CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
MIM Corporation

I. PREAMBLE

MIM Corporation ("MIM") 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 ensure compliance with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (hereinafter collectively referred to as the "Federal health care programs"), by MIM, its subsidiaries, and their employees and agents, including independent contractors, who provide a health care item or service paid for directly or indirectly by a Federal health care program (hereinafter, "Covered Persons"). Pharmacy networks for whom MIM provides pharmacy benefit management services are not Covered Persons. MIM's compliance with the terms and conditions in this CIA shall constitute an element of MIM's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, MIM is entering into a Settlement

Agreement with the United States, and this CIA is incorporated by reference into the Settlement Agreement.

On November 5, 1999, MIM provided to the OIG a copy of MIM's compliance manual entitled MIM Corporation, LEGAL AND ETHICAL POLICIES, COMPLIANCE MANUAL, October 1999 ("the MIM Compliance Manual"). The MIM Corporate Integrity Program described herein is intended to supplement MIM's compliance efforts and policies described in the MIM Compliance Manual. MIM's Compliance Manual makes clear that if there should be an inconsistency between the Compliance Manual and this CIA, the CIA shall control. If MIM becomes aware of any remaining inconsistencies, MIM shall amend the MIM Compliance Manual to conform to the CIA.

II. TERM OF THE CIA

The period of the compliance obligations assumed by MIM under this CIA shall be five (5) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the date on which the final signatory of this CIA executes this CIA (the "effective date").

III. CORPORATE INTEGRITY OBLIGATIONS

MIM shall establish a compliance program that includes the following elements.

A. <u>Compliance Officer</u>. The MIM Compliance Manual identifies MIM's Compliance Officer (see, MIM Compliance Manual, section 1). For at least the duration of this CIA, MIM shall continue to employ an individual to serve as Compliance Officer,

who 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 the requirements of the Federal health care programs. For at least the duration of this CIA, the Compliance Officer shall continue to be a member of senior management of MIM, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of MIM and shall be authorized to report to the Board of Directors at any time at his or her sole discretion. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by MIM to further its compliance objectives, as well as any reporting obligations created under this CIA. In the event a new Compliance Officer is appointed during the term of this CIA, MIM shall notify the OIG, in writing, within fifteen (15) days of that person assuming the position.

B. Written Standards. The MIM Compliance Manual establishes Policies and Procedures including a Code of Conduct (see, MIM Compliance Manual, section 1). The MIM Compliance Manual also contains Statements of Corporate Policy that establish Policies and Procedures in several areas, including the following: (1) Compliance with Legal and Ethical Policies; (2) Reporting and Investigating Suspected Violations of Legal and Ethical Policies; (3) Remedies and Sanctions for Violations of Legal and Ethical Policies; (4) Compliance with Laws Regulating Pharmacy Benefit Managers; (5) Conflicts of Interest; (6) Sanctioned Individuals; (7) Contact with the Press and

Government Agencies (*see*, MIM Compliance Manual, sections 2, 3, 4, 5, 10, 15 and 20, respectively). The Policies and Procedures specifically address the need to avoid conflicts of interest and the payment or receipt of unlawful remuneration when soliciting or referring business related to Federal health care programs. In addition, the Policies and Procedures include disciplinary guidelines and methods for employees to make disclosures or otherwise report on compliance issues to MIM management through the Confidential Disclosure Program required by section III.E, below.

For at least the duration of this CIA, MIM shall maintain the written Policies and Procedures regarding the operation of MIM's compliance program and its compliance with all Federal and State health care statutes, regulations and guidelines, including the requirements of the Federal health care programs. The Policies and Procedures shall, at a minimum, set forth:

a. MIM's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures or instructions otherwise communicated to MIM by the Health Care Financing Administration ("HCFA") (or other appropriate regulatory agencies) and the State of Tennessee and/or their respective agents;

- b. MIM's requirement that all Covered Persons, when employed by or doing business with MIM, shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with MIM's own Policies and Procedures (including the requirements of this CIA);
- c. the requirement that all Covered Persons, when employed by or doing business with MIM, shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or of MIM's own Policies and Procedures;
- d. the possible consequences to both MIM and to any subsidiary or Covered Person when employed by or doing business with MIM of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with MIM's own Policies and Procedures or of failure to report such non-compliance; and
- e. the right of all Covered Persons to use the confidential disclosure program, as well as MIM's commitment to confidentiality and non-retaliation with respect to disclosures.

