CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
ANNE ARUNDEL MEDICAL CENTER

I. PREAMBLE

Anne Arundel Medical Center 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") whose purpose is to ensure compliance by its physicians, employees, and other health care professionals, as well as all third parties with whom Anne Arundel may choose to engage to act as billing or coding agents or consultants, with the requirements of Medicare, Medicaid and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f))(hereinafter collectively referred to as the "Federal health care programs"). Anne Arundel's compliance with the terms and conditions in this CIA shall constitute an element of Anne Arundel's present responsibility with regard to participation in the Federal health care programs. Contemporaneously with this CIA, Anne Arundel 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 Anne Arundel under this CIA shall be five (5) years from the effective date of this CIA (unless otherwise specified). The effective date of this CIA will be the date on which the final signatory of this CIA executes the CIA. 5 years

III. CORPORATE INTEGRITY OBLIGATIONS

Anne Arundel shall establish a compliance program that includes the following elements:

A. Compliance Officer. Within ninety (90) days after the effective date of this CIA, Anne Arundel shall appoint an individual to serve as Compliance Officer, who shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with the requirements of the Federal health care programs. The Compliance Officer shall be a member of senior management of Anne Arundel, shall make regular (at least quarterly) reports regarding compliance matters

directly to the CEO and/or to the Board of Directors of Anne Arundel, and shall be authorized to report to the Board of Directors at any time. The Compliance Officer shall be responsible for monitoring the day-to-day activities engaged in by Anne Arundel 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, Anne Arundel shall notify OIG, in writing, within fifteen (15) days of such a change.

Anne Arundel shall also appoint a Compliance Committee within ninety (90) days after the effective date of this CIA. The Compliance Committee shall, at a minimum, include the Compliance Officer and any other appropriate officers within the Anne Arundel's corporate structure (e.g., senior executives of each major department, such as billing, clinical, human resources, audit, and operations) as are necessary to meet the requirements of this CIA. The Compliance Officer shall chair the Compliance Committee, and the Committee shall support the Compliance Officer in fulfilling his or her responsibilities.

B. Written Standards

1. *Code of Conduct.* Within ninety (90) days of the effective date of this CIA, Anne Arundel shall establish a Code of Conduct and distribute it to all employees, physicians with privileges, and other health care professionals, as well as all third parties with whom Anne Arundel may choose to engage to act as billing or coding agents or consultants (hereinafter collectively referred to as the "covered individuals"). Anne Arundel shall make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of managers, supervisors, and all other employees. The Code of Conduct shall, at a minimum, set forth:

a. Anne Arundel's commitment to full compliance with all statutes, regulations, and guidelines applicable to Federal health care programs, including its commitment to prepare and submit accurate billings consistent with Federal health care program regulations and procedures or instructions otherwise communicated by the Health Care Financing Administration ("HCFA") and its agents;

b. Anne Arundel's requirement that all covered individuals shall be expected to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Anne Arundel's own policies and procedures (including the requirements of this CIA);

c. the requirement that all covered individuals shall be expected to report suspected violations of any statute, regulation, or guideline applicable to Federal health care programs or of Anne Arundel's own policies and procedures with respect to reimbursement from Federal health care programs;

d. the possible consequences to both Anne Arundel and to any covered individuals of the failure to comply with all statutes, regulations, and guidelines applicable to Federal health care programs and with Anne Arundel's own policies and procedures or of failure to report such non-compliance; and

e. the right of all covered individuals to use the confidential disclosure program, as well as Anne Arundel's commitment to confidentiality and non-retaliation with respect to disclosures.

Within ninety (90) days of the effective date of the CIA, all covered individuals shall certify, in writing, that they have received, read, understand, and will abide by Anne Arundel'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 within ninety (90) days of the effective date of the CIA, whichever is later.

Anne Arundel 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.

All of the certifications referred to above will not be required of physicians with privileges who are not employees of Anne Arundel or for whose services Anne Arundel does not seek reimbursement from Federal health care programs, though Anne Arundel will use its best efforts to encourage such physicians to sign the certifications.

