SETTLEMENT AGREEMENT

I. <u>PARTIES</u>

This Settlement Agreement ("Agreement") is entered into among the United States of America ("United States"), acting through the United States Department of Justice and on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"); Relator Health Outcomes Technologies, Inc. ("Relator"); and Rhode Island Hospital ("RIH"), (hereafter referred to as "the Parties"), through their authorized representatives.

II. <u>PREAMBLE</u>

As a preamble to this Agreement, the Parties agree to the following:

A. The United States has intervened in a qui tam action and filed a complaint against
RIH in the United States District Court for the District of Rhode Island, Civil Action No.
01-243-ML ("Complaint"). The Complaint is incorporated herein by reference.

B. The Complaint includes civil claims against RIH under the False Claims Act, 31 U.S.C. §§ 3729-3733, and the common law doctrines of payment by mistake, unjust enrichment, and recoupment for engaging in the conduct alleged in the Complaint, including, but not limited to, the following conduct during the period from October 1, 1992 through September 30, 1997: RIH submitted or caused to be submitted claims to Medicare with the principal diagnosis code of ICD-9 Code 482.89 (pneumonia due to "other specified bacteria") that were allegedly not supported by the corresponding medical records and for which RIH allegedly received payments in excess of the amount to which it was entitled (hereinafter referred to as the "Covered Conduct").

Settlement Agreement among U.S., RIH, and Health Outcomes Technologies (FINAL) C. The United States also contends that it has certain administrative claims against RIH under the provisions for permissive exclusion from Medicare, Medicaid and other federal health care programs, 42 U.S.C. § 1320a-7(b), and the provisions for civil monetary penalties, 42 U.S.C. § 1320a-7a, for the Covered Conduct.

D. RIH denies any of the claims included in the Covered Conduct or any of the conduct of its agents or employees with respect to the claims included in the Covered Conduct was in violation of any Medicare rules, federal laws, including the False Claims Act, or common law doctrines. This Agreement is neither an admission of liability by RIH nor a concession by the United States or Relator that their claims are not well founded.

E. To avoid the delay, uncertainty, inconvenience and expense of protracted litigation of the above claims, the Parties have reached a full and final settlement as set forth in the Terms and Conditions below.

III. TERMS AND CONDITIONS

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. RIH agrees to pay to the United States the sum of \$625,000 (the "Settlement Amount") as follows: RIH agrees to make payment of the Settlement Amount by electronic funds transfer pursuant to written instructions to be provided by the Civil Division of the United States Department of Justice. RIH agrees to make this electronic funds transfer no later than ten days after the Effective Date of this Agreement.

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2. RIH agrees to cooperate fully and in good faith with the United States in the administrative, civil, or criminal investigation or prosecution of any person concerning the Covered Conduct, 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. Upon reasonable notice, RIH shall make reasonable efforts to facilitate access to, and encourage the cooperation of, its directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals, and will furnish to the United States, upon reasonable request, all non-privileged documents and records in its possession, custody or control relating to the Covered Conduct.

3. RIH releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that RIH has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

4. Subject to the exceptions in Paragraph 6 below, in consideration of the payment of the Settlement Amount and other obligations of RIH set forth in this Agreement, and conditioned upon RIH's payment in full of the Settlement Amount, the United States (on behalf of itself, its officers, agents, agencies, and departments), and Relator release RIH, its predecessors, successors, assigns, parent company, affiliates, and present and former officers, directors, employees, servants, agents, and attorneys from any civil or administrative monetary claim the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C.

§§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812 or the common law. The United States expressly reserves any claims against any entities and individuals other than those released above.

5. In consideration of the obligations of RIH set forth in this Agreement and the Declaration attached as Appendix A, conditioned upon RIH's payment in full of the Settlement Amount, the OIG-HHS releases and shall refrain from instituting, directing or maintaining any administrative claim or any action seeking exclusion from Medicare, Medicaid, or other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against RIH under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b) (permissive exclusion), for the Covered Conduct, except as reserved in Paragraph 6 below and as reserved in this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude RIH or others from Medicare, Medicaid or other federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion). Nothing in this Paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in Paragraph 6, below.

6. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including RIH) are any and all of the following:

a. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

b. Any criminal liability;

c. Except as explicitly stated in this Agreement, any administrative liability,

including mandatory exclusion from Federal health care programs;

d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

e. Any liability based upon such obligations as are created by this Agreement;

f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services, provided by RIH;

g. Any liability for claims based on a failure to deliver goods or services due;

h. Any liability for claims based on the submission of claims to Medicare with the principal diagnosis code of ICD-9 Code 482.89 after September 30, 1997;

i. Any liability for claims against outside consultants who provided advice relating to the Covered Conduct, other than attorneys.