Within one hundred and twenty (120) days of the effective date of the CIA, each Covered Person shall certify, in writing, that he or she has received, read, understands, and will abide by the Policies and Procedures set forth in MIM's Compliance Manual. New Covered Persons shall receive the Compliance Manual and shall complete the required certification within thirty (30) days after the commencement of their employment or independent contract or within one hundred and twenty (120) days of the effective date of the CIA, whichever is later. In addition, MIM shall make the promotion of, and adherence to, the Policies and Procedures an element in evaluating the performance of managers, supervisors, and all other Covered Persons. MIM shall make compliance staff and/or supervisors available to explain any and all Policies and Procedures to any inquiring Covered Persons.

MIM will annually review the Policies and Procedures and will make any necessary revisions. These revisions shall be distributed within thirty (30) days of the effective date of any such change. Covered Persons shall certify on an annual basis that they have received, read, understand and will abide by the Policies and Procedures set forth in the Compliance Manual. A summary of the Policies and Procedures will be provided to OIG in the Implementation Report. The Policies and Procedures will be available to OIG upon request.

C. Training and Education.1

- 1. General Training. Within one hundred and twenty (120) days of the effective date of this CIA, MIM shall provide at least one (1) hour of "General Training," as described below, to each Covered Person. This General Training shall explain:
 - a. MIM's Corporate Integrity Agreement requirements;
 - b. MIM's Compliance Program (including the Policies and
 Procedures as they pertain to general compliance issues);
 - c. fraud and abuse risk areas that pertain to pharmacy benefit managers, particularly those that contract with managed care organizations.

General Training materials shall be made available to the OIG, upon request.

New Covered Persons shall receive the General Training described above within thirty (30) days of the beginning of their employment or within one hundred and twenty (120) days after the effective date of this CIA, whichever is later. Each Covered Person shall receive retraining in General Training on an annual basis.

2. Specific Training. Within one hundred and twenty (120) days of the effective date of this CIA, each Covered Person who is involved directly or indirectly in

¹ The training and education requirements of this CIA do not apply to agents and independent contractors in the case of short-term workers who are not reasonably expected to work more than one month, except to the extent that such individual actually works in excess of one month during a 12-month period.

one or more of the following activities shall receive training as described in Attachment A hereto (MIM Breakdown of Specific Training), in addition to the general training required above to address the fraud and abuse risk areas that he or she should consider when carrying out one or more of the following activities:

- a. processing claims and pharmacy auditing;
- b. negotiating with pharmaceutical manufacturers, distributors or retailers;
- c. handling physician and consumer problems with the formulary and/or the drug benefit in question;
- d. managing compliance with the applicable drug formulary

 (including, but not limited to, processing medically necessary

 exception requests);
- e. providing disease management services; or
- f. collecting utilization data for a managed care organization or other applicable payor(s);
- g. sales and marketing;
- h. supervision of claims processing personnel; or
- i. supervision of non-claims processing personnel.

At a minimum, this Specific Training shall include a discussion of the following:

- a. the applicable reimbursement rules and principles of the
 Federal health care program(s) in question;
- b. the legal sanctions for improper billings to Federal health care programs;
- c. the prohibition against improper claims processing for Federal health care programs, including but not limited to the failure to process claims or inexcusable delay in processing claims;
- d. the prohibitions against paying or receiving remuneration to induce referrals as they relate to Federal health care programs;
- e. the issues of medical necessity and overutilization in the feefor-service context and underutilization in the managed care context;
- f. special issues related to pharmacy benefit management companies in Federal health care programs and their relationships with managed care organizations, pharmaceutical manufacturers, pharmacists, physicians and beneficiaries; and
- g. the legal sanctions for making false statements in connection with Federal health care programs.

