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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE

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U.S. DISTRICT COURT
EASTERN DIST. TENN.

UNITED STATES OF AMERICA, ex rel. LAURIE SALMONS and LISA BROCCO,	)	3:05-CV-210
Plaintiffs/Relators,	)	No.: Jordan/Shirley
v.	)	
HILL-ROM COMPANY, INC.,	)	
Defendant.	)	

BY _____ DEP. CLERK

QUI TAM COMPLAINT

Relators, Laurie Salmons and Lisa Brocco, through their attorneys and on behalf of the United States of America, for their Complaint against Hill-Rom Company, Inc., Defendant, allege as follows:

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II. NATURE OF THE CASE

1. This action is brought under the qui tam provisions of the United States False Claims Act, 31 U.S.C. § 3729, et seq. (FCA). This action arises from Defendant's fraudulent and improper claims and practices and policies. Defendant has certified compliance with federal statutes and regulations controlling medical benefit payments in violation of the laws of the United States. Defendant has received funds from the United States Treasury to which it is not entitled and which the United States would not otherwise have been required to pay. The proximate result of Defendant's conduct is unjustified and illegal enrichment of Defendant and the waste of millions of federal dollars.

2. Relators seek through this action to recover damages and civil penalties arising from the false and improper charges contained in claims for payment which Defendant and those with which it was acting in concert caused to be submitted to the government under the federal Medicare and Medicaid programs.

3. The False Claims Act provides, inter alia, that any person who knowingly submits a false or fraudulent claim to the Federal government for payment or approval is liable to the Government for a civil penalty of not less than $5,500.00 and not more than $11,000.00 for each claim, plus three times the amount of the false claim. 31 U.S.C. § 3729(a).

4. Under the Act, a person ('relator") with knowledge of false or fraudulent claims

against the Government may bring an action on behalf of the Government and himself. Such an action must be filed under seal, without service on the defendant, for sixty days. The seal period is designed to permit the Government to (1) pursue its own investigation of the matter without the Defendant's knowledge of the suit and (2) determine whether to join and take over prosecution of the suit. At the time the suit is filed, the relator must provide a written statement of all material evidence in his possession to the U.S. Attorney General. 31 U.S.C. § 3730.

5. Relators' claims are based on Defendant's submission of false and fraudulent claims and billing statements to the United States for durable medical equipment during the period from at least 1994 and continuing through the date of the filing of this Complaint. During the relevant times, Defendant submitted numerous claims to Medicare and/or Medicaid for bed support surfaces when such surfaces were not medically necessary, and/or when Defendant lacked adequate documentation and records to support the claims, and it concealed refunds and failed to make refunds due to Medicare and Medicaid as a result of improper billing. During said time period Defendant submitted numerous claims to Medicare and/or Medicaid falsely certifying it was in compliance when it was not.

6. On behalf of the United States, Relators seek through this action to recover damages and civil penalties arising from false claims for payment that Defendant caused to be submitted to the United States under a federally funded health care benefit program and from retaining refunds due and payable to the United States.

III. THE PARTIES

A. The Relators

7. Relator, Laurie Salmons, is a citizen and resident of Knoxville, Tennessee. Relator, Laurie Salmons, is a Registered Nurse. She is a former employee of Defendant, first employed in July, 1987 as a Medical Sales Consultant in Acute Care. The Relator, Laurie Salmons, reported to Kathy Eaton, the Regional Director of the South Atlantic Region that consists of North Carolina, Virginia and Tennessee. In 1994, Laurie Salmons changed to home care, and eventually became a supervisor over five Account Sales Representatives ("ASRs") as the Account Manager for

Tennessee. The Relator, Laurie Salmons, remained as the Account Manager for Tennessee until February 2002. In February, 2002, Defendant laid off 45 employees and Relator, Laurie Salmons, was retained effective March 1, 2002, but as an ASR in Knoxville. In July, 2002, Relator, Laurie Salmons, resigned her position at Hill-Rom Clinical Division when she accepted a position as Director of Disease State Management-Wound with a large Home Health Agency, Amedisys. At the time of the separation of her employment from Defendant, she was an ASR for the Knoxville, Tennessee area. She resigned from Amedisys, Inc., on August 1, 2004, and she is currently self employed in healthcare.

8. Relator, Lisa Brocco, is a citizen and resident of Hendersonville, Tennessee. She is a Registered Nurse. She was hired by Defendant as a Medical Sales Consultant in Acute Care in May, 1983. She changed to home care in March of 1995 and became an ASR assigned to Middle Tennessee and Western Kentucky. The Relator, Lisa Brocco, also worked out of the South Atlantic Region. Relator, Lisa Brocco, has served in the position of ASR from March 1995 to present. She is a current employee of Defendant as of the time of the filing of this Complaint.

B. The Defendant And Its Business

9. Defendant has its main corporate offices located at 700 State Route 46E, Batesville, Indiana 47006-8835, and also has corporate offices in Charleston, South Carolina. Defendant does business in the State of Tennessee and may be served with process through its Registered Agent, CT Corporation System, at 800 S. Gay Street, Suite 2021, Knoxville, Tennessee 37929-9710.

10. Defendant is an international company operating throughout the United States and in other countries. Defendant employs approximately 6,000 people worldwide. Defendant is an operating company of Hillenbrand Industries, Inc. Hillenbrand is a publicly traded holding company for three wholly owned businesses serving funeral services and health care industries. Along with Advanced Respiratory, Inc., Defendant forms Hillenbrand's Clinical Division.

11. Defendant is one of the major providers of durable medical equipment (DME) in the U.S., including Group 2 bed support surfaces. Many of these support surfaces are billed to and paid for by Medicare and Medicaid. Defendant supplies hospital beds and support surfaces used on top

of beds to treat patients with decubitus ulcers; technically, pressure sores. Relators state that Defendant rents hospital beds and support surfaces. Defendant bills Medicare, Medicaid, and private insurance and other payers for rental of medical equipment. Relators allege that Defendant's home care division has revenues of approximately, sixty million dollars ($60,000,000.00) a year of which a substantial part is derived from Medicare and Medicaid.

12. Relators allege that Defendant provides several types of support products and different forms are used for each type. The terms Group 1, Group 2, and Group 3 bed support surfaces, are Medicare terms. Group 1 includes foam mattresses, which are purchased outright for $200, or alternating pressure pads, which are rented for $15 per month. Relators state that Group 1 bed support surfaces consist of a variety of non-powered and powered pressure reducing overlays and mattresses. Group 2 bed support surfaces includes more sophisticated non-powered and powered pressure reducing overlays and mattresses and low air loss electric hospital beds. Group 3 is limited to air fluidized beds. In addition, Relators state that Defendant also provides service and maintenance for bed support surfaces rented to Medicare patients. Group 2 bed support surfaces are rented by Medicare beneficiaries on a monthly basis for as much as $700. The Group 3 Clinitron bed rents on a monthly basis for between $2,000 and $3,000. With the exception of Group 1 bed support surfaces, Defendant produces and owns the Group 2 and Group 3 bed support surfaces that it leases.

13. Relators allege that Defendant employs approximately 72 Account Sales Representatives ("ASR") and each receives commissions on rentals in their territory, and each ASR at any given time would have an average of approximately 50 Group 2 bed support surfaces in use in their territory. Relators state that Defendant has regional sales directors who supervise anywhere from seven to twelve ASRs. Relators state that ASRs mainly engage in selling. Relators state that ASRs promote Defendant's products and try to set up referrals to encourage home health care agencies to refer their patients to Defendant when appropriate. ASRs make sales calls on home health care agencies and hospital discharge planners and social workers to obtain referrals for patients in need of bed support surfaces. Occasionally, ASRs visit specialized physicians, such as

plastic surgeons. Relators state that many ASRs are nurses. Relators state that ASRs earn commissions of approximately three to fifteen percent of their sales depending on sales volume. On information and belief, Relators allege that the average ASR makes approximately $70,000 per year in salary, commissions, and bonuses.

IV. SOURCE OF RELATORS' ALLEGATIONS

14. Relators state that all allegations in this Complaint are based on evidence obtained directly by Relators independently, and through their own labor and efforts. The information and evidence that they have obtained or of which they have personal knowledge, and on which these allegations of violations of the Federal False Claims Act are based, consist of documents, computer data, conversations with authorized agents and employees of Defendant, and knowledge of other actions taken pursuant to policy, practice, or instructions while employed by Defendant. Relators are therefore original sources of information within the meaning of the False Claims Act, 31 U.S.C. § 3730(e)(4)(B).

V. JURISDICTION AND VENUE

15. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 (federal question), 28 U.S.C. § 1345 (United States as Plaintiff), and 31 U.S.C. §§ 3729-3733 (False Claims Act).

16. In addition, to promote judicial efficiency, this Court may exercise supplemental jurisdiction over claims under state common law pursuant to 28 U.S.C. § 3732(b) and 28 U.S.C. § 1367(a), in that all state created claims pleaded or that may be pleaded in this case arise out of a common nucleus of operative facts.

17. This Court has personal jurisdiction over Defendant pursuant to 31 U.S.C. § 3732(a) because Defendant does business in the Eastern District of Tennessee.

18. Venue lies within the Eastern District of Tennessee pursuant to 28 U.S.C. §§ 1391(b) and (c)) and 31 U.S.C. § 3732(a) because some of the acts and practices alleged in this Complaint occurred in this District.

