

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement ("Agreement") is entered into between 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 Leesburg Regional Medical Center ("Leesburg"), (hereafter referred to as "the Parties"), through their authorized representatives.

II. PREAMBLE

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

A. Leesburg is a health care provider, and submitted or caused to be submitted, claims to Medicare for the inpatient treatment of Medicare beneficiaries.

B. The United States contends that Leesburg submitted or caused to be submitted claims for payment to the Medicare Program ("Medicare"), Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395 ddd(1997).

C. Medicare payments to a hospital for inpatient treatment rendered to a beneficiary generally are based upon the beneficiary's "principal diagnosis," as set forth by the

hospital.

D. The Medicare program relies upon participating hospitals to properly indicate the principal diagnosis through the use of standard diagnosis codes.¹

E. The United States conducted an investigation into inpatient payment claims submitted to Medicare with the principal diagnosis code of 482.89 (pneumonia due to "other specified bacteria").

F. The United States contends that it has certain civil claims against Leesburg under the False Claims Act, 31 U.S.C. §§ 3729-3733, and other federal statutes and/or common law doctrines as more specifically identified in paragraph 5 below, for the following alleged conduct during the period from October 1, 1992 to December 31, 2000: Leesburg submitted or caused to be submitted claims to Medicare with the principal diagnosis code of 482.89 that were not supported by the corresponding medical records (hereinafter referred to as the "Covered Conduct"). The United States alleges that, as a result of these claims, Leesburg received payments to which it was not entitled.

G. The United States also contends that it has certain administrative claims against Leesburg under the provisions for permissive exclusion from Medicare, Medicaid and other federal

¹ International Classification of Diseases, 9th Revision, Clinical Modification ("ICD-9-CM").

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.

H. Leesburg has provided information to the United States in response to the government's investigation of the Covered Conduct, including patient files for which claims were submitted to the Medicare program with the principal diagnosis of ICD-9 code 482.89, and Leesburg represents that such response has been truthful, accurate, and complete to the best of its knowledge and ability.

I. Leesburg denies the contentions of the United States as set forth in Paragraphs F and G above and as set forth in United States ex rel. Health Outcomes Technologies Inc. v. Leesburg Regional Medical Center (M.D. Fla.) (UNDER SEAL).

J. To avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, the Parties have reached a full and final settlement as set forth 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. Leesburg agrees to pay to the United States \$1,476,104 (the "Settlement Amount") as follows: Leesburg 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. Leesburg agrees to make this electronic funds transfer no later than five days from the effective date of this Agreement.

2. Leesburg agrees to cooperate fully and in good faith with the United States in the administrative, civil or criminal investigation or prosecution of any other person concerning the Covered Conduct by providing accurate, truthful, and complete information whenever, wherever, to whomever and in whatever form the United States reasonably may request. Upon reasonable notice, Leesburg will furnish to the United States all documents and records in its possession, custody or control relating to the Covered Conduct, other than documents that are privileged or attorney work product, and will make reasonable efforts to facilitate access to, and encourage the cooperation of, its directors, officers, and employees for interviews and testimony, provided however, that notwithstanding any provision of this agreement: (1) Leesburg is not required to request of its present or former officers, directors, employees or agents that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) Leesburg is not required to take any action against its officers, directors, employees or agents for following their attorney's advice; and (3) Leesburg is not

required to waive any privilege or claim of work product.

3. Leesburg has entered into a Corporate Integrity Agreement with HHS, attached as Exhibit A, which is incorporated into this Agreement by reference. Leesburg will implement its obligations under the Corporate Integrity Agreement as set forth in the Corporate Integrity Agreement.

4. Leesburg releases the United States, HHS, and each of their agencies, officers, agents, employees, and contractors and their employees and Relator from any and all claims, causes of action, adjustments, and set-offs of any kind arising out of or pertaining to the Covered Conduct, including the investigation of the Covered Conduct and this Agreement.

