CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
GALICHIA MEDICAL GROUP, P.A.

I. PREAMBLE

Galichia Medical Group, P.A. ("GMED") hereby enters into this Corporate Integrity Agreement ("CIA") with the Office of Inspector General ("OIG") of the United States Department of Health and Human Services ("HHS") to promote compliance by its subsidiaries and/or affiliates; its officers, directors, and/or employees (including physicians); and its contractors and/or agents who participate in the provision, sales or marketing of health care items or services separately billable to any Federal health care program for which GMED claims reimbursement from any Federal health care programs, or in the preparation, documentation or submission of claims, reports or other requests for reimbursement for such items or services (all of the above hereinafter referred to as "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 CIA, GMED is entering into a Settlement Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

II. TERM OF THE CIA

The period of the compliance obligations assumed by GMED under this CIA shall be 6 years from the effective date of this CIA (unless otherwise specificed), or for the period of time GMED remains obligated by the payment terms of the Settlement Agreement, whichever is shorter, but in any event for not less than 5 years (unless otherwise specified). The effective date of this CIA will be the date on which the final signatory of this CIA executes this CIA.

Sections VII, VIII, IX, X and XI shall remain in effect until GMED submits all information required by OIG as part of the final Annual Report.

III. CORPORATE INTEGRITY OBLIGATIONS

GMED warrants and represents that in February 1998 GMED formally established a Corporate Compliance Plan (hereinafter referred to as "Program"). GMED hereby agrees to maintain its current Program, which it shall amend, as necessary, to ensure that it includes the following elements:

A. Compliance Officer and Committee.

1. *Compliance Officer.* GMED represents that it currently has a Compliance Officer as part of its Program. Within 90 days after the effective date of this CIA, GMED shall amend its Program, if necessary, to ensure that the Compliance Officer meets the following requirements. The Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements. The Compliance Officer shall be a member of senior management of GMED, shall make periodic (at least quarterly) reports regarding compliance matters directly to Dr. Galichia, and shall be authorized to report on such matters to Dr. Galichia. The Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by GMED as well as for any reporting obligations created under this CIA.

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

2. *Compliance Committee.* GMED represents that it currently has a Compliance Committee as part of its Program. Within 90 days of the effective date of this CIA, GMED shall amend its Program, if necessary, to ensure that the Compliance Committee meets the following requirements. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other members of senior management necessary to meet the requirements of this CIA (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall oversee monitoring of internal and external audits and investigations).

Any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties

necessary to meet the obligations in this CIA, must be reported to OIG, in writing, within 15 days of such a change.

B. Written Standards.

1. *Code of Conduct.* GMED represents that it currently has a Code of Conduct as part of its Program. Within 90 days of the effective date of this CIA, GMED shall amend its Program, if necessary, to ensure that the Code of Conduct meets the following requirements. The Code of Conduct shall be distributed to all Covered Persons within 90 days of the effective date of this CIA. GMED shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees. The Code of Conduct shall, at a minimum, set forth:

a. GMED'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. the requirement that all of GMED's Covered Persons shall be expected to comply with all Federal health care program requirements and with GMED's own Policies and Procedures as implemented pursuant to section III.B (including the requirements of this CIA);

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

d. the possible consequences to both GMED and Covered Persons of failure to comply with all Federal health care program requirements and with GMED's own Policies and Procedures 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 GMED's commitment to maintain confidentiality, as appropriate, and non-retaliation with respect to disclosures.

Within 90 days of the effective date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understood, and will abide by GMED's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within two weeks after becoming a Covered Person or within 90 days of the effective date of the CIA, whichever is later.

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

2. *Policies and Procedures*. Within 120 days of the effective date of this CIA, GMED shall implement written Policies and Procedures regarding the operation of GMED's compliance program and its compliance with Federal health care program requirements. At a minimum, the Policies and Procedures shall address:

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

b. the Federal health care program requirements for the provision and reimbursement of physician Evaluation and Management ("E&M") services, with a focus on developing policies and procedures designed to ensure that GMED's coding and billing of E&M services to the Federal health care programs are consistent with the level of service actually rendered by the physician or any other health care professional documented in the medical record; and

c. the Federal health care program requirements regarding medical necessity, with a focus on developing policies and procedures designed to ensure that GMED bills the Federal health care programs for items and services consistent with national coverage determinations, HCFA program manuals, and local medical review policies.