Specific Training materials shall be made available to OIG, upon request. Persons providing the Specific Training must be knowledgeable about the subject areas. New Covered Persons shall receive the Specific Training described above within thirty (30) days of the beginning of their employment or within one hundred and twenty (120) days after the effective date of this CIA, whichever is later. Each year, every Covered Person subject to these Specific Training requirements shall receive annual retraining in the subject areas described above for a period of time that is at least half of the Specific Training requirement for applicable new Covered Persons, but in no event will the Specific Training retraining be less than one hour.

- 3. Certification. Each Covered Person shall certify, in writing, that he or she has attended the required training. The certification shall specify the type of training received and the date received. The Compliance Officer shall retain the certifications, along with specific course materials. These shall be made available to OIG upon request.
- D. Review Procedures. MIM shall retain one or more entity(ies), such as accounting, auditing, law (as appropriate), or consulting firm(s) (hereinafter "Independent Review Organization(s)"), to perform review procedures to assist MIM in assessing the adequacy of its drug benefit management and compliance practices pursuant to this CIA. This shall be an annual requirement and shall cover a twelve (12) month period. The Independent Review Organization must have expertise in the claims processing, formulary management, reporting and other requirements of the Federal health care

programs from which MIM seeks reimbursement either directly or indirectly. The Independent Review Organization must be retained to conduct the audit of the first year within one hundred and twenty (120) days of the effective date of this CIA.

The Independent Review Organization will conduct two separate engagements.

One will be an analysis of MIM's claims processing, formulary management, reporting and other requirements of the Federal health care programs to assist MIM and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("drug-benefit management engagement"). The second engagement will determine whether MIM is in compliance with this CIA ("compliance engagement").

1. Drug-Benefit Management Engagement. The drug-benefit management engagement shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims for Federal health care programs processed by MIM for the relevant period. The sample size shall be determined through the use of a probe sample. At a minimum, the full sample must be within a ninety (90) percent confidence level and a precision of twenty-five (25) percent. The probe sample must contain at least thirty (30) sample units and cannot be used as part of the full sample. Both the probe sample and the sample must be selected through random numbers. MIM shall use OIG's Office of Audit Services Statistical Sampling Software, also known as "RAT-STATS," which is available through the Internet at "www.hhs.gov/progorg/oas/ratstat.html".

Each annual drug-benefit management engagement analysis shall include the following components in its methodology:

- a. Drug-Benefit Management Engagement Objective: A statement stating clearly the objective intended to be achieved by the drug-benefit management engagement and the procedure or combination of procedures that will be applied to achieve the objective.
- b. Drug-Benefit Management Engagement Population: Identify
 the population, which is the group about which information is
 needed. Explain the methodology used to develop the
 population and provide the basis for this determination.
- c. Sources of Data: Provide a full description of the source of the information upon which the drug benefit management engagement conclusions will be based, including the legal or other standards applied, documents relied upon, payment data, and/or any contractual obligations.
- d. Sampling Unit: Define the sampling unit, which is any of the designated elements that comprise the population of interest.

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

The drug-benefit management engagement shall provide:

- a. findings regarding the accuracy and integrity of MIM's drugbenefit management system (including, but not limited to, its strengths and weaknesses, internal controls, and effectiveness);
- b. findings regarding whether MIM is properly processing claims reimbursed by Federal health care programs (i.e., properly reimbursing providers for goods and services provided to Federal health care program beneficiaries).
- c. findings regarding MIM's procedures to correct inaccurate or untimely claims processing;
- d. findings regarding any problems revealed by the audit regarding MIM's contractual dealings with manufacturers, distributors and retailers; and
- e. findings regarding the steps MIM is taking to bring its operations into compliance or to correct problems identified by the audit.

2. Compliance Engagement. An Independent Review Organization shall also conduct a compliance engagement that shall provide findings regarding whether MIM's program, 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.

A complete copy of the Independent Review Organization(s)'s drug-benefit management engagement and compliance engagement shall be included in each of MIM's Annual Reports to OIG.