5. Subject to the exceptions in Paragraph 7 below, in consideration of the obligations of Leesburg set forth in this Agreement, conditioned upon Leesburg's payment in full of the Settlement Amount, the United States (on behalf of itself, its officers, agents, and its agencies and departments referenced above in paragraph 4), and Relator agree to release Leesburg, its predecessors, corporate members, subsidiaries, successors, assigns, and current and former directors, officers, and employees from any civil or administrative monetary claim the United States has or may have 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 theories of payment by mistake, unjust enrichment, breach of contract and fraud, for the Covered Conduct. Except as provided above, the United States expressly reserves any claims against any entities and individuals other than Leesburg.

6. In consideration of the obligations of Leesburg set forth in this Agreement and the Corporate Compliance Agreement referred to in Paragraph 3, and conditioned upon Leesburg's payment in full of the Settlement Amount, the OIG-HHS agrees to release and 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 Leesburg 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 this Paragraph. The OIG-HHS expressly reserves all rights to comply with any statutory obligations to exclude Leesburg 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 7, below.

7. 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 Leesburg) are any and all of the following:

- (1) Any civil, criminal or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code);
- (2) Any criminal liability;
- (3) Except as explicitly otherwise stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- (4) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- (5) Any claims based upon such obligations as are created by this Agreement;
- (6) Any express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services, provided by Leesburg;
- (7) Any claims based on a failure to deliver items or services billed;
- (8) Any civil or administrative claims against any individuals, including officers and employees, who, related to the Covered Conduct, receive written notification that they are a target of a criminal investigation, are criminally indicted or charged, or are convicted (by verdict or plea).

8. Leesburg waives and will not assert any defenses it may

have to any criminal prosecution or administrative action relating to the Covered Conduct, which defenses may be based in whole or in part on a contention that, under the Double Jeopardy or Excessive Fines Clause of the Constitution, this settlement bars a remedy sought in such criminal prosecution or administrative action. Leesburg agrees that this settlement is not punitive in purpose or effect. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

9. Leesburg agrees not to resubmit to any Medicare carrier or intermediary or any State payer any previously denied claims related to the Covered Conduct, and agrees not to appeal any such denials of claims.

10. Leesburg agrees that all costs (as defined in the Federal Acquisition Regulations ("FAR") § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ddd (1997) and 1396-1396v (1997), and the regulations promulgated thereunder) incurred by or on behalf of Leesburg in connection with: (1) the matters covered by this Agreement, (2) the Government's audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement, (3) Leesburg's investigation, audit, defense, and corrective actions

undertaken in response to the Government's audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees and obligations undertaken pursuant to the Corporate Integrity Agreement), (4) the negotiation of this Agreement and the Corporate Integrity Agreement, and (5) the payment made pursuant to this Agreement, are unallowable costs on Government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, Veterans Affairs Program, and Federal Employee Health Benefits Program (hereafter, "unallowable costs"). These unallowable costs will be separately estimated and accounted for by Leesburg and Leesburg 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 such unallowable costs through any cost report, cost statement, information statement or payment request submitted by Leesburg or any of its subsidiaries to the Medicare, Medicaid, TRICARE, VA or FEHBP programs.

Leesburg further agrees that within 60 days of the effective date of this Agreement it will identify 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 Leesburg, 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. Leesburg agrees that the United States will be entitled to recoup from Leesburg any overpayment as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements or requests for payment. 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 Leesburg on the effect of inclusion of unallowable costs (as defined in this paragraph) on Leesburg's 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.

11. This Agreement is intended to be for the benefit of the Parties only, and, except as provided in paragraph 5, by this instrument the Parties do not release any claims against any other person or entity.

12. Leesburg agrees that it will not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents or sponsors. Leesburg waives any causes of action against these beneficiaries or their parents or sponsors based upon the claims for payment covered by this Agreement.

13. After this Agreement is executed and the Settlement Amount is received by the United States, the United States and Relator will notify the Court that they stipulate and request that Leesburg be dismissed with prejudice from the action captioned United States ex rel. Health Outcomes Technologies v. Leesburg Regional Medical Center (UNDER SEAL), in the United States District Court for the Middle District of Florida.

