

**INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
WARREN BUCK ELK**

I. PREAMBLE

Warren Buck Elk (Buck Elk) hereby enters into this Integrity Agreement (Agreement) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance by Buck Elk, and by all Covered Persons and Covered Entities (as these terms are defined herein) with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care programs). This Agreement applies to Buck Elk and to any Covered Entities. Contemporaneously with this Agreement, Buck Elk is entering into a Settlement Agreement with the United States, and this Agreement is incorporated by reference into the Settlement Agreement.

II. TERM OF THE AGREEMENT

A. The period of the compliance obligations assumed by Buck Elk under this Agreement shall be five (5) years from the Effective Date of this Agreement. The Effective Date of this Agreement shall be the date on which the final signatory executes this Agreement (Effective Date). Each one-year period beginning with the one-year period following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days from OIG's receipt of: (1) Buck Elk's final Annual Report, or (2) any additional materials submitted by Buck Elk pursuant to OIG's request, whichever is later.

C. The scope of this Agreement shall be governed by the following definitions:

1. "Covered Entity" includes: (a) any entity in which Buck Elk, after the Effective Date, acquires an ownership or control interest, as defined in 42 U.S.C. § 1320a-3(a)(3), or (b) any entities that Buck Elk operates or

has a management contract or arrangement to provide management and administrative services that gives him control over the day-to-day operations over the organization or entity. The Pine Ridge and Eagle Butte dialysis facilities that Buck Elk owned in part prior to this Agreement are not Covered Entities.

2. "Covered Persons" includes:

a. Buck Elk; and

b. all employees, contractors, subcontractors, agents, and other persons who on a regular basis (i.e., more often than two weeks over a 52-week period) on behalf of any Covered Entity: (1) perform patient care duties; (2) make assessments of patients that affect treatment decisions; (3) perform functions relating to quality of care; (4) make decisions or provide oversight about staffing, patient care, policies and procedures, or this Agreement; or (5) perform any function that relates to or is covered by this Agreement, including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions (excluding the Monitor).

III. INTEGRITY OBLIGATIONS

Each Covered Entity shall establish a compliance program that includes the following elements.

A. Compliance Contact.

Within 30 days after the Effective Date, each Covered Entity shall designate a person to be responsible for compliance activities (Compliance Contact). Each Covered Entity shall maintain a Compliance Contact for the term of this IA. The Compliance Contact shall be responsible for: (1) developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with Federal health care program requirements; (2) monitoring day-to-day compliance activities; and (3) meeting all reporting obligations created under this Agreement.

Each Covered Entity shall report to OIG, in writing, any changes in the identity or job responsibilities of the Compliance Contact, or any actions or

changes that would affect the Compliance Contact's ability to perform the duties necessary to meet the obligations in this Agreement, within 15 days after such change. The name, address, telephone number, and a description of any job responsibilities performed by the Compliance Contact shall be included in the Implementation Report.

B. Posting of Notice

Within the 90 days after the Effective Date, each Covered Entity shall post in a prominent place, accessible to all patients and Covered Persons, a notice detailing its commitment to comply with all Federal health care program requirements in the conduct of its business.

This notice shall include the following information: (i) a means (e.g., telephone number or address) by which quality of care concerns and other issues may be reported anonymously; (ii) the Covered Entity's commitment to maintain the confidentiality of the report; and (iii) notification that reporting concerns and issues will not result in retribution or retaliation by the Covered Entity.

This notice shall also include the HHS OIG Fraud Hotline telephone number (1-800-HHS-TIPS) as a confidential means by which suspected fraud or abuse in the Federal health care programs may be reported.

A copy of this notice shall be included in the Implementation Report.

C. Written Policies and Procedures

Within 90 days after the Effective Date, each Covered Entity shall develop, implement, and distribute written Policies and Procedures to all Covered Persons. In addition, each Covered Entity shall make the promotion of, and adherence to, the written Policies and Procedures an element in evaluating the performance of all employees. The written Policies and Procedures shall, at a minimum, set forth:

- a. Measures designed to ensure that each Covered Entity fully complies with Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and all applicable regulations, directives, and guidelines promulgated pursuant to these statutes, including, but not limited to, 42 C.F.R. Part 405 Subpart U (Conditions for Coverage of Suppliers of End-Stage

Renal Disease (ESRD) Services), and any other state or local statutes, regulations, directives, or guidelines that address quality of care in facilities that furnish dialysis services;

