable requirements in this ICA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within 150 days after the effective date of this ICA, the UT MSP shall submit a written report to OIG summarizing the status of its implementation of the requirements of this ICA. This Implementation Report shall include:

1. the name, address, phone number and position description of the Chief Compliance Officer required by Section III.A;

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

3. a copy of Rush's Compliance Manual required by Section III.B.1;

4. a copy of Rush's Compliance Policy Manual required by Section III.B.2;

5. a copy of the UT MSP Compliance Policy Manual required by Section III.B.3;

6. a description of the training required by Section III.C, 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;

7. a certification by the Chief Compliance Officer that:

   a. the Rush Compliance Policy Manual and the UT MSP Compliance Policy Manual required by Section III.B have been developed, are being implemented, and have been made available to all Covered Persons;

b. all Covered Persons have completed the Compliance Manual certification required by Section III.B.1; 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.

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

9. the identity of the IRO(s) and the proposed start and completion dates of the first annual review;

10. a summary of personnel actions taken pursuant to Section III.F.;

11. a list of all of the UT MSP'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 contractor's name and address that issued each provider identification number;

12. to the extent not already furnished to OIG, or if modified, a description of the UT MSP's corporate and organizational structures, including a list of all employees, contractors, and vendors, identification of any parent and sister companies, subsidiaries and their respective lines of business; and

13. the certification required by Section V.C.

B. Annual Reports. The UT MSP shall submit to OIG Annual Reports with respect to the status of and findings regarding the UT MSP's compliance activities for each of the three 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 change in the identity or position description of the Chief Compliance Officer and/or members of the Compliance Committee described in Section III.A;

2. a certification by the Chief Compliance Officer that:

a. All Covered Persons have completed any Rush Compliance Manual 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. Rush and the UT MSP have complied with their 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; and (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 Rush and UT MSP Compliance Policy Manuals required by Section III.B and the reasons for such changes (e.g., change in contractor policy);

4. a description of the 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, and a schedule of when the training sessions were held;

5. a complete copy of all 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;

6. the UT MSP's response and corrective action plan(s) related to any issues raised by the IRO(s);

7. a summary of Material Deficiencies (as defined in III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Material Deficiencies;

8. a report of the aggregate overpayments that have been returned by the UT MSP 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;

9. a summary of the disclosures in the confidential disclosure log of Potential UT MSP Compliance Issues required by Section III.E that: (a) relate to Federal health care programs; or (b) allege abuse or neglect of patients;

10. a description of any personnel actions (other than hiring) taken by the UT MSP 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;

11. 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;

12. a description of all changes to the most recently provided list (as updated) of the UT MSP'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

13. the certification required by Section V.C.

The first Annual Report shall be received by the OIG no later than one year and 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Chief Compliance Officer that: (1) except as otherwise described in the applicable report, the UT MSP is in compliance with all of the requirements of this ICA, to the best of his or her knowledge; and (2) the Chief 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: The UT MSP 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 exempt from disclosure under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. The UT MSP 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 202.205.0604

The UT MSP:

Catherine A. Jacobson,
Associate Vice President for Program Evaluation,
Chief Compliance Officer
Rush Compliance Office
707 South Wood Street, Suite 317
Phone 312.942.5303
Fax 312.942.4233

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

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 Rush and the UT MSP's books, records, and other documents and supporting materials that relate to UT MSP and/or conduct on-site reviews of any of the UT MSP's locations for the purpose of verifying and evaluating: (a) the UT MSP's compliance with the terms of this ICA; and (b) the UT MSP's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Rush or the UT MSP to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Rush or the UT MSP'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. Rush and the UT MSP agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Rush and the UT MSP's employees may elect to be interviewed with or without a representative of Rush or the UT MSP present.

