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

HUMANA INC.

## I. PREAMBLE

Humana Inc., including its subsidiaries and affiliates, if any, ("Humana") 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 seek to ensure compliance by its employees (as well as certain third parties with whom Humana may contract as consultants or subcontractors) with the requirements of the Federal health care programs, including but not limited to the Medicare+Choice program (as currently defined at 42 U.S.C. § 1395w-21 et. seq., and 42 C.F.R. Parts 400, 403, 410, 411, 417 and 422). Humana's compliance with the terms and conditions in this CIA shall constitute an element of Humana's present responsibility with regard to participation in the Federal health care programs. This CIA is being executed in . connection with an investigation by the OIG relating to Humana's classification of certain Medicare beneficiaries as dually eligible under the Medicare and Medicaid programs. Contemporaneous with this CIA, Humana 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 Humana under this CIA shall be five years from the effective date of this CIA. The effective date of this CIA will be the date on which the final signatory of this CIA executes this CIA.

## III. CORPORATE INTEGRITY OBLIGATIONS

Humana has established and implemented a compliance program that, for at least the term of this CIA, shall be maintained so as to include the following elements.

A. Compliance Officer. In 1995, Humana appointed a Compliance Officer. The Compliance Officer shall be responsible for developing, implementing, and monitoring 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. The Compliance Officer is a member of senior management of Humana and is not the Chief Financial Officer ("CFO") or the General Counsel ("GC") or within the Office of General Counsel ("OGC") of Humana. Any person later appointed as the Compliance Officer shall be a member of senior management of Humana and not the CFO or the GC or within the OGC of Humana. The Compliance Officer shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and/or to the Board of Directors of Humana and shall be authorized to report to the Board of Directors at any time. The Compliance Officer is and shall remain authorized to monitor the day-to-day activities engaged in by Humana 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, Humana shall notify the OIG, in writing, within fifteen (15) days prior to such a change.

In performing her duties, the Compliance Officer utilizes and shall continue to utilize HCFA's Contractor Performance Monitoring System (currently available through the Internet at www.hcfa.gov/medicare/monitor.htm) to assess Humana's adherence to certain HCFA requirements for managed care contractors. Further, with regard to data submission by Humana to HCFA, the Compliance Officer shall have full authority to stop the submission of data that she believes is erroneous and would result in an overpayment to Humana, until such time as the issue in question is resolved.

Humana has appointed a Compliance Committee comprised of the Compliance Officer, the Associate General Counsel, a senior manager from Sales & Marketing, a senior manager from Human Resources, a senior manager from Internal Audit, the Chief Medical Officer, the Chief Operating Officer, the Chief Financial Officer, a senior manager from Corporate Communications, and a senior manager from Humana Military Healthcare Services. In the event there is a change in the composition of the Compliance Committee during the term of the CIA, the Compliance Committee shall, at a minimum, include the Compliance Officer and other employees serving in the same capacity as the current members of the Compliance Committee, or any other appropriate officers as necessary to meet the requirements of this CIA within Humana's corporate structure (e.g.,

senior executives of each major department, such as marketing, utilization review, quality assurance, appeals and grievance, claims processing, enrollment/disenrollment, information systems, provider contracting, finance, clinical, human resources, and audit). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling her responsibilities.

## B. Written Standards.

1. Code of Conduct. Within one-hundred and fifty (150) days of the effective date of this CIA, Humana shall review and revise, if appropriate, its established Code of Conduct. At its own discretion, Humana may fulfill its obligation under this section by revising and reissuing its Code of Business Conduct, First Edition, ©1995, Humana, that is distributed to new employees upon joining Humana. Within onehundred and fifty (150) days of the effective date of this CIA Humana shall distribute the Code of Conduct required by this CIA to (a) any officer, director, or employee of Humana or (b) any other person who (i) furnishes health care items or services at a facility owned or operated by Humana (i.e., in the event that Humana offers a staff model managed care product) for which Humana claims reimbursement from any Federal health care program, or (ii) directly participates in the preparation or submission of data or reimbursement requests from any Federal health care program on behalf of Humana (hereinafter, "Covered Person"), as well as any individual or entity with whom Humana contracts to provide services and supplies to beneficiaries of Federal health care programs (hereinafter, "Contracted Provider"). In order to meet this requirement, Humana may distribute to all Covered Persons and Contracted Providers the <u>Code of Business Conduct</u> with a supplement containing any revisions to the <u>Code of Business Conduct</u> that Humana adopts in order to fulfill its obligations under this section.

