SETTLEMENT AGREEMENT AND RELEASE

This Settlement Agreement and Release ("Agreement") is entered into this 17Th day of Marchin 1998, by and between the United States of America, through the United States Attorney for the Eastern District of Pennsylvania, the United States

Department of Justice, and the Office of Inspector General

("OIG") of the United States Department of Health and Human

Services (collectively, "the United States"), and Easton Hospital

("Hospital").

PREAMBLE

- A. The Medicare program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395, et seq., is administered by the United States Department of Health and Human Services ("HHS").
- B. Medicare payments to a hospital for inpatient treatment rendered to a Medicare beneficiary generally are based upon the beneficiary's "principal diagnosis," as set forth by the-hospital. The Medicare program relies upon participating hospitals to properly indicate the principal diagnosis through the use of standard diagnosis codes.
- C. Hospital is a Medicare provider, and submitted claims to Medicare for the inpatient treatment of Medicare

International Classification of Diseases, 9th Revision, Clinical Modification ("ICD-9-CM").

beneficiaries.

- D. The United States conducted an investigation into inpatient payment claims submitted to Medicare by Hospital with the principal diagnosis code of 482.89 (pneumonia due to "other specified bacteria"), which claims were submitted by Hospital during the period October 1, 1992 to March 31, 1997. The United States alleges that Hospital violated the False Claims Act, 31 U.S.C. § 3729, et seq., during this period by submitting to Medicare, with the 482.89 principal diagnosis code, claims that were not supported by the corresponding medical records ("the covered matter"). The United States alleges that, as a result of these claims, Hospital received payments to which it was not entitled.
- E. Hospital denies any wrongdoing or liability in connection with its use of the 482.89 principal diagnosis code. Hospital states it has complied fully with the United States' request for information needed to resolve this issue.
- F. Hospital has provided documents and information to the United States in response to the government's investigation of the covered matter, including patient files for which claims were submitted to Medicare with the principal diagnosis code of 482.89, and Hospital represents that such response has been

truthful, accurate, and complete to the best of its knowledge, information and belief.

- G. The United States and Hospital ("the Parties") mutually desire to settle, compromise, and resolve the issues and disputes between them arising out of the covered matter in order to avoid the delay, inconvenience, uncertainty, and expense of litigation.
- H. The Parties agree that this Agreement, and all information and documents voluntarily provided to the other party in connection with the settlement of the covered matter, do not constitute admissions by any person or entity, and shall not be construed as admissions by any person or entity, in any proceeding (including, but not limited to any criminal proceeding), with respect to any issue of fact or law pertaining to the covered matter.

TERMS AND CONDITIONS

In reliance upon the representations contained herein and in consideration of the mutual promises, covenants, and obligations herein, and for good and valuable consideration mutually presented and received, and with full authority to enter into this Agreement and to be bound thereby, and incorporating the foregoing recitals, the United States and Hospital agree as

follows:

Hospital agrees to pay to the United States the sum of \$1,120,000.00 ("the Settlement Amount"). Immediately upon the execution of this Agreement, the receipt by Hospital of a signed Agreement between the United States and Relator, and the receipt of instructions from the undersigned Assistant United States Attorney, Hospital shall pay the Settlement Amount by electronic funds transfer to the United States of America pursuant to those instructions. If this transfer is not timely made, then the United States at its sole option may declare Hospital to be in default under this Agreement, and exercise one or more of the following rights: (1) declare this Agreement breached and proceed against Hospital with respect to the covered matter in United States District Court, under the False Claims Act and otherwise; (2) file an action for specific performance of the terms of this Agreement; (3) exclude Hospital from participation in the. Medicare and other Federal and State health care programs (as defined in 42 U.S.C. § 1320a-7(h) and 1320a-7b(f)); (4) satisfy Hospital's debt to the United States for the Settlement Amount by an offset of monies payable to Hospital by any department, agency, or agent of the United States; and (5) exercise any other right granted by law, or recognizable at common law or in equity.