VIII. DOCUMENT AND RECORD RETENTION

The UT MSP shall maintain for inspection all documents and records relating to

reimbursement from the Federal health care programs, or to compliance with this ICA, for four (4) years (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 the UT MSP prior to any release by OIG of information submitted by the UT MSP pursuant to its obligations under this ICA and identified upon submission by the UT MSP as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, the UT MSP shall have the rights set forth at 45 C.F.R. § 5.65(d). the UT MSP 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

The UT MSP is expected to fully and timely comply with all of its ICA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, the UT MSP 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 the UT MSP fails to have in place any of the following:

a. a Chief Compliance Officer as described by Section III.A.1;

b. a Compliance Committee as described by Section III.A.2;

c. the Rush Compliance Manual as described by Section III.B.1;

d. the Rush Compliance Policy Manual as described by Section III.B.2 and 3;

e. the UT MSP Compliance Policy Manual as described by Section III.B.3;

f. a requirement that Covered Persons be trained as described in Section III.C; and

g. a Confidential Disclosure Program as described in Section III.E.

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 the UT MSP 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 the UT MSP 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 the UT MSP employs, contracts with, or grants staff privileges to an Ineligible Person and that person: (i) has responsibility for, or involvement with, the UT MSP'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 demanded for any time period during which the UT MSP 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 Rush or the UT MSP 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 the UT MSP fails to grant access.)

6. A Stipulated Penalty of $1,000 for each day the UT MSP fails to comply fully and adequately with any obligation of this ICA not already covered in paragraphs 1-5. In its notice to the UT MSP, OIG shall state the specific grounds for its

determination that the UT MSP has failed to comply fully and adequately with the ICA obligation(s) at issue and steps the UT MSP must take to comply with the ICA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to the UT MSP of the failure to comply.)

B. Timely Written Requests for Extensions. The UT MSP 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. 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 the UT MSP fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until two business days after the UT MSP 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 the UT MSP 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 the UT MSP of: (a) the UT MSP'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, the UT MSP 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 the UT MSP elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until the UT MSP cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this ICA and shall be grounds for imposition of the Monetary Penalty for Material Breach 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 the UT MSP 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. Monetary Penalty for Material Breach of this ICA

1. *Definition of Material Breach.* A material breach of this ICA means:

a. a failure by the UT MSP to report a material deficiency, take corrective action and make the appropriate refunds, as required in Section III.H;

b. repeated or flagrant violations 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 Collect Material Breach Penalty.* The parties agree that a material breach of this ICA by the UT MSP constitutes grounds for OIG to impose an enhanced stipulated penalty that is separate and apart from the Stipulated Penalties described Section X.A, above. This monetary penalty (hereinafter referred to as the "Material Breach Penalty") shall be $25,000 per day. Upon a determination by OIG that the UT MSP has materially breached this ICA and that a Material Breach Penalty should be imposed, OIG shall notify the UT MSP of: (a) the UT MSP's material breach; and (b) OIG's intent to exercise its contractual right to impose the Material Breach Penalty (this notification is hereinafter referred to as the "Notice of Material Breach").

3. *Opportunity to Cure.* The UT MSP shall have 30 days from the date of receipt of the Notice of Material Breach to demonstrate to OIG's satisfaction that:

a. the UT MSP is in full compliance with this ICA;

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

4. *Penalty Letter.* If at the conclusion of the 30-day period, the UT MSP fails to satisfy the requirements of Section X.D.3, OIG may impose the Material Breach Penalty on the UT MSP, and the Material Breach Penalty shall begin to accrue that day. OIG will notify the UT MSP in writing of its determination to impose the Material Breach Penalty on the UT MSP (this letter shall be referred to hereinafter as the "Material Breach Penalty Letter"). Within ten (10) days of receipt of the Material Breach Penalty Letter, the UT MSP shall either (a) cure the material breach to OIG's satisfaction and pay the applicable Material Breach Penalty; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of material breach, pursuant to the agreed upon provisions set forth below in Section X.D.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to the UT MSP of its Demand Letter or of its Material Breach Penalty Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this ICA, the UT MSP 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 Material Breach Penalty sought pursuant to this ICA. Specifically, OIG's determination to demand payment of Stipulated Penalties or a Material Breach Penalty shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board ("DAB"), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalty or a Material Breach Penalty shall be made within ten (10) days of the receipt of the Demand Letter or of the Material Breach Penalty 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 the UT MSP was in full and timely compliance with the obligations of this ICA for which the OIG demands payment; and (b) the period of noncompliance. The UT MSP shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ agrees with OIG with regard to a finding of a breach of this ICA and orders the UT MSP to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision, notwithstanding that the UT MSP may request review of the ALJ decision by the DAB.