As it already does with regard to employees and the <u>Code of Business Conduct</u>,

Humana shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of managers, supervisors, and all Covered Persons. The Code of Conduct shall, at a minimum, continue to set forth:

- a. Humana's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to provide quality health care consistent with Federal and applicable State health care program regulations and procedures or instructions otherwise communicated by the Health Care Financing Administration ("HCFA") (or other appropriate regulatory agencies) and/or its agents;
- b. Humana's requirement that all of its Covered Persons shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Humana's own policies and procedures (including the requirements of this CIA) in

the course of their employment or contractual relationship with Humana;

- c. Humana's requirement that all of its Contracted Providers shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Humana's own policies and procedures (including the requirements of this CIA) related to the contract with Humana;
- d. the requirement that all of Humana's Covered Persons shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or of Humana's own policies and procedures in the course of their employment or contractual relationship with Humana;
- e. the possible consequences to both Humana and to any Covered Person of failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs, and with Humana's own policies and procedures or of failure to report such non-compliance, in the course of their employment or contractual relationship with Humana;
- f. the right of all Covered Persons to use the confidential disclosure program, as well as Humana's commitment to confidentiality and non-retaliation with respect to disclosures;

g. access to the confidential disclosure program for all Contracted Providers, as well as Humana's commitment to confidentiality and non-retaliation with respect to disclosures.

As Humana employees already have been required to do with regard to the Code of Business Conduct, within one-hundred and eighty (180) days of the effective date of the CIA, each Covered Person shall certify in writing that he or she has received, read, understood, and agreed to abide by Humana's Code of Conduct, except that each Covered Person who is a Humana employee located in Miami, Florida or Louisville, Kentucky shall certify in writing, within one-hundred and fifty (150) days of the effective date of the CIA, that he or she has received, read, understood, and agreed to abide by Humana's Code of Conduct. Covered Persons hired after the effective date of this CIA shall receive the Code of Conduct and shall complete the required certification within thirty (30) days after the commencement of their employment or contract(s) or within one-hundred and eighty (180) days of the effective date of the CIA (one-hundred and fifty (150) days for Humana employees located in Miami, Florida or Louisville, Kentucky), whichever is later. These certifications shall be maintained in a reasonable manner for at least the term of this CIA. Contracted Providers that enter into contracts with Humana after the effective date of this CIA shall receive the Code of Conduct within two (2) weeks after the commencement of the contract(s) or within one-hundred and fifty (150) days of the effective date of the CIA, whichever is later.

Humana will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed to Covered Persons and Contracted Providers within sixty (60) days of initiating such a change. As Humana employees have been required to do with regard to the Code of Business Conduct, Covered Persons shall certify on an annual basis that they have received, read, understood and agreed to abide by the Code of Conduct.

2. Policies and Procedures. Humana has implemented and will comply with written Policies and Procedures regarding the operation of Humana'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 in which Humana participates. For at least the term of this CIA, the written Policies and Procedures shall continue to address the requirements set forth by HCFA's Center for Health Plans and Providers ("CHPP"), including any operational policy letters, regulations or additional guidance that is provided to Medicare+Choice organizations offering coordinated care plans. In addition, the Policies and Procedures shall include disciplinary guidelines and methods for Covered Persons and Contracted Providers to make disclosures or otherwise report on compliance issues to Humana management through the Confidential Disclosure Program required by section III.E., below, and shall continue to include guidelines to protect persons using the Confidential Disclosure Program.

Within one-hundred and fifty (150) days of the effective date of this CIA, Humana shall compile its Policies and Procedures into one resource (e.g., a multi-binder set) that shall be reasonably available for review by Covered Persons and Contracted Providers. This resource shall enable Covered Persons and Contracted Providers to review Policies and Procedures in any area of Humana's operations addressed by the Policies and Procedures. Humana shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. A summary index 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.

The relevant portions of the Policies and Procedures have been distributed or made available to all appropriate Covered Persons. In the event that the Policies and Procedures are later amended, the relevant portions of the Policies and Procedures shall be distributed or made available to all Covered Persons and Contracted Providers.

Compliance staff and supervisors shall continue to be available to explain any and all Policies and Procedures.

