CORPORATE INTEGRITY AGREEMENT BETWEEN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND ROCKY MOUNTAIN HOSPITAL AND MEDICAL SERVICE

I. PREAMBLE

Rocky Mountain Hospital and Medical Service d/b/a Blue Cross Blue Shield of Colorado ("BCBSC") 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"), the Health Care Financing Administration ("HCFA"), and the Colorado Department of Health Care Policy and Financing ("DHCPF") to demonstrate that BCBSC will possess the high degree of business honesty and integrity required in contracting with HCFA and the State of Colorado with respect to any Medicare Part A agreement, Part B contract, Part C contract, any Medicare Health Maintenance Organization contract, Children's Basic Health Care Plan of Colorado, any Medicare risk sharing contract, or any other Medicare contracts or agreements entered into with such government agencies during the duration of this CIA (hereinafter collectively referred to as "health care contracts"). BCBSC agrees to abide by and comply with the rules, regulations, and procedures set forth in the health care contracts, by HCFA and DHCPF, and by all other applicable Federal and State health care programs in carrying out its

obligations under this CIA. BCBSC's compliance with the terms and conditions in this CIA shall constitute an element of BCBSC's present responsibility with regard to contracting with and participating in the Federal health care programs. This CIA is designed to ensure compliance by BCBSC's officers, directors, employees (either directly or as an agent or contractor) who are responsible for administering the health care contracts, or otherwise responsible for drafting, implementing, or overseeing the practices, policies, or procedures for or on behalf of BCBSC that relate to the health care contracts (hereinafter referred to as "covered individuals"). Contemporaneously with this CIA, BCBSC 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 BCBSC under this CIA shall be five (5) years from the effective date of this CIA (unless otherwise specified herein). 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

BCBSC has established a compliance program prior to entering into this CIA. To the extent BCBSC has already implemented the requirements set forth in this CIA as part of its compliance program, BCBSC shall maintain those elements at least for the duration

¹ This term, as used throughout this CIA, is defined at 42 U.S.C. § 1320a-7b(f). Blue Cross Blue Shield of Colorado CIA

of this CIA. To the extent such requirements have not been implemented, BCBSC shall establish those elements within the time frames set forth herein.

A. Compliance Officer and Compliance Committee. BCBSC has appointed a Compliance Officer. This individual 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 health care contracts. The Compliance Officer shall be a member of senior management of BCBSC, shall make regular (at least quarterly) reports regarding compliance matters directly to the CEO and to the Board of Directors of BCBSC and shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall be responsible and available for monitoring the day-to-day activities engaged in by BCBSC 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, BCBSC shall notify the OIG, in writing, within fifteen (15) days of such a change.

BCBSC shall also appoint a Compliance Committee within one hundred and twenty (120) days after the effective date of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate officers as necessary to meet the requirements of this CIA within BCBSC's corporate structure (e.g., senior executives responsible for each contract, executives responsible for setting policies and procedures, and individuals responsible for maintaining communications with

governmental entities). The Compliance Officer shall chair the Compliance Committee and the Committee shall support the Compliance Officer in fulfilling his/her responsibilities.

B. Written Standards.

- 1. Code of Conduct. Prior to the execution of this CIA, BCBSC established a Code of Business Conduct ("Code of Conduct"). Within one hundred and twenty (120) days of the effective date of this CIA, BCBSC shall review its Code of Conduct to ensure that, to the extent not already accomplished, it reflects the values and requirements set forth herein. The Code of Conduct shall be distributed to all covered individuals within one hundred and twenty (120) days of the effective date of this CIA. BCBSC shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other covered individuals. The Code of Conduct shall, at a minimum, set forth:
 - a. BCBSC's commitment to full compliance with all terms, statutes, regulations, and guidelines applicable to health care contracts;
 - b. BCBSC's requirement that all of its covered individuals shall be expected to comply with all terms, statutes, regulations, and guidelines applicable to health care contracts and with BCBSC's own policies and procedures (including the requirements of this CIA);

- c. the requirement that all of BCBSC's covered individuals shall be expected to report suspected violations of any term, statute, regulation, or guideline applicable to health care contracts or of BCBSC's own policies and procedures;
- d. the possible consequences to both BCBSC and to any covered individual of failure to comply with all terms, statutes, regulations, and guidelines applicable to Federal health care programs and with BCBSC's own policies and procedures or of failure to report such non-compliance; and
- e. the right of all covered individual to use the confidential disclosure program, as well as BCBSC's commitment to confidentiality and non-retaliation with respect to reports or disclosures.

