SETTLEMENT AGREEMENT

This Settlement Agreement is entered into this <u>l'4</u> day of <u>Fe braggery</u>, 2007, by and between the United States of America, including the United States Attorney's Office for the Eastern District of Pennsylvania ("USAO") and the Department of Health and Human Services, Office of Inspector General ("OIG") (collectively "United States"), and Brighten at Broomall ("Brighten"), to resolve potential civil claims more fully described herein. This Agreement is effective on the date of signature of the last signatory to the Agreement ("Effective Date"). The period of the obligations assumed by Brighten under this Agreement shall be three (3) years from the Effective Date (unless otherwise specified).

WHEREAS, Brighten is a long term care facility located at 43 Church Lane, Broomall, PA;

WHEREAS, as a result of an investigation by the United States, the United States contends that it has certain civil claims against Brighten under the False Claims Act, 31 U.S.C. §§ 3729-3733, other federal statutes and/or at common law, for submitting or causing to be submitted, claims for payment for inadequate and/or worthless services that were rendered to residents of Brighten from July 2004 - December 2005. Specifically, the United States contends that Brighten (a) provided inadequate/worthless care regarding: provision of adequate nutrition to meet the nutritional needs of residents; provision of medication to residents; monitoring weight loss; falls; diabetic care; pressure ulcer care, including the prevention and treatment of wounds; incontinence care: care provided by physicians and (b) submitted and/or caused the submission of claims for reimbursement to Federal health care programs in connection therewith. The United States, through the Centers for Medicare and Medicaid Services ("CMS"), also has cited Brighten for various deficiencies, including but not necessarily limited to the foregoing

conduct, in a survey completed on June 9, 2005. All of the foregoing is hereinafter referred to as the "Covered Conduct".

WHEREAS, Brighten denies any wrongdoing, inadequacy or liability in regard to the care rendered to the residents of Brighten;

WHEREAS, the parties agree that this Settlement Agreement does not constitute and shall not be construed as an admission of any liability, inadequacy or wrongdoing on the part of Brighten;

WHEREAS, the parties wish to resolve this matter in an amicable manner without the need for protracted litigation;

NOW THEREFORE, for and in consideration of the mutual covenants and conditions contained herein and other good and valuable consideration, the parties, intending to be legally bound, enter into the following:

- 1. By no later than December 31, 2006 Agreement, Brighten agrees to pay the sum of \$45,000 Dollars in settlement of its potential civil liability to the United States relating to the Covered Conduct.
- 2. Additionally, as a further part of this Agreement, Brighten agrees to establish a "Quality of Care/Quality of Life Fund" ("the Fund") through which Twenty Thousand dollars (\$20,000) will be expended in addition to any expenditures for programs, services and equipment already budgeted in the ordinary course of business by Brighten and its parent company and or affiliates. The Fund shall be used to enhance the quality of life of the residents of Brighten and the quality of care provided to them. To that end, within twelve (12) months from the Effective Date of this Agreement, Brighten shall expend all monies comprising the Fund on programs, services and equipment that will improve the quality of life and care rendered to Brighten

residents. Brighten will expend the Fund based on the recommendation of the Monitors retained as part of this Agreement. The Parties intend that the expending of monies from the Fund is to be wholly in addition to monies expended from Brighten's ordinary operating expenses. Thus, in no instance shall Brighten expend any amount of the Fund on types of programs, services, and/or equipment for which operating expenses were utilized in the twelve months prior to the Effective Date of this Agreement. Brighten shall provide the U.S. Attorney's office with quarterly reports regarding the expenditure of monies from the Fund. In the event that the Fund amount is not fully expended and/or obligated within the 12 month period, Brighten shall immediately remit to the U.S. Attorney's Office a lump sum for the difference between the \$20,000 and the amount that was actually expended and/or obligated. The U.S. Attorney's office shall have the unrestricted right to audit Brighten in order to establish compliance with this paragraph. Together, the

- 3. Subject to the exceptions in Paragraph 4 below, in consideration of the obligations of Brighten set forth in this Agreement, conditioned upon Brighten's full payment of the Settlement Amount, and subject to Paragraphs 13 and 16, below, the United States (on behalf of itself, its officers, agents, agencies, and departments) agrees to release Brighten 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; the common law theories of payment by mistake, unjust enrichment, and fraud, for the Covered Conduct. No individuals are released by this Agreement.
- 4. In consideration of the obligations of Brighten set forth in this Agreement, conditioned upon Brighten's full payment of the Settlement Amount, and subject to Paragraph