# C. <u>Training and Education</u>.

1. General Training. Humana provides and shall continue to provide training regarding its Compliance Program and its Code of Conduct. Within one-hundred and eighty (180) days of the effective date of this CIA, Humana shall provide at least two (2) hours of training to each Covered Person, except that Humana shall provide at least Humana.FN3.wpd

two (2) hours of training to each Covered Person who is a Humana employee located in Miami, Florida or Louisville, Kentucky, within one-hundred and fifty (150) days of the effective date of this CIA. This general training shall explain, at a minimum, Humana's:

- a. Corporate Integrity Agreement requirements;
- b. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues); and
- c. Code of Conduct.

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

Covered Persons hired after the effective date of this CIA shall receive the general training described above within thirty (30) days of commencing their employment or within one-hundred and eighty (180) days (one-hundred and fifty (150) days for Humana employees located in Miami, Florida or Louisville, Kentucky) after the effective date of this CIA, whichever is later. Every Covered Person shall receive such general training on an annual basis.

2. Specific Training. Humana provides and shall continue to provide training in each of the below-described subject areas. Within one-hundred and eighty (180) days (one-hundred and fifty (150) days for Humana employees located in Miami, Florida and Louisville, Kentucky) of the effective date of this CIA, each Covered Person who is directly involved in one or more of the following subject areas shall receive at least three (3) hours of specific training devoted to the applicable subject matter

(hereafter, "Specific Training"), in addition to the general training required above: data collection and submission for enrollment/disenrollment, encounter data, and adjusted community rates; claims processing; marketing; utilization review; quality assurance; and appeals and grievance procedures. This Specific Training shall include a discussion of:

- a. the particular subject matter in which the individual is involved and the specific risk areas associated with that subject matter (*i.e.*, an individual involved in marketing should receive at least three hours of specific training on the risk areas associated with managed care marketing);
- b. the policies, procedures and other requirements applicable to the specific subject matter in which the individual is involved;
- c. the personal obligation of each individual involved in the provision of services for Federal health care programs, to ensure that reasonable and appropriate care is provided to beneficiaries of Federal health care programs;
- d. applicable statutes, regulations and operational policy letters;
- e. the legal sanctions for improper conduct; and
- f. examples of proper and improper conduct.

These training materials shall be made available to OIG, upon request. Persons providing the training must be knowledgeable about the applicable subject area(s) and shall coordinate such training with the Compliance Officer.

Covered Persons hired after the effective date of this CIA for whom Specific Training under this provision is required, shall receive this training within thirty (30) days of the beginning of their employment or within one-hundred and eighty (180) days (one-hundred and fifty (150) days for Humana employees located in Miami, Florida and Louisville, Kentucky) after the effective date of this CIA, whichever is later. If a new Covered Person has any responsibility for any of the Specific Training subject areas enumerated above, another Covered Person who has supervisory experience and already has completed the Specific Training, shall review all of the new Covered Person's work regarding the applicable subject area(s), until the new Covered Person has completed the applicable Specific Training.

Each Covered Person shall receive such Specific Training on an annual basis.

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 certifications shall be retained by the manager(s) responsible for the training, who shall certify in writing to the Compliance Officer the extent to which training has been completed and whether the certifications of Covered Persons have been obtained. The Compliance Officer shall retain the certifications of the managers. These certifications and the course materials themselves shall be made available to OIG upon request.

D. Engagements to Perform Annual Assessments. Humana currently utilizes both internal and external audit resources to seek to ensure compliance with various federal and state laws. Annually, Humana shall conduct agreed-upon procedures engagements to assist Humana and OIG in assessing Humana's enrollment data submission, encounter data submission, adjusted community rate data submission, claims processing, and marketing/disenrollment practices with respect to Federal health care programs. An additional engagement will determine whether Humana is in compliance with this CIA ("compliance engagement"). Accordingly, Humana will conduct six separate agreed-upon procedures engagements. These engagements shall be an annual requirement and each shall cover a twelve (12) month period.

For the first year of the CIA, Humana shall retain one or more outside entities, such as accounting, auditing or consulting firms (hereinafter, "Independent Review Organization(s)"), to perform all of the engagements, including the compliance engagement. Within one-hundred and fifty (150) days of the effective date of this CIA, the Independent Review Organization(s) must be retained to conduct the engagements of the first year. The Independent Review Organization(s) must have expertise in the procedures being assessed, as well as the reporting and other requirements of the Federal health care programs from which Humana obtains reimbursement.