Within one hundred and twenty (120) days of the effective date of the CIA, each covered individual shall certify, in writing, that he or she has received, read, understands, and will abide by BCBSC's Code of Conduct. New covered individuals shall receive the Code of Conduct and shall complete the required certification within two (2) weeks after the commencement of their employment or contract or within one hundred and twenty (120) days of the effective date of the CIA, whichever is later.

BCBSC will annually review the Code of Conduct and will make any necessary revisions. These revisions shall be distributed within thirty (30) days of initiating such a

change. All covered individuals shall certify on an annual basis that they have received, read, understand and will abide by the Code of Conduct.

2. Policies and Procedures. Within one hundred and twenty (120) days of the effective date of this CIA, BCBSC shall develop and initiate implementation of written Policies and Procedures regarding the operation of BCBSC's compliance program and its compliance with all Federal and state health care statutes, regulations, and guidelines, including the terms and conditions of the health care contracts. At a minimum, the Policies and Procedures shall specifically address the ongoing responsibilities to disclose information to HCFA, OIG, and DHCPF concerning any suspected misconduct relating to the health care contracts and, when required, to accurately report BCBSC's performance to HCFA, OIG, DHCPF, or other governmental entities. In addition, the Policies and Procedures shall include disciplinary guidelines for failure to report any suspected misconduct to HCFA, OIG, and DHCPF, and methods for employees to make disclosures or otherwise report on compliance issues to BCBSC management through the Confidential Disclosure Program required by section III.E. BCBSC shall assess the Policies and Procedures at least annually, and, if necessary update them, unless more frequent updates are required. 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.

Within one hundred and twenty (120) days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be distributed to all appropriate covered individuals. Compliance staff or supervisors should be available to explain any and all policies and procedures.

C. Training and Education.

- 1. Training. Within one hundred and twenty (120) days of the effective date of this CIA, BCBSC shall provide at least two (2) hours of training to each covered individual. This general training shall explain BCBSC's:
 - a. Corporate Integrity Agreement requirements;
 - b. Compliance Program;
 - c. Code of Conduct; and
 - d. Policies and Procedures.

The training material shall be made available to the OIG, upon request.

New covered individuals 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. Until they have had the requisite training, such new personnel will work under the direct supervision of a person who has received such training. Each year, every covered individual shall receive such general training on an annual basis.

- 2. Certification. Each covered individual 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. BCBSC shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization"), to perform review procedures to assist BCBSC in assessing the adequacy of its compliance practices pursuant to this CIA and the applicable contract. This shall be an annual requirement and shall cover a twelve (12) month period. The Independent Review Organization must have expertise in the requirements of the BCBSC health care contracts. 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 BCBSC's compliance with the health care contracts to assist the BCBSC, OIG, HCFA, and DHCPF in determining compliance with all applicable terms, statutes, regulations, and directives/guidance ("contract engagement"). The second engagement will determine whether BCBSC is in compliance with this CIA ("compliance engagement").

- 1. Contract Engagement. The contract engagement shall consist of a review of:
 - a. the internal controls over claims processing with findings as to whether claims are paid timely and accurately;
 - b. the timeliness of responses to inquiries from beneficiaries, recipients, members or any individual associated with a governmental entity, with findings of whether correspondence and other inquiries are responded to in a timely fashion, and to the extent applicable, within the time frames set forth in any of the health care contracts;
 - c. system controls designed to avoid manipulation of underlying data files used by the government in evaluating BCBSC's administration of health care contracts and findings concerning whether the controls adequately prevent such manipulation; and
 - d. the practices, policies and procedures for disclosing misconduct to the government and findings concerning whether they effectively promote disclosure.

The contract engagement shall also provide findings regarding the steps BCBSC is taking to bring its operations into compliance or to correct problems identified by the audit. This engagement will specify the reviewing methods used, such as the Generally Accepted Accounting Principles, and include the methods for any statistical sampling.