- b. Measures designed to ensure that all members of each Covered Entity's staff are qualified to perform the duties and the responsibilities assigned to them to meet such Federal, State, and local professional requirements as may apply;
- c. Measures designed to ensure that a functional, safe, sanitary, and comfortable environment for patients and personnel exists, and reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards;
- d. Measures designed to ensure that any trainees utilized in providing ESRD services are under the direct supervision of qualified professional personnel;
- e. Measures designed to ensure that all personnel participate in educational programs on a regular basis, and that these programs cover initial orientation, and continuing inservice training, including procedures for infection control;
- f. Measures designed to ensure that patient care policies at each Covered Entity's ESRD facilities meet the requirements of 45 C.F.R. § 405.2136(f);
- g. Measures designed to ensure that for patients at each Covered Entity's ESRD facilities there is evaluation of the progress each patient is making toward the goals stated in the patient's long term program and patient's care plan, and that such evaluations are carried out through regularly scheduled conferences, with participation by the staff involved in the patient care, and in accordance with 42 C.F.R. § 405.2137;
- h. Measures designed to ensure that the health care of every patient is under the continuing supervision of a physician and that a physician is available in emergency situations;
- i. Measures designed to ensure that for patients at each Covered Entity's ESRD facilities the governing body of the facility

designates a qualified physician as director of the ESRD services in accordance with 42 C.F.R. § 405.2161; and that the appointment is made upon the recommendation of the facility's organized medical staff, if there is one;

- j. Measures designed to ensure that all patients in each Covered Entity's ESRD facilities are fully informed: (a) of their rights and responsibilities, and of all the rules and regulations governing patient conduct and responsibilities; (b) of services available in the facility and of related charges including charges for services not covered under title XVIII of the Social Security Act; (c) by a physician of their medical condition unless medically contraindicated; (d) regarding the facility's reuse of dialysis supplies, including hemodialyzers; and (e) regarding their suitability for transplantation and home dialysis;
- k. Measures designed to ensure that all patients in each Covered Entity's ESRD facilities: (a) are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research; and (b) are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees, and are given advance notice to ensure orderly transfer or discharge;
- l. Measures designed to ensure that all patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment;
- m. Measures designed to ensure that all patients are ensured confidential treatment of their medical and personal records, and may approve or refuse release of such records to any individual outside the facility, except in the case of their transfer to another health care institution as required by Federal, State, or local law and the Secretary for proper administration of the program;
- n. Measures designed to ensure that all patients are encouraged and assisted to understand and exercise their rights and that grievances and recommended changes in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction

over the facility, through any representative of the patient's choice, without restraint or interference and without fear of discrimination or reprisal;

- o. Measures designed to ensure that for patients at each Covered Entity's ESRD facilities complete medical records are maintained on all patients in accordance with 42 C.F.R. § 405.2139 and accepted professional standards and practices related to information in the medical record, protection of medical records information, completion of medical records, centralization of clinical information, retention and preservation of records, efficient processing of medical records, and transfer of medical information;
- p. Measures designed to ensure that the physical environment in which the ESRD services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public in accordance with factors listed in 42 C.F.R. § 405.2140;
- q. Measures designed to ensure that properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and non-medical emergencies in accordance with 42 C.F.R. § 405.2162;
- r. Measures designed to ensure cooperation by the Covered Persons with the Monitor in the performance of his or her duties as set forth *infra*;
- s. Measures designed to ensure that compliance issues are identified internally (*e.g.*, through reports to supervisors, hotline complaints, internal audits, patient satisfaction surveys, CMS quality indicators, facility-specific key indicators, or internal surveys) or externally (*e.g.*, through CMS or state survey agency reports, consultants, or Monitor's Reports) and are promptly and appropriately investigated and, if the investigation substantiates compliance issues, each Covered Entity implements effective and timely corrective action plans and monitors compliance with such plans;
- t. Measures designed to ensure that contractors, subcontractors and agents that fall within the ambit of Covered Persons are

appropriately supervised to ensure that they are acting within the parameters of the Policies and Procedures and the requirements of Federal health care programs;

- u. Measures designed to ensure that appropriate and qualified individuals perform the internal quality audits and reviews;
- v. Nonretaliation policies and methods for employees to make disclosures or otherwise report on compliance issues through the Disclosure Program required by Section III.E; and
- w. Measures designed to ensure that, pursuant to 42 C.F.R. § 405.2137, each Covered Entity's ESRD facilities maintain and implement for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality.

Within 90 days after the Effective Date, each Covered Person shall certify in writing that he or she has received, read, understood, and shall abide by each Covered Entity's written Policies and Procedures. New Covered Persons shall receive and review the written Policies and Procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 90 days after the Effective Date, whichever is later.

At least annually (and more frequently if appropriate), each Covered Entity shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

Copies of the written Policies and Procedures shall be included in the Implementation Report. Copies of any written Policies and Procedures that are subsequently revised shall be included in the next Annual Report along with a summary of any change or amendment to each Policy and Procedure required by this Section and the reason for each change.

D. Training and Education.

1. General Training. Within ninety (90) days after the Effective Date, each Covered Entity shall provide at least two (2) hours of general training to each Covered Person.¹

This training, at a minimum, shall cover the following topics:

- a. The requirements of this Agreement;
- b. an overview of the Covered Entity's compliance program; and
- c. the written Policies and Procedures developed pursuant to Section III.C, above.