VI. SUMMARY OF RELATORS' CLAIMS

19. Although Defendant had numerous compliance problems going back to the time period Relators were transferred into Defendant's home care section, Defendant's compliance problems sky rocketed beginning in December 2001 when Defendant formed Order Management Group ("OMG") which became responsible for handling paperwork for the initial placement of the bed support surfaces, handling billing functions, monitoring patients to insure medical necessity continued to exist, and making sure appropriate paperwork existed to show medical necessity. At that time, Defendant laid off the clinical field employees, and failed to provide OMG with sufficient staff or clinically trained staff to properly perform their duties. From 2001 forward, the medical necessity part of OMG's job and documentation part of OMG's job was not being performed, especially on patients who had been placed on Group 2 support surfaces. These patients may have initially qualified for the bed support surfaces, but on numerous occasions, the bed sores healed and the patients remained on the bed support surfaces for long periods of time after medical necessity no longer existed. As a result, Defendant has submitted numerous claims to Medicare or Medicaid on patients for unnecessary medical treatment and/or where there was inadequate documentation establishing medical necessity. The Relators estimate that Defendant has submitted claims to Medicare or Medicaid of approximately $10,000,000.00 to $15,000,000.00 per year on patients who did not qualify based on medical necessity and/or where there was no documentation establishing medical necessity.

20. Relators allege that it is Defendant's practices primarily with respect to Group 2 bed support surfaces that are the basis of the subject matter of this complaint, but Defendant's practices with respect to its other support surfaces also involve false and fraudulent claims. Medicare claims in connection with Group 2 bed support surfaces use the claims procedure code EO277 and E0372. On an annual basis, Relators would estimate that Defendant bills Medicare approximately Thirty Million dollars ($30,000,000.00) a year for Group 2 bed support surfaces.

21. Relators allege that Defendant has violated 31 U.S.C. § 3729, *et seq.*, in that it:

1. Submitted numerous improper, false and/or fraudulent claims for payment to

Medicare and/or Medicaid:

A. On patients who were inappropriately placed on bed support surfaces when they did not have qualifying pressure sores, and therefore where medical necessity did not exist; and

B. On patients who initially qualified for bed support surfaces, but who remained on the bed support surfaces for long periods of time after they ceased to qualify, and therefore where medical necessity did not exist.

2. Defendant submitted numerous claims when it falsely certified it had appropriate documentation indicating medical necessity, but when it had no such documentation.

3. Defendant is aware of or had reason to know it had received payments on numerous claims it was not entitled to and it failed to refund such overpayments to the United States, but rather concealed refunds due.

VII. FEDERAL MEDICARE HEALTH CARE BENEFIT PROGRAM: APPLICABLE LAW AND REGULATIONS

22. Various provisions of the United States Code authorize payment of federally funded benefits by federal and state health care benefit programs, which include programs known as Medicare and Medicaid.

23. The Social Security Act codified in Title 42 of the United States Code authorizes the payment of certain benefits for medical treatment of persons who are qualified on the basis of age, disability, or affliction with end-stage renal disease. This health care benefit program is known as Medicare. Reimbursement of hospital costs or charges is governed by Part A of Medicare, 42 U.S.C. §§ 1395c through 1395i-5, and reimbursement of physicians' charges as well as medical goods and supplies is subject to Part B, 42 U.S.C. §§ 1395j through 1395w-4. Post-institutional home health services are subject to Part A, 42 U.S.C. § 1395d(a)(3). Some Durable Medical Equipment ("DME") costs may be reimbursed under part A pursuant to 42 U.S.C. § 1395f(k). As part of Part B benefits,

Medicare pays certain costs associated with home health care pursuant to 42 U.S.C. § 1395k(a)(2)(A). These costs include durable medical equipment ("DME") provided by qualified suppliers. 42 U.S.C. §§ 1395l(a)(1)(I), (Q), (V); 1395m(a)(7), (8), (21)(B); 1395m(j); 1395w-3(a)(2)(A). See generally, 42 U.S.C. §§ 1395x(m), 1395x(n), 1395x(o), 1395x(s)(6), 1395x(u), 1395x(ee), and 1395x(tt).

24. Funds to support these federal health benefit programs are appropriated from the United States Treasury as required pursuant to 42 U.S.C. § 1395w and other provisions of the United States Code.

25. Acting for the United States through the Department of Health, the Centers for Medicare and Medicaid Services (CMS, formerly the Health Care Finance Administration (HCFA)) administers the Medicare and Medicaid programs and has the authority to promulgate regulations. 42 U.S.C. § 1395hh(a)(1); 42 C.F.R. §§ 400.200, 489.1(c).

26. CMS makes periodic payments to providers (including suppliers of medical goods) and physicians who submit claims under Medicare reimbursement provisions. 42 U.S.C. § 1395l(a); 42 C.F.R., Parts 414, 415, and 424. See generally, 42 C.F.R., Part 489. Pursuant to statutory authority, CMS obtains the services of intermediaries to process and pay claims by providers, suppliers, and physicians seeking reimbursement under the Medicare statute. 42 U.S.C. § 1395u. Fiscal intermediaries also pay home health care claims. 42 U.S.C. § 1395u(b)(2)(E). Payment may be made to a provider or supplier only when supported by necessary and accurate information. 42 U.S.C. § 1395l(e). See generally, 42 C.F.R., Part 483, Subpart B; 42 C.F.R. § 489.20(f).

27. Under Part A, providers and suppliers are entitled to reimbursement based on several methods, depending on the relation of the provider or supplier to Medicare as a participating or nonparticipating provider. 42 C.F.R. §§ 409.3, 424.3, 424.51; 42 C.F.R. § 413, Subpart J. Under 42 U.S.C. § 1395d, benefits are available for inpatient hospital services, post-hospital extended care services, including home health care, and hospice care. A physician must certify that such treatment is necessary. 42 U.S.C. § 1395f(a)(2). The method of payment of benefits is authorized by 42 U.S.C. § 1395f(b) and 42 U.S.C. § 1395g. In some instances, payment is based on a per diem

amount. E.g., 42 U.S.C. § 1395yy. Supplies are covered as allowed by regulation. 42 C.F.R. §§ 409.14, 410.12, 424.55. Durable Medical Equipment ("DME") is also covered under Part A in some instances. 42 C.F.R. § 409.45(e).

28. Specific types of medical services, goods, and supplies are covered under Medicare Part B. The scope of benefits is controlled by 42 U.S.C. § 1395k and 42 C.F.R. § 410.10. Benefits include physicians' services as well as incidental services and supplies commonly provided in the performance of physicians' services and also certain diagnostic services, 42 U.S.C. §§ 1395k(a), 1395x(q), 1395x(s)(1), 1395w-4(f)(4)(A) (physicians' reimbursable services), and 1395xx(a)(1). See generally, 42 C.F.R. Parts 410, 411, 414, 415, and 422.

29. By statute, Medicare regulations controlling payments under Part B establish the reimbursement of provider supplies, goods, and services. 42 U.S.C. § 1395m; 42 C.F.R. Part 414, Subparts D and I; 42 C.F.R. Part 405, Subpart E. Under Medicare Part B, certain providers and suppliers may become participating providers and suppliers and accept assignments of coverage from qualified patients to obtain reimbursements under Medicare. 42 U.S.C. § 1395u(h)(1); 42 U.S.C. § 1395u(i); 42 C.F.R. §§ 414.20 and 489.13(a). Participating providers and suppliers are required to follow billing, accounting, and documentation requirements imposed by regulations and fiscal intermediaries. 42 U.S.C. § 1320c-5(a); 42 U.S.C. § 1320a-7(b)(11); 42 U.S.C. § 1395u(i); 42 C.F.R. §§ 424.5, 489.20(f).

30. Medicare Part B claims must be coded as required by regulation. 42 U.S.C. § 1395yy(a)(10); 42 C.F.R. §§ 414.2, 414.20, 424.32. Physician certification is required before payment may be made for Part B benefits. 42 U.S.C. § 1395n(a); 42 C.F.R. §§ 424.13, 424.20, 489.21. Providers or suppliers may be reimbursed for the reasonable costs of these services and items as provided by regulation. 42 U.S.C. §§ 1395x(v)(1)(E), 1395tt(a), and 1395yy; 42 C.F.R. §§ 413.1, 413.13. All requests for payment for these services or medical goods must include a Medicare provider number. 42 U.S.C. §§ 1395u(t), and 1395cc. Any amounts in benefits incorrectly overpaid must be accounted for by the provider or supplier. 42 U.S.C. §§ 1395cc(a)(1)(C), (a)(1)(H)(ii).

31. Home Health Care Services are authorized by Medicare under 42 U.S.C. §

1395d(a)(3) for Part A and 42 U.S.C. § 1395k(a)(2)(A) under Part B. See also, 42 C.F.R. §§ 409.40, 410.1(a)(1), and 410.80, as well as Part 484. These services are provided by Home Health Agencies as defined by 42 U.S.C. § 1395x(o). Home Health Agencies may enter into an agreement to participate in Medicare as provided by 42 C.F.R. §§ 489.2(b)(3) and 489.10(c), (d), (e). Home Health Agencies may be accredited by accreditation bodies to establish eligibility to participate in Medicare. 42 U.S.C. §§ 1395bb and 1395cc(a)(1)(P), (Q). See also, 42 U.S.C. §§ 1395z and 1395aa(a); 42 C.F.R. §§ 488.1 and 488.6. Home Health Services are defined by 42 U.S.C. § 1395x(m) to include durable medical equipment ("DME") as required by a plan of care established by a physician. 42 U.S.C. § 1395m(j)(5); 42 C.F.R. §§ 409.43, 410.3(a)(3), and 484.18. Home Health Agencies may make arrangements with suppliers to provide DME to their patients. E.g., 42 U.S.C. § 1395u(p)(4); 42 C.F.R. §§ 410.150(b)(5), (6), (19) and 410.152(d),(g).