The Policies and Procedures shall be available to OIG, upon request.

Within 120 days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all individuals whose job functions are

related to those Policies and Procedures. Appropriate and knowledgeable staff should be available to explain the Policies and Procedures.

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

C. Training and Education.

1. *General Training.* GMED represents that during the fall of 1999, it provided general compliance training, covering its Code of Conduct, compliance program and relevant policies and procedures, to all its employees with the exception of employed physicians. Within 120 days of the effective date of this CIA, GMED shall provide at least 1 hours of general training to each Covered Person, who received such aforementioned training. GMED shall provide at least 2 hours of general training to each Covered Person, who did not receive such aforementioned training. This training shall explain GMED's:

a. CIA requirements; and

b. Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

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

New Covered Persons shall receive the general training described above within 30 days of becoming a Covered Person or within 120 days after the effective date of this CIA, whichever is later. After receiving the initial training described above, each Covered Person shall receive at least 1 hour of general training annually.

2. *Specific Training.* GMED represents that certain members of its coding and billing staff have since January 1, 2000 received relevant outside training regarding billing matters. Outside training provided since January 1, 2000 but prior to the effective date of this CIA that meets the requirements set forth below in III.C.2.a-f shall be counted toward the minimum time requirements set forth below. Within 120 days of the effective date of this CIA, each Covered Person who is involved in the delivery of patient care

items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program (hereinafter referred to as "Relevant Covered Persons") shall receive at least 5 hours of specific training in addition to the general training required above. This specific training shall include a discussion of:

a. the submission of accurate bills for services rendered to Federal health care program patients, and the submission of bills only for items or services that are reasonable and necessary under Federal health care program requirements;

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

c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;

d. applicable reimbursement statutes, regulations, and program requirements and directives;

e. the legal sanctions for improper billings; and

f. examples of proper and improper billing practices.

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

Relevant Covered Persons shall receive this training within 30 days of the beginning of their employment or becoming Relevant Covered Persons or within 120 days of the effective date of this CIA, whichever is later. A GMED employee who has completed the specific training shall review a new Relevant Covered Person's work, to the extent that the work relates to the delivery of patient care items or services and/or in the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Relevant Covered Person completes applicable training.

After receiving the initial training described in this section, every Relevant Covered Person shall receive at least 3 hours of specific training annually.

3. *Certification.* Each individual who is required to attend training shall certify, in writing (or in electronic form, if GMED provides computerized training) that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or his or her designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

D. Review Procedures.

1. *Retention of Independent Review Organization.* GMED shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization" or "IRO") to perform review procedures to assist GMED in assessing the adequacy of its policies and procedures and compliance practices pursuant to this CIA. The reviews will be performed annually and cover each of the one-year periods beginning on the effective date of this CIA or the anniversary of that date. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which GMED seeks reimbursement. The Independent Review Organization must be retained to conduct the audit of the first year within 90 days of the effective date of this CIA. The IRO will conduct two separate engagements. One will be an analysis of GMED's billing to the Federal health care programs to assist GMED in determining compliance with all applicable Federal health care program requirements ("billing engagement"). The billing engagement shall be composed of two separate reviews, a "Claims Review" and a "Systems Review." Such Reviews shall be performed in accordance with the procedures set forth below. The second engagement will determine whether GMED is in compliance with this CIA ("compliance engagement").

2. *Statistical Sampling and Appraisal.* All matters related to this CIA that involve statistical sampling or appraisal shall be conducted using the OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," available on the Internet at www.hhs.gov/oas/ratstat.html. Wherever the CIA requires the use of a random sample, the sample shall be selected and appraised using RAT-STATS and GMED or its IRO shall retain all of the supporting documentation related to the selection and appraisal of the samples.