New Covered Persons shall receive the general training described above within thirty (30) days after becoming a Covered Person, or within ninety (90) days after the Effective Date, whichever is later. After receiving the initial General Training, described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. Specific Training. Within ninety (90) days after the Effective Date, each Covered Person who is involved directly or indirectly in the delivery of patient care (including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions) shall receive at least eight (8) hours of training in addition to the General Training required above. This training shall include a discussion of the policies and procedures set forth in Section III.C, including, but not limited to:

- a. Required qualifications of members of the staff to meet Federal, State, and local professional requirements as may apply;

¹Any nonemployee who is hired on a temporary basis (regardless of whether he or she is considered a "Covered Person") is required to follow the policies and procedures of the facility and this Agreement. Each Covered Entity shall ensure that there is sufficient supervision to ensure that a temporary nonemployee is acting within the parameters of such policies and procedures. Any temporary nonemployee who works in a Covered Entity's facilities for more than a thirty (30) day period, regardless of how many days during that period the person is actually present in the facility, must complete the training requirements set forth herein.

- b. Orientation to the facility and the staff's work responsibilities upon employment;
- c. Policies, procedures, and other requirements applicable to the documentation of medical records;
- d. Procedures for contacting medical staff in case of patient emergency; and
- e. Processes and authorization for writing prescriptions, long-term programs, and patient care plans.

3. Certification. Each individual that is required to receive training shall certify in writing, or in electronic form if the training is computerized, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Contact shall retain the certifications along with all training materials. The training materials shall be provided in the Implementation Report, and to the extent the training is revised, shall also be included in the Annual Reports. The certifications shall be made available to OIG, upon request.

4. Qualifications of Trainer(s). Persons providing the training shall be knowledgeable about ESRD dialysis services and care.

5. Update of Training. Each Covered Entity shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during the Claims Review, and any other relevant information.

6. Computer Based Training. Each Covered Entity may provide the training required under this Agreement through appropriate computer-based training approaches. If a Covered Entity chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

E. Independent Monitor

Within sixty (60) days after the Effective Date each Covered Entity shall retain an appropriately qualified monitoring team (the "Monitor"), appointed by the OIG

after consultation with Buck Elk. The Monitor may retain additional personnel, including, but not limited to, independent consultants, if needed to help meet the Monitor's obligations under this Agreement. Buck Elk shall be responsible for all costs incurred by the Monitor, including, but not limited to, travel costs, consultants, administrative personnel, office space and equipment, or additional personnel. The Monitor shall charge a reasonable amount for his or her fees and expenses. Failure to pay the Monitor within thirty (30) calendar days of submission of its invoices for services previously rendered shall constitute a breach of the Agreement and shall subject Buck Elk to one or more of the remedies set forth in Section X *infra*. The Monitor may be removed solely at the discretion of the OIG. If the Monitor resigns or is removed for any reason prior to the termination of the Agreement, Buck Elk shall retain another Monitor appointed by the OIG, with the same functions and authorities. The Monitor may confer and correspond with Buck Elk and OIG on an *ex parte* basis.

1. The Monitor shall be responsible for assessing the effectiveness, reliability and thoroughness of the following:
 - a. each Covered Entity's internal quality control systems, including, but not limited to:
 - (1) whether the systems in place to promote quality of care and to respond to quality of care issues are acting in a timely and effective manner;
 - (2) whether the communication system is effective, allowing for accurate information, decisions, and results of decisions to be transmitted to the proper individuals in a timely fashion; and
 - (3) whether the training programs are effective and thorough.
 - b. each Covered Entity's response to quality of care issues, which shall include an assessment of:
 - (1) the Covered Entity's ability to identify the problem;
 - (2) the Covered Entity's ability to determine the scope of the problem, including, but not limited to whether the problem is isolated or systemic;

- (3) the Covered Entity's ability to create a corrective action plan to respond to the problem;
 - (4) the Covered Entity's ability to execute the corrective action plan; and
 - (5) the Covered Entity's ability to evaluate whether the assessment, corrective action plan, and execution of that plan was effective, reliable, and thorough.
- c. Each Covered Entity's development and implementation of corrective action plans and the timeliness of such actions;
 - d. Each Covered Entity's proactive steps to ensure that each patient receives care in accordance with:
 - (1) basic care, treatment and protection from harm standards;
 - (2) the rules and regulations set forth in 42 C.F.R. Part 405 Subpart U;
 - (3) state and local statutes, regulations, and other directives or guidelines; and
 - (4) the policies and procedures adopted by the Covered Entity and set forth in this Agreement.