- 2. Hospital agrees to cooperate fully and in good faith with the United States in the civil or criminal prosecution of any person concerning the covered matter, and concerning similar matters involving other hospitals and others, by providing accurate, truthful, and complete information whenever, wherever, to whomever, and in whatever form the United States reasonably may request. Nothing in this Paragraph, however, affects any privilege that might be available to Hospital or any statutory or regulatory obligation of Hospital, or Hospital's ability to object to the request on the grounds of such privilege or obligation; the United States reserves its right to contest the assertion of any such privilege or obligation by Hospital. Hospital agrees to the following specific representations and undertakings:
- a. Hospital will use its best efforts to provide such information, and related documents, within ten (10) working days of receipt of a request. If necessary, Hospital will notify the United States of any difficulty in timely complying with any such request, and will advise the United States of the additional amount of time estimated to be needed to respond to such request.
- b. Hospital understands that it has undertaken an obligation to provide truthful and accurate information and

testimony by itself and through its employees. Hospital agrees that it shall take no action which could cause any person to fail to provide such testimony (other than the assertion of a privilege or statutory regulatory obligation), or could cause any person to believe that the provision of truthful and accurate testimony could adversely affect such person's employment or any contractual relationship.

- and subject to its right to assert a privilege or statutory or regulatory obligation as set forth above, encourage its employees and members of its medical staff to cooperate in the government's investigation, to make themselves available for interviews and testimony, and to provide requested records.
- d. Should it be judged by the United States that Hospital has failed to cooperate fully or has intentionally given false, misleading, or incomplete information or testimeny, Hospital thereafter shall be subject to prosecution for any criminal violation of which the United States has knowledge, including, but not limited to, perjury, obstruction of justice, and false statements.
- 3. Corporate Integrity Program. Hospital agrees to take the following steps (set forth in this paragraph 3 of this

Agreement) with the goals of ensuring compliance with all applicable health care statutes, regulations, policies, procedures, and requirements and ensuring Hospital's accurate submission of claims to Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). The corporate integrity requirements of this paragraph apply to the three year period following the execution of this Agreement (unless otherwise specified).

- a. <u>Compliance Officer</u>. Within 120 days after the execution of this Agreement, Hospital shall designate a Compliance Officer who shall be responsible for developing, implementing, monitoring, adapting, reporting on, and certifying compliance with, policies and procedures and practices designed to ensure compliance with the requirements set forth in this paragraph, and with the requirements of Medicare, Medicaid, and all other Federal health care programs. The Compliance Officer shall be a member of senior management of Hospital (i.e., not subordinate to Hospital's general counsel, CFO, or similar officer) and shall make regular (at least semi-annually) reports regarding compliance matters directly to the Hospital CEO and/or to the Board of Directors of Hospital.
 - b. Policies and Procedures. Within 120 days after the

execution of this Agreement, Hospital shall develop and effectively implement written Policies and Procedures regarding compliance with all federal and state health care statutes, regulations, and guidelines, including the requirements of Medicare, Medicaid, and other Federal health care programs. Policies and Procedures shall specifically require that all diagnosis codes submitted to Medicare, Medicaid, or any other Federal health care program for claims purposes be properly supported by documentation by the treating physician in the patient's medical record. The Policies and Procedures shall require that all inpatient claims intended to be submitted to Medicare with a principal diagnosis code of 482.89 (or any successor to this code) shall first be subject to pre-billing review to ensure that the diagnosis code was properly assigned. The Policies and Procedures shall include disciplinary guidelines and methods for employees to make complaints and notifications about compliance issues to Hospital management through the Confidential Disclosure Program required by subparagraph (e). Hospital shall update the Policies and Procedures at least annually and more frequently as appropriate. The Policies and Procedures shall be distributed by Hospital individually to all employees, all contractors, and to all other individuals affected by them, including but not limited to staff physicians and all personnel with responsibilities pertaining to coding. Within 120 days after the execution of this Agreement, or within one week after the commencement of the individual's relationship with the hospital (e.g., employment or contract), whichever is later, and annually thereafter, each individual who should receive the Policies and Procedures shall certify that he or she has read and understands the Policies and Procedures. Hospital shall keep a copy of these certifications on file for at least one year after the completion of the corporate integrity period mandated by this paragraph.