16, below (concerning bankruptcy proceedings commenced within 91 days of the Effective Date of this Agreement or any payment made under this Agreement), the OIG agrees to release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) against Brighten under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law) or 42 U.S.C. § 1320a-7(b)(7) (permissive exclusion for fraud, kickbacks, and other prohibited activities) for the Covered Conduct, except as reserved in Paragraph 5, below, and as reserved in this Paragraph. The OIG expressly reserves all rights to comply with any statutory obligations to exclude Brighten from Medicare, Medicaid, or other Federal health care programs under 42 U.S.C. § 1320a-7(a) (mandatory exclusion) based upon the Covered Conduct. Nothing in this Paragraph precludes the OIG from taking action against entities or persons, or for conduct and practices, for which claims have been reserved in Paragraph 5, below.

- 5. 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 Brighten) are the following:
- (a) Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);
 - (b) Any criminal liability;
- (c) Except as explicitly stated in this Agreement, any administrative liability, including mandatory exclusion from Federal health care programs;
- (d) Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;

- (e) Any liability based upon such obligations as are created by this Agreement;
- (f) Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct;
 - (g) Any liability of individuals, including officers and employees;
- (h) Any civil or administrative liability of individuals (including current or former directors, officers, employees, agents, or shareholders of Brighten) who receive written notification that they are the target of a criminal investigation (as defined in the United States Attorneys' Manual), are indicted, charged, or convicted, or who enter into a plea agreement related to the Covered Conduct.
- 6. Brighten waives and shall not assert any defenses Brighten 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 Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. 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.
- 7. Brighten fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Brighten has asserted, could have asserted, or may assert in the

future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

- 8. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare carrier or intermediary or any state payer, related to the Covered Conduct; and Brighten 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.
 - 9. Brighten agrees to the following:
- (a). <u>Unallowable Costs Defined:</u> that all costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395ggg and 1396-1396v; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Brighten, its present or former officers, directors, employees, shareholders, and agents in connection with the following shall be "unallowable costs" on government contracts and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP):
 - (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Brighten's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
 - (4) the negotiation and performance of this Agreement;

- (5) the payment Brighten makes to the United States pursuant to this Agreement, including any costs and attorneys fees; and
- (6) the negotiation of, and obligations undertaken pursuant to the Settlement Agreement to:
- (i) the retention of and payments to an independent monitor as described in paragraph 21 infra; and
- (ii) the preparation and submission of reports to the United States. However, nothing in this Paragraph 9.a.(6) that may apply to the obligations undertaken pursuant to the Settlement Agreement affects the status of costs that are not allowable based on any other authority applicable to Brighten. (All costs described or set forth in this Paragraph 9.a. are hereafter "unallowable costs.")
- shall be separately determined and accounted for in nonreimbursable cost centers or otherwise as appropriate by Brighten, and Brighten shall 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 Brighten or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.
- Payment: Brighten further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid 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 Brighten or any of its subsidiaries or affiliates, and shall 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. Brighten agrees that the United States, at a minimum, shall be entitled to recoup from Brighten any overpayment plus applicable interest and penalties as a result of the inclusion of such unallowable costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

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 Brighten or any of its subsidiaries or Brighten or any of its subsidiaries or affiliates' 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.

10. Brighten agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Brighten shall encourage and agrees not to impair the cooperation of its directors, officers, and employees and use its best efforts to make available and encourage the cooperation of its former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. Brighten agrees, upon request, also to furnish to the United States complete and unredacted copies of all documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct which it has undertaken.

- 11. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity.
- 12. Brighten waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.
- Statements) to the United States and the United States has relied on the accuracy and completeness of those Financial Statements in reaching this Agreement. Brighten warrants that the Financial Statements are complete, accurate, and current. In the event the United States learns of asset(s) in which Brighten had an interest at the time of this Agreement that were not disclosed in the Financial Statements, or in the event the United States learns of any misrepresentation by Brighten on, or in connection with, the Financial Statements, and in the event such nondisclosure or misrepresentation changes the estimated net worth set forth on the Financial Statements by \$5,000 or more, the United States may at its option: (a) rescind this Agreement and file suit based on the Covered Conduct; or (b) let the Agreement stand and collect the full Settlement Amount plus one hundred percent (100%) of the value of the net worth of Brighten previously undisclosed. Brighten agrees not to contest any collection action undertaken by the United States pursuant to this provision.
- 14. In the event that the United States, pursuant to Paragraph 13, opts to rescind this Agreement, Brighten agrees not to plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any civil or administrative claims that (a) are filed by the United States within 30 calendar days of written notification to Brighten that this Agreement has been rescinded, and (b) relate to the Covered

Conduct, except to the extent these defenses were available on the Effective Date of this agreement.