2. The Monitor shall have:

- a. immediate access to facilities, at any time and without prior notice, to assess compliance with this Agreement, to assess the effectiveness of the internal quality assurance mechanisms, and to ensure that the data being generated is accurate;
- b. immediate access to: (1) the CMS quality indicators; (2) internal or external surveys or reports; (3) hotline complaints; (4) any patient satisfaction surveys; (5) staffing data in the format requested by the Monitor, including reports of any facility where more than ten (10) percent of the staff are hired on a temporary basis; (6) reports of abuse, neglect, or an incident that required hospitalization or emergency room treatment; (7) reports of any

incident involving a patient that prompts a full internal investigation; (8) patient records; (9) documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, or other such committee; and (10) any other data in the format the Monitor determines relevant to fulfilling the duties required under this Agreement; and

- c. immediate access to patients, and staff for interviews outside the presence of the Covered Entity's supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals. The Monitor shall give full consideration to an individual's clinical condition before interviewing a patient.

3. *Buck Elk and each Covered Entity's Obligations.* Buck Elk and each Covered Entity shall:

- a. ensure the Monitor's immediate access to the facilities, individuals, and documents, and assist in obtaining full cooperation by current employees, contractors and agents;
- b. provide the Monitor a report monthly, or sooner if requested by the Monitor, regarding each of the following occurrences:
 - (1) Deaths or injuries related to delay of care;
 - (2) Deaths or injuries related to use of medications;
 - (3) Deaths or injuries related to abuse or neglect (as defined in the applicable Federal guidelines);
 - (4) Strikes or other work actions; and
 - (5) Any other incident that involves or causes actual harm to a patient when such incident prompts a full internal investigation.

Each such report shall contain the full name, social security number, and date of birth of the patient(s) involved, the date of death or incident, and a brief description of the events surrounding the death or incident.

- c. assist in locating and, if requested, obtaining cooperation from past employees, contractors, agents, and residents, patients, and their families;
- d. provide access to current patients, and contact information for their families and guardians, and not impede their cooperation with the Monitor;
- e. provide the last known contact information for former patients, their families, or guardians consistent with the rights of such individuals under state or Federal law, and not impede their cooperation;
- f. address any written recommendation made by the Monitor either by substantially implementing the Monitor's recommendations or by explaining in writing why it has elected not to do so;
- g. pay the Monitor's bills within 30 days of receipt. While Buck Elk must pay all the Monitor's bills within 30 days, Buck Elk may bring any disputed Monitor's Costs or bills to OIG's attention; and
- h. not sue or otherwise bring any action against the Monitor related to any findings made by the Monitor or related to any exclusion or other sanction of Buck Elk or a Covered Entity under this Agreement; provided, however, that this clause shall not apply to any suit or other action based solely on the dishonest or illegal acts of the Monitor, whether acting alone or in collusion with others.

4. *The Monitor's Obligations.* The Monitor shall:

- a. respect the legal rights, privacy, and dignity of all Covered Persons and patients;
- b. where independently required by applicable law or professional licensing standards, to report any finding to an appropriate regulatory or law enforcement authority, simultaneously submit copies of such reports to the OIG, to the Covered Entity, and to Buck Elk;

c. at all times act reasonably in connection with its duties under the Agreement including when requesting information from a Covered Entity or Buck Elk;

d. simultaneously provide quarterly reports to each Covered Entity, to Buck Elk, and to OIG concerning the findings made to date;

e. submit bills to Buck Elk on a consolidated basis no more than once per month, and submit an annual summary representing an accounting of its costs throughout the year to Buck Elk and to OIG. The Monitor shall submit to Buck Elk and the OIG an annual report representing an accounting of its costs throughout the year;

f. not be bound by any other private or governmental agency's findings or conclusions, including, but not limited to CMS, or the state survey agency. Likewise, such private and governmental agencies shall not be bound by the Monitor's findings or conclusions. The Monitor's reports shall not be the sole basis for determining deficiencies by the state survey agencies. The parties agree that CMS and its contractors shall not introduce any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence into any proceeding involving a Medicare or Medicaid survey, certification, or other enforcement action against any Covered Entity or Buck Elk, and any Covered Entity or Buck Elk shall similarly be restricted from using material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence in any of these proceedings. Nothing in the previous sentence, however, shall preclude the OIG, Buck Elk, or a Covered Entity from using any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor in any action under the Agreement or pursuant to any other OIG authorities or in any other situations not explicitly excluded in this subsection;

g. abide by the legal requirements of each Covered Entity to maintain the confidentiality of each patient's personal and clinical records. Nothing in this subsection, however, shall limit or affect the Monitor's obligation to provide information, including information from patient clinical records, to the OIG, and, when legally or professionally required, reporting to other agencies;

h. abide by the provisions of the Health Insurance Portability and Accountability Act ("HIPAA") of 1996 to the extent required by law including, without limitation, entering into a business associate agreement with Covered Entity facilities;

i. except to the extent required by law, maintain the confidentiality of any proprietary financial and operational information, processes, procedures and forms obtained in connection with its duties under this Agreement and not comment publicly concerning its findings except to the extent authorized by the OIG; and

j. visit each Covered Entity's facilities as often as the Monitor believes it necessary to perform its functions.