14. By this Agreement, the Relator and Relator's Counsel will release and will be deemed to release Leesburg, 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.

15. Conditioned on Leesburg's payment in full of the Settlement Amount, Relator shall receive from the United States a payment amounting to \$206,655. The United States shall pay relator this amount within a reasonable time after receipt by the United States from Leesburg 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.

16. On receipt of the payment described in Paragraph 15 above, Relator will 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 the Complaint as against Leesburg, including any claim pursuant to 31 U.S.C. § 3730(d) to a share of any settlement proceeds received from Leesburg, and in full satisfaction and settlement of claims under this Agreement.

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

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

19. 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 Middle District of Florida, except that disputes arising under

the Corporate Integrity Agreement (attached as Exhibit A) shall be resolved exclusively under the dispute resolution provisions set forth in the Corporate Integrity Agreement.

20. This Agreement, including Exhibit A, constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties, except that only Leesburg and OIG-HHS must agree in writing to modify the Corporate Integrity Agreement.

21. All parties consent to the disclosure of this Agreement, and information about this Agreement, to the public.

22. The undersigned individuals signing this Agreement on behalf of Leesburg represent and warrant that they are authorized to execute this Agreement on behalf of the entity. 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.

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

25. This Agreement is effective on the date of signature of the last signatory to the Agreement.

THE UNITED STATES OF AMERICA

DATED: 1/23/03

BY: *Michael Rubinstein*
MICHAEL RUBINSTEIN
Assistant United States Attorney

DATED: _____

BY: _____
MICHAEL F. HERTZ
JOYCE R. BRANDA
JAMIE ANN YAVELBERG
KEITH E. DOBBINS
Civil Division
U.S. Department of Justice

DATED: _____

BY: _____
LEWIS MORRIS
Chief Counsel to the
Inspector General
Office of Inspector General
United States Department of
Health and Human Services

LEESBURG REGIONAL MEDICAL CENTER

DATED: _____

BY: _____
Leesburg Regional Medical
Center

DATED: _____

BY: _____
MCDERMOTT, WILL & EMERY
227 West Monroe Street
Chicago, IL 60606-5096
Counsel for Leesburg Regional
Medical Center

25. This Agreement is effective on the date of signature of the last signatory to the Agreement.

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____


MICHAEL RUBINSTEIN
Assistant United States Attorney

DATED: 1/17/03

BY: 

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

DATED: 7/19/03

BY: 

LEWIS MORRIS
Chief Counsel to the
Inspector General
Office of Inspector General
United States Department of
Health and Human Services

LEESBURG REGIONAL MEDICAL CENTER

DATED: _____

BY: _____

Leesburg Regional Medical
Center

DATED: _____

BY: _____

MCDERMOTT, WILL & EMERY
227 West Monroe Street
Chicago, IL 60606-5096
Counsel for Leesburg Regional
Medical Center

25. This Agreement is effective on the date of signature of the last signatory to the Agreement.

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

MICHAEL RUBINSTEIN
Assistant United States Attorney

DATED: _____

BY: _____

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

DATED: _____

BY: _____

LEWIS MORRIS
Chief Counsel to the
Inspector General
Office of Inspector General
United States Department of
Health and Human Services

LEESBURG REGIONAL MEDICAL CENTER

DATED: 1-16-03

BY: _____

RICHARD L. WOOTEN PRESIDENT & CEO
Leesburg Regional Medical
Center

DATED: 1-14-03

BY: _____

MCDERMOTT, WILL & EMERY
227 West Monroe Street
Chicago, IL 60606-5096
Counsel for Leesburg Regional
Medical Center

RELATOR HEALTH OUTCOMES TECHNOLOGIES

DATED: 1-17-03

BY: 
TRUJILLO RODRIGUEZ & RICHARDS, LLC
Counsel for Relator
Health Outcomes Technologies