Any random sampling shall be done in accordance with RATSTATS, which is available through the Internet at "www.hhs.gov/progorg/oas/ratstat.html."

If BCBSC enters into a Part C contract, BCBSC agrees to modify the provisions of this section to include a review by the Independent Review Organization that relates to the administration of that contract, including, but not limited to, a review of the encounter data, the enrollment data, and the Adjusted Community Rate.

2. Compliance Engagement. An Independent Review Organization shall also conduct a compliance engagement, that shall provide findings regarding whether BCBSC'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 contract and compliance engagement shall be included in each of BCBSC's Annual Reports to OIG.

Nothing in this CIA shall be construed to abrogate any existing reporting requirements by HCFA or DHCPF.

3. Verification/Validation. In the event that the OIG has reason to believe that BCBSC's analyses required by this section (section III.D) fail to conform to BCBSC's obligations under this section or indicate improper actions under any of the health care contracts that were not otherwise adequately addressed in the audit report, and OIG thus determines that it is necessary to conduct an independent analysis or review to determine

whether or the extent to which BCBSC is complying with its obligations under this CIA, BCBSC agrees to pay for the reasonable cost of any such analysis or review by OIG or any of its designated agents no more than once each 12 month period

E. Confidential Disclosure Program. Prior to the execution of this CIA, BCBSC established a Confidential Disclosure Program. Within one hundred and twenty (120) days of the effective date of this CIA, the Confidential Disclosure Program shall be reviewed to ensure that it meets the requirements set forth herein. It must include measures (e.g., a toll-free compliance telephone 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 issues or questions associated with BCBSC's policies, practices, or procedures with respect to the health care contracts or the Federal health care programs, believed by the individual to be inappropriate. BCBSC shall publicize the existence of the hotline (e.g., e-mail to employees or post 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, BCBSC 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 for the award of a Federal government contract or 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. BCBSC shall not hire employees or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, BCBSC shall screen all prospective employees and prospective contractors 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 List of Excluded Individuals/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").

- 3. Review and Removal Requirement. Within one hundred and twenty (120) days of the effective date of this CIA, BCBSC will review its list of covered individuals against the Exclusion Lists. Thereafter, BCBSC will review the list once semi-annually. If BCBSC has notice that a covered individual has become an Ineligible Person, BCBSC will remove such person from responsibility for, or involvement with, BCBSC's business operations related to the health care contracts or Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered or ordered by the person are paid in whole or part, directly or indirectly, by health care contracts 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 BCBSC has notice that a covered individual is charged with a criminal offense related to any Federal contract or Federal health care program, or is debarred, suspended or proposed for exclusion during his or her employment or contract with BCBSC, within ten (10) days of receiving such notice BCBSC will remove such individual from responsibility for, or involvement with,

BCBSC's business operations related to the health care contracts until the resolution of such criminal action, suspension, or proposed exclusion.

G. Notification of Proceedings. Within thirty (30) days of discovery, BCBSC shall notify OIG in writing of any ongoing investigation or legal proceeding conducted or brought by a governmental entity or its agents involving an allegation that BCBSC, or any covered individual, has committed a crime or has engaged in fraudulent activities or any other misconduct relating to the health care contracts. 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. BCBSC 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.

If, at any time, BCBSC discovers any credible evidence of misconduct related to the administration of the health care contracts by a BCBSC covered individual, BCBSC shall within thirty (30) days of discovering the misconduct notify OIG. If it relates to a HCFA health care contract or agreement, then notice shall be provided concurrently to HCFA. If it relates to the contract with DHCPF, then notice shall be provided concurrently to DHCPF. BCBSC shall take remedial steps within sixty (60) days of discovery to correct the problem, including preventing the misconduct from recurring. The notice to OIG, and, if applicable, HCFA or DHCPF, shall include:

- 1. a complete description of the misconduct, including the names and positions of the individuals involved;
- 2. action(s) taken to correct and prevent such misconduct from recurring; and
- 3. financial ramifications of the misconduct, if any.