32. Payments are made to Home Health Agencies pursuant to 42 U.S.C. § 1395f(k) and for DME as provided in 42 U.S.C. § 1395m(a)(1). Conditions are placed upon the participation of Home Health Agencies under 42 U.S.C. § 1395bbb. Moreover, payment of claims is subject to 42 U.S.C. § 1395n, which requires, among other things, not only that a physician certify and subsequently recertify medical need when services or items are furnished over an extended period of time, but that such certifications and recertifications be documented and their continued medical necessity monitored in conformity with an established plan of care. 42 U.S.C. § 1395n(a)(2)(A); 42 C.F.R. §§ 409.41(b), 409.43(c)(3), 409.44(a), 410.12(a)(3), 411.1(a), 424.11(b), 424.22, 424.24, and 484.55. Recertifications must be conducted at least once every two months by a physician to establish continuing medical necessity. 42 C.F.R. § 484.55(d)(1). Home Health Agencies are required to maintain clinical records on their patients. 42 U.S.C. § 1395x(o)(3). See also, 42 U.S.C. §§ 1395x(s), 1395x(u), 1395x(ee)(2)(D), and 1395x(tt); 42 C.F.R. § 409.44, 424.11, 484.18, 484.48, and 489.21(a)(1).

33. Auditable medical records maintained by Home Health Agencies must contain sufficient documentation to support billing codes submitted as the basis of payment by Medicare carriers and must not be based on assumptions regarding the appropriate code and no bill may be

submitted without proper documentation. E.g., 42 C.F.R. § 405.512(a). Claims by Home Health Agencies must be filed with the appropriate fiscal intermediary pursuant to 42 U.S.C. § 1395u(b)(2)(E) and 42 C.F.R. § 424.32. No payment may be made for undocumented or unnecessary medical services. 42 U.S.C. § 1395y(a); 42 C.F.R. §§ 405.207(a), 424.24(b) and (f), 489.21(b)(1), 1001.701, and 1001.901.

34. Medicare benefits under Part B include durable medical equipment necessary for the treatment of any covered condition. 42 U.S.C. §§ 1395m(a)(13), 1395x(n), 1395x(s)(6); 42 C.F.R. §§ 405.500, 410.3(3), 410.10(h). DME is provided by a supplier qualified to participate in Medicare. 42 U.S.C. § 1395x(d). Regulations define suppliers as any entity that sells or rents DME to Part A or Part B covered beneficiaries. 42 C.F.R. § 424.57(a). Benefits for DME are payable under Part B as provided in 42 U.S.C. § 1395l(a)(1)(I) and (V) as well as 42 U.S.C. § 1395m(a). See also 42 C.F.R. § 414, Subpart D. In order for any DME to be covered, a physician or other authorized person must specify the type of equipment and write a prescription for the item. 42 U.S.C. §§ 1395m(a)(1)(E)(ii), 1395m(a)(11)(B); 42 C.F.R. § 410.12(a)(3). Part B pays for the rental or purchase of DME for the treatment of decubitus ulcers

> "if the equipment is ordered in writing by the beneficiary's attending physician, or by a specialty physician on referral from the beneficiary's attending physician, and the written order is furnished to the supplier before the delivery of the equipment," 42 C.F.R. § 410.38(d)(1),

and the prescribing physician monitors use of the equipment, 42 C.F.R. § 410.38(d)(2). No payment will be made for such DME unless medical necessity is properly documented. 42 U.S.C. § 1395m(a)(1)(E)(v); 42 C.F.R. § 405.501(d), 410.12(b). Cf. 42 U.S.C. § 1395m(a)(21)(B) (nonparticipating suppliers of hospital beds and air mattresses).

35. In conformity with these provisions, certificates of medical necessity are required for DME and must contain the identification of the supplier and the beneficiary, a description of the DME, the proper product code, and any necessary administrative information aside from information relating to the beneficiary's medical condition. 42 U.S.C. § 1395m(j)(2)(A)(i). The statute further defines a certificate of medical necessity as "a form or other document containing information

required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395m(j)(2)(B).

36. Pursuant to 42 U.S.C. § 1395m(a)(12) and § 1395u(a), for the administration of Medicare DME benefits, CMS divides the country into regions denominated A, B, C, and D. Tennessee is in Region C. 42 C.F.R. § 421.210(c). Regional carriers are designated for handling DME claims. 42 C.F.R. § 421.210(a). All suppliers of DME must obtain and periodically renew a supplier number pursuant to 42 U.S.C. § 1395m(j)(1)(A), and such suppliers may only obtain a number if those suppliers have met the standards imposed by statutes and regulations pursuant to 42 U.S.C. § 1395m(j)(1)(B)(ii)(I). See also, 42 C.F.R. §§ 424.57(b), 424.57(c)(1), (d), (e). Some medical devices and DME are subject to competitive acquisition regulations under 42 U.S.C. § 1395w-3(a)(2)(A). See also, 42 C.F.R. § 405.502(a)(6). Payments based on reasonable charges for certain DME are subject to 42 C.F.R. § 405.511 and coding systems must be used for these claims under 42 C.F.R. § 405.512(a).

37. Under 42 C.F.R. § 414.210, "Medicare pays for durable medical equipment ... including a separate payment for maintenance and servicing," 42 C.F.R. § 414.210(a), including DME "(capped rental items), as specified in § 414.229," § 414.210(b)(iv). Payment for maintenance and servicing of a rental item is thus subject to 42 C.F.R. §§ 414.210(e)(2) and 414.229. Equipment may be replaced in some instances subject to provisions on continuous use but the reasonable useful lifetime of DME cannot exceed 5 years from the date DME is delivered to the beneficiary. 42 C.F.R. § 414.210(f)(1). In the case of DME subject to capped rental under 42 C.F.R. § 414.229, the monthly fee schedule cannot exceed 10% of the purchase price for the first three months and 7.5% of the purchase price for the remaining months but in the tenth month of continuous use suppliers must offer beneficiaries a purchase option. 42 C.F.R. § 414.229(b)(2), (d)(2). If purchase is not elected by the beneficiary, "payment continues on a rental basis not to exceed a period of continuous use of longer than 15 months." 42 C.F.R. § 414.229(d)(2)(i). After this 15 month period, rental is capped and the supplier must supply DME "without charge, other than a charge for maintenance and

service fees, until medical necessity ends or Medicare coverage ceases." Id. Continuous use is defined in 42 C.F.R. § 414.230(b) as a period beginning with the first month of need and lasting until "a beneficiary's medical need for a particular item ... ends," id. Moreover, the criteria for a new rental period when use of DME is interrupted for a period of more than 60 consecutive days can begin only with a new prescription for DME and new documentation of medical necessity. 42 C.F.R. § 414.230(d).

38. Consequently, payments for DME are made on a monthly basis for the rental of such items during the period of medical need but may not exceed a continuous period of use longer than 15 months subject to certain conditions as to offering DME to the beneficiary for purchase. 42 U.S.C. § 1395m(a)(7)(A); 42 C.F.R. § 424.57(c)(5). Moreover, a supplier may bill for service and maintenance after the 15 month cap every six months but no rental may be paid after imposition of the cap when DME is used for a continuous time. 42 U.S.C. §§ 1395m(a)(7)(A)(iv), (v), (vi); 1395m(a)(11)(A).

39. The administration of Medicare relies on the physician's judgment in the first instance as to what services, prescriptions, supplies, or equipment and thus what charges will be medically necessary. 42 U.S.C. § 1395f(a); 42 U.S.C. § 1395n(a)(2)(B); 42 C.F.R. §§ 410.12(a)(3), 424.10, 424.24. Payments from Medicare are made based on accurate information required to determine the amount due for medical care ordered by physicians. 42 U.S.C. § 1395l(e); 42 U.S.C. § 1395n(a)(2); 42 U.S.C. § 1395u(p)(1). See generally, 42 C.F.R. Part 410, Subpart B; 42 C.F.R. Part 424, Subpart B; 42 C.F.R. §§ 405.803, 424.5(a)(6). No payment may be made when medical goods or services are not shown to be medically necessary. E.g., 42 U.S.C. § 1395y(a)(1)(A), (B).

40. Various claims forms and other regulatory requirements to obtain reimbursement require that the provider or supplier certify that the required medical care or supplies were actually provided at the level reported and were medically necessary and that the charges for the care do not exceed the charges paid by the general public for similar care as required by 42 U.S.C. § 1395n(a)(2). See also 42 U.S.C. § 1320c-5(a); 42 C.F.R. §§ 411.400, 411.406; 42 C.F.R. Part 424, Subpart B; 42 C.F.R. Part 410, Subpart B. Certification is also required that the information submitted is correct

and supported by documentation and treatment records. Id. See also, 42 U.S.C. § 1320c-5(a); 42 C.F.R. § 424.24. Certifying medical necessity of goods knowing that those goods were not delivered or provided or were delivered or provided solely for profit constitutes submission of a false or fraudulent claim. Intentionally billing Medicare for excessive charges is a felony under 42 U.S.C. § 1320a-7b(d).

41. The Medicare statute requires the creation of regulations controlling the factors used to determine the level of payments for various services, goods, and supplies provided to Medicare beneficiaries. 42 U.S.C. §§ 1395m, 1395u(b)(8); 42 U.S.C. § 1395x(v); 42 C.F.R. §§ 405.503, 405.511; 42 C.F.R., Part 414.

42. Under the statutorily mandated regulatory system establishing five-digit billing codes for use in making Medicare claims for reimbursement, various codes and modifiers are used to designate the level of service provided. 42 U.S.C. § 1395u(p)(1); 42 U.S.C. § 1395w-4(c)(5); 42 U.S.C. § 1395w-3a. Using what is known as the Health Care Common Procedure Coding System, providers and suppliers bill services and goods according to designated code numbers corresponding to the level of medical service or equipment provided. 42 C.F.R. §§ 405.512, 414.40; 42 C.F.R. § 424.32(a)(2).