For the second, third, fourth and fifth years of the CIA, Humana shall retain an Independent Review Organization to perform the compliance engagement. However, for Humana.FN3.wpd

the remaining engagements for the second, third, fourth and fifth years of the CIA,
Humana either may retain the Independent Review Organization(s) or it may conduct
such engagements internally, by using qualified employees who are independent of the
functions being reviewed. If, during years two, three, four and five, these engagements
are conducted internally, Humana shall retain an Independent Review Organization in the
second, third, fourth and fifth years to verify the propriety and accuracy of the internallyperformed engagements and to verify that the engagements were conducted in accordance
with the agreed-upon procedures described below.

Where the engagement requires a review of a *statistically valid* sample of items, as specified below, the review shall be a variable appraisal and the following parameters shall apply: 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 full sample must be selected through random numbers. To make a selection through random numbers, Humana and/or the Independent Review Organization 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*.

1. Enrollment Data Engagement. Humana utilizes a Medicare Enrollment and Disenrollment Policy and Procedure Manual to govern the enrollment process. The

purpose of the enrollment data engagement is to determine the accuracy and reliability of Humana's submission of enrollment data to HCFA, including data indicating dates of death by beneficiaries, Medicare/Medicaid dual eligibility, institutionalization, and ESRD status. The enrollment data engagement shall consist of a review of a statistically valid sample of cases that can be projected to the population of claims for the relevant one-year time period. Each annual enrollment data assessment shall include the following components in its methodology:

- a. Enrollment Data Engagement Objective: A clear statement of the objective of the enrollment data engagement and the procedure(s) that will be applied to achieve the objective.
- b. Enrollment Data Engagement Population: Identify the population, which is the group about whom data must be gathered and analyzed. 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 data upon which the enrollment data engagement's conclusion(s) will be based, including the legal or other standards applied, documents relied upon, 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 enrollment data engagement shall provide:

- a. findings regarding Humana's enrollment data submission operation (including, but not limited to, the operation of the enrollment data certification process, the strengths and weaknesses of the process that provides the basis for the certification, the internal controls of the process by which certification is obtained, and the overall effectiveness of the system);
- b. findings regarding whether Humana is utilizing proper and appropriate methods in its enrollment data submission;
- c. findings regarding Humana's procedures to correct enrollment data that is incorrect;
- d. findings regarding whether Humana's request and receipt of enhanced capitation payments in cases of Medicare/Medicaid dual-eligibility, institutionalization and ESRD status, are proper and appropriate, including, but not limited to, whether Humana's requests for enhanced capitation can be supported by documentation (e.g., copies of Medicaid cards and/or the HI Mini-Master database for dual eligibility verification);

- e. findings regarding the steps Humana is taking to bring its operations into compliance or to correct problems identified by the engagement.
- 2. Encounter Data Engagement. The purpose of the encounter data engagement is to determine the accuracy and reliability of Humana's submission of encounter data to HCFA. The encounter data engagement shall consist of a review of a statistically valid sample of cases that can be projected to the population of claims for the relevant one-year time period. Each annual encounter data assessment shall include the following components in its methodology:
  - a. Encounter Data Engagement Objective: A clear statement of the objective of the encounter data engagement and the procedure(s) that will be applied to achieve the objective.
  - b. Encounter Data Engagement Population: Identify the population, which is the group about whom data must be gathered and analyzed. 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 data upon which the encounter data engagement's conclusion(s) will be based, including the legal or other standards applied, documents relied upon, 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 encounter data engagement shall provide:

- a. findings regarding Humana's encounter data submission operation (including, but not limited to, the operation of the encounter data certification process, the strengths and weaknesses of the process that provides the basis for the certification, the internal controls of the process by which certification is obtained, and the overall effectiveness of the system);
- b. findings regarding whether Humana is utilizing proper and appropriate methods in its encounter data submission;
- c. findings regarding Humana's procedures to correct encounter data that is incorrect;
- d. findings regarding the steps Humana is taking to bring its operations into compliance or to correct problems identified by the audit.
- 3. Adjusted Community Rate Data Engagement. The purpose of the adjusted community rate data engagement is to determine the accuracy and reliability of Humana's submission of adjusted community rate data to HCFA. The annual adjusted

community rate proposal should be reviewed. Each annual adjusted community rate review shall include the following components in its methodology:

- a. Adjusted Community Rate Data Engagement Objective: A clear statement of the objective of the adjusted community rate data engagement and the procedure(s) that will be applied to achieve the objective.
- b. Base Year Amounts: Identify the base year amounts (usually two years prior) and evaluate whether there is proper documentation (e.g., general ledger) to support those amounts.
- c. Rate Proposal: Identify the estimates that were used to develop the adjusted community rate proposal and evaluate whether those estimates are reasonable and supported by proper documentation.
- d. Evaluate the accuracy of all calculations on the worksheets included in the adjusted community rate proposal.
- e. Evaluate any and all other figures relied upon in the adjusted community rate proposal for accuracy and support by proper documentation.

The adjusted community rate data engagement shall provide:

a. findings regarding Humana's adjusted community rate data submission operation (including, but not limited to, the operation of the adjusted community rate data certification process, the strengths and weaknesses of the process that provides the basis for the certification, the internal controls

- of the process by which certification is obtained, and the overall effectiveness of the system);
- b. findings regarding whether Humana is utilizing proper and appropriate methods in its adjusted community rate data submission;
- c. findings regarding Humana's procedures to correct adjusted community rate data that is incorrect;
- d. findings regarding the steps Humana is taking to bring its operations into compliance or to correct problems identified by the audit.
- 4. Claims Processing Engagement. Humana utilizes a Medicare Claims Processing Manual to govern claims processing. The purpose of the claims processing engagement is to determine whether Humana is in compliance with the prompt payment provisions of 42 C.F.R. § 422.520. The claims processing engagement shall consist of a review of a statistically valid sample of claims that can be projected to the population of claims for the relevant time period. Each annual claims processing engagement shall include the following components in its methodology:
  - a. Claims Processing Engagement Objective: A clear statement of the objective of the claims processing engagement and the procedure(s) that will be applied to achieve the objective.
  - b. Claims Processing Engagement Population: Identify the population, which is the group about whom data must be gathered and analyzed.

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 data upon which the claims processing engagement's conclusion(s) 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 claims processing engagement shall provide:

- a. findings regarding Humana's claims processing operation (including, but not limited to, the operation of the claims processing system, strengths and weaknesses of this system, internal controls, effectiveness of the system);
- b. findings regarding whether Humana is processing claims for services billed to Humana on behalf of Medicare beneficiaries in a proper and timely manner;
- c. findings regarding Humana's procedures to correct inaccurate or untimely claims processing; and

- d. findings regarding the steps Humana is taking to bring its operations into compliance or to correct problems identified by the audit.
- 5. Marketing/Disenrollment Engagement. Humana utilizes a Medicare Sales Manager Training Manual and a Medicare Sales Training and Development Manual to guide its sales and marketing practices. In addition, Humana requires sales agents to undergo training, testing and annual retesting and to sign a Medicare Sales Marketing Practices Statement to emphasize the importance of pursuing legal and ethical marketing practices. The purpose of the marketing/disenrollment engagement is to determine whether Humana is discriminating on the basis of the health status of individuals when enrolling or disenrolling beneficiaries of Federal health care programs. These risk areas are described in greater detail at Sections II.A.2.(b) and (c) of the OIG's Draft Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans, 64 Fed. Reg. 33875, June 1999. The Independent Review Organization shall use a combination of methods to perform this engagement, including, but not necessarily limited to the following: the use of "secret shoppers" to test Humana's marketing efforts and sales agents; telephone enrollment verification following the receipt of an enrollment application to test Humana's marketing efforts and sales agents; surveys of current enrollees; and exit interviews of former enrollees regarding their experiences with Humana's marketing and disenrollment process.

Each annual marketing/disenrollment engagement shall include the following components in its methodology:

- a. Marketing/Disenrollment Engagement Objective: A clear statement of the marketing/disenrollment engagement's objective and the procedure(s) that will be applied to achieve the objective.
- b. Sources of Data: Provide a full description of the source of the information upon which the marketing/disenrollment engagement's conclusions will be based, including the legal or other standards applied, documents relied upon, and/or any contractual obligations.