7. <u>Integrity Requirements</u>. RIH shall not be required to enter into a separate Corporate Integrity Agreement but agrees that for a period of three (3) years from the Effective Date of this Agreement it shall comply with the following provisions in order to assure OIG-HHS that RIH will continue its present compliance program:

a. <u>Continued Implementation of Corporate Compliance Program</u>. RIH shall continue to implement its Corporate Compliance Program, as described in the Declaration attached hereto and incorporated herein by this reference as Appendix A, and continue to provide, at a minimum, the same level of resources currently provided, throughout this time period. RIH may amend its Corporate Compliance Program as it deems necessary, so long as those amendments are consistent with the overall objective of ensuring compliance with the requirements of Medicare, Medicaid, and all other Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f).

Reporting of Overpayments. RIH shall promptly refund to the appropriate b. Federal health care program payor any identified Overpayment(s). For purposes of this Agreement, an "Overpayment" shall mean the amount of money RIH has received in excess of the amount due and payable under any Federal health care program requirements. If, at any time, RIH identifies or learns of any Overpayment, RIH shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 90 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, RIH 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, RIH 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 Appendix C to this Agreement.

c. <u>Reportable Events</u>. RIH shall report to HHS-OIG in writing within 30 days after making a determination (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) that there is a Reportable Event, which shall mean anything that involves: (1) a substantial Overpayment or (2) 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. In such report, RIH shall include the following information:

(1) If the Reportable Event results in an Overpayment, the report to
HHS-OIG shall be made at the same time as the notification to the payor required in
Subparagraph 7(b), 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;

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

(3) a description of RIH's actions taken to correct the Reportable

Event; and

(4) any further steps RIH plans to take to address the Reportable Event and prevent it from recurring.

d. <u>Notification of Government Investigation or Legal Proceedings</u>. Within 30 days after discovery, RIH shall notify HHS-OIG, in writing, of any ongoing investigation or legal proceeding known to RIH conducted or brought by a governmental entity or its agents involving an allegation that RIH 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. RIH shall also provide written notice to HHS-OIG within 30 days after the resolution of the matter, and shall provide HHS-OIG with a description of the findings and/or results of the proceedings, if any.

e. <u>Annual Reporting Requirements</u>. Each one-year period, beginning with the one-year period following the Effective Date of this Agreement, shall be referred to as a "Reporting Period." RIH shall submit to HHS-OIG annually a report that sets forth, under penalty of perjury, the following information for each Reporting Period (Annual Report):

(1) A description of any material amendments to its Corporate Compliance Program;

(2) Any changes to the level of resources dedicated to its Corporate Compliance Program;

(3) A summary of any internal or external reviews, audits, or analyses of its Corporate Compliance Program and any corrective action plans developed in response to such those reviews, audits, or analyses;

(4) A summary of any internal or external reviews, audits, or analyses related to the selection of appropriate ICD-9-CM Codes for Medicare claims and any corrective action plans developed in response to such reviews, audits, or analyses;

(5) A report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: inpatient Medicare, outpatient Medicare, Medicaid (report each state separately, if applicable), and other Federal health care programs. Overpayment amounts that are routinely reconciled or adjusted pursuant to policies and procedures established by the payor do not need to be included in this aggregate Overpayment report; and

(6) A certification that, during the Reporting period, RIH has complied with the Integrity Requirements of this Agreement. The first Annual Report shall be received by HHS-OIG no later 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by HHS-OIG no later than the anniversary date of the due date of the first Annual Report.

f. <u>Notifications and Submission of Annual Reports</u>. Unless otherwise specified in writing after the Effective Date of the Agreement, all notifications and Annual Reports required under this Paragraph 7 shall be submitted to the following addresses:

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, D.C. 20201 Telephone: 202-619-2078 Facsimile: 202-205-0604

RIH:

Thomas P. Igoe Compliance Officer, Lifespan Suite 240 Physicians Office Building Rhode Island Hospital 593 Eddy Street Providence, RI 02903 Telephone: 401-444-4728 Facsimile: 401-444-5842

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Unless otherwise specified, all notifications and reports required by this Paragraph 7 may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such report or notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