- Brighten warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and shall remain solvent following its payment to the United States of the Settlement Amount. Further, the Parties warrant that, in evaluating whether to execute this Agreement, they (a) have intended that the mutual promises, covenants, and obligations set forth constitute a contemporaneous exchange for new value given to Brighten, within the meaning of 11 U.S.C. § 547(c)(1); and (b) conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which Brighten was or became indebted, on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).
- 16. If, within 91 days of the Effective Date of this Agreement or any payment made under this Agreement, Brighten commences, or a third party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors (a) seeking to have any order for relief of Brighten's debts, or seeking to adjudicate Brighten as bankrupt or insolvent; or (b) seeking appointment of a receiver, trustee, custodian, or other similar official for Brighten or for all or any substantial part of Brighten's assets, Brighten agrees as follows:
- a. Brighten's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and Brighten shall not argue or otherwise take the position in any such case, proceeding, or action that: (i) Brighten's obligations under this Agreement may

be avoided under 11 U.S.C. §§ 547 or 548; (ii) Brighten was insolvent at the time this Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to Brighten.

b. If Brighten's obligations under this Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Agreement, and bring any civil and/or administrative claim, action, or proceeding against Brighten for the claims that would otherwise be covered by the releases provided in Paragraphs 3 and 4 above. Brighten agrees that (i) any such claims, actions, or proceedings brought by the United States (including any proceedings to exclude Brighten from participation in Medicare, Medicaid, or other Federal health care programs) are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and Brighten shall not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) Brighten shall not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceedings that are brought by the United States within 30 calendar days of written notification to Brighten that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the effective date of the agreement; and (iii) the United States has a valid claim against Brighten for treble damages and penalties, and the United States may pursue its claim in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding.

- c. Brighten acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided in this Agreement.
- 17. Brighten shall comply fully with the applicable laws, rules and regulations governing the Medicare and Medicaid Programs and the Nursing Home Reform Act.
- that Brighten shall continue to have a compliance plan (the "Compliance Program") that incorporates the policies and principles set forth in OIG's Compliance Program Guidance for Nursing Facilities and is aimed at ensuring Brighten's adherence with Federal health care programs requirements. All of Brighten's employees shall continue to participate in the Compliance Program. The Compliance Program shall continue to include, among other things, a Code of Conduct, a Compliance Officer, a Quality Assurance Committee, policies and procedures for implementing the Compliance Program, training and education requirements, a mechanism for individuals to report incidents of non-compliance in an anonymous manner, disciplinary actions for individuals violating compliance policies and procedures, and mechanisms for the ongoing monitoring and auditing of Brighten's operations as they relate to quality of care. Brighten agrees to maintain the Compliance Program in full operation for three years from the Effective Date of this Agreement and to update the Compliance Program pursuant to statutory and regulatory changes.
- 19. To the extent not already established, within 90 days after the Effective Date,
 Brighten shall develop and begin implementing written Policies and Procedures regarding the
 operation of Brighten's compliance program and its compliance with all Federal and state health
 care statutes, regulations, directives, and guidelines, including the requirements of the Federal

health care programs. At a minimum, Brighten's Policies and Procedures shall specifically address:

- Measures designed to ensure that Brighten fully complies with

 Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§

 1395-1395ggg and 1396-1396v, and all regulations, directives, and guidelines promulgated pursuant to these statutes, including, but not limited to, 42 C.F.R. Parts 424, 482, and 483, and any other state or local statutes, regulations, directives, or guidelines that address quality of care in nursing homes;
- (b) Measures designed to ensure that Brighten complies with all requirements applicable to Medicare's Prospective Payment

 System (PPS) for skilled nursing facilities, including, but not limited to: ensuring the accuracy of the clinical data required under the Minimum Data Set (MDS) as specified by the Resident