The marketing/disenrollment engagement shall provide:

- a. findings regarding whether Humana discriminates on the basis of health status when enrolling and disenrolling beneficiaries of Federal health care programs;
- b. findings regarding whether Humana is utilizing proper and appropriate methods to avoid such discrimination in marketing and disenrollment;
- c. findings regarding Humana's procedures to correct marketing or disenrollment practices that are improper or inappropriate, if any; and
- d. findings regarding the steps Humana is taking to bring its operations into compliance or to correct problems identified by the engagement.

- 6. Compliance Engagement. The purpose of the compliance engagement is to provide findings regarding whether Humana'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 reports or other rendering of conclusions pursuant to these engagements shall be included in each of Humana's Annual Reports to the OIG.
- 7. 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 Humana is complying with its obligations under this CIA, Humana agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.
- E. Confidential Disclosure Program. Humana has established and shall maintain a Confidential Disclosure Program, which includes measures (e.g., a toll-free compliance telephone hot line) to enable employees, contractors, agents 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 compliance issues or questions associated with Humana's policies, practices or procedures with respect to the Federal health care programs. Humana shall continue to publicize the existence of its 24 hour/7 day per week hotline (e.g., in e-mails to Covered Persons, notices to Contracted Providers, on wallet

cards, on pay stubs, and posting of the hotline number on an Intranet or in prominent common areas).

The Confidential Disclosure Program shall continue to emphasize a nonretribution, non-retaliation policy, and 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, Humana 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. <u>Ineligible Persons</u>.

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 Humana.FN3.wpd

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. Humana shall not hire or engage as subcontractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Humana shall screen all prospective Covered Persons and prospective Contracted Providers prior to engaging their services or executing contracts 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 list of excluded individuals and entities (available through the Internet at http://www.dhhs.gov/progorg/oig) (these lists and reports will hereinafter be referred to as the "Exclusion Lists"). With regard to the screening of Contracted Provider applicants and Covered Person applicants who are health care practitioners, Humana shall review relevant information available from the National Practitioner Data Bank and the Healthcare Integrity Protection Data Bank.
- 3. Review and Removal Requirement. Within one-hundred and fifty (150) days of the effective date of this CIA, Humana will review its list of current Covered Persons and Contracted Providers against the Exclusion Lists. Thereafter, Humana will Humana.FN3.wpd

review the list semi-annually. If Humana has notice that a Covered Person or a Contracted Provider has become an Ineligible Person, Humana will remove such person from responsibility for, or involvement with, Humana'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 Humana has notice that an employee or contractor has been convicted of a criminal offense related to any Federal health care program, or has been suspended or excluded during his or her employment or contract with Humana, within ten (10) days of receiving such notice Humana will remove such individual from responsibility for, or involvement with, Humana's business operations related to the Federal health care programs. If Humana has notice that a Contracted Provider is charged with a criminal offense related to any Federal health care program, or is proposed for exclusion during the term of the Contracted Provider's contract, Humana shall take such reasonable action that it deems appropriate to safeguard the quality of care provided to beneficiaries of any Federal health care program by such Contracted Provider.

G. Notification of Proceedings. Within thirty (30) days of discovery, Humana shall notify OIG, in writing, of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents in their official capacities involving an allegation that Humana has committed a crime or has engaged in fraudulent activities or any other knowing misconduct related to a Federal health care program. 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. Humana 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, Humana identifies or learns of any policies, procedures and/or practices that result in an overpayment, Humana shall notify the payor (e.g., HCFA's CHPP or Regional Office or contractor) within thirty (30) days of discovering the overpayment and take remedial steps within sixty (60) days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including steps to prevent the underlying problem and the overpayments from recurring. If the overpayment is discovered as the result of any of the activities required by this CIA, 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 beneficiary-specific information or provider-specific information used to determine the overpayment (e.g., beneficiary health insurance number, enrollment date, payment date, and provider number(s), etc.);
- f. the plan number or contract number under which the repayment is being made; and
- g. the cost reporting period [if applicable].
- 2. Reporting of Material Deficiencies. If Humana determines that there is a material deficiency, Humana shall notify the OIG within thirty (30) days of discovering the material deficiency. If the material deficiency results in an overpayment, the report to the OIG shall be made at the same time as the report 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 material deficiency resulted in an overpayment, the report to the OIG shall include:

- a. a complete description of the material deficiency, including the relevant facts, persons involved, and legal and program authorities;
- b. Humana's actions to correct the material deficiency; and
- c. any further steps Humana plans to take to address such material deficiency and prevent it from recurring.
- 3. Definition of "Overpayment." For purposes of this CIA, an "overpayment" shall mean the amount of money the provider or health plan has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or program directives, including carrier and intermediary instructions.
- 4. Definition of "Material Deficiency." For purposes of this CIA, a "material deficiency" means anything that involves: (i) a substantial overpayment or improper payment relating to any Federal health care program; (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; or (iii) in the event that Humana provides health care, i.e., through a staff model managed care product, the provision of items or services of a quality that fails to meet professionally recognized standards of health care. A material deficiency may be the result of an isolated event or a series of occurrences.