execution of this Agreement, Hospital shall require and provide at least two hours of training to each and every employee of Hospital with responsibility for the provision, documentation, or billing of inpatient hospital services. This general training shall: (1) cover Hospital's Policies and Procedures; (2) reinforce the need for strict compliance with the applicable statutes, regulations, policies, procedures, and program guidelines, and Hospital's Policies and Procedures; and (3) advise employees that any failure to comply may result in disciplinary action. Annually thereafter, Hospital shall require

and provide one hour of such training to such individuals. employees shall receive the general training described above within one week of the beginning of their employment (or within 120 days after the execution of this Agreement, if the employment begins during that period). In addition to the general training described above, within 120 days after execution of this Agreement or within 60 days of the beginning of their employment, whichever is later, each and every person involved in the assignment of diagnosis or procedure codes for billing Medicare, Medicaid, or any other Federal health care programs shall receive at least five hours of training regarding the applicable statutes, regulations, policies, procedures, and program quidelines for Medicare, Medicaid, and all other Federal health care programs. If a person has any responsibility for the assignment of diagnosis or procedure codes prior to completing this coding training, a Hospital employee who has completed the coding training shall review all of the untrained person's work regarding the assignment of diagnosis or billing codes. Annually thereafter, Hospital shall require and provide three hours of the above described coding training to such individuals. Hospital shall make such training available to physicians with privileges and use its best efforts to encourage their attendance and

participation.

d. Audits and Disclosures. Prior to the first anniversary of the execution of this Agreement, Hospital shallretain a third-party to perform an audit (consistent with the guidelines of the OIG's Office of Audit Services, e.g., OAS Policies and Procedures, Chapter 20-02, Transmittal 96:04, 8/5/96) designed to ensure compliance with the written Policies and Procedures described in subparagraph (b), with this Agreement, and with all applicable federal and state health care statutes, regulations, policies, procedures, and program requirements. Annually thereafter, Hospital shall perform, or retain a third-party to perform, the same types of audits. Such audits should cover areas of potential fraud, abuse, or waste, as identified by Hospital or by the government, see, e.g., OIG's Compliance Program Guidance for Hospitals, 63 Federal Register 8987 (February 23, 1998). Such audits shall focus particular attention on coding and the activities of physicians and personnel involved in the identification and coding of diagnoses for the purpose of billing Medicare, Medicaid, or any other Federal health care program. The audits must be retained by Hospital for at least one year after the completion of the corporate integrity period mandated by this paragraph. If, as a

result of these audits or through any other means, Hospital discovers any billing or coding policies, procedures and/or practices that result in a material deficiency, Hospital shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days of discovering the deficiency and take remedial steps within 60 days (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the deficiency from reoccurring. The notice to the payor should state that the repayment is being made in accordance with the terms of this Agreement and should include: (1) the methodology by which the overpayment was determined; (2) any claim specific information used to determine the overpayment; and (3) the amount of the overpayment. For purposes of this Agreement, a "material deficiency" shall mean anything that has a significant, adverse financial impact upon the Medicare and/or Medicaid programs, which may be the result of an isolated event or a series of occurrences, and which lacks conformity with Medicare and/or Medicaid reimbursement principles or other applicable statutes, and the regulations and written directives issued by the Health Care Financing Administration ("HCFA") and/or its agents, or any other agency charged with administering the health care program implicated and/or its agents. Contemporaneous with Hospital's

notification to the payor as provided above, Hospital shall notify OIG of: (i) their findings concerning the material deficiency; (ii) Hospital's actions to correct such material deficiency; and (iii) any further steps the Hospital plans to take to address such material deficiency and prevent it from reoccurring. While this reporting requirement focuses on occurrences having a "significant, adverse financial impact," this provision does not excuse the Hospital's statutory obligation as a Medicare or Medicaid participant to bring to a: payor's attention any other billing deficiencies, however de minimis, make appropriate refunds and take any steps necessary to prevent the occurrence in the future. In the event, after discussions with Hospital, that the OIG determines that it is necessary to conduct an independent audit or review to determine whether or the extent to which Hospital is complying with its obligations under this Agreement, Hospital agrees to pay for the reasonable cost of any such audit or review.

e. <u>Confidential Disclosure Program.</u> Within 120 days after the execution of this Agreement, Hospital shall establish a Confidential Disclosure Program enabling employees, and agents and contractors, if applicable, to communicate about compliance issues to the Compliance Officer. The Confidential Disclosure