43. A practice known as "upcoding" in the completion of Medicare claim forms involves misclassifying or mischaracterizing diagnoses, treatments, or goods to increase the level of reimbursement. Engaging in a persistent practice or pattern of "upcoding" is fraudulent. Improperly "upcoded" medical services or goods are not medically necessary or reasonable charges.

44. The practice known as "overutilization" occurs when services that are not medically necessary are billed to Medicare.

45. Under Medicare Part B, providers of medical services and goods to Medicare recipients submit claims for reimbursement to a Medicare carrier or fiscal intermediary on a form numbered "CMS 1500." 42 U.S.C. § 1395m(a); 42 U.S.C. § 1395w-4(g)(4)(A); 42 C.F.R. Part 424, Subpart C; 42 C.F.R. §§ 424.5(a)(5), 424.32. This form requires the provider or supplier to provide an identification number, patient information, and the five-digit code identifying the services or

items for which reimbursement is sought. A CMS 1500 lists those services or items provided to a single patient and may include a number of codes for treatment or items but constitutes a single claim for reimbursement.

46. A "clean claim" is one that has no defect or impropriety (including the lack of required substantiating documentation) or other circumstance indicating a need for special claim evaluation so that timely reimbursement of the provider or supplier is possible. 42 U.S.C. § 1395u(c)(2)(B)(i). A clean claim is to be paid promptly. 42 U.S.C. § 1395u(c)(2)(A); 42 U.S.C. § 1395h(c); 42 C.F.R. § 402.3.

47. The completion of claim forms using incorrect or improper or unsupported coding for charges causes the United States to pay claims for services or goods that were not provided or were not medically necessary. By certifying such a claim form, the provider or supplier is falsifying a document to obtain payment from the United States. When compliance with Medicare statutes and regulations is a condition of payment, falsely certifying such compliance constitutes falsification of a claim.

48. Under 42 U.S.C. § 1320a-7b(a)(3), providers, suppliers, and physicians taking Medicare assignments as well as beneficiaries themselves have a statutorily created duty to disclose overpayments and billing errors to the Medicare carrier. See also, e.g., 42 C.F.R. §§ 401.601(d)(iii), 411.353(d); 42 C.F.R. Part 405, Subpart C. A provider, supplier, or physician may not collect any amount not authorized by statute or regulation and such amounts must be refunded as appropriate. 42 C.F.R. §§ 489.40, 489.41. Under 42 U.S.C. § 1320a-7b(a)(3), intentional concealment of or intentional failure to disclose such overpayments or billing errors is a felony.

49. When CMS pays a claim for medical care or goods not provided or medically unnecessary, or when CMS has overpaid claims for any variety of reasons, including duplicate processing of charges, uncovered services, services for which the charge is unreasonable, or as a result of retaining duplicate payments, a refund is due to and a debt is created in favor of CMS. 42 U.S.C. § 1395u(l)(3). In such cases, the overpayment is subject to recoupment. 42 U.S.C. § 1395gg. See generally, 42 C.F.R. Part 405, Subpart C. CMS is entitled to collect interest on overpayments.

42 U.S.C. § 1395l(j). In addition, contractual obligations with CMS carriers or intermediaries require providers or suppliers to refund overpayments to such fiscal intermediaries. E.g., 42 U.S.C. § 1395u; 42 C.F.R. § 489.20(g).

50. Under Defendant's agreement as suppliers of DME under the Medicare and Medicaid provisions of the Social Security Act, Relators state that Defendant is required to maintain records to support the DME provided and for the determination of reasonable costs under 42 U.S.C. § 1395x(v). See also, 42 U.S.C. § 1395tt.

51. Relators state that DME suppliers utilize a manual from Medicare for coding called the DMERC manual. When the proper code is put on a bill with a modifier indicating that the patient meets medical necessity, the bill may be transmitted electronically. Each DMERC manual is designated by region. Region C includes Tennessee and other Southern states. Relators state that, as is the case in all Medicare regions, Medicare's Region D DMERC Supplier Manual, Chapter 3, page 5, revised January, 2003, states that for any supplied item of DME to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's condition to demonstrate medical necessity for the type of item supplied and for the frequency or duration of use. This information must include the patient's diagnosis, duration of the patient's condition, the clinical course, prognosis, as well as other information. A copy of any CMN should be kept in the patient's record. A Durable Medical Equipment Regional Carrier (DMERC) may deny any claim for which a supplier has insufficient proof of medical necessity. A simple form is by itself insufficient and additional records must substantiate any information on a CMN or other document showing medical necessity. Thus, in addition to the initial SOP, claims must be supported by a copy of the home health nurse's notes and the patient's chart and these must be available on a monthly basis.

52. Relators allege that properly supported claims by DME suppliers for providing bed support surfaces are indicated by a code modifier, "KX," which requires a supplier to have a monthly clinical records documenting continued medical necessity. This modifier was previously denoted as "ZX" and appears on some documentation. Both modifiers are used to show that medical necessity exists at the time that a bill is sent to Medicare. The "KX" modifier indicates that the

patient is being monitored, that medical necessity has been documented and that this documentation exists in the patient's home health care agency or the DME supplier's records.

53. Defendant submits its claims to Medicare electronically as permitted by 42 C.F.R. § 424.32(d). Defendant's invoices state the name of the product or service provided and the amount due. Relators state that the billing transactions reflected in Defendant's records would establish how bills were created and sent. Relators state that at the end of the month, Defendant's computer system bills Medicare for DME transactions. Relators state that rental payments for medical equipment are paid directly to Defendant and the patient receives a copy of a form called an explanation of benefits.

54. Relators allege that Certificates of Medical Necessity (CMN) are required before DME suppliers may provide medical equipment for planned home therapy for Group 1 and Group 2 bed support surfaces. Standardized intracompany CMN forms are used by DME suppliers for this purpose. Defendant uses a standard form from Hillenbrand Industries, titled "Statement of Ordering Physician, Group II, Support Services" (SOP) to support claims for rental of home health care Group 2 bed support surfaces. In order to bill Medicare for a Group 2 bed, a SOP showing medical necessity would have to exist and it would have to reflect that a patient qualified on the basis of appropriate stage pressure sores.

55. Relators state that after a bed support surface has been placed with a patient, it can be rented for up to nine months at which time a letter is sent to the patient offering to allow the patient to purchase or continue renting the bed support surface. This is standard practice and if the patient exercises the purchase option, the DME supplier then receives 13 months of payment and title is transferred to the patient. If the patient checks the continued rental option or fails to respond in 30 days, rental may continue for up to a total not to exceed 15 months, assuming the patient continues to qualify on the basis of medical necessity. Thereafter, if a patient meets medical necessity, the DME supplier may bill Medicare for maintenance and service every six (6) months.

56. Relators state that Defendant is a Medicare and Medicaid participating supplier and has entered into agreements with regional DME carriers that process and pay DME claims as delegated by CMS. Relators state that Defendant certifies its compliance with Medicare and

Medicaid regulations to obtain payments and participate in the Medicare and Medicaid programs.

57. Medicare is subject to anti-fraud and anti-kickback legislation. 42 U.S.C. §§ 1320a-7b(a)(6), (d)(1), and (f)(2). These restrictions forbid imposing excessive charges. Id. A provider, supplier, or a physician engaging in prohibited activities that result in submission of claims for excessive charges or for unnecessary medical services may be excluded from participation in federally funded health care benefit programs, including Medicare. 42 U.S.C. § 1320a-7. Suppliers and providers may not structure their marketing or sales plans so that improper incentives are created for overutilization of Medicare benefits. Sales commission programs that provide bonuses or other incentives based on volume of revenue produced tend to generate claims based on these improper incentives rather than medical necessity. 42 U.S.C. § 1320a-7a(i)(6); 42 C.F.R. § 1001.701, 1001.951, 1003.101. Fraudulent or improper practices justifying recoupment or other sanctions include noncompliance with contractual terms, excessive billing or overcharges, billing for undocumented services, knowingly providing incomplete or inaccurate information, persistent maintenance of poor records, and falsifying certifications.

VIII. SUBSTANTIVE ALLEGATIONS

58. Relators allege that Medicare only requires that the DME supplier have proper documentation to support the claims in the file, but does not otherwise monitor it in a meaningful manner, and Defendant has taken full advantage of Medicare's failure to monitor by submitting numerous false claims on patients on its bed support surfaces when it knew or should have known that medical necessity did not exist and/or where documentation establishing medical necessity did not exist. As a result of Defendant's practices, overutilization has occurred from at least 1994 up to the date of the filing of this complaint, but as hereinafter stated, the overutilization became massive on and after 2001 and said overutilization continues as of the date of the filing of this complaint.

59. The length of time a patient needs for healing of pressure sores depends upon the stage or extent of the sores. Patients with pressure sores are classified by the severity of their condition. To qualify for Group 2 bed support surfaces, a patient must have multiple stage 2, or

single stage 3, or stage 4 wounds. To qualify for a Group 2 bed support surface, a patient must have pressure sores on the trunk and pelvis, and most patients using the Group 2 beds have only stage 2 wounds. A stage 2 wound is a simple breaking of the skin similar to a blister and these wounds usually heal in 30 to 60 days, and usually in no more than about 90 days, depending on the condition of the patient. Once healed, the patient no longer qualifies for the Group 2 bed support surfaces, yet it is well known among employees of the Defendant that patients remain on Defendant's Group 2 bed support surfaces for extensive periods after medical necessity has ceased to exist. Defendant's Field Business Reports reflect the duration that Group 2 bed support surfaces are being provided to patients. These reports reflect the payor as well as the patient, and if used properly, would permit easy follow up on patient status. The reports reflect the date on which a patient is initially provided a bed support surface. These reports are generated weekly. These reports put Defendant's agents and employees on notice that numerous patients are remaining on the Group 2 bed support surfaces for unusually long periods of time and well beyond their thirty (30) to ninety (90) day expected times to heal, yet no effective follow up has been done by Defendant prior to submission of numerous claims to Medicare or Medicaid to verify continued medical necessity, and/or to insure appropriate paperwork exists.