2. *Policies and Procedures*. Within ninety (90) days of the effective date of this CIA, Anne Arundel shall develop and initiate implementation of written Policies and Procedures regarding the operation of Anne Arundel's compliance program and its compliance with all federal and state health care statutes, regulations, and guidelines, including the requirements of the Federal health care programs. Among other things, the Policies and Procedures shall be designed to assure that all claims submitted to Medicare and Medicaid are accurate and correctly identify the services rendered, including those services rendered as part of Anne Arundel's outpatient programs and home IV therapy program. In addition, the Policies and Procedures shall include disciplinary guidelines and methods for covered individuals to make disclosures or otherwise report on compliance issues to Anne Arundel management through the Confidential Disclosure Program required by section III.E. Anne Arundel shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. 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 ninety (90) days of the effective date of the CIA, the relevant portions of the Policies and Procedures shall be made available 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. *General Training.* Within ninety (90) days of the effective date of this CIA, Anne Arundel will begin to provide at least two (2) hours of general training to all covered individuals, subject to Section III.C.3 below. The training will be completed within 180 days of the effective date of the CIA. This general training shall explain Anne Arundel's:

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

Persons providing the training must have expertise in the subject area. The training materials shall be made available to OIG upon request.

All covered individuals who have received the general training described above within the six (6) months before the effective date of this CIA need not receive such training again until one year after the effective date of the CIA, provided that they sign the requisite certifications. New covered individuals shall receive the general training described above within thirty (30) days of the beginning of their employment or within 180 days after the effective date of this CIA, whichever is later. Each year thereafter, all covered individuals shall receive one hour of such general training on an annual basis.

2. *Specific Training.* Within ninety (90) days of the effective date of this CIA, Anne Arundel will begin to provide to all covered individuals who are involved directly or indirectly in the delivery of patient care or in the preparation or submission of claims for reimbursement for such care (including, but not limited to, coding and billing) for any Federal health care programs at least four (4) hours of training in addition to the general training required above. The training will be completed within 180 days of the effective date of the CIA. Depending on the individual participants' job duties, this specific training shall include a discussion of:

a. the submission of accurate bills for services rendered to Medicare and/or Medicaid patients;
b. policies, procedures and other requirements applicable to the documentation of medical records;
c. the personal obligation of each individual involved in the billing process to ensure that such billings are accurate;
d. applicable reimbursement rules and statutes;
e. the legal sanctions for improper billings; and

f. examples of proper and improper billing practices.

Persons providing the training must have expertise in the subject area. The training materials shall be made available to OIG upon request.

Affected new covered individuals shall receive this training within thirty (30) days of the beginning of their employment or within 180 days of the effective date of this CIA, whichever is later. If a new covered individual has any responsibility for the preparation or submission of claims or the assignment of procedure codes prior to completing this specific training, a covered individual who has completed the specific training shall review all of the untrained person's work.

All covered individuals who have received the specific training described above within the six (6) months before the effective date of this CIA need not receive such training again until one year after the effective date of the CIA, provided that they sign the requisite certifications. . Every covered individual shall receive such specific training on an annual basis, subject to Section III.C.3 below.

3. *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. The certifications shall be made available to OIG upon request. The training and certifications will not be required of physicians with privileges who are not employees of Anne Arundel or for whose services Anne Arundel does not seek reimbursement from Federal health care programs, though Anne Arundel will use its best efforts to encourage such physicians to attend the training sessions and sign the certifications.

D. Review Procedures. Anne Arundel shall retain an entity, such as an accounting, auditing or consulting firm (hereinafter "Independent Review Organization"), to perform review procedures to assist Anne Arundel in assessing the adequacy of its billing and compliance practices pursuant to this CIA. This shall be an annual requirement and shall cover a twelve (12) month period. The Independent Review Organization must have expertise in the billing, coding, reporting and other requirements of the Federal health care programs from which Anne Arundel seeks reimbursement. The Independent Review Organization must be retained to conduct the audit of the first year within ninety (90) days of the effective date of this CIA.

IRO REQUIREMENT

The Independent Review Organization will conduct two separate engagements. One will be an analysis of Anne Arundel's billing to the Federal health care programs to assist Anne Arundel and OIG in determining compliance with all applicable statutes, regulations, and directives/guidance ("billing engagement"). The second engagement will determine whether Anne Arundel is in compliance with this CIA ("compliance engagement").

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

Each annual billing engagement analysis shall include the following components in its methodology:

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

The billing engagement shall provide:

a. findings regarding Anne Arundel's billing and coding operation (including, but not limited to, the operation of the billing system, strengths and weaknesses of this system, internal controls, effectiveness of the system);
b. findings regarding whether Anne Arundel is submitting accurate claims and cost reports for services billed to the Federal health care programs, including those submitted for outpatient IV therapy and home IV therapy;
c. findings regarding Anne Arundel's procedures to correct inaccurate billings or codings to the Federal health care programs;
d. findings regarding the steps Anne Arundel is taking to bring its operations into compliance or to correct problems identified by the audit.

2. *Compliance Engagement.* An Independent Review Organization shall also conduct a compliance engagement that shall provide findings regarding whether Anne Arundel'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 billing and compliance engagement letter shall be included in each of Anne Arundel's Annual Reports to OIG.