3. *Material Breach 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 regarding imposition of a Material Breach Penalty shall be:

a. whether the UT MSP was in material breach of this ICA;

b. whether such breach was continuing on the date of the Material Breach Penalty Letter;

c. the number of days that the UP MSP was in material breach of this ICA; and

d. whether the alleged material breach could not have been cured within the 30 day period, but that:

(i) the UT MSP had begun to take action to cure the material breach within that period;

(ii) the UT MSP has pursued and is pursuing such action with due diligence; and

(iii) the UT MSP provided to OIG within that period a reasonable timetable for curing the material breach and the UT MSP has followed the timetable.

If the ALJ finds for OIG with regard to a finding of material breach of this ICA and order the UT MSP to pay a Material Breach Penalty, such Material Breach Penalty

shall become due and payable 20 days after the ALJ issues such a decision, notwithstanding that the UT MSP may request review of the ALJ decision by the DAB.

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 ICA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this ICA.

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, the UT MSP and OIG agree as follows:

A. This ICA shall be binding on the successors, assigns, and transferees of the UT MSP;

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; and

D. The undersigned Rush and UT MSP signatories represent and warrant that they are authorized to execute this ICA. 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 THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

12/13/07
DATE

ON BEHALF OF RUSH PRESBYTERIAN - ST. LUKE'S MEDICAL CENTER AND
THE UNIVERSITY TRANSPLANT MEDICAL SERVICE PLAN

Leo M. Henikoff, M.D.
President and Chief Executive Officer
Rush Presbyterian-St. Luke's Medical Center

12-11-00
DATE

Catherine A. Jacobson
Associate Vice President for Program Evaluation
Chief Compliance Officer
Rush Presbyterian-St. Luke's Medical Center

DATE

Richard Prinz, M.D.
Director,
University Transplant Medical Service Plan
Rush Presbyterian-St. Luke's Medical Center

DATE

Sheldon T. Zenner, Esq.
Katten Muchin Zavis
Counsel to Rush Presbyterian-St. Luke's
Medical Center and the University
Transplant Medical Services Plan

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12-12-00
DATE

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DATE

Sheldon T. Zenner, Esq.
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Counsel to Rush Presbyterian-St. Luke's
Medical Center and the University
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THE UNIVERSITY TRANSPLANT MEDICAL SERVICE PLAN

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Richard Prinz, M.D.
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Rush Presbyterian-St. Luke's Medical Center

12-12-00
DATE

Sheldon T. Zenner, Esq.
Katten Muchin Zavis
Counsel to Rush Presbyterian-St. Luke's
Medical Center and the University
Transplant Medical Services Plan

1-5-01
DATE

INDEX OF APPENDICES

APPENDIX A

A. Claims Review.

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

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

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

c. Overpayment: Consistent with the definition of Overpayment as articulated in Section III.H.1.a of the ICA, the amount of money the UT MSP has received in excess of the amount due and payable under any Federal health care program requirements. For the purposes of the Claims Review and all reporting to the OIG under this ICA, the UT MSP shall not subtract or "net out" underpayments when determining the amount of relevant Overpayments.

d. Paid Claim: A code or line item submitted by the UT MSP and for which the UT MSP has received reimbursement from the Medicare program.

e. Population: All Items for which the UT MSP has submitted a code or line item and for which the UT MSP has received reimbursement from the Medicare program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.