 Assessment Instrument User's Manual; ensuring that staff are appropriately and accurately using the current Resource Utilization Groups (RUG) classification system; and ensuring the accuracy of billing and cost report preparation policies and procedures;
- (c) Measures designed to ensure the coordinated interdisciplinary approach to providing care to nursing home residents, including, but not limited to the following areas addressed in 42 C.F.R. § 483: resident assessment and care planning; nutrition; diabetes care; wound care; infection control; fall prevention, recovery, and

assessment; abuse and neglect policies and reporting procedures; protection from harm procedures; appropriate drug therapies; appropriate mental health services; provision of basic care needs; incontinence care; resident rights and restraint use; activities of daily living (ADL) care; therapy services; quality of life, including accommodation of needs and activities; and assessment of resident competence to make treatment decisions;

- (d) Measures designed to ensure that Brighten has an appropriate and effective protocol designed to prevent falls by patients and residents, including appropriate fall prevention strategies, reporting requirements, and post-fall recovery and reassessment plans;
- (e) Measures designed to ensure compliance with the completion of accurate clinical assessments and other clinical documentation as required by applicable Federal law, which shall include: (1) that all patient and resident care information be recorded in ink or permanent print; (2) that corrections shall only be made in accordance with accepted health information management standards; (3) that erasures shall not be allowable; and (4) that clinical records may not be rewritten or destroyed to hide or otherwise make a prior entry unreadable or inaccessible;
- (f) Measures designed to ensure that staffing needs are decided first and foremost upon achieving the level of care for Brighten's

- patients and residents required by federal and state laws, including, but not limited to, 42 C.F.R. § 483.30 (nursing facilities);
- Measures that specify that if the director of nursing (or other person who is making staffing decisions at Brighten) disagrees with a staffing determination that is not in compliance with state or federal regulations or this Agreement and that significantly affects patient care made by the Administrator or other individuals at the district, region, or corporate level, and is unable to resolve the issue through the normal chain of responsibility, then that person must immediately call the hotline and the Monitor. Nothing in this subsection prohibits or prevents such person from contacting the hotline or the Monitor without first going through the normal chain of responsibility;
- (h) Measures designed to inform employees of the staffing requirements of federal and state law and this Agreement;
- (i) Measures to inform employees during orientation and during other training required by this Agreement that staffing levels are a critical aspect of patient and resident care, and that if any person has a concern about the level of staffing there are many avenues available to report such concerns, including, but not limited to, the Administrator, the Hotline, or directly to the Compliance Officer or Monitor;

- (j) Measures designed to minimize the number of individuals working at Brighten who are on a temporary assignment or not employed by Brighten and measures designed to create and maintain a standardized system to track the number of individuals at Brighten who fall within this category so that the number/proportion of or changing trends in such staff can be adequately identified by Brighten or the Monitor;
- (k) Measures designed to ensure that all residents and patients are served in the least restrictive environment and most integrated setting appropriate to their needs;
- (l) Measures designed to promote adherence to the compliance and quality of care standards set forth in the applicable statutes and regulations by including such adherence as a significant factor in determining the compensation to Administrators and Directors of Nursing, and the individuals responsible for such compliance at the corporate level;
- (m) Measures designed to ensure cooperation by Brighten and its employees with the Monitor in the performance of his or her duties as set forth *infra*;
- (n) Measures designed to ensure that compliance issues are identified internally (e.g., through reports to supervisors, hotline complaints, internal audits, patient satisfaction surveys, CMS quality indicators and quality measures, facility-specific key indicators, or internal

surveys) or externally (e.g., through CMS or state survey agency reports, consultants, or Monitor's Reports) and are promptly and appropriately investigated and, that if the investigation substantiates compliance issues, Brighten implements effective and timely corrective action plans and monitors compliance with such plans;

- (o) Measures designed to effectively collect and analyze staffing data,
 including staff-to-resident ratio, staff turnover, and staffing during
 the periods in which falls occurred;
- (p) Measures designed to ensure that contractors, subcontractors and agents are appropriately supervised to ensure that they are acting within the parameters of Brighten's Policies and Procedures and the requirements of Federal health care programs;
- (q) Measures designed to ensure that appropriate and qualified individuals perform the internal quality audits and reviews;
- (r) Nonretaliation policies and method for employees to make
 disclosures or otherwise report on compliance issues through the
 Disclosure Program;
- (s) Disciplinary guidelines to reflect Brighten's Code of Conduct requirements; and
- (t) Measures designed to ensure that Brighten has a system to require and centrally collect reports relating to incidents, falls, accidents, abuse, and neglect. The reports required under this system shall be