IV. New Contracts

In the event that BCBSC obtains new health care contracts with the government after the effective date of this CIA, BCBSC shall notify OIG and HCFA of this fact within thirty (30) days of the date of the health care contract. The requirements of this CIA shall apply to all subsequent health care contracts for the duration of the 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, BCBSC shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA. This Implementation Report shall include:

- 1. the name, address, phone number and position description of the Compliance Officer required by section III.A;
- 2. the names and positions of the members of the Compliance Committee required by section III.A;
- 3. a copy of BCBSC'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;
- 6. a certification by the Compliance Officer that:
 - a. the Policies and Procedures required by section III.B have been developed, are being implemented, and have been distributed to all pertinent covered individuals;
 - b. all covered individuals have completed the Code of Conduct certification required by section III.B.1; and
 - c. all covered individuals have completed the training and executed the certification required by section III.C.
- 7. a description of the confidential disclosure program required by section III.E;
- 8. the identity of the Independent Review Organization(s) and the proposed start and completion date of the first audit; and
- 9. a summary of personnel actions taken pursuant to section III.F.
- B. Annual Reports. BCBSC shall submit to OIG an Annual Report with respect to the status and findings of BCBSC's compliance activities.

The Annual Reports shall include:

1. any change in the identity or position description of the Compliance Officer and/or members of the Compliance Committee described in section III.A;

- 2. a certification by the Compliance Officer that:
 - a. all covered individuals have completed the annual Code of Conduct certification required by section III.B.1; and
 - b. all covered individuals have completed the training and executed the certification required by section III.C;
- 3. notification of any changes or amendments to the Code of Conduct or 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 contract and compliance engagement, including a copy of the methodology used;
- 5. BCBSC's response/corrective action plan to any issues raised by the Independent Review Organization;
- 6. a summary of misconduct reported throughout the course of the previous twelve (12) months pursuant to III.H;
- 7. a copy of the confidential disclosure log required by section III.E;
- 8. a description of any personnel action (other than hiring) taken by BCBSC as a result of the obligations in section III.F;
- 9. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that BCBSC has

committed a crime, has engaged in fraudulent activities, or other misconduct which have been 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 requests for information;

- 10. a corrective action plan to address the misconduct identified in section III.H; and
- 11. a listing of all of the BCBSC's health care contracts.

The first Annual Report shall be received by the OIG no later than one year and thirty (30) 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) BCBSC 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. There shall also be a statement by the Chairman of the Board that the Board of Directors has verified that, to the best of its knowledge, the requirements of this CIA have been met and that supporting documentation is available for inspection.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

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, D.C. 20201
Phone 202.619.2078
Fax 202.205.0604

HCFA:

Deputy Director, Medicare Contractor Management Center for Beneficiary Services Health Care Financing Administration Mail Stop: C5-16-03 7500 Security Boulevard Baltimore, Maryland Tel. 410.786.6686 Fax. 410.786.5487

DHCPF:

Office of Program Development
Department of Health Care Policy and Financing
1575 Sherman Street
Denver, Colorado 80203-1714
Tel. 303.866.3227
Fax. 303.866.2803

BCBSC:

Blue Cross and Blue Shield of Colorado 700 Broadway Denver, Colorado 80273 Tel. 303.831.2828

Fax. 303.830.0887

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 and photocopy BCBSC's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) BCBSC's compliance with the terms of this CIA; and (b) BCBSC's compliance with the requirements of the health care contracts it administers. The documentation described above shall be made available by BCBSC 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 the covered individuals who consent to be interviewed at the individuals's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the covered individual and OIG. BCBSC agrees to assist OIG in contacting and arranging interviews with such covered individual upon OIG's request. BCBSC's officers and employees may elect to be interviewed with or without a representative of BCBSC present.

VIII. DOCUMENT AND RECORD RETENTION

BCBSC shall maintain for inspection all documents and records relating to the health care contracts 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 BCBSC prior to any release by OIG of information submitted by BCBSC pursuant to its obligations under this CIA and identified upon submission by BCBSC as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. BCBSC 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.