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

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

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

a. Confidence and Precision Requirements. The Claims Review Sample must contain a sufficient number of Items so that if the Overpayments identified in the Claims Review Sample were projected to the Population, the projection would provide a 90% confidence level and a maximum relative precision (i.e., semi-width of the confidence interval) of plus or minus 25% of the point estimate. In other words, if the Claims Review Overpayment results were projected to the Population at a 90% confidence level, the confidence interval (expressed in dollars) must be sufficiently narrow that the upper bound of the confidence interval would not exceed 125% of the midpoint of the confidence interval (the point estimate), and the lower bound of the confidence interval would not be less than 75% of the midpoint of the confidence interval.

b. Use of a Probe Sample to Determine Claims Review Sample Size. To determine how many Items must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, the mean and the standard deviation of the Population must be estimated. These estimates shall be developed through the use of a single Probe Sample. The Probe Sample shall be used to determine the minimum Claims Review Sample size through one of the two following options:

i. *Probe Sample with a Minimum Size of Thirty Items*. The Probe Sample shall include at least 30 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by the UT MSP for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this Probe Sample, then a second Probe Sample, of at least 30 Items, must be selected and reviewed. The estimated mean and standard deviation

of the Population (based on the amount of Overpayments received by the UT MSP for each sample Item) shall be determined from this Probe Sample, using RAT-STATS' "Variable Appraisals" function. If no Overpayments are found in this second Probe Sample, then the Claims Review can be terminated with the results of the second Probe Sample, and the results of the two Probe Samples shall be reported in lieu of the Claims Review when preparing and submitting the Claims Review Report (see Section B, below); or

ii. *Probe Sample with a Minimum Size of Fifty Items.* The Probe Sample shall include at least 50 Items, and shall be selected through the use of RAT-STATS' "Random Numbers" function. Once all Paid Claims associated with the Items included in the Probe Sample have been reviewed, the estimated mean and standard deviation of the Population shall be determined. This determination is based on the Overpayment amount received by the UT MSP for each Item in the sample. The "Variable Appraisals" function of RAT-STATS shall be used to calculate the estimated mean and standard deviation of the Population. For purposes of estimating the mean and standard deviation of the Population, and entering this information into the "Variable Appraisals" function of RAT-STATS, any underpayment identified for a Paid Claim in the Probe Sample shall be treated as a zero overpayment. If no Overpayments are found in this 50 Item Probe Sample, then the Claims Review can be terminated with the review of the Probe Sample and the results of the Probe Sample shall be reported in lieu of the results of the Claims Review when preparing and submitting the Claims Review Report (see Section B, below).

c. Calculation of Claims Review Sample Size and Selection of the Claims Review Sample. The estimates of the mean and the standard deviation of the Population obtained through the review of the Probe Sample shall be used to calculate the minimum size of the Claims Review Sample. In order to determine the minimum number of Items that must be included in the Claims Review Sample to meet the 90% confidence level and 25% precision requirements, RAT-STATS' "Sample Size Estimators" (located under the "Utility Programs" file) shall be used. The Claims Review Sample shall be selected by using RAT-STATS' "Random Numbers" function, and shall be selected from the entire Population, with the Population including those Items reviewed as part of the Probe Sample, so that all Items in the Population have an equal chance of inclusion in the

Claims Review Sample.

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

e. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review and/or the Probe Sample, any Paid Claim for which the UT MSP cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by the UT MSP for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

f. Use of First Samples Drawn. For the purposes of all samples (Probe Sample(s) and Claims Review Sample(s)) discussed in this Appendix, the Paid Claims associated with the Items selected in the first sample (or first sample for each strata, if applicable) shall be used. In other words, it is not permissible to generate a number of random samples and then select one for use as the Probe Sample or Claims Review Sample.