HHS-OIG Inspection, Audit, and Review Rights. In addition to any other g. rights HHS-OIG may have by statute, regulation, or contract, HHS-OIG or its duly authorized representative(s) may examine or request copies of RIH's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of RIH's locations for the purpose of verifying and evaluating: (a) RIH's compliance with the terms of the Integrity Requirements of this Agreement; and (b) RIH's compliance with the requirements of the Federal health care programs in which it participates. The documentation described above shall be made available by RIH to HHS-OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, HHS-OIG or its duly authorized representative(s) may interview any of RIH'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 individual and HHS-OIG. RIH shall assist HHS-OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon HHS-OIG's request. RIH's employees may elect to be interviewed with or without a representative of RIH present.

h. <u>Document and Record Retention</u>. RIH shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with the Integrity Requirements of this Agreement, for four (4) years (or longer if otherwise required by law).

8. RIH waives and shall not assert in any criminal prosecution or administrative action relating to the Covered Conduct any defense that may be based in whole or in part on a contention that the Double Jeopardy Clause in the Fifth Amendment of the Constitution or the Excessive Fines Clause in the Eighth Amendment of the Constitution bars any remedy sought in such criminal prosecution or administrative action. RIH agrees that this Agreement is not punitive in purpose or effect. Nothing in this paragraph or any other provision of the Settlement constitutes an agreement by the United States concerning the characterization of the Settlement Amount or any other payments for purposes of the Internal Revenue laws, Title 26 of the United States Code.

9. RIH shall not resubmit to any Medicare intermediary or any other federal healthcare program any previously denied claims or claims that RIH has previously refunded or repaid and that are described in the Covered Conduct and shall not appeal any such denials of claims.

10. RIH agrees to the following:

(a) <u>Unallowable Costs Defined:</u> that all costs (as defined in the Federal Acquisition Regulations, 48 C.F.R. § 31.205-47, and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v, and the regulations and official program directives promulgated thereunder) incurred by or on behalf of RIH, its present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "unallowable costs" on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program

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(1) the matters covered by this Agreement,

(2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement,

(3) RIH's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees),

(4) the negotiation and performance of this Agreement,

(5) the payment RIH makes pursuant to this Agreement,

(6) the negotiations of any obligations undertaken pursuant to the Integrity Requirements of Paragraph 7 to prepare and submit reports to the OIG-HHS.

(All costs described or set forth in this paragraph 10(a) are hereafter, "unallowable costs".)

(b) <u>Future Treatment of Unallowable Costs:</u> Unallowable costs, if any, shall be separately determined and accounted for in non-reimbursable cost centers by RIH 1) through accounting records to the extent that is possible; 2) through memorandum records including diaries and informal logs, regardless of whether such records are part of official documentation, where accounting records are not available; and 3) through itemized estimates based on best available information, including all written records and the recollection of all relevant individuals, where no other accounting basis is available. -RIH will not charge such unallowable costs directly or indirectly to any contracts with the United States or any State Medicaid Program or seek payment for any such unallowable costs through any cost report, cost statement, information statement or payment request submitted by RIH or any of its subsidiaries to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

Treatment of Unallowable Costs Previously Submitted for Payment: RIH (c) further agrees that within 60 days of the Effective Date of this Agreement it shall identify (1) through accounting records to the extent that is possible; 2) through memorandum records including diaries and informal logs, regardless of whether such records are part of official documentation, where accounting records are not available; and 3) through itemized estimates based on best available information, including all written records and the recollection of all relevant individuals, where no other accounting basis is available) to applicable Medicare and TRICARE fiscal intermediaries, carriers and/or contractors, and Medicaid, VA and FEHBP fiscal agents, any unallowable costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid Program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by RIH or any of its subsidiaries or affiliates, and will request, and agree, that such cost reports, cost statements, information reports or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. RIH agrees that the United States, at a minimum, shall be entitled to recoup from RIH any overpayment plus applicable interest and penalties as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements or requests for payment.

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Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice, and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by RIH or any of its subsidiaries on the effect of inclusion of unallowable costs (as defined in this Paragraph) on RIH or any of its subsidiaries' cost reports, cost statements or information reports. Nothing in this Agreement shall constitute a waiver of the rights of the United States to examine or reexamine the unallowable costs described in this Paragraph.

(d) Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine or reexamine RIH's books and records to determine that no unallowable costs have been claimed in accordance with the provisions of this Paragraph.