Program shall include methods, such as a toll-free compliance "hotline," for employees, agents, and contractors to disclose any practices or procedures with respect to Medicare, Medicaid, or any other Federal health care program, alleged by the individual to be inappropriate, to the Compliance Officer or some other person who is not in the reporting individual's chain of command. The Confidential Disclosure Program shall emphasize a nonretribution, non-retaliation policy, and shall include a reporting mechanism for anonymous, confidential communication. Hospital shall use intake procedures designed to elicit all relevant information from individuals reporting alleged misconduct. For any disclosure that is sufficiently specific that it reasonably (1) permits a determination of the appropriateness of the alleged improper practice, and (2) provides opportunity for the taking of corrective action, Hospital shall require the internal review of the allegations set forth in such disclosure and ensure that proper follow-up is conducted. Hospital shall, in good faith, make a preliminary inquiry into the allegations set forth in every disclosure to ensure that it has obtained all of the information necessary to determine whether it should conduct an internal review as provided above. The Compliance Officer shall maintain a

confidential disclosure log, which shall include a record of each allegation received, status of the investigation of the allegation, and any corrective action taken in response to the investigation. The Compliance Officer shall maintain all documentation related to information in the log and make such documents available for inspection by the OIG upon request.

Excluded Individuals. Effective upon the date of execution of this Agreement, Hospital shall not employ, contract with, or otherwise use the services of any individual whom Hospital knows or should have known, after reasonable inquiry, (a) has been convicted of a criminal offense related to health care (unless the individual has been reinstated to participation in Medicare after being excluded because of the conviction), or (b) is currently listed by a federal agency as excluded, debarred, or otherwise ineligible for participation in any Federal health care program. In furtherance of this requirement, Hospital agrees to make reasonable inquiry as to any individual who is a prospective employee, agent, or individual considered for engagement by Hospital as an independent contractor by reviewing the General Services Administration's List of Parties Excluded from Federal Programs (available over the internet at http://www.arnet.gov/epls) and the HHS/OIG Cumulative Sanction

Report (available over the internet at http://www.dhhs.gov/progorg/oig).

Initial and Annual Reports. Within 120 days after the execution of this Agreement, Hospital shall submit a written report to the OIG. This initial report shall include: (1) the name and position description of the Compliance Officer described in subparagraph (a); (2) the written Policies and Procedures required by subparagraph (b); and (3) a description of the training programs implemented pursuant to subparagraph (c) and a summary of the activities undertaken in furtherance of the training programs, including schedules and topic outlines from the training sessions. Thereafter, Hospital shall submit to the OIG a written report annually within 30 days after the first, second, and third anniversary dates of the execution of this Agreement, with respect to the status and findings of Hospital's compliance activities. The annual reports shall include: (1) any change in the identity or position description of the Compliance Officer described in subparagraph (a); (2) any changes or amendments to the Policies and Procedures required by subparagraph (b); (3) a description of any changes in the training programs implemented pursuant to subparagraph (c) and a summary of the activities undertaken in furtherance of the .

training programs, including schedules and topic outlines for the training sessions; (4) a description of the audits conducted pursuant to subparagraph (d), their results, problems (including but not limited to the aggregate amount of overpayments) identified in the audits, and corrective actions taken to address those problems; (5) a description of the disclosures received and actions taken by Hospital pursuant to subparagraph (e) and a copy of the a confidential disclosure log required by that paragraph; (6) a description of any personnel action taken by Hospital as:a result of the obligations in subparagraph (f); (7) a description of any ongoing investigation or legal proceeding conducted or brought by a governmental entity involving an allegation that Hospital has committed a crime or has engaged in fraudulent activities; and (8) a certification by the Compliance Officer verifying that Hospital is in compliance with all of the

requirements of this paragraph. All reports or other correspondence required by this Agreement to be made to the OIG shall be sent to:

Civil Recoveries Branch - Compliance Unit Office of Counsel to the Inspector General Office of Inspector General Department of Health and Human Services 330 Independence Ave., SW, Room 5527 Washington, DC 20201 Telephone: (202) 619-2078 Facsimile: (202) 205-0604

Correspondence with Hospital shall be directed to:

Barbara W. Bigelow
Compliance Officer
Internal Auditor
Easton Hospital
250 South 21st Street
Easton, PA 18042
Telephone: (610) 250-4525
Facsimile (610) 250-4847

h. Breach and Default Provisions

Hospital's compliance with the terms and conditions in this paragraph shall constitute an element of Hospital's present responsibility with regard to participation in Federal health care programs. Full and timely compliance by Hospital shall be expected throughout the duration of the compliance period required by this paragraph with respect to all of the obligations herein agreed to by Hospital. All modifications to this paragraph (including changes to dates on which an obligation is

due to be met) shall be requested in writing and agreed to by the OIG in writing prior to the date on which the modification is expected to take effect.