60. Defendant has a form entitled "Statement of Continuing Medical Necessity -- Group 2 Support Surfaces." This form is rarely used. Initially, doctors will order bed support surfaces for usually a lifetime period, written as 99 on the Statement of Ordering Physician. If a doctor uses "99," further paperwork is not completed, and Defendant submits numerous claims assuming the patients continue to qualify on the basis of medical necessity.

61. Through the commission structure, Defendant's ASRs have an incentive to place and keep as many Group 2 beds in the field as possible even if the patients do not qualify for them or even after the patients cease to qualify for them, because the more bed support surfaces placed and maintained in the field, the higher their commissions. Relators allege that performance of ASRs is evaluated on the basis of the number of bed support surfaces placed and maintained in the field. Relators allege that clinical representatives have quotas for placements of Group 2 bed support

surfaces under Defendant's business plan. If placements or revenues fall, ASR's can be put on performance improvement plans that could lead to termination. Relators allege that incentives have also been given to ASRs through contests for the highest number of weekly placements, with bonuses such as $200 gift certificates or 42 inch televisions. It is against the monetary interest of the ASR's to have the nonqualifying patients removed from the bed support surfaces, and Defendant has made it abundantly clear to all ASR's that their duty is to obtain sales, and they expressly have no duties to confirm medical necessity.

62. In December 2001, Defendant created the Order Management Group (OMG) located in Charleston, South Carolina. (In or about August 16, 2003, OMG was subsequently renamed the Finance Processing Group (FPG) and placed under Defendant's Finance Department located in Batesville, Indiana, but the duties essentially remained the same. In this Complaint, the organization will continue to be referred to as OMG). OMG was assigned the task on a nationwide basis of obtaining SOPs from the physician at the time of initial placement of the bed support surfaces, handling billing, accounting for receipts, handling reimbursements, handling denials, and handling refunds. OMG was also supposed to communicate with patients and providers to make sure the medical files had appropriate documentation of medical necessity and that the patients still qualified for said bed support surfaces, but as hereinafter stated, OMG failed to perform these functions.

63. Relators allege that when OMG was established in December 2001, Defendant layed off the clinical support specialists who were in the field and thereafter assigned only a minimal staff of primarily non-clinical employees to OMG that was totally inadequate to keep up with the work load of doing both initial placements of Group 2 bed support surfaces (SOP duties), handling billing and accounting functions, and performing necessary follow up. As a result, OMG focused on its revenue generating functions, and did not follow up to determine whether medical necessity continued to exist after initial placement of bed support surfaces and did not follow up to determine whether there was appropriate paperwork in place documenting medical necessity, but Defendant continued to bill Medicare and Medicaid falsely certifying that it was in compliance. As a result, numerous false and fraudulent claims have been submitted to Medicare and Medicaid.

64. Relators allege that prior to the formation of OMG in 2001, Defendant had a "policy" of performing 90 day reviews after the initial placement of the Group 2 bed support surfaces even though it billed Medicare or Medicaid monthly. This "policy", however, was not emphasized or enforced, and such reviews were only sporadically performed. As a result, numerous claims were filed when medical necessity did not exist and when appropriate paperwork establishing medical necessity was not in place. To the extent the 90 day reviews were conducted, the reviews consisted primarily of a telephone call to determine whether medical necessity for a bed support surface continued to exist, or management employees would ask clinical personnel to pull charts. Some sales directors simply allowed the clinical personnel to select which charts would be examined. Regional Directors, moreover, would not request 90 day re-certifications period, and the Regional Directors had no tracking mechanism to make sure the 90 day re-certifications were occurring. Chris Sisson, a Clinical Sales Consultant for Defendant and for Tennessee for four years, informed Relator, Laurie Salmons in 2000 that he rarely conducted 90 day reviews because Defendant never required them, and Defendant never monitored whether recertifications were being conducted. Due to "more pressing duties," Mr. Sisson only checked on healing status sporadically, and this was a common practice among the clinical staff. Prior to the establishment of OMG in December 2001, Relators allege that ASRs and Clinical Sales Consultants had contact with patients and were generally aware of how long bed support surfaces had been placed. In conversations with patients, Relators allege that ASRs or Clinical Sales Consultants would often learn when the patient's wounds had healed, and as appropriate, some ASRs or Clinical Sales Consultants would arrange to exchange Group 2 bed support surfaces for a Group 1 surfaces when the patients no longer qualified for Group 2 beds even though it would negatively impact their sales. After OMG was established in 2001, this informal practice was discontinued, because all certification duties were expressly removed from the field.

65. Relators state that Defendant's noncompliance increased substantially after 2001 due to the establishment of OMG. The clinical sales consultants were laid off and responsibility for documentation and determining medical necessity was removed from the field and delegated to non-

clinical personnel in OMG, and OMG was persistently understaffed. As a result, OMG's main focus became revenue generating functions such as bed support placements and billing, and not monitoring documentation or whether medical necessity continued to exist. Relators state after OMG was created, ASRs, their managers, or Regional Sales Director, had no assigned duties to insure medical necessity existed or to insure whether medical necessity was documented, because under Defendant's established "policy," this was not their responsibility, and they were instructed by Debbie Heatherly in the Medicare Compliance Department as well as by Kim Archer and the regional sales directors that this was not part of their job duties. Moreover, it was clearly against the ASR's economic interest to have patients removed from bed surfaces.

66. Relator, Salmons, states she did not monitor medical necessity or medical documentation in any way after OMG was established because it was made clear to her this was not her responsibility, and she had only sporadically done this before OMG took over.

67. Relators allege that the effect of moving the certification/recertification/documentation responsibilities in December of 2001 from the field clinical representatives to OMG was to permit massive overutilization of Defendant's bed support surfaces for extended periods and to permit substantial undocumented billing.

68. As a result of the practices herein alleged, Relator, Laurie Salmons, estimates that in her Knoxville territory, the average duration of placement of Group 2 bed support surfaces is and has been approximately 10 months - well after the time period for many of the placements where medical necessity has ceased to exist. Relator, Lisa Brocco, estimates that of the approximate 130 patients on Defendant's bed support surfaces in her territory at any given time, approximately 30 (or 23%) would no longer qualify for the bed support surfaces if Defendant made an effort to recertify them. This estimate includes patients who are also on Group 3 bed support surfaces but the percentage would be higher if only Group 2 bed support surfaces were counted. Relator, Lisa Brocco, states that at any given time she would have approximately 80 to 90 patients in this Group 2 category, and that at different times anywhere from approximately thirty (30%) to fifty percent (50%) of these patients would fail to qualify for the bed support surfaces based on medical necessity

if Defendant made an effort to recertify its patients. Relators estimate that the percentages of nonqualifying patients would be similar throughout Defendant's operation, and that this situation has continued since OMG was established in December of 2001.

69. Since 2001, Defendant has announced different programs whereby supposedly Defendant was to begin 30 day or 90 day reviews, but as of the date of the filing of this suit no such programs have been effectively implemented. Without meaningful follow-up to verify continuing medical necessity, Relators allege that few patients initially approved for Group 2 bed support surfaces are eliminated from the books even though many patients who initially qualify for a Group 2 bed support surface would have healed within thirty to ninety days.

70. Relators state that private payers and Medicaid require periodic recertification of Group 2 bed support surfaces. Relators allege that Defendant has a recertification process in place for private insurance payers and Medicaid. Relators allege that Defendant makes an effort to recertify private insurance patients but knowingly permits Medicare to continue paying for Group 2 bed support surfaces without verifying medical necessity and without determining whether proper documentation exists. As a result, numerous claims have been paid by Medicare when the patients do not qualify and/or where supporting documentation does not exist. Relators state that a statistical study would demonstrate that a dramatic increase in the duration of placement of Defendant's Group 2 bed support surfaces provided to Medicare patients has occurred since 2001 as a result of Defendant's fraudulent practices.

71. Relators state that Claire Bales was in charge of OMG temporarily as of September, 2002. Her title was Acting Director of OMG, and she was temporarily assigned to OMG from Hillenbrand Industries to attempt to deal with excessive unbilled reports. Prior to Clair Bales, Mark Davis ran the OMG office. Relator, Lisa Brocco, is in possession of a copy of an email from Claire Bales to her dated September 16, 2002, in which responsibility for obtaining the SOP and other documentation was discussed. Relator, Lisa Brocco, communicated her concerns to Claire Bales that SOPs were not being done on a timely basis and that the change in management procedures within OMG was the cause of these lapses, resulting in customer dissatisfaction. These delays were also

causing the unbilled report to contain a higher number of unbilled placements than necessary. Claire Bales acknowledged that compliance was a major issue for Defendant.

72. Relator, Lisa Brocco, states that Karen Klein, a Med. B. Manager, informed her of a "secret" meeting in Charleston, South Carolina, in about January, 2003, involving Howard Miller, Kathy Klein, Debbie Heatherly, and Kathy Eaton in which a discussion was held concerning Defendant's lack of a 30 day review process to verify continuing medical necessity. It was discussed that if such a review process was implemented, there would be a profound negative impact on Defendant's revenues. Relators allege that a Medicare audit apparently prompted this January, 2003 meeting. Relators allege that approximately four to five months after the meeting, Howard Miller transferred to another division of Hill-Rom and as of the date of the filing of the Complaint, Defendant had still not implemented an effective 30 day or 90 day recertification process.

73. Relator, Lisa Brocco, received an e-mail dated January 4, 2003, from Lorna Weber, Manager of Sales and Service Operations, and Debbie Heatherly, Manager of Compliance and Regulatory, to Katherine Eaton, Relator, Lisa Brocco's supervisor, regarding a new patient form, which included space for documentation of patient condition. Relator, Brocco, used this e-mail as a way to document her understanding that the monthly followup (which was not occurring) was OMG's responsibility, but her boss, Kathy Eaton, never answered the question.