F. Disclosure Program.

Within ninety (90) days after the Effective Date, each Covered Entity shall establish a Disclosure Program that includes a mechanism (e.g., a toll-free compliance telephone line) to enable individuals to disclose to the Compliance Contact or some other person who is not in the reporting individual's chain of command any identified issues or questions associated with the Covered Entity's policies, conduct, practices, or procedures with respect to quality of care or a Federal health care program, believed by the individual to be a potential violation of criminal, civil, or administrative law or the applicable standard of care. Each Covered Entity shall appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas such as the waiting rooms).

The Disclosure Program shall emphasize a nonretribution, nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Upon receipt of a disclosure, the Compliance Contact (or designee) shall gather the information in such a way as to elicit all relevant information from the disclosing individual. The Compliance Contact (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, the Covered Entity shall conduct an internal review of the allegations set forth in such

a disclosure and ensure that proper follow-up is conducted, including that the inappropriate or improper practice ceases immediately.

The Compliance Contact shall maintain a disclosure log, which shall include a record and summary of each allegation received (whether anonymous or not), the status of the respective investigations, and any corrective action taken in response to the investigation. The disclosure log shall be sent to the Monitor not less than weekly and shall be made available to the OIG upon request.

G. Ineligible Persons.

1. *Definitions.* For purposes of this Agreement:

a. an “Ineligible Person” shall include an individual or entity who:

i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or

ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.

b. “Exclusion Lists” include:

i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>); and

ii. the General Services Administration’s List of Parties Excluded from Federal Programs (available through the Internet at <http://epls.arnet.gov>).

c. “Screened Persons” include prospective and current owners, officers, directors, employees, contractors, and agents of each Covered Entity.

2. *Screening Requirements.* Each Covered Entity shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Each Covered Entity shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, and shall require such persons to disclose whether they are an Ineligible Person.
- b. Each Covered Entity shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. Each Covered Entity shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) each Covered Entity to refrain from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

3. *Removal Requirement.* If a Covered Entity or Buck Elk has actual notice that a Screened Person has become an Ineligible Person, the Covered Entity or Buck Elk shall remove such person from responsibility for, or involvement with, Buck Elk's or the Covered Entity's business operations related to the Federal health care programs and shall remove such person from any position for which the person's compensation or the items or services furnished, 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 a Covered Entity or Buck Elk has actual notice that a Screened Person is charged with a criminal offense that falls within the ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during his or her employment or contract term, the Covered Entity or Buck Elk shall take all appropriate actions to ensure that the responsibilities of that person have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

H. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery, Buck Elk or a Covered Entity shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Buck Elk or a Covered Entity conducted or brought by a governmental entity or its agents involving an allegation that Buck Elk or a Covered Entity has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Buck Elk or the Covered Entity shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

In addition, within 15 days after notification, Buck Elk or the Covered Entity shall notify OIG, in writing, of any adverse final determination made by a Federal, State, or local Government agency or accrediting or certifying agency (e.g., JCAHO) regarding quality of care issues.

I. Reporting.

1. *Overpayments.*

a. Definition of Overpayments. For purposes of this Agreement, an “Overpayment” shall mean the amount of money a Covered Entity has received in excess of the amount due and payable under any Federal health care program requirements.

b. Reporting of Overpayments. If, at any time, a Covered Entity identifies or learns of any Overpayment, Buck Elk or the Covered Entity shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, the Covered Entity shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified, within 30 days after identification, the Covered Entity shall notify the payor of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed.

Notification and repayment to the payor shall be done in accordance with the payor's policies, and, for Medicare contractors, shall include the information contained on the Overpayment Refund Form, provided as an Appendix to this Agreement. Notwithstanding the above, notification and repayment of any Overpayment amount that routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Reportable Events.

a. Definition of Reportable Event. For purposes of this Agreement, a "Reportable Event" means anything that involves:

i. a substantial Overpayment; or

ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized; or

iii. a violation of the obligation to provide items or services of a quality that meets professionally recognized standards of health care where such violation has occurred in one or more instances and presents an imminent danger to the health, safety, or well-being of a Federal health care program beneficiary or places the beneficiary unnecessarily in high-risk situations.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. Reporting of Reportable Events. If Buck Elk or a Covered Entity determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, the Covered Entity shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.I.1, and shall include all of the information on the Overpayment Refund Form, as well as:

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

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

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

iii. a description of Buck Elk or the Covered Entity's actions taken to correct the Reportable Event; and

iv. any further steps Buck Elk or the Covered Entity plans to take to address the Reportable Event and prevent it from recurring.