B. Claims Review Report. The following information shall be included in each Claims Review Report:

1. ***Claims Review Methodology***

a. Claims Review Objective: A clear statement of the objective intended to be achieved by the Claims Review.

b. Sampling Unit: A description of the Item as that term is utilized for the Claims Review. As noted in Section A.1.b above, for purposes of this Billing Engagement, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

c. Claims Review Population: A description of the Population subject to the Claims Review.

d. Sampling Frame: A description of the sampling frame, which is the totality of Items from which the Probe and Claims Review Sample have 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. Sources of Data: A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, HCFA program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

f. Review Protocol: A narrative description of how the Claims Review was conducted and what was evaluated.

2. ***Statistical Sampling Documentation***

a. The number of Items appraised in the Probe Sample(s) and in the Claims Review Sample.

b. A copy of the RAT-STATS printout of the random numbers generated by the "Random Numbers" function.

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

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

e. The Sampling Frame used in the Probe Sample(s) and the Claims Review Sample will be available to the OIG upon request.

3. ***Claims Review Results***

a. Total number and percentage of instances in which the IRO determined that the Paid Claim submitted by the UT MSP ("Claim 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 in which the Claim Submitted

differed from the Correct Claim and in which such difference resulted in an Overpayment to the UT MSP.

c. The total dollar amount of all Paid Claims in the Claims Review Sample and the total dollar amount of Overpayments associated with the Paid Claims identified by the Claims Review. (This is the total dollar amount of the Overpayments identified in Section B.3.b above.) The IRO may, in its report to the UT MSP, identify underpayments, but any underpayments identified during the Claims Review shall not be offset or "netted out" of the total dollar amount of Paid Claims or of the Overpayments when reporting these amounts in the Claims Review Report to the OIG.

d. 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 the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

4. ***Credentials.*** The names and credentials of the individuals who: (1) designed the statistical sampling procedures and the review methodology utilized for the Claims Review; and (2) performed the Claims Review.

Attachment 1

Claim Review Results

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

OVERPAYMENT REFUND

TO BE COMPLETED BY MEDICARE CONTRACTOR

Date: _____
Contractor Deposit Control # _____ Date of Deposit: _____
Contractor Contact Name: _____ Phone # _____
Contractor Address: _____
Contractor Fax: _____

TO BE COMPLETED BY PROVIDER/PHYSICIAN/SUPPLIER

Please complete and forward to Medicare Contractor. This form, or a similar document containing the following information, should accompany every voluntary refund so that receipt of check is properly recorded and applied.

PROVIDER/PHYSICIAN/SUPPLIERNAME _____
ADDRESS _____
PROVIDER/PHYSICIAN/SUPPLIER # _____ CHECK NUMBER# _____
CONTACT PERSON: _____ PHONE # _____
AMOUNT OF CHECK $ _____ CHECK DATE _____

REFUND INFORMATION

For each Claim, provide the following:
Patient Name _____ HIC # _____
Medicare Claim Number _____ Claim Amount Refunded $ _____
Reason Code for Claim Adjustment: _____ (Select reason code from list below. Use one reaso
n per claim)

(Please list all claim numbers involved. Attach separate sheet, if necessary)

Note: If Specific Patient/HIC/Claim #/Claim Amount data not available for all claims due to Statistical Sampling, please indicate methodology and formula used to determine amount and reason for overpayment: _____

For Institutional Facilities Only:
Cost Report Year(s) _____
(If multiple cost report years are involved, provide a breakdown by amount and corresponding cost report year.)
For OIG Reporting Requirements:
Do you have a Corporate Integrity Agreement with OIG? Yes No

Reason Codes:

Billing/Clerical Error
01 - Corrected Date of Service
02 - Duplicate
03 - Corrected CPT Code
04 - Not Our Patient(s)
05 - Modifier Added/Removed
06 - Billed in Error
07 - Corrected CPT Code

MSP/Other Payer Involvement
08 - MSP Group Health Plan Insurance
09 - MSP No Fault Insurance
10 - MSP Liability Insurance
11 - MSP, Workers Comp.(Including Black Lung
12 - Veterans Administration