74. Relator, Laurie Salmons, states that she has spoken with Defendant's management employees concerning lack of any meaningful process or procedure for periodic recertification of medical necessity on several occasions. Relator, Laurie Salmons, states that she spoke with Joe Brickner, Defendant's National Accounts Director in Kennesaw, Georgia, and he admitted that Defendant failed to follow up on patients to determine whether they still met medical necessity and that Defendant failed to verify there was proper supporting documentation of medical necessity, and he admitted a new policy was overdue. Joe Brickner was formerly a Regional Director for several states in the Southeast, and as of December, 2003, he was the National Accounts Director until subsequently leaving Defendant's employment.

75. Relators state that Karen Klein was a Medicare Manager in the Charleston corporate

office and handled Medicare denials from approximately 1999 to present. Relator, Lisa Brocco, states that she has spoken with Karen Klein on two or three occasions concerning the general problem with lack of documentation of medical necessity and of Defendant's failure to follow up on patients assigned to Group 2 bed support surfaces to insure continuing medical necessity. Relators allege that Karen Klein admitted that a review process was needed and she admitted her concern that an effective review process would decrease revenues, perhaps by as much as fifty percent (50%) nationwide. Relators allege that Karen Klein stated that she had expressed concerns over the lack of a review process to the Vice President of Sales, Howard Miller, as well as other executives at Defendant but Defendant fails and otherwise refuses to correct this situation due to the negative financial impact that would occur despite the knowledge that false claims are being made.

76. Defendant had in April, 2003, a printed policy entitled "Compliance Program." Relators have a copy of this version of Defendant's compliance program. In § A.5.a, pages 21-25, the importance of obtaining the necessary documentation to support a finding of medical necessity is emphasized. On page 22, the manual notes that "[a]s a condition for payment, Medicare requires a patient's treating physician to certify initially and recertify at least every 62 days (2 months) that" a patient still qualified for DME and that Defendant had monitored the patient's condition. On page 49 of the April, 2003 Compliance Program manual, instructions are clear that Defendant is responsible for obtaining information establishing medical necessity, which must be submitted to the DMERC upon DMERC request. Additional guidance on documenting medical necessity is found in § B.7, at pages 64-86. However, Defendant has consistently failed to follow this program.

77. Relators allege that on August 25, 2003, by email, Defendant announced "new compliance procedures" to require clinical documentation and follow-up, but these "new compliance procedures" were not followed. The directive came from Alisa Cribb, a supervisor in OMG, and stated that Defendant intended to launch Medicare Part B documentation follow-up nationally on Tuesday, September 2, 2003. Relators state that this program followed a pilot program in the Southeast region. Relators state that the new procedure allegedly involved OMG requiring clinical documentation for Group 2 Medicare Part B patients from either the home health care agencies or

the physician at the time of placement. Relators state that Defendant was to utilize an automated process to generate letters to clinical contacts ten days prior to each billing cycle. Relators state that the letters requested information concerning the patient's continuing qualification. Relators allege that this new procedure, if followed, would have been a change from past practice because no follow-up had previously been done by OMG after obtaining the initial SOP at the time of placement, but this "new procedure" has not been followed by Defendant and it has not been effective to correct overutilization. Relator, Lisa Brocco, states that only 2 or 3 patients were removed from beds in her area, and many more should have been pulled if a good faith follow up had been implemented by Defendant. Relator, Lisa Brocco, states that she e-mailed Alisa Cribb, supervisor, on September 2, 2003 about the change in policy and specifically asked about what OMG had been doing prior to this change. Alisa Cribb explained the new 30 and 90 day letters, but never responded as to what OMG had been doing to follow up previously.

78. Relator, Lisa Brocco, has spoken with various ASR's including Kelly Farris, ASR for Cincinnati, Ohio, and Ron Jekle, ASR for Louisville, Kentucky, about the way Defendant had a stated policy regarding "fraud" but in practice has engaged in fraudulent conduct by allowing Group 2 patients to continue receiving Group 2 bed support surfaces without recertification or documentation. Relator, Lisa Brocco, states that ASRs and other Defendant's employees are under pressure to keep the sales numbers high and removing Group 2 bed support surfaces will not achieve this. It is well known within the company that if Defendant ever instituted an effective recertification program that millions of dollars in revenue would be lost, and as a result, no effective recertification plan has ever been implemented by Defendant up to the date of the filing of this complaint.

79. It has recently been stated in writing that ASR's expressly have no duties with respect to paperwork and documentation. On March 17, 2005, Kim Archer, Director of Home Care Sales Operations sent an email to Regional Directors and others providing and instructing them that their sales reps were <u>not</u> to gather any documents or do any follow ups with respect to medical necessity on Med B placements for small Stage III ulcers:

"[t]he sales rep is not to collect any documents or do any follow up calls unless asked

> to do so in writing, via email, from FPG.[1] This will help us identify the frequency that sales is involved. As a management team, the RD's have to enforce this. Do not let your reps volunteer to collect this data because they are going to be there anyway."

Additionally, the email indicated that any "small stage III" patients that have been identified for a thirty (30) or sixty (60) day follow-up will be completed, but going forward all small stage III's will be put on a ninety (90) day schedule.

80. Medicare limits payment for bed support surfaces to a certain time period but will continue to pay service and maintenance fees periodically. Yvonne Johnson was in OMG and responsible for recertification capped patients. At one time Yvonne Johnson was the only person in OMG responsible for doing this. At some point Emma Bradford in Defendant's Medicare department dealt with capped accounts within Relator, Lisa Brocco's territory. Relators allege that OMG has also persistently failed to follow up on capped patients. On December 8, 2003, Annette Wallace sent an email to Relator, Lisa Brocco, and Nikita Johnson, with copies to Beth Rogers and Tom Melpolder, concerning follow-up on cap units and Relator, Lisa Brocco, responded by email that she had been asking to have capped patients followed up for nearly two years to determine if they continued to qualify and repeated that she had been told that this was not a priority. However, Defendant was billing Medicare and Medicaid falsely certifying medical necessity existed as to capped patients as well. Carol Corning handles Medicare denials at Defendant's corporate office. Carol Corning stated to Relator, Lisa Brocco, that she had a hard time appealing denials because Defendant failed to demonstrate that patients met medical necessity because documents had not been obtained at placement. Defendant recently determined that it would not bill Medicare for certain service and maintenance contracts on capped patients after such a long period of time because it did not want to throw up a "red flag" to Medicare as to its recertification practices or lack thereof. Relators estimate on information and belief that some 1,750 patients would fall into this capped and unbilled category nationwide. Relators allege that these patients and home health agencies are essentially receiving free bed support surfaces which in turn constitutes an in kind kick back.

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[1]Formerly, OMG.

A Defendant's High Level Agents and Employees Admit it Still Does Not Follow Up on Patients to Make Sure They Continue to Meet Medical Necessity

81. On February 24, 2005, Relator, Lisa Brocco, had a conversation with Kim Kennedy, Administrative Law Judge (ALJ) Analyst from Hill-Rom. Kim Kennedy, Administrative Law Judge Analyst, works directly under Karen Klein, Medicare Part B Manager. Relator, Lisa Brocco, was starting a patient on one of Defendant's Group 2 products. While the Relator, Lisa Brocco, had her on the phone, the Relator asked her about an incident that had happened on an account of called Amedysis Home Health Agency in Portland, TN, and she explained that she was asked by Penny McFarlin about a patient, V.C. The nurse apparently had received a letter from Defendant's Finance Processing Group (FPG) (formerly known as OMG), asking if they were treating this patient and what her wound status was. The Relator told Ms. Kennedy that this patient had died, and asked her if she knew why they would be asking about this after the patient had died. Ms. Kennedy checked in the computer and said that the patient is not in a denial status and she was not sure why they would be asking about her wound status. Ms. Kennedy stated, "we have been paid on all her claims." Relator asked Ms. Kennedy if Defendant was following up to make sure that the patients continued to meet medical necessity, and Ms. Kennedy said, "no, I doubt it." The Relator asked: "who is following up in FPG to make sure patients are meeting medical necessity each month?" and Ms. Kennedy responded, "to tell you the truth, I don't believe anyone is."

82. Relator, Lisa Brocco, attended a meeting on March 1, 2005 in Charleston, South Carolina that included ten (10) to twelve (12) ASRs from different areas of the country, the top performers. The ASRs were from Region C, and the other attendees at the meeting included three Sales Directors, Mitch Mize, Kathy Eaton, and Connie Morris, Karen Klein, Medicare Part B Manager, Debbie Heatherly, Director of Regulatory and Compliance, Wendy Christian, Marketing Manager, who was making the presentation. The purpose of the meeting was concerning the relaunching of the Defendant's Clinitron bed. During the meeting, Relator, Lisa Brocco, asked the question: "what the monthly recertification process was going to be for the Clinitron?" because Relator wanted to be clear on it. The answer was, "it was going to require a short note from the

doctor - they would obtain clinical notes from the patient's home health agency or wound center every month and then they would send this to the doctor's office and the doctor would have to write about the progress of the patient on the bed. And, if they were not progressing, why not, and if that continued then the bed would be removed." Wendy Christian, Marketing Manager, then stated that

> "there will be no exceptions to this, a bill will not drop monthly until this is in and complete, no exceptions, the bed will be pulled first, because I do not believe that we have the proper follow up process on patients that are on our Group 2 support surfaces and we will not be doing that with the Clinitron."