- 3. Disclosure of Overpayments and Reportable Events. If, as a result of these engagements, MIM or the Independent Review Organization(s) identifies any claims processing, formulary management or other policies, procedures and/or practices that result in an overpayment from or Reportable Event (defined in section III.H) related to any Federal health care program or its agents, MIM shall follow the Reporting procedures set forth below at section III.H.
- 4. Verification/Validation. In the event that the OIG determines that it is necessary to conduct an independent review to determine whether or the extent to which MIM is complying with its obligations under this CIA, upon receipt of notice and explanation from the OIG of the need for such independent review, MIM agrees to pay for the reasonable cost of any such review by the OIG or any of its designated agents.

E. Confidential Disclosure Program. Within one-hundred and twenty (120) days after the effective date of this CIA, MIM shall implement (to the extent it has not already done so) the Confidential Disclosure Program described at Chapters 3 and 4 of its Compliance Manual, which program must include measures (e.g., a toll-free compliance telephone line) to enable Covered Persons or other individuals to disclose to the Compliance Officer or some other person who is not in the reporting individual's chain of command, any identified issues or questions associated with MIM's policies, practices or procedures with respect to the Federal health care program, believed by the individual to be inappropriate. As provided in MIM's Compliance Manual, all Covered Persons working for MIM are required to report suspected legal or compliance violations. In addition to describing the hotline in the MIM Compliance Manual, MIM shall publicize the existence of the hotline (e.g., in e-mails to employees and by posting the hotline number 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 communication. Upon receipt of a complaint, the Compliance Officer (or designee) shall gather the information in such a way as to elicit all relevant information from the individual reporting the alleged misconduct. 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, MIM 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 shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

F. Ineligible Persons.

- 1. Definition. For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.
- 2. Screening Requirements. MIM shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, MIM shall screen all prospective Covered Persons prior to engaging their services by (i) requiring applicants to disclose whether they are Ineligible Persons, and (ii) reviewing the General Services Administration's List of Parties Excluded from Federal Programs

(available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG

Cumulative Sanction Report (available through the Internet at

http://www.dhhs.gov/progorg/oig) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

- 3. Review and Removal Requirement. Within ninety (90) days of the effective date of this CIA, MIM will review its list of current Covered Persons against the Exclusion Lists. Thereafter, MIM will review the list semi-annually. If MIM has notice that a Covered Person has become an Ineligible Person, MIM will remove such person from responsibility for, or involvement with, MIM'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 MIM has notice that a Covered Person is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with MIM, within 10 days of receiving such notice MIM will remove such individual from responsibility for, or involvement with, MIM's business operations

related to the Federal health care programs until such criminal action, suspension, or proposed exclusion is resolved.

G. Notification of Proceedings. Within thirty (30) days of discovery, MIM shall notify OIG, in writing, of any ongoing investigation or legal proceeding of which it is aware conducted or brought by a governmental entity or its agents involving an allegation that MIM has committed a crime or has engaged in fraudulent activities or any other knowing misconduct. 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. MIM shall also provide written notice to OIG within thirty (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. Reporting of Overpayments. If, at any time, MIM identifies or learns of any billing, coding or other policies, procedures and/or practices that result in an overpayment, MIM shall notify the payor (e.g., TennCare managed care organization or Medicaid agency or Medicare fiscal intermediary or carrier, as applicable) using any prescribed form of such payor, within 30 days of discovering that an overpayment has been made, and take remedial steps within a time frame agreed to with the payor to correct the problem, including preventing the underlying problem and the overpayments

from recurring. Where the payor has no prescribed form, the notice to the payor shall include:

- a. a statement that the refund is being made pursuant to this CIA;
- b. a description of the complete circumstances surrounding the overpayment;
- c. the methodology by which the overpayment was determined;
- d. the amount of the overpayment;
- e. any claim-specific information used to determine the overpayment (e.g., beneficiary health insurance number, claim number, service date, and payment date);
- f. the provider identification number under which the repayment is being made.

Where it is not feasible for MIM to include all such information in the notice within the time frame specified, MIM shall specify in the notice the time frame in which it can reasonably furnish this information to the payor.