Miscellaneous
13 - Insufficient Documentation
14 - Patient Enrolled in an HMO
15 - Services Not Rendered
16 - Medical Necessity
17 - Other (Please Specify)
_____

AMENDMENT TO THE INSTITUTIONAL COMPLIANCE AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND RUSH-PRESBYTERIAN-ST. LUKE'S MEDICAL CENTER ON BEHALF OF THE UNIVERSITY TRANSPLANT MEDICAL SERVICE PLAN

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Rush-Presbyterian-St. Luke's Medical Center ("Rush") on behalf of The University Transplant Medical Service Plan ("UT MSP") entered into an Institutional Compliance Agreement ("ICA") on January 5, 2001.

A. Pursuant to section XI.C. of UT MSP's ICA, modifications to the ICA may be made with the prior written consent of both the OIG and UT MSP. Therefore, the OIG and UT MSP hereby agree that UT MSP's ICA will be amended as follows:

Section III.D., Review Procedures of the ICA is hereby superceded by the attached new section III.D., Review Procedures.

Appendix A of UT MSP's ICA is hereby superceded by the attached new Appendix A.

B. The OIG and UT MSP agree that all other sections of UT MSP's ICA will remain unchanged and in effect, unless specifically amended upon the prior written consent of the OIG and UT MSP.

C. The undersigned UT MSP signatories represent and warrant that they are authorized to execute this Amendment. The undersigned OIG signatory represents that he is signing the Amendment in his official capacity and that he is authorized to execute this Amendment.

D. The effective date of this Amendment will be the date on which the final signatory of this Amendment signs this Amendment.

ON BEHALF OF RUSH-PRESBYTERIAN-ST. LUKE'S MEDICAL CENTER AND THE UNIVERSITY TRANSPLANT MEDICAL SERVICE PLAN

Catherine A. Jacobson — Jan. 7, 2002

Catherine A. Jacobson
Associate Vice President for Program Evaluation
Chief Compliance Officer
Rush-Presbyterian-St. Luke's Medical Center

DATE

Larry Goodman, M.D.
Senior Vice President, Medical Affairs
Dean, College of Medicine

1/11/02

DATE

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

Lewis Morris
Assistant Inspector General for Legal Affairs
Office of Inspector General
U.S. Department of Health and Human Services

1/16/02
DATE

D. Review Procedures.

1. *Rush University Transplant Follow-Up Audit.* Rush and the UT MSP have represented to OIG that as of February, 2000, the Rush Corporate Compliance Committee has adopted a Follow-Up Audit Proposal for the UT MSP (Appendix E). Rush and the UT MSP shall continue to implement the Follow-Up Audit as set forth in Appendix E for the term of this ICA.

2. *General Description.*

a. Retention of Independent Review Organization. Within 120 days of the effective date of this ICA, the UT MSP 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 the UT MSP in assessing and evaluating its billing and coding practices and its compliance obligations pursuant to this ICA and the Settlement Agreement. Each IRO retained by the UT MSP shall have expertise in the billing, coding, reporting and other requirements related to the care of transplant patients in particular and the general requirements of the Federal health care program(s) from which the UT MSP seeks reimbursement. Each IRO shall assess, along with the UT MSP, 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 the UT MSP's billing and coding to the Federal health care programs ("Claims Review") and shall analyze the UT MSP's compliance with the obligations assumed under this ICA and Settlement Agreement ("Compliance Review").

b. Frequency of Claims Review. The Claims Review shall be performed annually and shall cover each of the one-year periods of the ICA beginning with the effective date of this ICA. 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, the UT MSP may elect to engage Rush's Internal Audit Department to conduct the Claims Review for Claims Review periods 2 and 3.

c. Frequency of Compliance Review. The Compliance Review shall be performed by the IRO for the first one-year period beginning with the effective date of this ICA.