- of a nature to allow the Quality Assurance Committee meaningful information to be able to determine: 1) if there is a quality of care problem; and 2) the scope and severity of the problem.
- (u) Measures designed to ensure that Brighten has an effective quality assurance and review program that, at a minimum, performs the following functions:
 - (1) makes findings of whether the patients and residents at

 Brighton are receiving the quality of care and quality of life

 consistent with basic care, treatment, and protection from

 harm standards, including but not limited to, 42 C.F.R.

 Parts 482 and 483 and any other applicable Federal and

 state statutes, regulations, and directives;
 - (2) makes findings of whether the policies and procedures mandated by this Agreement are created, implemented, and enforced;
 - (3) makes findings of whether training is performed in accordance with this Agreement;
 - (4) makes findings of whether hotline complaints are appropriately investigated; and
 - (5) makes findings of whether corrective action plans are timely created, implemented, and enforced.

Brighten shall assess and update as necessary the Policies and Procedures at least annually and more frequently, as appropriate. The Policies and Procedures shall be available to the United States upon request.

Within 90 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all employees. Compliance staff or supervisors shall be available to explain any and all policies and procedures.

20. Training and Education.

- A. General Training. Brighten shall continue to provide at least one (1) hour of training to each employee annually. This general training shall explain Brighten's:
 - a. Compliance Program (including the Policies and Procedures as they pertain to general compliance issues); and
 - b. Code of Conduct.
- B. Specific Training. Brighten shall continue to provide specific training of each employee, contractor, and agent who is involved directly or indirectly in the delivery of patient or resident care (including individuals who are responsible for quality assurance, setting policies or procedures, or making staffing decisions). Such employees shall receive at least four hours of training pertinent to their responsibilities in addition to the general training required above. This training, which shall be completed within one year after the Effective Date of the Agreement and conducted at least annually thereafter, shall include a discussion of the policies and procedures set forth in Paragraph 19, including, but not limited to:
- (1) Policies, procedures, and other requirements applicable to the documentation of medical records; and

(2) The coordinated interdisciplinary approach to providing care to residents, including, but not limited to, resident assessment and care planning; nutrition; diabetes care; wound care; infection control; abuse and neglect policies and reporting procedures; appropriate drug therapies; appropriate mental health services; provision of basic care needs; incontinence care; resident rights and restraint use; ADL care; therapy services; quality of life, including accommodation of needs and activities; and assessment of the resident's competence to make treatment decisions.

In addition to the specific training described above, Brighten shall conduct periodic training on an "as needed" basis (but at least semi-annually) on those quality of care issues identified by the Quality Asssurance Committee and Internal Audit Program. In determining what training should be performed, Brighten shall review the complaints received, satisfaction surveys, staff turnover data, any state or federal surveys, including those performed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or other such private agencies, any internal surveys, the CMS quality indicators and quality measures, and the findings, reports and recommendations of the Monitor. Such training shall be for a minimum of four hours total annually. Such training shall be provided to all employees, contractors, and agents who are responsible for patient or resident care at Brighten.

All training materials shall be made available to the United States upon request. Persons providing the training must have sufficient expertise in the subject area.

21. <u>Independent Monitor</u>. Brighten has retained an appropriately qualified Independent Monitor (the "Monitor"), Susan Renz and Marie Boltz, appointed by the United States after consultation with Brighten. The Monitor may retain additional personnel, including. but not limited to, independent consultants, if needed to help meet the Monitor's obligations

under this Agreement. Brighten shall be responsible for all costs incurred by the Monitor, including, but not limited to, travel costs, consultants, administrative personnel, office space and equipment, or additional personnel. The Monitor shall charge a reasonable amount for his or her fees and expenses. Failure to pay the Monitor within 30 calendar days of submission of his or her invoices for services previously rendered shall constitute a breach of this Agreement and shall subject Brighten to one or more of the remedies set forth in paragraph 23 *infra*. The Monitor may be removed solely at the discretion of the United States. If the Monitor resigns or is removed for any reason prior to the termination of the Agreement, Brighten shall retain another Monitor appointed by the United States, with the same functions and authorities. The Monitor may confer and correspond with Brighten and the United States on an *ex parte* basis.