2. Reporting of Reportable Events. If MIM determines that a Reportable Event has occurred, MIM shall notify the OIG within 30 days of such determination. If the Reportable Event results in an overpayment, MIM shall notify the OIG at the same time as the notice to the payor and shall include all of the information required by section III.H.1 plus: (i) the payor's name, address, and contact person where the overpayment

was sent; and (ii) the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid. Regardless of whether the Reportable Event resulted in an overpayment, MIM shall report to the OIG the following:

- a. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and program authorities;
- b. MIM's actions to correct the Reportable Event; and
- c. any further steps MIM plans to take to address such Reportable Event and prevent it from recurring.
- 3. Definition of "Overpayment." For purposes of this CIA, an "overpayment" shall mean the amount of money MIM has received in excess of the amount due and payable pursuant to Federal health care programs' statutes, regulations or program directives applicable to MIM, including carrier, intermediary, Medicaid agency and TennCare managed care organization instructions.
- 4. Definition of "Reportable Event." For purposes of this CIA, a "Reportable Event" 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 are authorized.

IV. **NEW LOCATIONS**

In the event that MIM purchases or establishes new business units after the effective date of this CIA, MIM shall notify OIG of this fact within thirty (30) days of the date of purchase or establishment. This notification shall include the location of the new operation(s), phone number, fax number, Federal health care program provider number(s) (if any), and the corresponding payor(s) (contractor specific) that has issued each provider number. All Covered Persons at such locations shall be subject to the requirements in this CIA that apply to new Covered Persons (e.g., completing certifications and undergoing training).

V. IMPLEMENTATION AND ANNUAL REPORTS

A. <u>Implementation Report</u>. Within one hundred and fifty (150) days after the effective date of this CIA, MIM shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

- any changes to the identity and position of the Compliance Officer
 required by section III.A, from the description currently set forth at Section
 of the MIM Compliance Manual;
- 2. any further revisions made to MIM's Policies and Procedures set forth in the MIM Compliance Manual in order to bring them into compliance with this CIA;

- 3. a description of the training programs required by section III.C, including a description of the targeted audiences and a schedule of when the training sessions were held;
- 4. 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 pertinent Covered Persons;
 - b. all Covered Persons have completed the Compliance Manual certification required by section III.B; and
 - c. all Covered Persons have completed the training and executed the certification required by section III.C.
- 5. a description of the confidential disclosure program required by section III.E;
- 6. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first audit;
- 7. a summary of personnel actions taken pursuant to section III.F; and
- 8. a summary of any reporting undertaken pursuant to sections III.D.3. and/or III.H since the effective date of this CIA.
- B. Annual Reports. MIM shall submit to OIG an Annual Report with respect to the status and findings of MIM's compliance activities.

The Annual Reports shall include:

- any change in the identity or position description of the Compliance
 Officer described in section III.A;
- 2. a certification by the Compliance Officer that:
 - a. all Covered Persons have completed the annual Compliance

 Manual certification required by section III.B; and
 - b. all Covered Persons have completed the training and executed the certification required by section III.C.
- 3. notification of any changes or amendments to the Policies and Procedures required by section III.B and the reasons for such changes;
- 4. a complete copy of the report prepared pursuant to the Independent Review Organization(s)'s drug-benefit management and compliance engagement, including a copy of the methodology used;
- 5. MIM's response/corrective action plan to any issues raised by the Independent Review Organization;
- 6. a summary of the Reportable Events and misconduct reported throughout the course of the previous twelve (12) months pursuant to III.D.3 and III.H.
- 7. a report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect

result of implementing this CIA. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately), and other Federal health care programs;

- 8. a copy of the confidential disclosure log required by section III.E;
- 9. a description of any personnel action (other than hiring) taken by MIM as a result of the obligations in section III.F;
- 10. a summary describing any ongoing investigation or legal proceeding known to MIM conducted or brought by a governmental entity involving an allegation that MIM has committed a crime or has engaged in fraudulent activities, which should 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, legal proceeding or requests for information;
- 11. a corrective action plan to address the probable violations of law identified in section III.H; and
- 12. a listing of all of MIM'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 Federal health care program provider identification number(s)

and the payor (specific contractor or State agency) that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and ninety (90) days after the effective date of this CIA. Subsequent Annual Reports shall be submitted no later than sixty (60) days after the anniversary date of the effective date of this CIA.