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# IV. NEW BUSINESS UNITS

In the event that Humana purchases or establishes, after the effective date of this CIA, new business units that participate in the Federal health care programs, Humana shall notify OIG of this fact thirty (30) days prior to 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 contract 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). All Contracted Providers associated with such new locations shall be treated in a manner consistent with the terms of this CIA.

## V. IMPLEMENTATION AND ANNUAL REPORTS

A. <u>Implementation Report</u>. Within one-hundred and fifty (150) days after the effective date of this CIA, Humana 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 thencurrent Compliance Officer required by section III.A;
- 2. the names and positions of the then-current members of the Compliance Committee required by section III.A;
- 3. a copy of Humana'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 programs required by section III.C., including a description of the targeted audiences and a schedule of when the training sessions were held or are scheduled to be held;
- 6. a certification by the Compliance Officer addressing whether:
  - a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed or made available to all pertinent Covered Persons and Contracted Providers;
  - b. all Covered Persons who are Humana employees located in Miami, Florida and Louisville, Kentucky, have completed the Code of Conduct certification required by section III.B.1; and
  - c. all Covered Persons who are Humana employees located in Miami, Florida and Louisville, Kentucky, have completed the training and executed the certification required by section III.C.
- 7. a copy of the proposed audit work plan as identified in section III.D.5;
- 8. a description of the confidential disclosure program required by section III.E;
- 9. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first audit; and

- 10. a summary of personnel actions taken pursuant to section III.F.
- B. <u>Annual Reports</u>. Humana shall submit to OIG Annual Reports with respect to the status and findings of Humana's compliance activities for each of the one-year periods covered by this CIA. The Annual Reports shall include:
  - 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 addressing whether:
    - a. all Covered Persons have completed the annual Code of Conduct certification required by section III.B.1; 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 (e.g., change in contractor policy);
  - 4. a complete copy of the report(s) prepared pursuant to the Independent Review Organization's engagements required by this CIA, including a description of the methodology used;
  - 5. Humana's response/corrective action plan to any issues raised by the Independent Review Organization;

- 6. a summary of overpayments and material deficiencies reported pursuant to Section III.H., during the period covered by the Annual Report;
- 7. a report of the aggregate overpayments that have been returned to the Federal health care programs, during the period covered by the Annual Report;
- 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 Humana as a result of the obligations in section III.F;
- 10. a summary and/or update describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity, involving an allegation that Humana has committed a crime or has engaged in fraudulent activities or other knowing misconduct, which must be reported pursuant to section III.G. The statement shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation, legal proceeding or inquiry;
- 11. a corrective action plan to address the probable violations of law identified in section III.H;
- 12. a copy of Humana's certifications of enrollment data (including dualeligibility status, institutionalization, hospice status and ESRD status),

encounter data and adjusted community rate data, provided to HCFA during the period covered by the Annual Report;

13. a listing of all of Humana's locations (including both street and mailing addresses), the name under which Humana is doing business at each location, the phone and fax numbers for each location, and the contract number associated with the health plan in each location.

The first Annual Report shall be received by OIG no later than one year and forty-five (45) days after the effective date of this CIA. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. <u>Certifications</u>. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer, under penalty of perjury, that: (1) Humana 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

## Humana:

Sheri Mitchell Compliance Officer Humana Inc. 500 West Main St. Louisville, KY 40202 Phone 502.580.1909 Fax 502.580.3854

## 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 Humana's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) Humana's compliance with the terms of this CIA; and (b) Humana's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Humana 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 Humana's Covered Persons who consent to be interviewed at his, her or its place of business during normal business hours or at such other place and time as may be mutually agreed upon between the Covered Person and OIG. Humana agrees to assist OIG in contacting and arranging interviews with such Covered Persons at OIG's request. Humana's employees may elect to be interviewed with or without a representative of Humana present.