11. The Parties do not intend for there to be any third party beneficiaries to this Agreement. The Parties do not release any claims against any other person or entity, except to the extent expressly provided for in Paragraph 3, 4, 5, and 12.

12. RIH waives and shall not seek payment in the future for any of the health care claims covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

13. RIH warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for

new value given to RIH, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended and do, in fact, represent a reasonably equivalent exchange of value which is not intended to hinder, delay, or defraud any entity to which RIH was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

14. After this Agreement is executed and the Settlement Amount is received by the United States, the Parties will file with the Court within 10 days a stipulation that pursuant and subject to the terms of this Agreement (1) the Complaint filed by the United States against RIH in the action captioned <u>United States ex rel. Health Outcomes Technologies v. Rhode Island Hospital</u>, Civil Action No. 01-243-ML, in the United States District Court for the District of Rhode Island be dismissed with prejudice and (2) RIH be dismissed as a defendant in the complaint filed by Relator, transferred to the United States District Court for the District of Rhode Island, and assigned Civil Action No. 01-243-ML. It is understood and agreed by the parties that the dismissal will not be construed to bar any subsequent action relating to any billings by RIH to Medicare after September 30, 1997.

15. By this Agreement, the Relator and Relator's Counsel will release and will be deemed to release RIH, from any claim that the Relator and/or Relator's Counsel may have under 31 U.S.C. § 3730(d) to pay Relator's or Relator's Counsel attorneys' fees, expenses and costs.

16. Conditioned on RIH's payment in full of the Settlement Amount, Relator shall receive from the United States a payment amounting to \$ 90,172.21, which is calculated based upon both the Settlement Amount and an amount of \$19,087.19 that RIH had previously

refunded to the United States in connection with some of the claims included in the Covered Conduct. The United States shall pay Relator this amount within a reasonable time after receipt by the United States from RIH of the Settlement Amount. It is expressly understood and agreed that the United States in no way promises or guarantees nor is liable to Relator for the collection or payment of any funds pursuant to this Agreement or the payment or any Relator's share payments except as provided herein for funds actually collected and received by the United States.

17. On receipt of the payment described in Paragraph 16 above, Relator shall release and will be deemed to have released and forever discharged the United States, its officers, agents, and employees from any liability arising from the filing of Relator's complaint as against RIH, including any claim pursuant to 31 U.S.C. § 3730(d) to a share of any settlement proceeds received from RIH, and in full satisfaction and settlement of claims under this Agreement. Relator agrees and confirms that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

18. Each party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

19. RIH represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.

20. This Agreement is governed by the laws of the United States. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties under this Agreement will be the United States District Court for the District of Rhode Island, except that disputes arising under the Integrity Requirements of Paragraph 7 shall be resolved exclusively under the dispute resolution provisions at Appendix B to this Agreement.

21. This Agreement, the Declaration, and the Breach and Default Provisions, which are incorporated by reference, constitute the complete agreement between and among the Parties. This Agreement may not be amended except by written consent of the Parties, except that only RIH and OIG-HHS must agree in writing to modification of the Declaration attached as Appendix A or the Breach and Default Provisions attached as Appendix B.

22. The undersigned individual signing this Agreement on behalf of RIH represents and warrants that he or she is authorized to execute this Agreement on behalf of that entity. The individual signing this Agreement on behalf of the Relator represents and warrants that he is authorized by Relator to execute this Agreement. The undersigned United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.

23. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

24. This Agreement is binding on successors, transferees, and assigns.

25. The "Effective Date" of this Agreement shall be the date of signature of the last signatory to the Agreement.

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THE UNITED STATES OF AMERICA

DATED: <u>2/12/04</u>

BY:

MICHAEL F. HERTZ JOYCE R. BRANDA KEITH E. DOBBINS Civil Division U.S. Department of Justice

DATED: ____/11/04

BY:

LARRY J. GOLDBERG Assistant to the Inspector General for Legal Affairs Office of Inspector General United States Department of Health and Human Services

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RHODE ISLAND HOSPITAL

DATED: '04

BY: PH AMARAL, M.D. .10S

Rhode Island Hospital

12/04 DATED: 2

BY:

RÍCHARD P. WARD ROPES & GRAY One International Place Boston, MA 02110 Counsel for Rhode Island Hospital

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RELATOR HEALTH OUTCOMES TECHNOLOGIES

DATED: 2-11-0 ¥

BY:

KENNETH TRUJILLO TRUJILLO RODRIGUEZ & RICHARDS, LLC Attorneys for Relator Health Outcomes Technologies