- A. The Monitor shall be responsible for assessing the effectiveness, reliability and thoroughness of the following:
 - (1) Brighten's internal quality control systems, including, but not limited to:
 - a. whether the systems in place to promote quality of care and to respond to quality of care issues are acting in a timely and effective manner;

- b. whether the communication system is effective, allowing
 for accurate information, decisions, and results of decisions
 to be transmitted to the proper individuals in a timely
 fashion; and
- c. whether the training programs are effective and thorough.
- (2) Brighten's response to quality of care issues, which shall include an assessment of:
 - a. Brighten's ability to identify the problem;
 - Brighten's ability to determine the scope of the problem, including,
 but not limited to whether the problem is isolated or systemic;
 - c. Brighten's ability to create a corrective action plan to respond to the problem;
 - d. Brighten's ability to execute the corrective action plan; and
 - e. Brighten's ability to evaluate whether the assessment, corrective action plan, and execution of that plan was effective, reliable, and thorough.
- (3) Brighten's development and implementation of corrective action plans and the timeliness of such actions;
- (4) Brighten's proactive steps to ensure that each patient and resident receives care in accordance with:
 - a. basic care, treatment and protection from harm standards;
 - b. the rules and regulations set forth in 42 C.F.R. Parts 482 and 483;

- state and local statutes, regulations, and other directives or guidelines; and
- d. the policies and procedures adopted by Brighten and set forth in this Agreement.

B. The Monitor shall have:

- (1) immediate access to Brighten and its facility, at any time and without prior notice, to assess compliance with this Agreement, to assess the effectiveness of the internal quality assurance mechanisms, and to ensure that the data being generated is accurate;
- (2) immediate access to: (a) the CMS quality indicators and quality measures; (b) internal or external surveys or reports; (c) hotline complaints; (d) resident satisfaction surveys; (e) staffing data in the format requested by the Monitor, including reports of any time more than 10 percent of the staff are hired on a temporary basis; (f) reports of abuse, neglect, or an incident that required hospitalization or emergency room treatment; (g) reports of any falls; (h) reports of any incident involving a patient or resident that prompts a full internal investigation; (i) patient or resident records; (j) documents in the possession or control of any quality assurance committee, peer review committee, medical review committee, or other such committee; and (k) any other data in the format the

- Monitor determines relevant to fulfilling the duties required under this Agreement; and
- immediate access to patients, residents, and employees for interviews outside the presence of Brighten supervisory staff or counsel, provided such interviews are conducted in accordance with all applicable laws and the rights of such individuals. The Monitor shall give full consideration to an individual's clinical condition before interviewing a resident or patient.

C. Brighten's Obligations. Brighten shall:

- (1) ensure the Monitor's immediate access to Brighten and its facility, individuals, and documents, and assist in obtaining full cooperation by its current employees, contractors and agents;
- (2) provide the Monitor a report monthly, or sooner if requested by the Monitor, regarding each of the following occurrences:
 - a. Deaths or injuries related to use of restraints;
 - Deaths or injuries related to use of psychotropic medications;
 - c. Suicides;
 - d. Deaths or injuries related to abuse or neglect (as defined in the applicable Federal guidelines);
 - e. Fires, storm damage, flooding, or major equipment failures at Brighten;
 - f. Strikes or other work actions;

- g. Manmade disasters that pose a threat to residents (*e.g.*, toxic waste spills); and
- h. Any other incident that involves or causes actual harm to a resident when such incident prompts a full internal investigation.

Each such report shall contain the full name, social security number, and date of birth of the resident(s) involved, the date of death or incident, a brief description of the events surrounding the death or incident, the identities of the persons involved, the status of the investigation, and any corrective action taken in response to the investigation, and any other steps taken to prevent recurrence;

- (3) assist in locating and, if requested, obtaining cooperation from past employees, contractors, agents, and residents, patients, and their families;
- (4) provide access to current residents and patients, and contact information for their families and guardians, and not impede their cooperation with the Monitor;
- (5) provide to its Quality Assurance Compliance Committee copies of all documents and reports provided to the Monitor;
- (6) provide the last known contact information for former residents, patients, their families, or guardians consistent with the rights of such individuals under state or Federal law, and not impede their cooperation;