Relator was surprised that this admission would be made in a group meeting and in front of the Director of Regulatory and Compliance and the Medicare Part B Manager. The Compliance Director did not react in any manner to this acknowledgment or attempt to disclaim it in any manner, neither did the Medicare Part B Manager, and this, to the Relator, was a major admission that no recertification process has been occurring for Group 2 bed support surfaces.

83. Defendant's compliance problems have continued for a long period of time. For example, Relator, Lisa Brocco, states that Jan Rascoe was Defendant's Regulatory Compliance Officer under Amy Jordan, J.D., and she discussed Defendant's improper billing and compliance practices with her in or about 2001 and before, and Ms. Rascoe admitted to Relator, Lisa Brocco, that serious compliance issues existed and she told Relator, Brocco: "I have a box of files under my bed of illegal stuff that could bury Hill-Rom." Ms. Rascoe said, "I keep the box of papers in case I ever needed them to defend myself." Ms. Rascoe held this position for approximately seven years to in or about August, 2001.

B. With Respect to Audits Conducted by Relators Verifying Noncompliance, and Other Specific Examples of Noncompliance

84. Relators have conducted their own audits of certain patients in Tennessee, Georgia, and Texas in December of 2003 and January of 2004. The audits revealed that 14 patients were billed to Medicare for a total of 66 to 67 months of nonqualifying services, amounting to between $33,500 to $40,200± in overcharges. These excessive claims for Group 2 bed support surfaces rentals resulted from Defendant's failure to effectively monitor patients being approved for Group 2 bed surfaces and/or based on Defendant's failure to follow up on said patients to insure continuing

medical necessity.

85. Of approximately the 30 to 45 charts audited, the Relators have obtained fourteen (14) case examples of varying fraudulent billing consistent with the allegations in this complaint, and they have the clinical records to back it up as documentation of the fraud. In summary, the audits revealed eight (8) patients who were placed on Group 2 bed support surfaces, but who never qualified, six (6) patients who initially qualified for a Group 2 bed support surfaces but healed and thereafter remained on the Group 2 support surfaces. The specifics were as follows, to-wit:

1. Patient A[2] was discharged from hospital on 7/21/03 with wound care for left heel and buttocks. (Attachment telephone order - home health). Hill-Rom Group 2 placed under patient on 7/24/03. Wound healed 8/20/03. (Attachment telephone order - home health). Discontinue home health services. Relator placed call to patient in December 2003 during audit. Patient stated that he had healed some time ago. Patient billed for therapy unit at least 4 months after healed. (Non-qualifying).

2. Patient B[2] was placed on Hill-Rom Group 2 therapy on 6/20/03. Wound charted as laceration, below the knee incision. (Attachment - adult nursing assessment). No pressure ulcer noted. 8/14/03 home health chart (Attachment - skin integrity form), wound one - below the knee amputation, wound two - right foot ulcer (non-qualifying wounds). Patient was discharged from home health without documentation of ever having a trunk/pelvis pressure ulcer. Patient did not qualify for Group 2 support surface.

3. Patient C[2] was placed on Silkair mattress Hill-Rom Group 2 unit #HA102814 on 1/15/02 and remains on the unit as of 2/25/05. (Attachment - field business reports 12/8/03 and 2/25/05). 3/1/02 physician orders for wound care describe only heel dressings. (Attachment - MD orders - Tennessee Christian Medical Center). 9/23/03 (Attachment - skin integrity documentation form) shows measurements on heel

[2]Names omitted for confidentiality reasons but will be disclosed in Disclosure Statement.

ulcers only - Stage 1 and Stage 2, non-qualifying ulcers for Group 2 mattress. Per clinical notes/documentation patient never qualified for Group 2 therapy and was billed to CMS for an entire 15 months period and remains on.

4. Patient D[2] on 8/3/03 started care for home health. On 8/19/03 (Attachment - skilled nursing visit note statement that sacral wound healed, shows two right extremity wounds. On 9/26/03, placed on Group 2 therapy Hill-Rom. On 9/27/03 (Attachment - wound care addendum note) two right lower extremity wounds only - no qualifying wounds for Group 2 placement. On 9/30/03, (Attachment - Oasis recertification note) one Stage 2 pressure ulcer on sacrum, ulcer on right extremity - non-qualifying for Group 2. On 10/7/03, (Attachment - nursing visit note) "sacrum appears to be healed." On 12/11/03, Relator makes phone call to patient - patient remains on therapy unit without qualifying wounds. Patient never qualified for Group 2 placement per clinical documentation.

5. Patient E[2] (Note: No chart documentation available on this patient. Relator, Laurie Salmons personally completed this chart audit at Amedisys Home Health in the Corpus Christie branch location). In June 2003, patient placed on Group 2 therapy from Hill-Rom. On 7/18 - 7/22/03, patient in hospital. On 7/24/03, patient readmits to home health - one Stage 2 documented. On 8/7/03, clinical note - "red only" stated per nurse. On 8/28/03, clinical note - no measurements for wound - healed. On 9/18/03, Oasis documentation - MO440 shows no wound. On 10/9/03, no wound documentation. On 10/30/03, clinical note - multiple wounds documented. Patient with non-qualifying wounds for Group 2 therapy for several months.

6. Patient F[2] (Attachment - telephone order) Stage 1 ulcer on back. On 5/16/03, (Attachment - telephone order) Stage 2 ulcer on back. On 5/16/03, Hill-Rom Group 2 ordered. On 5/20/03, placed on Group 2. On 5/22/03, Stage 1 ulcer noted (Attachment - telephone order). Patient transferred to hospice in September 2003. No further wounds noted. Group 2 placed for non-qualifying wounds - at least 4

months billing.

7. Patient G[2], physician ordered Group 2 Hill-Rom mattress on 2/17/03. (Attachment - Statement of Ordering Physician) documentation of appropriate placement criteria. Patient was placed on Group 2 on 2/19/03. Skilled nursing report from 9/1/03 shows no documentation of pressure ulcers except for one Stage 1 on right hip. All other wounds healed. (Attachment - skilled nurse visit report - 2 pages). As of 4/7/05, patient continues to remain on unit and billing to CMS continued through 15 months and into capped rental period. Patient qualified for only 8 months.

8. Patient H[2], clinical documentation shows that patient had Stage 2 ulcers for Group 2 placement (Attachment - wound sheet - Amedisys). Patient was placed on Group 2 therapy in May 2002. Relator, Lisa Brocco followed up on capped rental patient in March 2004 and found that patient had expired on 1/4/04 - two months prior. Patient's daughter also stated that patient only had sores for a few months after placement. (Attachment - continued medical necessity follow up completed by home care rep). Daughter also stated that patient did not have sores during entire period from 8/10/03 - 1/4/04. (No follow up procedure in place by Hill-Rom).

9. Patient I[2], (Attachment - Medicare card copy). Statement of Ordering Physician dated 7/30/02 provided order and documentation of Stage 2 pressure ulcers for Group 2 placement. (Attachment x 2). Unit was discontinued on 6/22/03 when patient was admitted to nursing home. Care giver states that patient only had wounds for one month after placement. Medicare was billed for 10 months after patient no longer qualified. Care giver states that no one from Hill-Rom ever called to check on qualifying wounds.

10. Patient J[2] was placed on a Hill-Rom Group 2 unit on 7/11/03 and remained on unit through at least 11/7/03. Relator, Laurie Salmons, had conversation with Clinical Manager at Ft. Oglethorpe nursing office in late 2003. Clinical Manager states that the only documentation found on clinical chart was on 6/17/03 stating "red area on

the right hip 6cm, no skin breakdown." This above statement describes Stage 1 ulcer and is not qualification for Group 2 therapy. July Oasis chart documentation shows no pressure ulcers. Patient discharged from home health on 9/16/03. No attachments, this audit was through a phone conversation with clinical manager from home health agency attending to patient.

11. Patient K[2], three documents state that patient has Stage 3 pressure ulcer. (Statement of Ordering Physician, wound nurse note, skin integrity addendum). On 8/18/03, (Attachment x 3). Patient placed on Group 2 Hill-Rom unit on 8/28/03. Skilled note from chart of 11/14/03 and 11/20/03 shows wounds healed. (Attachment x 2). Patient no longer qualified for unit as of 11/14/03 and continued billing to Medicare through 4/31/04. (5 months non-qualified billing).

12. Patient L[2], Statement of Ordering physician dated 12/6/02. (Attachment). Patient was placed on Group 2 unit (HA108263) on 12/11/02. NHC home care skilled nursing report. (Attachment - 4 pages). On 11/4/03, wound care provided. On 11/7/03, no further wound documentation - skin breakdown healed. Bed Removal Notification - patient no longer qualifies, dated 1/5/04. Payment denied by CMS, (attachment) document states a removal will be completed on 1/19/04. on 1/19/04. Sales rep told to "do nothing." On 4/6/05, Relator, Lisa Brocco, states that patient is still on Group 2 unit.

13. Patient M[2] was placed on a Hill-Rom Group 2 surface on 7/11/03. On 5/21/03, start of home health care. Admission Oasis shows no wounds - MO440. No verbal orders available for dressing changes. No documentation in clinical home health chart regarding any wounds. No placement criteria. Patient did not qualify for Group 2 per chart.

14. Patient N[2] was placed on a Group 2 Hill-Rom surface on 9/30/03. On 9/23/03 start of home health care. Patient admitted with left foot and mid thigh wounds bilaterally. No documentation in clinical home health chart regarding appropriate

wound criteria for placement. Patient did not qualify for Group 2 per chart.

86. Relator, Laurie Salmons, states that an employee of Amedisys in Texas told her on or about November, 2003, that she could find no documentation justifying a Group 2 bed support surface for Patient E[2] above but the patient continued to have the bed support surface regardless. The documentation which was reviewed by Relator showed that the patient had wounds off and on but no qualifying wounds after the latest hospital discharge. When the nurse was questioned as to why patient still had the mattress, the nurse said, "I told Hill-Rom to pick it up, but no matter, this patient heals and breaks out a lot, so it is better they left it." He had the Group 2 bed support surface from June 2003 to late in the year 2003 past October. Relators allege that this bed support surface was not picked up by Defendant even though it was notified of healing.