A. Stipulated Penalties for Failure to Comply with Certain .

Obligations

As a contractual remedy, Hospital and OIG hereby agree that failure to comply with certain obligations set forth in this paragraph 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 \$1,000 (which shall begin to accrue on the date the obligation became due) for each day Hospital fails to have in place any of the following during the entire period beginning 120 days after the execution of this Agreement and concluding at the end of the corporate integrity period required by this Agreement:
 - a. a Compliance Officer;
 - b. written Policies and Procedures;
 - an education and training program;
 - d. a mechanism for obtaining compliance audits and reporting material deficiencies; and

- e. a Confidential Disclosure Program;
- A stipulated penalty of \$1,000 (which shall begin to accrue on the date the obligation became due) for each day Hospital fails meet the deadline set forth in subparagraph (g) to provide a written report within 120 days of the execution of this Agreement and submission of annual written reports within 30 days of the first, second, and third anniversary dates of the execution of this Agreement.
- (3) A stipulated penalty of \$1,000 (which shall begin to accrue on the date the failure to comply began) for each day Hospital employs or contracts with an individual after that individual has been listed by a federal agency as excluded, debarred, suspended or otherwise ineligible for participation in the Medicare, Medicaid or any other Federal health care program (as defined in 42 U.S.C. § 1320a-7b(f)). This stipulated penalty shall not be demanded if Hospital can demonstrate that it did not discover the individual's exclusion or other ineligibility after making a reasonable inquiry (as described in subparagraph (f)) as to the current or potential status of the employee

or consultant engaged.

- (4) A stipulated penalty of \$1,000 (which shall begin to accrue on the date that the OIG provides notice to Hospital of the failure to comply) for each day Hospital fails to meet any of the following requirements:
 - a. the Compliance Officer discharging duties as required in subparagraph (a);
 - b. the written Policies and Procedures meet the requirements in subparagraph (b);
 - c. the education and training program meets the requirements in subparagraph (c);
 - d. the audits and reports are submitted to the OIG and otherwise meet the requirements in subparagraph (d); and
 - e. a Confidential Disclosure Program meets the requirements of subparagraph (e); or
 - f. the reports submitted to the OIG meet the requirements of subparagraph (g).
- B. Payment of Stipulated Penalties

Upon finding that Hospital has failed to comply with any of the obligations described in section A, the OIG shall notify

Hospital by Certified mail of: (i) Hospital's failure to comply; and (ii) the OIG's exercise of its contractual right to demand payment of the stipulated penalties (this notification is hereinafter referred to as the "Demand Letter"). Within 15 days of the date of the Demand Letter, Hospital shall either: (i) cure the breach to the OIG's satisfaction and pay the applicable stipulated penalties; (ii) request a hearing before an HHS administrative law judge (ALJ) to dispute the OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in section D of this subparagraph; or (iii) be in material breach of this paragraph.

Hospital may submit a timely written request for an extension of time to perform any act or file an notification or report required by this paragraph. Notwithstanding any other provision in this section, if OIG grants the timely written request, Stipulated Penalties shall not begin to accrue unless and until Hospital fails to meet the deadline granted by the extension. Notwithstanding any other provision in this section, if OIG denies a timely written request, Stipulated Penalties shall not begin to accrue until two business days following Hospital's receipt of OIG's written denial of such a request. 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 notification or report is due to be filed.

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 the OIG at the address set forth in subparagraph (g).

Except as otherwise noted, these provisions for payment of stipulated penalties shall not affect or otherwise set a standard for the OIG's determination that Hospital has materially breached this Paragraph, which decision shall be made at the OIG's discretion and governed by the provisions in section C of this subparagraph, below.