3. *Claims Review.* The claims review shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims for the relevant period. The sample size shall be determined through the use of a probe sample. The probe sample must contain at least 30 sample units and cannot be used as

part of the full sample. The full sample must contain a sufficient number of units so that when the sample results are projected to the population of claims, the projection provides a minimum 90% confidence level and a maximum precision of plus or minus 25% of the point estimate (i.e., the upper and lower bounds of the 90% confidence interval shall not exceed 125% and shall not fall below 75% of the midpoint of the confidence interval, respectively). Both the probe sample and the full sample must be selected through random number sampling. Each of the annual claims reviews shall include the following components in its methodology:

a. Claims Review Objective: a clear statement of the objective intended to be achieved by the claims review and the procedure or combination of procedures that will be applied to achieve the objective;

b. Claims Review Population: the identity of the population, which is the group about which information is needed and an explanation of the methodology used to develop the population and provide the basis for this determination;

c. Sources of Data: a full description of the source of the information upon which the Claims Review conclusions will be based, including the legal or other standards applied, documents relied upon, and/or payment data;

d. Sampling Unit: a definition of the sampling unit, which is any of the designated elements that comprise the population of interest; and

e. Sampling Frame: the identity of the sampling frame, which is the totality of the sampling units from which the sample will be selected.

4. *Systems Review.* The Systems Review shall consist of a thorough review of the following:

a. GMED'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

b. GMED'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).

5. *Billing Engagements Findings*. Each of the annual billing engagements (i.e., the "claims review" and "systems review" together) shall provide findings regarding the following:

a. the strengths and weaknesses in GMED's billing and coding systems and/or operations;

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

c. whether GMED is submitting accurate claims and/or cost reports for services billed to the Federal health care programs;

d. GMED's procedures to correct inaccurate billing, coding or reporting to Federal health care programs;

e. whether GMED's billing for E&M services are in compliance with Federal health care program requirements, and whether GMED is billing for items and services in compliance with medical necessity requirements as defined by national coverage determinations, HCFA program manuals, and local medical review policies. This review shall be performed by clinical personnel with cardiology expertise. In making such determinations, the IRO shall apply the treating physician rule.

f. whether GMED has complied with its obligation under the Settlement Agreements: (a) not to resubmit any previously denied claims related to the conduct addressed in the Settlement Agreements, and its obligation not to appeal any such denials of claims, and (b) not to charge to or otherwise seek payment for unallowable costs (as defined in the Settlement Agreements) and its obligation to identify and adjust any past charges of unallowable costs; and

g. the steps GMED is taking to bring its operations into compliance or to correct problems identified by the IRO's prior year's systems or claims review.

6. *Compliance Engagement.* The IRO shall also conduct a compliance engagement that shall provide findings regarding whether GMED's programs, policies, procedures and operations comply with the terms of this CIA. This engagement shall include section by section findings regarding the requirements of this CIA.

7. *Reporting.* The IRO shall annually produce reports corresponding to the billing and compliance engagements and including all of the information required by this section of the CIA. A complete copy of all of the IRO's review reports with respect to each year shall be included in each of GMED's Annual Reports to OIG.

8. *Verification/Validation.* In the event that OIG has reason to believe that any of GMED's billing reviews conducted by the IRO fail to conform to its obligations under the CIA or indicate improper billings not otherwise adequately addressed in the annual review report(s), and thus determines that it is necessary to conduct an independent review to determine whether or the extent to which GMED is complying with its obligations under this CIA, GMED agrees to pay for the reasonable cost of any such review by OIG or any of its designated agents. Prior to proceeding with such a review, OIG shall notify GMED of its intent to do so and its reasons for believing such a review is necessary, and shall in good faith attempt to resolve any billing review issues without proceeding with an independent review, although OIG shall retain sole discretion to determine whether to proceed with an independent review.

E. Confidential Disclosure Program.

Within 90 days after the effective date of this CIA, GMED shall establish a Confidential Disclosure Program, which must include a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with GMED'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. GMED shall 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, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, GMED shall conduct an internal review of the allegations set forth in such a disclosure and ensure that proper follow-up is conducted.

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

F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, 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.* GMED shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, GMED shall screen all prospective employees and prospective contractors prior to engaging their services by: (a) requiring applicants to disclose whether they are Ineligible Persons; and (b) 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 90 days of the effective date of this CIA, GMED shall review its list of current employees and contractors against the Exclusion Lists. Thereafter, GMED shall review the list semi-annually. In addition,

GMED shall require employees and contractors to disclose immediately any debarment, exclusion or other event that makes the employee an Ineligible Person.