C. Examples of Medicare Being Billed For Deceased Patients

1. Patient O[2], this patient was placed on a Hill-Rom Group 2 unit and expired. Patient expired on May 1, 2003. Hill-Rom billed CMS for this patient after her expiration date due to not having a 30 day recertification system in place. CMS notified Hill-Rom through patient EOB that they wanted monies returned or would not be paying and at that point Hill-Rom made plans to pick up the units. No recertification system in place to prevent incorrect billing to Medicare.

2. Patient P[2], this patient was placed on a Hill-Rom Group 2 unit and expired. Patient expired on October 1, 2003. Hill-Rom billed CMS for this patient after her expiration date due to not having a 30 day recertification system in place. CMS notified Hill-Rom through patient EOB that they wanted monies returned or would not be paying and at that point Hill-Rom made plans to pick up the units. No recertification system in place to prevent incorrect billing to Medicare.

3. Patient Q[2], this patient was placed on a Hill-Rom Group 2 unit and expired. Patient expired on November 18, 2003. Hill-Rom billed CMS for this patient after his expiration date due to not having a 30 day recertification system in place. CMS notified Hill-Rom through patient EOB that they wanted monies returned or would

not be paying and at that point Hill-Rom made plans to pick up the units. No recertification system in place to prevent incorrect billing to Medicare.

D. A Nationwide Audit Would Verify Relators' Allegations

87. Relators allege that an audit of Defendant's records would also reflect that it maintains inadequate documentation to support the initial placement of Group 2 bed support surfaces and other support surfaces, and inadequate documentation of continuing medical necessity after the support surfaces are placed, and it has falsely certified otherwise to Medicare and Medicaid. Without proper documentation, Relators allege that Defendant is required to refund all payments to Medicare and Medicaid.

E. Statutory Violations

88. Defendant has violated 31 U.S.C. § 3729 in that it knowingly submitted numerous claims falsely certifying it was in compliance with Federal Laws and Regulations, a condition for reimbursement, when it was not.

89. Defendant has violated 31 U.S.C. § 3729 in that it knowingly submitted numerous claims in using the "ZX" or "KX" modifiers for bed support surfaces when the patients were not being monitored, where medical necessity did not exist, and where documentation of medical necessity did not exist.

90. Defendant has violated 31 U.S.C. § 3729 in that it knowingly billed Medicare and Medicaid for unnecessary medical treatment, and it has engaged in a pattern of overutilization.

91. Relators state that Defendant has violated 31 U.S.C. § 3729 in that it intentionally or recklessly permitted its employees to create incorrect bills for DME and submitted claims to the United States that falsely reflected excessive charges that were subsequently paid by the United States.

92. Relators state that Defendant has violated 31 U.S.C. § 3729 in that it was aware of or had reason to know that it had received payments on claims to which it was not entitled and failed to refund such overpayments to the United States as required by statute, regulations, and its supplier contracts, but rather concealed same.

F. Damages

93. Relators allege that Defendant profited unlawfully from making improper claims for DME rentals and service and maintenance fees and the payment and retention of overpayments to which it was not legally entitled. Relators allege that the United States was damaged as a result of the conduct of Defendant in submitting or causing to be submitted false or fraudulent claims.

COUNT ONE

94. Relators reallege paragraphs 1 through 93 and incorporate them here by reference as if fully set forth.

95. In violation of 31 U.S.C. § 3729(a)(1), Defendant knowingly or acting with reckless disregard or deliberate ignorance of their truth or falsity presented or caused to be presented false or fraudulent claims for payment or approval to the United States, including claims for excessive DME rentals and service and maintenance fees that were either not medically necessary or documented as medically necessary, that were improperly coded, or that represented reimbursements that should have been refunded as overpayments to the United States.

96. By virtue of these false or fraudulent claims on the part of Defendant, the United States suffered damages and therefore is entitled to multiple damages under the False Claims Act, as determined at trial, plus a civil penalty of $5,000 to $10,000 for each violation.

COUNT TWO

97. Relators reallege paragraphs 1 through 96 and incorporate them here by reference as if fully set forth.

98. In violation of 31 U.S.C. § 3729(a)(2), Defendant knowingly or acting with reckless disregard or deliberate ignorance of their truth or falsity made, used, or caused to be made or used, false records or statements, including false certifications and representations by Defendant upon submission or resubmission of false claims for reimbursements under Medicare for the purpose of obtaining payment or approval of false or fraudulent claims from the United States.

99. By virtue of using or making false records or false statements, Defendant caused the United States to suffer damages and the United States is therefore entitled to treble damages under

the False Claims Act, as determined at trial, plus a civil penalty of $5,000 to $10,000 for each violation.

COUNT THREE

100. Relators reallege paragraphs 1 through 99 and incorporate them here by reference as if fully set forth.

101. In violation of 31 U.S.C. § 3729(a)(7), Defendant knowingly or acting with reckless disregard or deliberate ignorance of their truth or falsity made, used, or caused to be made or used false records or false statements, including false certifications by Defendant in submitting claims, to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States.

102. By virtue of using or making false records or false statements, Defendant caused the United States to suffer damages and the United States is therefore entitled to treble damages under the False Claims Act, as determined at trial, plus a civil penalty of $5,000 to $10,000 for each violation.

COUNT FOUR

103. Relators reallege paragraphs 1 through 102 and incorporate them here by reference as if fully set forth.

104. This is a claim for the recovery of monies paid by the United States to Defendant as a result of mistaken understandings of fact.

105. The false claims that Defendant submitted to the United States' agents were paid by the United States based upon mistaken or erroneous understandings of material facts.

106. The United States, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of Defendant's certifications and representations, paid Defendant certain sums of money to which Defendant was not legally entitled and Defendant is thus liable to account and pay such amounts, as determined at trial, to the United States.

COUNT FIVE

107. Relators reallege paragraphs 1 through 106 and incorporate them here by reference

as if fully set forth.

108. This is a claim for recovery of monies by which Defendant has been unjustly enriched.

109. By directly or indirectly obtaining federal funds to which Defendant was not legally entitled, Defendant was unjustly enriched and is liable to account and pay such amounts, as determined at trial, to the United States.

COUNT SIX

110. Relators reallege paragraphs 1 through 109 and incorporate them by here by reference as if fully set forth.

111. This is a claim for disgorgement of illegal profits earned by Defendant as a result of statutory violations in the manner in which Defendant billed a federal health benefit program and maintained its records and accounts and in failing to make refunds of overpayments due to the United States.

112. Defendant concealed illegal activities through false statements, false claims, false records, and its failure to abide by its statutory, regulatory, and contractual duties to disclose the existence of such overpayments.

113. The United States did not detect Defendant's illegal conduct.

114. The United States requests that the Court exercise equitable and statutory powers to require Defendant to disgorge all illegal profits earned as a result of Defendant's statutory violations.

115. The United States requests a full accounting of all revenues, as well as interest, received by Defendant during all relevant times.

COUNT SEVEN

116. Relators reallege paragraphs 1 through 115 and incorporate them by here by reference as if fully set forth.

117. This is a claim for recoupment of monies unlawfully paid by the United States to Defendant contrary to statute or regulation.

118. The United States paid Defendant certain sums of money to which Defendant was not

entitled and Defendant is thus liable under the law of recoupment to account and return such sums, as determined at trial, to the United States.

COUNT EIGHT

119. Relators reallege paragraphs 1 through 118 and incorporate them by here by reference as if fully set forth.

120. Defendant made material and false representations in the submission of claims for reimbursement from a federally funded health benefit program and in the concealment of overpayments with the intention that the United States be deprived of refunds or be caused to pay funds to Defendant to which it was not legally entitled.

121. Had the true state of facts been known to the United States, the United States would not have made reimbursements to Defendant or would have sought recovery of overpayments as provided by law.

122. As a result of the conduct of Defendant, the United States has been damaged in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Relators demand on behalf of the United States and pray that judgment be entered in their favor against Defendant as follows:

1. Assess a civil penalty of not less than $5,500.00 and not more than $11,000.00 against Defendant for each and every false claim set forth herein, as provided by 31 U.S.C. § 3729(a);

2. Award damages in the sum of three times the amount fraudulently billed to Medicare and Medicaid as set forth herein, as provided by 31 U.S.C. § 3729(a), plus interest;

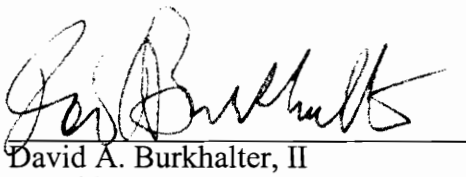
3. Award them reasonable expenses, attorney's fees and costs, as provided by 31 U.S.C. § 3730(d);

4. Exclude Defendant from participation in Federal health care programs; and

5. For such other and further relief as this Court deems just and proper.

JURY TRIAL DEMANDED

Relators hereby demand a jury trial.

By: 

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CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing document was served upon counsel of record by placing same in the United States mail this the 20th day of April, 2005 with proper postage affixed thereto, addressed to the following:

Alberto Gonzales
United States Attorney General
U.S. Department of Justice
10th & Constitution Avenues, N.W.
Washington, D.C. 20530
Attn: United States False Claims Act filing

Harry S. Mattice, Jr.
United States Attorney for the Eastern District of Tennessee
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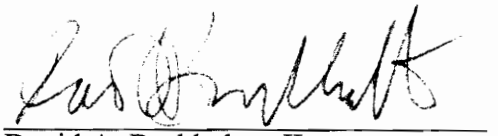

David A. Burkhalter, II