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

3. *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 this ICA, which is incorporated by reference.

a. Discovery Sample. The IRO shall randomly select and review a sample of 50 Medicare Paid Claims submitted by or on behalf of the UT MSP. The Paid Claims shall be reviewed based on the supporting documentation available at the UT MSP or under the UT MSP'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, the UT MSP should, as appropriate, further analyze any errors identified in the Discovery Sample. The UT MSP 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.3.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 the UT MSP or under the UT MSP'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, the UT MSP 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 the UT MSP 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 the UT MSP's Discovery Sample identifies an Error Rate of 5% or greater, the UT MSP's IRO also shall 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 the UT MSP its 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.H.1 of the ICA, the UT MSP 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. The UT MSP 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.

4. *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.

5. *Compliance Review.* The IRO shall conduct a review of the UT MSP's compliance activities. The Compliance Review shall consist of a review of the UT MSP's compliance with the unallowable cost provisions of the Settlement Agreement. The IRO shall determine whether Rush and the UT MSP have complied with their obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and its obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from 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 Rush and the UT MSP or any of their subsidiaries. To the extent that such cost reports, cost statements, information reports or payment requests, even if already settled, have been adjusted to account for the effect of the inclusion of the unallowable costs, the IRO will determine if such adjustments were proper. In making this determination, the IRO may need to review cost reports and/or financial statements from the year in which the Settlement Agreement was executed, as well as from previous.

6. *Compliance Review Report.* The IRO shall prepare a report based upon the Compliance Review performed. The Compliance Review Report shall include the IRO's findings and supporting rationale regarding the unallowable costs review and whether Rush and the UT MSP have complied with their obligation not to charge to, or otherwise seek payment from, Federal or State payors for unallowable costs (as defined in the Settlement Agreement) and their obligation to identify to applicable Federal or State payors any unallowable costs included in payments previously sought from such payor.

7. *Validation Review.* In the event the OIG has reason to believe that: (a) the UT MSP's Claims Review or Compliance Review fails to conform to the requirements of this ICA; or (b) the findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Compliance Review complied with the requirements of the ICA and/or the findings or Claims Review results are inaccurate ("Validation Review"). The UT MSP 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 the UT MSP's annual report and any additional materials requested by the OIG (as described in section II) are received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify the UT MSP 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, the UT MSP may request a meeting with the OIG to discuss the results of any Claims Review or Compliance Review submissions or findings; present any additional or relevant information to clarify the results of the Claims Review or Compliance Review or to correct the inaccuracy of the Claims Review; and/or propose alternatives to the proposed Validation Review. The UT MSP 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 Compliance Review issues with the UT MSP 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.

8. *Internal Billing Review Option.*

a. Subject to approval from OIG and subject to the conditions set forth below, after the IRO has completed the Claims Review for the first Claims Review period, the UT MSP may, at its option, engage Rush's Internal Audit Department to 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. If the UT MSP chooses to exercise the internal billing review option, the results shall be validated by an IRO and shall comply with all of the requirements outlined herein and in section III.D.3 above.

b. Prior to exercising the internal billing review option, Rush and the UT MSP agree: i) to develop and adopt a written formal internal audit workplan for the UT MSP consistent with the terms of this ICA and in conjunction with the IRO; ii) to devote sufficient resources and staff to enable it to implement the internal audit workplan; and iii) that Rush's Internal Audit Department shall assign persons to the internal billing review who are qualified and experienced in accepted auditing and control processes, and who possess expertise in billing, coding and Medicare program requirements. In addition, Rush and the UT MSP agree that the persons assigned to implement the internal billing review 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.

c. Consistent with the requirements of section III.D.3 and III.D.4, the internal billing review shall include a Claims Review and the required report of findings. The internal billing review shall also include a report from an IRO that verifies that the requirements of section III.D.3 have been satisfied. As part of any such verification performed by an IRO under this ICA, the IRO shall conduct a review of at least 20% of the claims reviewed by Rush's Internal Audit Department in each year. If, in its sole discretion, OIG determines that such internal billing review satisfactorily establishes the adequacy of the UT MSP's billing and compliance practices pursuant to this ICA during Claims Review period 2, OIG will allow

the UT MSP to engage Rush's Internal Audit Department in lieu of engaging an IRO for Claims Review period 3.