C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer under penalty of perjury, that: (1) MIM 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, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing subsequent to the effective date of this CIA, all notifications and reports required under this CIA shall be submitted to the entities listed below:

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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

MIM:

Barry A. Posner, Esq. Vice President & General Counsel MIM Corporation 100 Clearbrook Road Elmsford, NY 10523

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 MIM's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) MIM's compliance with the terms of this CIA; and (b) MIM's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by MIM 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 MIM's Covered Persons 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. MIM agrees to assist OIG in contacting and arranging interviews with such Covered Persons upon OIG's request. MIM's employees may elect to be interviewed with or without a representative of MIM present.

VIII. DOCUMENT AND RECORD RETENTION

MIM shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs or to compliance with this CIA, one year longer than the term of this CIA (or longer if otherwise required by law).

IX. DISCLOSURES

Subject to HHS's Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify MIM prior to any release by OIG of information submitted by MIM pursuant to its obligations under this CIA and identified upon submission by MIM as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. MIM shall refrain from identifying any information as trade secrets, commercial or financial information and privileged and confidential that does not meet the criteria for exemption from disclosure under FOIA.

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X. Breach and Default Provisions

MIM is expected to fully and timely comply with all of the obligations herein throughout the term of this CIA or other time frames herein agreed to.

A. <u>Stipulated Penalties for Failure to Comply with Certain Obligations</u>. As a contractual remedy, MIM 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, beginning one-hundred and twenty (120) days after the effective date of this CIA and concluding at the end of the term of this CIA, MIM fails to have in place any of the following:
 - a. a Compliance Officer;
 - b. written Policies and Procedures;
 - c. a training program; and
 - d. a Confidential Disclosure Program.
- 2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day MIM fails to meet any of the deadlines to submit the Implementation Report or the Annual Reports to the OIG.

- 3. A Stipulated Penalty of \$2,000 (which shall begin to accrue on the date the failure to comply began) for each day MIM:
- a. hires or enters into a contract with an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)) (this Stipulated Penalty shall not be demanded for any time period during which MIM 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.2) as to the status of the person);
- b. employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, MIM'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 (this Stipulated Penalty shall not be demanded for any time period during which MIM 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.3) as to the status of the person); or
- c. employs or contracts with a person who: (i) has been charged with a criminal offense related to any Federal health care program, or (ii) is suspended or

proposed for exclusion, and that person has responsibility for, or involvement with, MIM's business operations related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period before 10 days after MIM received notice of the relevant matter or after the resolution of the matter as described in section III.F.4).

- 4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date MIM fails to grant access) for each day MIM fails to grant access to the information or documentation as required in section VII of this CIA.
- 5. A Stipulated Penalty of \$1,000 (which shall begin to accrue ten (10) days after the date that OIG provides notice to MIM of the failure to comply) for each day MIM fails to comply fully with any obligation of this CIA. With respect to the Stipulated Penalty provision described in this section X.A.5 only, the OIG shall not seek a Stipulated Penalty if MIM demonstrates to the OIG's satisfaction that the alleged failure to comply could not be cured within the 10-day period, but that: (i) MIM has begun to take action to cure the failure to comply, (ii) MIM is pursuing such action with due diligence, and (iii) MIM has provided to the OIG a reasonable timetable for curing the failure to comply.

B. Payment of Stipulated Penalties.

1. Demand Letter. Upon a finding that MIM has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify MIM by personal service or certified mail of (a) the specific

grounds for its determination that MIM has failed to comply fully with the CIA; 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").

Within ten (10) days of MIM's receipt of the Demand Letter, MIM shall either (a) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section X.D. In the event MIM elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until MIM cures, to the 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.C.

2. Timely Written Requests for Extensions. MIM may 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 MIM fails to meet the revised deadline as agreed to by the OIG-approved extension. 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 (2) business days after MIM receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) 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.

- 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 otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for the OIG's determination that MIM has materially breached this CIA, which decision shall be made at the OIG's discretion and governed by the provisions in section X.C, below.