#### VIII. DOCUMENT AND RECORD RETENTION

Humana shall maintain for inspection all documents and records relating to capitated payments from the Medicare program or other Federal health care programs or relating to compliance with this CIA, for six (6) years (or longer if otherwise required).

#### IX. DISCLOSURES

Subject to HHS' Freedom of Information Act ("FOIA") procedures, set forth in 45 C.F.R. Part 5, the OIG shall make a reasonable effort to notify Humana prior to any release by OIG of information submitted by Humana pursuant to its obligations under this CIA, and identified upon submission by Humana as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Humana 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.

III

### X. Breach and Default Provisions

Humana 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, Humana 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 fifty (150) days after the effective date of this CIA and concluding at the end of the term of this CIA, Humana fails to have in place any of the following:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. written Code of Conduct;
- d. written Policies and Procedures;
- e. a training program; and
- f. 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 Humana 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 Humana:
- 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 Humana 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);
- b. employs or contracts with an Ineligible Person and that person: (i) has responsibility for, or involvement with, Humana'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 in 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 Humana 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); or

- c. employs or contracts with a person who: (i) has been convicted of a criminal offense related to any Federal health care program, or (ii) is suspended or excluded, and that person has responsibility for, or involvement with, Humana'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 Humana received notice of the relevant matter or after the resolution of the matter).
- 4. A Stipulated Penalty of \$1,500 (which shall begin to accrue on the date that Humana fails to grant access) for each day Humana 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 Humana of the failure to comply) for each day Humana fails to comply fully and adequately with any obligation of this CIA. In its notice to Humana, the OIG shall state the specific grounds for its determination that Humana has failed to comply fully and adequately with the CIA obligation(s) at issue.

#### B. Payment of Stipulated Penalties.

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

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Humana'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").

Within fifteen (15) days of the date of the Demand Letter, Humana 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 Humana elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Humana 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. Humana 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 Humana 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 Humana 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 Humana 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 Humana constitutes an independent basis for Humana'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 Humana has materially breached this CIA and that exclusion should be imposed, the OIG shall notify Humana by certified mail of (a) Humana'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. Humana 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. Humana 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) Humana has begun to take action to cure the material breach, (ii) Humana is pursuing such action with due diligence, and (iii) Humana 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, Humana fails to satisfy the requirements of section X.C.2, OIG may exclude Humana from participation in the Federal health care programs under the terms set forth herein. OIG will notify Humana in writing of its determination to exclude Humana (this letter shall be referred to hereinafter as the "Exclusion Letter"). 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

Humana is excluded under the provisions of this CIA, Humana 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 Humana to report a known material deficiency, 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 sectionX.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.
  - e. any conduct that constitutes a serious threat to the quality of care received by a Medicare beneficiary, in the event that Humana provides health care, i.e., through a staff model managed care product.

# D. Dispute Resolution

1. Review Rights. Upon the OIG's delivery to Humana of its Demand
Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the
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resolution of disputes arising under the obligation of this CIA, Humana shall be afforded certain review rights comparable to the ones that are provided at 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 Humana was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. Humana 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 Humana to pay Stipulated Penalties, such Stipulated Penalties shall

become due and payable twenty (20) days after the ALJ issues such a decision, notwithstanding that Humana may request review of the ALJ decision by the DAB.

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 under this CIA shall be (a) whether Humana 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 35 day period, and if not, whether (i) Humana had begun to take action to cure the material breach within that time period, (ii) Humana has pursued and is pursuing such action with due diligence, and (iii) Humana provided to OIG within that time 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. Humana's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Humana 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 Humana may request review of the ALJ decision by the DAB.

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## 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, Humana and OIG agree as follows:

A. this CIA shall be binding on the successors, assigns and transferees of Humana;

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 Humana 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 THE OFFICE OF INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

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**LEWIS MORRIS** 

Assistant Inspector General for Legal Affairs
Office of Inspector General

U. S. Department of Health and Human Services

Jane 5, 2000 DATE

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# ON BEHALF OF HUMANA INC.

Michael B. McCallister President and CEO	<u>5 - 30 - 0 c</u> DATE
Kathleen Pellegrino V.P. & Associate General Counsel	5-30-00 DATE
Joseph Casson Counsel to Humana Inc.	5-3/-60 DATE
Ira Raphaelson	5-3/-00 DATE

Counsel to Humana Inc.