3. *Disclosure of Overpayments and Material Deficiencies.* If, as a result of these engagements, Anne Arundel or the Independent Review Organization identifies any billing, coding or other policies, procedures and/or practices that result in an overpayment, Anne Arundel shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering the deficiency or overpayment and take remedial steps within 60 days of discovery (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the deficiency from recurring. The notice to the payor shall include:

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

If Anne Arundel determines an overpayment represents a material deficiency, contemporaneous with its notification to the payor as provided above, Anne Arundel shall also notify OIG of:

a. a complete description of the material deficiency;
b. the amount of overpayment due to the material deficiency;
c. Anne Arundel's action(s) to correct and prevent such material deficiency from recurring;
d. the payor's name, address, and contact person where the overpayment was sent;
e. the date of the check and identification number (or electronic transaction number) on which the overpayment was repaid.

For purposes of this CIA, an "overpayment" shall mean the amount of money Anne Arundel has received in excess of the amount due and payable under the Federal health care programs' statutes, regulations or program directives, including carrier and intermediary instructions.

For purposes of this CIA, a "material deficiency" shall mean anything that involves: (i) a substantial overpayment or improper payment relating to the Medicare and/or Medicaid programs, or (ii) conduct or policies that clearly violate the Medicare and/or Medicaid statutes, regulations or directives issued by HCFA and/or its agents. A material deficiency may be the result of an isolated event or a series of occurrences.

4. *Verification/Validation.* In the event that the OIG has reason to believe that Anne Arundel's Billing Engagement fails to conform to its obligations under the CIA or indicates improper billings not otherwise adequately addressed in the audit report, and thus determines that it is necessary to conduct an independent review to determine whether or the extent to which Anne Arundel is complying with its obligations under this CIA, Anne Arundel agrees to pay for the reasonable cost of any such review or engagement by the OIG or any of its designated agents.

E. Confidential Disclosure Program. Within ninety (90) days after the effective date of this CIA, Anne Arundel shall establish a Confidential Disclosure Program, which must include measures (e.g., a toll-free compliance telephone line or other effective anonymity mechanisms) to enable employees, contractors, agents or other individuals to disclose to the Compliance Officer, or to some other person not in the reporting individual's chain of command, any identified issues or questions associated with Anne Arundel's policies, practices or procedures with respect to the Federal health care program, believed by the individual to be inappropriate. Anne Arundel 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, Anne Arundel shall conduct an internal review of the allegations set forth in such disclosure and ensure that proper follow-up is conducted.

The Compliance Officer shall maintain a confidential disclosure log, which shall include a record and summary of each allegation received, the status of the respective investigations, and any corrective action taken in response to the investigation.

F. Ineligible Persons.

1. *Definition.* For purposes of this CIA, an "Ineligible Person" shall be any individual or entity who: (i) is currently excluded, suspended, debarred or otherwise ineligible to

participate in the Federal health care programs; or (ii) has been convicted of a criminal offense related to the provision of health care items or services and has not been reinstated in the Federal health care programs after a period of exclusion, suspension, debarment, or ineligibility.

2. *Screening Requirements*. Anne Arundel shall not hire or engage as contractors any Ineligible Person. To prevent hiring or contracting with any Ineligible Person, Anne Arundel 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 (currently available through the Internet at http://www.arnet.gov/epls) and the HHS/OIG List of Excluded Individuals/Entities (currently available through the Internet at http://www.dhhs.gov/progorg/oig) (these lists and reports will hereinafter be referred to as the "Exclusion Lists").

3. *Review and Removal Requirement*. Within ninety (90) days of the effective date of this CIA, Anne Arundel will review its list of current employees, contractors and physicians with staff privileges against the Exclusion Lists. Thereafter, Anne Arundel will review the list once quarterly. If Anne Arundel has notice that an employee, agent, or physician has become an Ineligible Person, Anne Arundel will remove such person from responsibility for, or involvement with, Anne Arundel's business operations related to the Federal health care programs and shall remove such person from any position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions*. If Anne Arundel has notice that an employee or contractor is charged with a criminal offense related to any Federal health care program, or is suspended or proposed for exclusion during his or her employment or contract with Anne Arundel, within 10 days of receiving such notice Anne Arundel will remove such individual from responsibility for, or involvement with, Anne Arundel's business operations related to the Federal health care programs until the resolution of such criminal action, suspension, or proposed exclusion.