C. Exclusion for Material Breach of this Paragraph

The parties agree that a material breach of this Paragraph
by Hospital constitutes an independent basis for Hospital's
exclusion from participation in Medicare, Medicaid, and all other
Federal health care programs (as defined in 42 U.S.C. § 1320a7b(f)). Upon a determination by the OIG that Hospital has
materially breached this Paragraph and that exclusion should be
imposed, the OIG shall notify Hospital by certified mail of: (i)
Hospital's material breach; and (ii) the 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 Letter"). Hospital shall have 35 days from the date of the letter to proceed as follows:

- (1) demonstrate to the OIG's satisfaction that Hospital is in full compliance with this Agreement;
- (2) cure the alleged material breach; or
- (3) demonstrate to the OIG's satisfaction that the alleged material breach cannot be cured within the 35 day period, but that (i) Hospital has begun to take action to cure the material breach, (ii) Hospital is pursuing such action with due diligence, and (iii) Hospital has provided to the OIG a reasonable timetable for curing the material breach.

If at the conclusion of the 35-day period (or other specific period as subsequently agreed by OIG and Hospital), Hospital fails to meet the requirements of provisions (1), (2), Or (3) above, OIG may exclude Hospital from participation in the Medicare, Medicaid and any other federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). OIG will notify Hospital in writing of its determination to exclude Hospital (this letter shall be referred to hereinafter as the "Exclusion Letter"). The

exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If Hospital is excluded under the provisions of this paragraph, Hospital may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

A material breach of this paragraph means: (i) a failure by Hospital to meet an obligation under this paragraph where the failure has a significant adverse impact on the integrity of Medicare, Medicaid, or any other Federal health care program (for example, a failure to report a material deficiency, take corrective action and pay the appropriate refunds, as provided in subparagraph (d)); or (ii) repeated or flagrant violations of the obligations under this paragraph, including, but not limited to, the obligations addressed in section A of this subparagraph.

In connection with the OIG's determination to exclude Hospital pursuant to this provision, Hospital shall have the right to dispute the OIG's determination in accordance with the agreed upon provisions set forth in section D of this subparagraph.

D. Dispute Resolution

Upon the OIG's delivery to Hospital 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 Paragraph, Hospital shall be entitled to some of the due process afforded a provider under 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 Agreement.

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 paragraph shall be: (i) whether Hospital was in full and timely compliance with the obligations of this paragraph for which the OIG demands payment; and, (ii) the period of noncompliance. Hospital shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. For purposes of paying stipulated penalties under this paragraph, and if Hospital chooses to seek review in lieu of curing the breach and paying the stipulated penalties, as set forth above, the ALJ's decision shall trigger Hospital's obligation to pay. Thus, payment will be due 20 days after the date that the ALJ issues the decision. Hospital's election of its contractual right to appeal to the Departmental Appeals Board shall not excuse its obligation to make payment upon issuance of the ALJ's decision.

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 breach of this paragraph shall be: (i) whether Hospital was in material breach of this paragraph; and (ii) whether such breach was continuing on the date of the Exclusion Letter. For purposes of the exclusion herein agreed to in the event of material breach of this paragraph, the ALJ's decision shall trigger the exclusion. Thus, the OIG may proceed with its exclusion of Hospital if and when the ALJ issues a decision in favor of the OIG. Hospital's election of its contractual right to appeal to the Departmental Appeals Board shall not abrogate the OIG's authority to exclude Hospital upon the issuance of the ALJ's decision. Subsequent to a final decision to exclude or suspend Hospital, Hospital shall have the right to seek reinstatement at any time pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004. Nothing in this Agreement shall prevent the OIG from excluding Hospital, consistent with its normal procedures and the legal rights of Hospital, for actions taken by Hospital that are not specifically covered by this Agreement.

4. Hospital releases the United States, HHS, and each of their agencies, officers, agents, employees, and contractors

and their employees from any and all claims, causes of action, adjustments, and set-offs of any kind arising out of or pertaining to the covered matter, including the investigation of the covered matter and this Agreement.

- 5. In consideration of the payment, representations, and undertakings described above, and except as provided below:
- a. The United States will release Hospital, including its current and former directors, officers, and employees (collectively the "Released Parties") from all civil or administrative monetary claims that it may have against the Released Parties pursuant to the False Claims Act (31 U.S.C. § 3729, et seq.), the Program Fraud Civil Remedies Act (31 U.S.C. § 3801, et seq.), the Civil Monetary Penalties Law, (42 U.S.C. § 1320a-7a), and common law for the covered matter.
- b. The United States will refrain from instituting or maintaining any administrative claim or action seeking exclusion from Medicare, Medicaid, or any other Federal health care programs of the Released Parties under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b) (permissive exclusion) with respect to the covered matter, except under the circumstances set forth in this Agreement.
 - The United States will move to dismiss the

claims against Hospital with prejudice in the action under seal in the United States District Court for the Eastern District of Pennsylvania at Civil Action 96-1552, including any claim for costs and/or attorney's fees which claims are deemed coextensive with the covered matter.