IV. NEW BUSINESS UNITS OR LOCATIONS

In the event that, after the Effective Date, Buck Elk or any Covered Entity sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Buck Elk shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number and/or supplier number, and the corresponding contractor's name and address that has issued each Medicare number. Each new business unit or location of Buck Elk or a Covered Entity shall be subject to all the requirements of this Agreement.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report.

Within one hundred and twenty (120) days after the Effective Date, Buck Elk and each Covered Entity shall submit a written report to OIG summarizing the status of implementation of the requirements of this Agreement. This Implementation Report shall include:

1. the name, address, phone number and position description of all individuals in positions described in section III.A;
2. a copy of the notice each Covered Entity posted in its office as required by Section III.B, a description of where the notice is posted, and the date the notice was posted;
3. the summary of the Policies and Procedures required by section III.C;
4. a description of the training programs required by section III.D, including a description of the targeted audiences and a schedule of when the training sessions were held;
5. a certification by the Compliance Contact that:
 - a. the Policies and Procedures required by section III.C have been developed, are being implemented, and have been made available to all pertinent Covered Persons;
 - b. all Covered Persons have completed the Policies and Procedures certification required by section III.C; and
 - c. all Covered Persons have completed the training and executed the certification required by section III.D.
6. a description of the confidential disclosure program required by section III.F;
7. a summary of personnel actions taken pursuant to section III.G; and
8. a list of Buck Elk's each Covered Entity's location (including mailing addresses), the corresponding name under which each location is doing business, the corresponding telephone numbers and facsimile numbers, each

location's Federal health care program provider identification numbers(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number.

B. Annual Reports. Buck Elk and each Covered Entity shall submit to OIG an Annual Report with respect to the status and findings of its compliance activities over the one year period covered by the Annual Report. Each Annual Report shall include:

1. any change in the identity or position description of individuals in positions described in section III.A, a change in any of the committees' structure or charter, or any change in the internal audit and review program;
2. any changes to the posted notice and the reason for such changes;
3. a certification by the Compliance Contact that:
 - a. all Covered Persons have completed the annual Policies and Procedures certification required by section III.C;
 - b. all Covered Persons have completed the training and executed the certification required by section III.D; and
 - c. the Covered Entity has effectively implemented all plans of correction related to problems identified under this Agreement, the Covered Entity's Compliance Program, or internal audits.
4. notification of any changes or amendments to the Policies and Procedures required by section III.C and the reasons for such changes (*e.g.*, change in contractor policy);
5. the Covered Entity's response/corrective action plan to any issues raised by the Monitor;
6. a copy of the confidential disclosure log required by section III.F (excluding any calls that relate solely to human resources issues);
7. a description of any personnel action (other than hiring) taken by the Covered Entity as a result of the obligations in section III.G, and the name, title, and responsibilities of any person that falls within the ambit of section

III.G.4, and the actions taken in response to the obligations set forth in that section;

8. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Buck Elk or the Covered Entity has committed a crime or has engaged in fraudulent activities, which has been reported pursuant to section III.H. 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; and

9. a description of all changes to the most recently provided list (as updated) of Buck Elk and each Covered Entity's locations (including mailing addresses), the corresponding name under which each location is doing business, the corresponding telephone numbers and facsimile numbers, each location's Federal health care program provider identification numbers(s), and the name, address, and telephone number of the payor (specific contractor) that issued each provider identification number.

The first Annual Report shall be received by the OIG no later than one year and ninety (90) days after the Effective Date. Subsequent Annual Reports shall be submitted no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The Implementation Report and Annual Reports shall include a certification by Buck Elk, under penalty of perjury, that: 1) Buck Elk and each Covered Entity is in compliance with all of the requirements of this Agreement, to the best of his knowledge; and 2) Buck Elk 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, all notifications and reports required under this Agreement shall be submitted to the entities listed below:

OIG: Administrative and Civil Remedies Branch
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, S.W.
Washington, DC 20201
Phone (202) 619-2078
Fax (202) 205-0604

Buck Elk: Warren Buck Elk
924 Ridgeview Court
Rapid City, SD 57702
Phone (605) 348-2618

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 Buck Elk's and any Covered Entity's books, records, and other documents and supporting materials and/or conduct an onsite review of Buck Elk's and any Covered Entity's operations for the purpose of verifying and evaluating: 1) Buck Elk's and Covered Entity's compliance with the terms of this Agreement; and 2) Buck Elk's and Covered Entity's compliance with the requirements of the Federal health care programs in which their facilities participate. The documentation described above shall be made available by Buck Elk and any Covered Entity 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 Covered Entity's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the employee, contractor, or agent and OIG. Buck Elk agrees to assist OIG in contacting and arranging interviews with such employees, contractors, or agents upon OIG's request. A Covered Entity's employees, contractors, and agents may elect to be interviewed with or without a representative of the Covered Entity present.