G. Notification of Proceedings. Within thirty (30) days of discovery, Anne Arundel 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 Anne Arundel has committed a crime or has engaged in fraudulent activities or any other knowing misconduct. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Anne Arundel shall also provide written notice to OIG within thirty (30) days of the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

H. Reporting.

1. *Credible evidence of misconduct.* If Anne Arundel discovers credible evidence of misconduct from any source and, after reasonable inquiry, has reason to believe that the misconduct may violate criminal, civil, or administrative law concerning Anne Arundel's practices relating to the Federal health care programs, then Anne Arundel shall promptly report the probable violation of law to OIG. Anne Arundel shall make this disclosure as soon as practicable, but not later than thirty (30) days after becoming aware of the existence of the probable violation. Anne Arundel's report to OIG shall include:

a. the findings concerning the probable violation, including the nature and extent of the probable violation;
b. Anne Arundel's actions to correct such probable violation; and
c. any further steps it plans to take to address such probable violation and prevent it from recurring.

To the extent the misconduct involves an overpayment, the report shall include the information listed in section III.D.3 regarding material deficiencies.

2. *Inappropriate Billing.* If Anne Arundel discovers inappropriate or incorrect billing through means other than the Independent Review Organization's engagement, Anne Arundel shall follow procedures in section III.D.3 regarding overpayments and material deficiencies.

IV. NEW LOCATIONS

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

V. IMPLEMENTATION AND ANNUAL REPORTS

A. Implementation Report. Within one hundred and twenty (120) days after the effective date of this CIA, Anne Arundel 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, telephone 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 Anne Arundel'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 made available 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. Anne Arundel shall submit to OIG an Annual Report with respect to the status and findings of Anne Arundel'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 Policies and Procedures required by section III.B and the reasons for such changes (e.g., change in contractor policy);

4. a complete copy of the report prepared pursuant to the Independent Review Organization's billing and compliance engagement, including a copy of the methodology used.

5. Anne Arundel's response/corrective action plan to any issues raised by the Independent Review Organization.

6. a summary of material deficiencies and reported throughout the course of the previous twelve (12) months pursuant to III.D.3 and III.H.

7. a report of the aggregate overpayments that have been returned to the Federal health care programs that were discovered as a direct or indirect result of implementing this CIA. Overpayment amounts should be broken down into the following categories: Medicare, Medicaid (report each applicable state separately) and other Federal health care programs;

8. a copy of the confidential disclosure log required by section III.E;

9. a description of any personnel action (other than hiring) taken by Anne Arundel as a result of the obligations in section III.F;

10. a summary describing any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Anne Arundel has committed a crime or has engaged in fraudulent activities, 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;

11. a corrective action plan to address the probable violations of law identified in section III.H; and

12. a listing of all of Anne Arundel's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding telephone numbers and fax numbers, each location's Federal health care program provider identification number(s) and the payor (specific contractor) that issued each provider identification number.

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

C. Certifications. The Implementation Report and Annual Reports shall include a certification by the Compliance Officer under penalty of perjury, that: (1) Anne Arundel is in compliance with all of the requirements of this CIA, to the best of his or her knowledge; and (2) the Compliance Officer has reviewed the Report and has made reasonable inquiry regarding its content and believes that, upon such inquiry, the information is accurate and truthful.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

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

OIG:

Civil Recoveries Branch - Compliance Unit
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201
Phone 202.619.2078
Fax 202.205.0604

Anne Arundel:

President
Anne Arundel Medical Center
Franklin & Cathedral Streets
Annapolis, MD 21401
ATTN: Compliance Officer
Phone: 410 267 1000
Fax: 410 267 1624

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 Anne Arundel's books, records, and other documents and supporting materials for the purpose of verifying and evaluating: (a) Anne Arundel's compliance with the terms of this CIA; and (b) Anne Arundel's compliance with the

requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by Anne Arundel 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 Anne Arundel's employees or other covered individuals who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Anne Arundel agrees to assist OIG in contacting and arranging interviews with such individuals upon OIG's request. Anne Arundel's employees may elect to be interviewed with or without a representative of Anne Arundel present.

VIII. DOCUMENT AND RECORD RETENTION

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

IX. DISCLOSURES

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

Anne Arundel 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, Anne Arundel and OIG 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 ninety (90) days after the effective date of this CIA and concluding at the end of the term of this CIA, Anne Arundel 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 Anne Arundel fails meet any of the deadlines to submit the Implementation Report or the Annual Reports to OIG.