If GMED has notice that an employee or contractor has become an Ineligible Person, GMED shall remove such person from responsibility for, or involvement with, GMED'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 GMED has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during his or her employment or contract, the GMED 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, GMED 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 GMED 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. GMED 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 CIA, an "overpayment" shall mean the amount of money GMED has received in excess of the amount due and payable under any Federal health care program requirements. GMED may not subtract any

underpayments for purposes of determining the amount of relevant "overpayments."

b. Reporting of Overpayments. If, at any time, GMED identifies or learns of any overpayments, GMED shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovery and and repay any identified overpayments within 30 days of discovery (or such additional time as may be agreed to by the payor) 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 contractor should be done in accordance with the contractor policies, and for Medicare contractors, must include the information contained on the Overpayment Refund Form, provided as Attachment ___ to this CIA.

2. *Material Deficiencies.*

a. Definition of Material Deficiency. For purposes of this CIA, 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 GMED determines that there is a Material Deficiency, GMED 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 GMED's actions taken to correct the Material Deficiency; and

(iv) any further steps GMED 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 CIA, GMED 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, GMED 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 CIA (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

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

1. the name, address, phone number and position description of the 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 GMED's Code of Conduct required by section III.B.1;

4. the summary of the Policies and Procedures required by section III.B.2;

5. 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;

6. a certification by the Compliance Officer that:

   a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all appropriate Covered Persons;

   b. all Covered Persons have completed the Code of Conduct 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.

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

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

9. a summary of personnel actions taken pursuant to section III.F;

10. a list of all of GMED'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; and

11. To the extent not already furnished to OIG, or if modified, a description of GMED's corporate structure, including identification of any parent and sister companies, subsidiaries and their respective lines of business.

B. Annual Reports. GMED shall submit to OIG Annual Reports with respect to the status of and findings regarding of GMED's compliance activities for each of the 6 one-year periods beginning on the effective date of the CIA (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 Compliance Officer and/or members of the Compliance Committee described in section III.A;

2. a certification by the Compliance Officer that:

a. all Covered Persons have completed the annual Code of Conduct certification 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. GMED has complied with its obligations under the Settlement Agreement: (i) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; 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 to identify and adjust any past charges or claims for unallowable costs;

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

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

4. a description of 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. GMED's response and corrective action plan(s) related to any issues raised in the IRO's report for the prior year;

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 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 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 GMED 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; and

12. a description of all changes to the most recently provided list (as updated) of GMED's locations (including locations and mailing addresses) as required by section V.A.10, the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Federal health care program provider identification number(s), and the contractor name and address that issued each provider identification number.

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 Compliance Officer that: (1) except as otherwise described in the applicable report, GMED is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

D. Designation of Information: GMED 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. GMED 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 CIA, all notifications and reports required under this CIA 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

GMED:

Ms. Vicki Dwyer
Compliance Officer
Galichia Medical Group, P.A.
551 North Hillside, Suite 400
Wichita, KS 67214
Phone 316.689.4165
Fax 316.689.4161

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

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 GMED's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of GMED's locations for the purpose of verifying and evaluating: (a)

GMED's compliance with the terms of this CIA; and (b) GMED's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by GMED 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 GMED'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. GMED agrees to assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. GMED's employees may elect to be interviewed with or without a representative of GMED present.

VIII. DOCUMENT AND RECORD RETENTION

GMED shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for 7 years (or 6 years in the event that the term of the CIA is 5 years as provided under section III) (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 GMED prior to any release by OIG of information submitted by GMED pursuant to its obligations under this CIA and identified upon submission by GMED as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, GMED shall have the rights set forth at 45 C.F.R. § 5.65(d). GMED 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

GMED is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, GMED and OIG hereby agree that failure to comply with certain obligations set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of $2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day GMED fails to have in place any of the following:

a. a Compliance Officer as described by section III.A.1;

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

c. a written Code of Conduct as described by section III.B.1;

d. written Policies and Procedures as described by section III.B.2;

e. a requirement that Covered Persons be trained as described in section III.C; and

f. 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 GMED 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 GMED 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 GMED employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, GMED'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 GMED 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 GMED fails to grant access to the information or documentation as required in section VII of this CIA. (This Stipulated Penalty shall begin to accrue on the date GMED fails to grant access.)