VIII. DOCUMENT AND RECORD RETENTION

Buck Elk and each Covered Entity shall maintain for inspection all documents and records relating to compliance with this Agreement, one year longer than the term of this Agreement (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 Buck Elk prior to any release by OIG of information submitted by Buck Elk or a Covered Entity pursuant to their obligations under this Agreement and identified upon submission as trade secrets, commercial or financial information and privileged and confidential under the FOIA rules. Buck Elk and any Covered Entity 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

Buck Elk and any Covered Entity are expected to fully and timely comply with all of the obligations herein throughout the term of this Agreement or other time frames herein agreed to.

A. Stipulated Penalties for Failure to Comply with Certain Obligations

As a contractual remedy, Buck Elk and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement (unless a timely written request for an extension has been requested and approved in accordance with Section B below) 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 \$750 (which shall begin to accrue on the day after the date the obligation became due) for each day Buck Elk or a Covered Entity fails to:

- a. have a Compliance Contact in accordance with the requirements of Section III.A;

b. establish and/or post a notice in accordance with the requirements of Section III.B;

c. establish, implement, maintain, distribute, and/or update the written Policies and Procedures in accordance with the requirements of Section III.C;

d. establish and implement a training program in accordance with the requirements of Section III.D.

e. retain and pay a Monitor in accordance with the requirements of Section III.E;

f. obtain and/or maintain the following documentation: Policies and Procedures certifications in accordance with the requirements of Section III.C, training certification(s) in accordance with the requirements of Section III.D, and/or documentation of screening and disclosure requirements in accordance with the requirements of Sections III.F and III.G.

g. screen Screened Persons in accordance with the requirements of Section III.G; or

j. notify OIG of a Government investigation or legal proceeding, in accordance with the requirements of Section III.H.

2. A Stipulated Penalty of \$1,000 (which shall begin to accrue on the day after the date the obligation became due) for each day Buck Elk or Covered Entity fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.

3. A Stipulated Penalty of \$750 for each day Buck Elk or a Covered Entity fails to grant access to the information or documentation as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Buck Elk or a Covered Entity fails to grant access.)

4. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Buck Elk as part of an Implementation Report, Annual Reports, additional documentation to a Report (as requested by OIG), or as otherwise required by this Agreement.

5. A stipulated penalty of \$2,500 (which shall begin to accrue ten (10) days after the date OIG provides notice to Buck Elk of the failure to comply) for each day Buck Elk fails to comply fully and adequately with any of his obligations with respect to the Monitor, as set forth in section III.E.3. In its notice to Buck Elk, the OIG shall state the specific grounds for its determination that Buck Elk has failed to comply fully and adequately with the Agreement obligation(s) at issue.

6. A Stipulated Penalty of \$750 for each day Buck Elk or a Covered Entity fails to comply fully and adequately with any obligation of this Agreement. OIG shall provide notice (Notice) to Buck Elk or the Covered Entity stating the specific grounds for its determination that Buck Elk or the Covered Entity has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps Buck Elk or the Covered Entity shall take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Buck Elk or the Covered Entity receives this Notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-5 of this Section.

B. Timely Written Requests for Extensions

Buck Elk or any Covered Entity may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or Report required by this Agreement. 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 Buck Elk or a Covered Entity fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or Report shall not begin to accrue until three business days after Buck Elk or a Covered Entity receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. Demand Letter. Upon a finding that Buck Elk or a Covered Entity has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Buck Elk or the Covered Entity of: (a) Buck Elk's or the Covered Entity's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, Buck Elk or a Covered Entity shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send in writing to OIG a request for a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Buck Elk or a Covered Entity elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Buck Elk or a Covered Entity cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under Section X.D.

3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. Independence from Material Breach Determination. Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Buck Elk or a Covered Entity has materially breached this Agreement, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this Agreement

1. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this Agreement by Buck Elk or a Covered Entity constitutes an independent basis for Buck Elk's or the Covered Entity'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 Buck Elk or a Covered Entity has materially breached this Agreement and that exclusion should be imposed, the OIG shall notify Buck Elk or the Covered Entity by certified mail of: a) the material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (Notice of Material Breach and Intent to Exclude). The exclusion may be directed at one or more Covered Entities or corporate entities, depending upon the facts of the breach.