3. A Stipulated Penalty of $2,000 (which shall begin to accrue on the date the failure to comply began) for each day Anne Arundel:

a. hires or engages as a contractor an Ineligible Person after that person has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program, contrary to the requirements of Section III.F.2 *supra* (this Stipulated Penalty shall not be demanded for any time period during which Anne Arundel 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. retains an employee or contractor or physician with privileges in a position with responsibility for, or involvement with, Anne Arundel's business operations related to the Federal health care programs or in a position for which the person's salary or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds, contrary to the requirements of Section III.F.2 *supra* (this Stipulated Penalty shall not be demanded for any time period during which Anne Arundel 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 Federal health care program, or (ii) is suspended or proposed for exclusion, and that person has responsibility for, or involvement with, Anne Arundel's business operations related to the Federal health care programs (this Stipulated Penalty shall not be demanded for any time period before 10 days after Anne Arundel 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 Anne Arundel fails to grant access) for each day Anne Arundel fails to grant access to the information or documentation as required in section V 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 Anne Arundel of the failure to comply) for each day Anne Arundel fails to comply fully and adequately with any obligation of this CIA. In its notice to Anne Arundel, OIG shall state the specific grounds for its determination that Anne Arundel 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 Anne Arundel has failed to comply with any of the obligations described in section X.A and upon determining that Stipulated Penalties are appropriate, OIG shall notify Anne Arundel by personal service or certified mail of (a) Anne Arundel's failure to comply; and (b) 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, Anne Arundel shall either (a) cure the breach to OIG's satisfaction and pay the applicable stipulated penalties; or (b) request a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the provisions set forth below in section X.D. In the event Anne Arundel elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Anne Arundel cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under section X.C.

2. *Timely Written Requests for Extensions.* Anne Arundel 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 Anne Arundel fails to meet the revised deadline as agreed to by 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 Anne Arundel receives OIG's written denial of such request. A "timely written request" is defined as a request in writing received by OIG at least five (5) business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

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

4. *Independence from Material Breach Determination.* Except as otherwise noted, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a

standard for OIG's determination that Anne Arundel has materially breached this CIA, which decision shall be made at 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 Anne Arundel constitutes an independent basis for Anne Arundel's exclusion from participation in the Federal health care programs, subject to the provisions of subsection 2 below. Upon a determination by OIG that Anne Arundel has materially breached this CIA and that exclusion should be imposed, OIG shall notify Anne Arundel by certified mail of (a) Anne Arundel'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.* Anne Arundel shall have thirty five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to OIG's satisfaction that:

a. With respect to the alleged breach, Anne Arundel 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) Anne Arundel has begun to take action to cure the material breach, (ii) Anne Arundel is pursuing such action with due diligence, and (iii) Anne Arundel 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, Anne Arundel fails to satisfy the requirements of section X.C.2, OIG may exclude Anne Arundel from participation in the Federal health care programs. OIG will notify Anne Arundel in writing of its determination to exclude Anne Arundel (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 Anne Arundel is excluded under the provisions of this CIA, Anne Arundel 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 Anne Arundel 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 OIG's delivery to Anne Arundel 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, Anne Arundel shall be afforded certain review rights comparable to those 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, 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 Anne Arundel was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Anne Arundel 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 OIG with regard to a finding of a breach of this CIA and orders Anne Arundel to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable twenty (20) days after the ALJ issues such a decision, notwithstanding that Anne Arundel 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 Anne Arundel was in material breach of this CIA; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) whether the alleged material breach cannot be cured within the 35 day period, but that (i) Anne Arundel has begun to take action to cure the material breach, (ii) Anne Arundel is pursuing such action with due diligence, and (iii) Anne Arundel 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 OIG. Anne Arundel's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Anne Arundel upon the issuance of the ALJ's decision. If the ALJ sustains the determination of OIG and rules that exclusion is authorized, such exclusion shall take effect twenty (20) days after the ALJ issues such a decision, notwithstanding that Anne Arundel 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, Anne Arundel and OIG agree as follows:

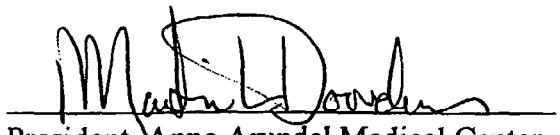
A. This CIA shall be binding on all departments, programs, operations, subsidiaries, successors, assigns and transferees of Anne Arundel;

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

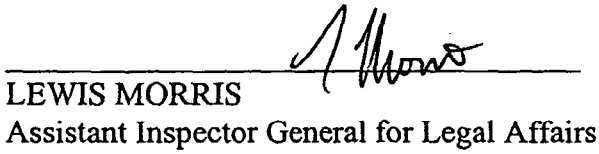
ON BEHALF OF ANNE ARUNDEL



President, Anne Arundel Medical Center

4-29-99
DATE

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



LEWIS MORRIS
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

4/26/99
DATE