d. In the event that OIG determines, in its sole discretion, that the UT MSP is unable to satisfactorily implement the audit workplan, devote sufficient resources and appropriate qualified staff, or conduct the internal billing review, the UT MSP agrees to engage an IRO to complete all remaining Claims Review requirements under this ICA. To the extent that OIG permits the UT MSP to perform internal billing reviews, the UT MSP must submit all the information required in section III.D.3 and III.D.4 as well as the results of the IRO's verification. If the UT MSP decides not to exercise its internal billing review option, the requirements applicable to engagement of an IRO to perform the Claims Review shall remain in effect for the term of this ICA.

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

APPENDIX A

A. Claims Review.

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

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

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

c. Paid Claim: A code or line item submitted by the UT MSP and for which the UT MSP has received reimbursement from the Medicare program.

d. Population: All Items for which the UT MSP has submitted a code or line item and for which the UT MSP has received reimbursement from the Medicare program (i.e., a Paid Claim) during the 12-month period covered by the Claims Review. To be included in the Population, an Item must have resulted in at least one Paid Claim.

e. Error Rate: The Error Rate shall be the percentage of net overpayments identified in the sample. The Error Rate is calculated by dividing the net Overpayment identified in the sample by the total dollar amount associated with the Items in the sample.

2. **Other Requirements.**

a. Paid Claims without Supporting Documentation. For the purpose of appraising Items included in the Claims Review, any Paid Claim for which the UT MSP cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by the UT MSP for such Paid Claim shall be deemed an Overpayment. Replacement sampling for Paid Claims with missing documentation is not permitted.

b. Use of First Samples Drawn. 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. Claims Review Report. The following information shall be included in the Claims Review Report for each Discovery Sample and Full Sample (if applicable).

1. **Claims Review Methodology.**

a. Sampling Unit: A description of the Item as that term is utilized for the Claims Review.

b. Claims Review Population: A description of the Population subject to the Claims Review.

c. Claims Review Objective: A clear statement of the objective intended to be achieved by the Claims Review.

d. Sampling Frame: 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. Source of Data: A description of the documentation relied upon by the IRO when performing the Claims Review (e.g., medical records, physician orders, certificates of medical necessity, requisition forms, local medical review policies, CMS program memoranda, Medicare carrier or intermediary manual or bulletins, other policies, regulations, or directives).

f. Review Protocol: A narrative description of how the Claims Review was conducted and what was evaluated.

2. **Claims Review Findings.**

a. A description of the UT MSP's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing.

b. The IRO's findings and supporting rationale regarding the Claims Review, including the results of the Discovery Sample, and the results of the Full Sample (if any) with the gross Overpayment amount, the net Overpayment amount, and the corresponding Error Rate(s) related to the net Overpayment. Note: for the purpose of this reporting, any potential cost settlements or other supplemental payments should not be included in the net Overpayment calculation. Rather, only underpayments identified as part of the Discovery Sample or Full Sample (as applicable) shall be included as part of the net Overpayment calculation.

c. The IRO's findings 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 by the IRO.

c. A copy of the statistical software printout(s) estimating how many Items are to be included in the Full Sample, if applicable.

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 in which the IRO determined that the Paid Claims submitted by the UT MSP ("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 in which the Claim Submitted differed from the Correct Claim and in which such difference resulted in an Overpayment to the UT MSP.

c. Total dollar amount of paid Items included in the sample and the net Overpayment associated with the sample.

d. Error Rate in the sample.

e. 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 the IRO), correct allowed amount (as determined by the IRO), dollar difference between allowed amount reimbursed by payor and the correct allowed amount. (See Attachment 1 to this Appendix.)

5. **Systems Review.** Observations and recommendations on possible improvements to the system(s) and process(es) that generated the 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; and (2) performed the Claims Review.