2. *Opportunity to cure.* Buck Elk or a Covered Entity 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. Buck Elk and the Covered Entity are in full compliance with this Agreement;
- b. The alleged material breach has been cured; or
- c. The alleged material breach cannot be cured within the thirty-five (35) day period, but that: (1) Buck Elk or the Covered Entity has begun to take action to cure the material breach; (2) Buck Elk or the Covered Entity is pursuing such action with due diligence; and (3) Buck Elk or the Covered Entity 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, Buck Elk or a Covered Entity fails to satisfy the requirements of section X.C.2, OIG may exclude Buck Elk and the Covered Entity from participation in the Federal health care programs. OIG shall notify Buck Elk and the Covered Entity in writing of its determination to excluded Buck Elk and the Covered Entity (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 shall also apply to all other Federal procurement and non-procurement programs. If Buck Elk or a Covered Entity is excluded under the provisions of this Agreement, Buck Elk or the Covered Entity may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

4. *Material Breach.* A material breach of this Agreement means:
- a. a failure to meet an obligation under the Agreement that has a material impact on the quality of care rendered to any residents or patients of a Covered Entity;
 - b. repeated or flagrant violations of the obligations under this Agreement, including, but not limited to, the obligations addressed in section X.B of this Agreement;
 - 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, pay or use the Monitor in accordance with section III.D.

E. Dispute Resolution

1. *Review Rights.* Upon the OIG's delivery to Buck Elk or to a Covered Entity of its Noncompliance Notice, Demand Letter, or Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this Agreement, Buck Elk or the Covered Entity shall be afforded certain review rights comparable to those set forth in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the specific performance, Stipulated Penalties, or exclusion sought pursuant to this Agreement. Specifically, an action for specific performance, a demand for payment of Stipulated Penalties, or an action for 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), a request for a hearing involving specific performance or Stipulated Penalties shall be made within fifteen (15) days of the date of the Demand Letter, and a request for a hearing involving exclusion shall be made within thirty (30) days of the date of the Exclusion Letter.

2. *Specific Performance 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 specific performance of Agreement provisions shall be: a) whether, at the time specified in the Noncompliance Notice, Buck Elk or a Covered Entity was in full and timely compliance with the obligations of this Agreement for which the OIG seeks specific performance; and b) whether Buck Elk or a Covered Entity failed to cure. Buck Elk or the Covered Entity shall have the burden of proving his or its full and timely compliance and the steps taken to cure the noncompliance, if any. If the ALJ finds

for the OIG, Buck Elk or the Covered Entity shall take the actions OIG deems necessary to cure within (20) days after the ALJ issues such a decision notwithstanding that Buck Elk or the Covered Entity may request review of the ALJ decision by the DAB.

3. *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 Agreement shall be: (a) whether Buck Elk or the Covered Entity was in full and timely compliance with the obligations of this Agreement for which the OIG demands payment; and (b) the period of noncompliance. Buck Elk or the Covered Entity shall have the burden of proving his or 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 Agreement and orders Buck Elk or the Covered Entity to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision notwithstanding that Buck Elk or the Covered Entity may request review of the ALJ decision by the DAB.

4. *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 Agreement shall be: a) whether Buck Elk or a Covered Entity was in material breach of this Agreement; 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 (1) Buck Elk or the Covered Entity has begun to take action to cure the material breach, (2) Buck Elk or the Covered Entity is pursuing such action with due diligence, and (3) Buck Elk or the Covered Entity 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. Buck Elk's or a Covered Entity's election of his or its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Buck Elk or a Covered Entity 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 Buck Elk or a Covered Entity may request review of the ALJ decision by the DAB.

5. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this Agreement agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this Agreement and Buck Elk agrees to waive any right he may have to appeal the decision

administratively, judicially or otherwise seek review by any court or other adjudicative forum.

6. *Review by Other Agencies.* Nothing in this Agreement shall affect the right of CMS or any other federal or state agency to enforce any statutory or regulatory authorities with respect to Buck Elk's and any Covered Entity's compliance with applicable state and Federal health care program requirements.

XI. EFFECTIVE AND BINDING AGREEMENT

A. This Agreement shall be binding on the successors, assigns, and transferees of Buck Elk. The OIG may decide to waive this successor liability provision upon consideration of verified proof to the OIG's satisfaction that: (1) Buck Elk has wholly divested himself of any interest or involvement, direct or indirect, in the transferred or assigned entity, (2) that the successor is an independent entity unrelated in any manner to Buck Elk, (3) that the successor has acquired its interest at fair market value in an arms' length transaction, and (4) that the successor has policies, procedures, and practices in effect to ensure its compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs, as well as a history of such compliance. The OIG may also request and consider other information regarding relevant factors as appropriate. The OIG will notify Buck Elk of its decision in writing.

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

C. The undersigned Buck Elk signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

ON BEHALF OF WARREN BUCK ELK

Warren Buck Elk
Warren Buck Elk

6-9-06
DATE

Legal Counsel to Warren Buck Elk:

Robert R. Ries
Bob Ries
Law Office of Robert R. Ries
555 Republic Drive, Suite 200
Dallas, Texas 75074

6-12-06
DATE

Terry Pechota
Terry Pechota, Esq.
Pechota Law Office
1617 Sheridan Lake road
Rapid City, South Dakota 57702

June 9, 2006
DATE

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



GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
U. S. Department of Health and Human Services

6/19/06

DATE