C. Exclusion for Material Breach of this CIA

1. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this CIA by MIM constitutes an independent basis for MIM's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that MIM has materially breached this CIA and that exclusion should be imposed, the OIG shall notify MIM by certified mail of (a) MIM'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").

- 2. Opportunity to cure. MIM shall have thirty-five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:
 - a. MIM 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 35-day period, but that: (i) MIM has begun to take action to cure the material breach, (ii) MIM is pursuing such action with due diligence, and (iii) MIM has provided to OIG a reasonable timetable for curing the material breach.
- 3. Exclusion Letter. If at the conclusion of the thirty five (35) day period, MIM fails to satisfy the requirements of section X.C.2, OIG may exclude MIM from participation in the Federal health care programs. OIG will notify MIM in writing of its determination to exclude MIM (this letter shall be referred to hereinafter as the "Exclusion Letter"). The Exclusion Letter shall state the specific grounds for the OIG's determination to exclude MIM. Subject to the Dispute Resolution provisions in section X.D, below, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other

federal procurement and non-procurement programs. If MIM is excluded under the provisions of this CIA, MIM may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

- 4. Material Breach. A material breach of this CIA means:
 - a. a failure by MIM to report a Reportable Event known to MIM, take corrective action and pay the appropriate refunds, as provided in section III.D;
 - b. repeated or flagrant violations of the obligations under this CIA, including, but not limited to, the obligations addressed in section X.A of this CIA;
 - c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with section X.B above; or
 - d. a failure to retain and use an Independent Review Organization for review purposes in accordance with section III.D.

D. Dispute Resolution

1. Review Rights. Upon the OIG's delivery to MIM of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this CIA, MIM 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, the 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 fifteen (15) days of the date of the Demand Letter and the request for a hearing involving exclusion shall be made within thirty (30) days of the date 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 MIM was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; (b) the period of noncompliance; and (c) with respect to a Stipulated Penalty authorized under section X.A.5 only, whether the failure to comply could not be cured within the 10-day period, but that by the end of that period (i) MIM had begun to take action to cure the failure to comply, (ii) MIM was and is pursuing such action with due diligence, and (iii) MIM had provided to the OIG a reasonable timetable for curing the material breach. MIM shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds for the OIG with regard to a finding of a breach of this CIA and orders MIM to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that MIM may request review of the ALJ decision by the DAB. If MIM MIM Corporate Integrity Agreement March 2000

requests review of the ALJ decision by the DAB, then MIM shall deposit the Stipulated Penalties amount into an interest-bearing escrow account pending the DAB's decision. If the DAB affirms the ALJ decision, the proceeds of the escrow account shall be immediately due and payable to the OIG. If the DAB overturns the ALJ decision, the escrow account shall be dissolved and the proceeds returned to MIM.

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 MIM was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach could not have been cured within the 35 day period, but that (i) MIM had begun to take action to cure the material breach within the 35 day period, (ii) MIM has pursued and is pursuing such action with due diligence, and (iii) MIM provided to OIG within the 15 day period a reasonable timetable for curing the material breach. For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. MIM's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude MIM upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that MIM 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 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 and MIM agrees to waive any right it may have to appeal the decision administratively, judicially or otherwise seek review by any court or other adjudicative forum.

XI. PRIVILEGE

Nothing in this CIA, or any communication or report made pursuant to this CIA, shall constitute or be construed as any waiver by MIM of MIM's attorney-client, work product or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect MIM's obligation to comply with the provisions of this CIA.

XII. 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, MIM and OIG agree as follows:

- A. This CIA shall be binding on the successors, assigns and transferees of MIM;
- B. This CIA shall become final and binding on the date the final signature is obtained on the CIA, which the parties may sign in separate counter parts;
- C. Any modifications to this CIA shall be made with the prior written consent of the parties to this CIA; and

D. The undersigned MIM 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 MIM CORPORATION

Rita Marcoux Compliance Officer MIM Corporation	3/15/00 DATE
Barry A. Posner Vice President and General Counsel MIM Corporation	<u>3/17/00</u> DATE
Thomas S. Crane	3/21/00 DATE

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.

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