X. Breach and Default Provisions

BCBSC 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. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, BCBSC 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 the day after the date the obligation becomes due and concluding at the end of the term of this CIA, BCBSC 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 BCBSC fails 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 BCBSC:
- 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 the award of a Federal government contract or 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 BCBSC 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, BCBSC's business operations related to the health care contracts; or (ii) is in a position for which the person's salary or the items or services rendered are paid in whole or part, directly or indirectly, by health care contracts or otherwise with Federal funds (this Stipulated Penalty shall not be demanded for any time period during which BCBSC 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 charged with a criminal offense related to any health care contract or Federal health care program; or (ii) is suspended, debarred, or proposed for exclusion, and that person has responsibility for, or involvement with, BCBSC's business operations related to the Federal health care programs or health care contracts (this Stipulated Penalty shall not be demanded for any time period before ten (10) days after BCBSC 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 the BCBSC fails to grant access) for each day BCBSC 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 BCBSC of the failure to comply) for each day BCBSC fails to comply fully and adequately with any other obligation of this CIA. In its notice to BCBSC, the OIG shall state the specific grounds for its determination that the BCBSC 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 BCBSC has failed to comply with any of the obligations described in section X.A and determining that Stipulated Penalties are appropriate, OIG shall notify BCBSC by personal service or certified mail of: (a) BCBSC'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, BCBSC 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 BCBSC elects to request an ALJ hearing, the

Stipulated Penalties shall continue to accrue until BCBSC cures, to the OIG's satisfaction, the alleged breach in dispute. In the event the ALJ (or, if appealed, the DAB) determines BCBSC was not in breach of this CIA, or has cured any breach, no Stipulated Penalties shall be due for any period of time when BCBSC was in compliance with the CIA. 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. BCBSC 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 BCBSC 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 BCBSC receives OIG's written denial of such request or the original deadline, whichever is later. 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 BCBSC 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 BCBSC constitutes an independent basis for BCBSC'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 BCBSC has materially breached this CIA and that exclusion should be imposed, the OIG shall notify BCBSC by certified mail of: (a) BCBSC'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. BCBSC 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. BCBSC 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) BCBSC has begun to take action to cure the material breach; (ii) BCBSC is pursuing such action with due diligence; and (iii) BCBSC 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, BCBSC fails to satisfy the requirements of section X.C.2, OIG may exclude BCBSC from participation in the Federal health care programs. OIG will notify BCBSC in writing of its determination to exclude BCBSC (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 BCBSC is excluded under the provisions of this CIA, BCBSC 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 BCBSC to report a 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 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 BCBSC 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, BCBSC 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. § 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 BCBSC was in full and timely compliance with the obligations of this CIA for which the OIG demands payment; and (b) the period of noncompliance. BCBSC 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 BCBSC to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that BCBSC 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 based on a material breach of this CIA shall be: (a) whether BCBSC 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 cannot be cured within the 35 day period, but that: (i) BCBSC has begun to take action to cure the material breach; (ii) BCBSC is pursuing such action with due diligence; and (iii) BCBSC has provided to OIG 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. BCBSC's election of its contractual right to appeal

to the DAB shall not abrogate the OIG's authority to exclude BCBSC 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 BCBSC may request review of the ALJ decision by the DAB.

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, BCBSC, OIG, HCFA, and DHCPF agree as follows:

- A. This CIA shall be binding on the successors, assigns and transferees of BCBSC, including any entities involved in a merger, acquisition, or partnership;
- 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 BCBSC signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG, HCFA, and DHCPF signatories represent that they are signing this CIA in their official capacity and that they are authorized to execute this CIA.

ON BEHALF OF BLUE CROSS BLUE SHIELD OF COLORADO

MICHAEL HUOTARI

Executive Vice President and General Counsel

Blue Cross Blue Shield of Colorado

7-28-99

DATE

JAMES LYONS

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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

7/9/99 DATE

ON BEHALF OF THE HEALTH CARE FINANCING ADMINISTRATION OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES

MARJORIE KANOF, M.D.

Deputy Director for Medicare Contractor Management

Center for Beneficiary Services

Health Care Financing Administration

MICHELLE SNYDER

Chief Financial Officer

Health Care Financing Administration

15 Jul 99

ON BEHALF OF THE COLORADO DEPARTMENT OF HEALTH CARE POLICY AND FINANCE

Director, Office of Program Development