6. A Stipulated Penalty of $1,000 for each day GMED fails to comply fully and adequately with any obligation of this CIA not already covered in paragraphs 1-5. In its notice to GMED, OIG shall state the specific grounds for its determination that GMED has failed to comply fully and adequately with the CIA obligation(s) at issue and steps the GMED must take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after the date that OIG provides notice to GMED of the failure to comply.)

B. Timely Written Requests for Extensions. GMED may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after GMED 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 GMED 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 GMED 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 GMED of: (a) GMED'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, GMED 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 GMED elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until GMED cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by 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 GMED has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in section X.D, below.

D. Exclusion for Material Breach of this CIA

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

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

b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A;

c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.C; or

d. a failure to retain and use an Independent Review Organization in accordance with section III.D.

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

3. *Opportunity to Cure.* GMED shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

a. GMED is in full compliance with this CIA;

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

4. *Exclusion Letter.* If at the conclusion of the 30-day period, GMED fails to satisfy the requirements of section X.D.3, OIG may exclude GMED from participation in the Federal health care programs. OIG will notify GMED in writing of its determination to exclude GMED (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in section X.E, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. If at the end of the period of exclusion, GMED wishes to apply for reinstatement, GMED must submit a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution

1. *Review Rights.* Upon OIG's delivery to GMED of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, GMED shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an 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 Penalties shall be made within 10 days of the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days of receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only

issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether GMED was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. GMED 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 CIA and orders GMED to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless GMED requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

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

a. whether GMED was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

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

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

(ii) GMED has pursued and is pursuing such action with due diligence; and

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

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for the GMED, only after a DAB decision in favor of OIG. GMED's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude GMED upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such

a decision, notwithstanding that GMED may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision.

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

XI. EFFECTIVE AND BINDING AGREEMENT

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

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

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

C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and

D. The undersigned GMED signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA.

ON BEHALF OF GALICHIA MEDICAL GROUP, P.A.

Jospeh P. Galichia, M.D. personally and on behalf of Galichia Medical Group, P.A.	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

5/3/02
DATE

ON BEHALF OF GALICHIA MEDICAL GROUP, P.A.

Jospeh P. Galichia, M.D. personally and
on behalf of Galichia Medical Group, P.A.

5-5-00

DATE

AMENDMENT TO THE CORPORATE INTEGRITY AGREEMENT BETWEEN THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND GALICHIA MEDICAL GROUP, P.A.

The Office of Inspector General ("OIG") of the Department of Health and Human Services and Galichia Medical Group, P.A. ("GMED) entered into a Corporate Integrity Agreement ("CIA") on May 19, 2000.

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

Section III.D., Review Procedures of the CIA is hereby superceded by the attached new section III.D., Review Procedures and Appendix A.

The attached Appendix A is hereby added to GMED's CIA.

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

C. The undersigned GMED signatory represent and warrant that he is 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.

D. Review Procedures.

1. *General Description.*

a. Retention of Independent Review Organization. Within 90 days of the effective date of this CIA, GMED 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 GMED in assessing and evaluating its billing and coding practices and systems, and its compliance obligations pursuant to this CIA and the Settlement Agreement. Each IRO retained by GMED shall have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which GMED seeks reimbursement. Each IRO shall assess, along with GMED, 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 GMED's billing and coding to the Federal health care programs ("Claims Review") and shall analyze GMED's compliance with the obligations assumed under this CIA 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 CIA beginning with the effective date of this CIA. The IRO(s) shall perform all components of each annual Claims Review.

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 CIA.

d. Retention of Records. The IRO and GMED 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 GMED related to the reviews).

2. *Claims Review.*

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

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

i. Results of Discovery Sample. If the Error Rate (as defined in Appendix A) 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, GMED should, as appropriate, further analyze any errors identified in the Discovery Sample. GMED recognizes that the OIG or other HHS component, in its discretion and as authorized by statute, regulation, or other appropriate authority may also analyze or review Paid Claims included, or errors identified, in the Discovery Sample.)