- 6. This Agreement, and the scope of the government's releases herein, specifically are limited to the covered matter as defined in Paragraph D. Except as provided in Paragraph D, the United States specifically reserves any claims it may have: with respect to quality of care, services, or products.
- or prosecution for any violations of federal criminal laws.

 Hospital agrees that it will waive and will not assert any defense based in whole or in part on the double jeopardy clause of the United States Constitution, or the decision of the U.S. Supreme Court in <u>United States v. Halper</u>, 490 U.S. 435-(1989), in any criminal prosecution arising out of the covered matter, and agrees that the Settlement Amount is not punitive in nature or effect for purposes of any such criminal prosecution.
- 8. This Agreement does not settle or release claims, if any, arising under federal tax laws or antitrust laws.

 Nothing in this Agreement constitutes an agreement by the United

States as to the characterization of the Settlement Amount for tax purposes.

- 9. It is recognized that, for purposes of the Bankruptcy Act, 11 U.S.C. § 501, et seq., the amounts due under this Agreement are not dischargeable.
- Medicare, Medicaid, and federal government contracting and grant accounting purposes, all costs (as defined in the Federal Acquisition Regulations ("FAR"), 48 C.F.R. § 31.205-47(a)), incurred by or on behalf of Hospital and/or its current or former officers, directors, shareholders, employees, parents, subsidiaries, divisions, predecessors, successors, and agents in connection with:
 - a. the matters covered by this Agreement;
- b. the government's audit and investigation of the matters covered by this Agreement;
- of the matters covered by this Agreement and corrective actions undertaken in response to the government's investigation specifically including the corporate integrity provisions of this Agreement;
 - d. the negotiation of this Agreement; and

- e. all payments and costs incurred pursuant to this Agreement, specifically including attorney's fees. Hospital shall separately estimate and account for these amounts, and Hospital shall not charge such amounts directly or indirectly to any contract with the United States, or to any grant from the United States, or to any cost report submitted to the Medicare or Medicaid programs.
- Paragraph 1 shall not be offset by any claims for payment now being withheld from payment by any Medicare or Medicaid carrier or intermediary; and Hospital agrees not to resubmit any claims to a Medicare or Medicaid carrier or intermediary that have been denied as of the date of this Agreement, and agrees not to appeal such denials of claims where such denial resulted from the practices described in Paragraph D.
- 12. Each party shall bear its own costs, including attorney's fees.
- between the United States and Hospital. Any modification to this Agreement must be in writing and must be signed and executed by all parties to this Agreement except that any modifications made with respect to the requirements of paragraph 3 may be made.

by written agreement between Hospital and the OIG.

- 14. This Agreement is binding upon and shall inure to the benefit of the Parties and their successors, assigns, heirs, agents, trustees, and employees. The Agreement shall become final, binding, and effective only upon signing by every party hereto.
- 15. The Agreement may be executed in multiple counterparts, each of which shall constitute an original, and all of which shall constitute one and the same agreement.
- 16. Each person who signs this Agreement in a representative capacity warrants that he or she is duly authorized to do so.

FOR THE UNITED STATES:

Senior Litigation Counsel

Manuer. 870 11/17/98
MICHAEL R. STILES
United States Attorney
(James D. Sheekan 11/17/98
JAMES G. SHEEHAN
Assistant United States Attorney
Chief, Civil Division
Secret intraktion 11/16/18
SUSAN DEIN BRICKLIN
Assistant United States Attorney

Dian flouts - 11-9-98

MICHAEL F. HERTZ JOYCE R. BRANDA DIANA J. YOUNTS Civil Division

U.S. Department of Justice

LEWIS MORRIS

Assistant Inspector General Office of the Inspector General U.S. Department of Health and Human Services

FOR EASTON HOSPITAL:

President and Chief Executive Officer

MARK L. MATTIOLI Attorney for Easton Hospital