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

b. Full Sample. If necessary, as determined by procedures set forth in Section III.D.2.a, the IRO shall perform an additional sample of Paid Claims using commonly accepted sampling methods and in accordance with Appendix A. The Full Sample should be designed to (1) estimate the actual Overpayment in the population with a 90% confidence level and with a maximum relative precision of 25% of the point estimate and (2) conform with the Centers for Medicare and Medicaid Services' statistical sampling for overpayment estimation guidelines. The Paid Claims shall be reviewed based on supporting documentation available at GMED or under GMED'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, GMED 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 GMED 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 GMED's Discovery Sample identifies an Error Rate of 5% or greater, GMED's IRO shall also conduct a Systems Review. Specifically, for each claim in the Discovery Sample and Full Sample that resulted in an Overpayment, the IRO should perform a "walk through" of the system(s) and process(es), that generated the claim to identify any problems or weaknesses that may have resulted in the identified Overpayments. The IRO shall provide to GMED 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 CIA, GMED 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. GMED agrees to make available to the OIG any and all documentation that reflects the refund of the Overpayment(s) to the payor and the associated documentation.

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

4. *Compliance Review.* The IRO shall conduct a review of GMED's compliance activities. The Compliance Review shall consist of a review of GMED's compliance with the obligations set forth in each section of this CIA.

5. *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 ~~JCMC~~'s GMED's compliance with the terms of each section of the CIA, as applicable.

6. *Validation Review.* In the event the OIG has reason to believe that: (a) GMED's Claims Review or Compliance Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Claims Review results are inaccurate, the OIG may, at its sole discretion, conduct its own review to determine whether the Claims Review or Compliance Review complied with the requirements of the CIA and/or the findings or Claims Review results are inaccurate ("Validation Review"). GMED 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 GMED's final submission (as described in section II) is received by the OIG.

Prior to initiating a Validation Review, the OIG shall notify GMED 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, GMED 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. GMED 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 GMED prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of the OIG.

7. *Independence Certification.* The IRO shall include in its report(s) to GMED 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 GMED 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 GMED and for which GMED has received reimbursement from the Medicare program and all other Federal health care programs.

d. Population: All Items for which GMED has submitted a code or line item and for which GMED has received reimbursement from the Medicare program and all other Federal health care programs (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 GMED cannot produce documentation sufficient to support the Paid Claim shall be considered an error and the total reimbursement received by GMED 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. For purposes of this Claims Review, the term "Item" may refer to any discrete unit that can be sampled (e.g., claim, line item, beneficiary, patient encounter, etc.).

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 GMED's billing and coding system(s), including the identification, by position description, of the personnel involved in coding and billing;

b. whether GMED's billing for E&M services are in compliance with Federal health care program requirements, and whether GMED is billing for items and services in compliance with medical necessity requirements as defined by national coverage determinations, Centers for Medicare and Medicaid Services program manuals, and local medical review policies. This review shall be performed by clinical personnel with cardiology expertise. In making such determinations, the IRO shall apply the treating physician rule;

c. whether GMED has complied with its obligation under the Settlement Agreements: (a) not to resubmit any previously denied claims related to the q1conduct addressed in the Settlement Agreements, and its obligation not to appeal any such denials of claims, and (b) not to charge to or otherwise seek payment for unallowable costs (as defined in the Settlement Agreements) and its obligation to identify and adjust any past charges of unallowable costs;

d. the IRO's findings, supporting rationale, and a summary of such findings and 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; and

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.

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 GMED ("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 GMED.

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.

Attachment 1

Claim Review Results

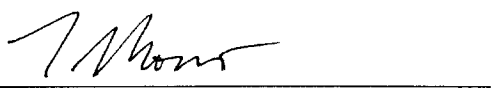
Federal Health Care Program Billed	Bene HIC #	Date of Service	Procedure Code Submitted	Procedure Code Reimbursed	Allowed Amount Reimbursed	Correct Procedure Code (IRO determined)	Correct Allowed Amt Reimbursed (IRO determined)	Dollar Difference between Amt Reimbursed and Correct Allowed Amt

ON BEHALF OF GALICHIA MEDICAL GROUP, P.A.

Joseph P. Galichia, M.D. personnally and
on behalf of Galichia Medical Group, P.A.

5-23-02
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

6/5/02
DATE