- (7) promptly address any written recommendation made by the Monitor either by substantially implementing the Monitor's recommendations or by explaining in writing why it has elected not to do so;
- (8) pay the Monitor's bills within 30 days of receipt. While Brighten must pay all the Monitor's bills within 30 days, Brighten may bring any disputed Monitor's Costs or bills to the attention of the United States; and
- (9) not sue or otherwise bring any action against the Monitor related to any findings made by the Monitor or related to any exclusion or other sanction of Brighten under this Brighten; provided, however, that this clause shall not apply to any suit or other action based solely on the dishonest or illegal acts of the Monitor, whether acting alone or in collusion with others.
- D. The Monitor's Obligations. The Monitor shall:
 - (1) respect the legal rights, privacy, and dignity of all employees, residents, and patients;
 - (2) where independently required to do so by applicable law or professional licensing standards, report any finding to an appropriate regulatory or law enforcement authority, simultaneously submit copies of such reports to the United States and to Brighten;
 - (3) at all times act reasonably in connection with its duties under the Brighten including when requesting information from Brighten;
 - (4) simultaneously provide quarterly reports to Brighten and the United States concerning the findings made to date;

- submit bills to Brighten on a consolidated basis no more than once per month, and submit an annual summary representing an accounting of its costs throughout the year to Brighten and to the United States. The Monitor shall submit to Brighten and the United States an annual report representing an accounting of its costs throughout the year;
- (6) not be bound by any other private or governmental agency's findings or conclusions, including, but not limited to, JCAHO, CMS, or the state survey agency. Likewise, such private and governmental agencies shall not be bound by the Monitor's findings or conclusions. The Monitor's reports shall not be the sole basis for determining deficiencies by the state survey agencies. The parties agree that CMS and its contractors shall not introduce any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence into any proceeding involving a Medicare or Medicaid survey, certification, or other enforcement action against Brighten, and Brighten shall similarly be restricted from using material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor as evidence in any of these proceedings. Nothing in the previous sentence, however, shall preclude the United States or Brighten from using any material generated by the Monitor, or any opinions, testimony, or conclusions from the Monitor in any action under this

- Agreement or pursuant to any other United States authorities or in any other situations not explicitly excluded in this subsection;
- (7) abide by the legal requirements of Brighten to maintain the confidentiality of each resident's personal and clinical records.
 Nothing in this subsection, however, shall limit or affect the Monitor's obligation to provide information, including information from patient and resident clinical records, to the United States, and, when legally or professionally required, reporting to other agencies;
- (8) abide by the provisions of the Health Insurance Portability and

 Accountability Act ("HIPAA") of 1996 to the extent required by
 law including, without limitation, entering into a business associate
 agreement with Covered Entity facilities;
- (9) except to the extent required by law, maintain the confidentiality of any proprietary financial and operational information, processes, procedures and forms obtained in connection with its duties under this Agreement and not comment publicly concerning its findings except to the extent authorized by the United States;
- (10) visit Brighten as often as the Monitor believes it necessary to perform its functions.
- 22. During the three-year period of this Agreement, thirty (30) days after the first, second and third anniversary date of this Agreement, Brighten will submit Annual Reports to the U.S. Attorney's Office and the OIG regarding the status of its compliance with this Agreement.

Each annual report shall include: (a) any amendments or revisions to Brighten's Compliance Plan made during the preceding year and the reasons for such changes (e.g. change in contractor policy); (b) a description of the training programs implemented pursuant to this Agreement, including a description of the targeted audiences and a schedule of when the training sessions were held; (c) a summary of the findings of all reviews conducted pursuant to the quality assurance and review program described in paragraph 19u. above and a summary of any corrective actions taken as a result of such reviews; Brighten's response and corrective actions taken regarding any issues raised by the Monitor; a certification by the Compliance Officer that all applicable persons have completed the required training; that Brighten is in compliance with all of the requirements of this Agreement, to the best of his or her knowledge; and that the Compliance Officer has reviewed the Annual Report and has made reasonable inquiry regarding its content and believes that the information is accurate and truthful.

- 23. In the event that Brighten fails to comply in good faith with any of the terms of this Settlement Agreement relating to it, or should any of Brighten's representations or warrants be materially false, the United States may, at its sole discretion, exercise one or more of the following rights:
 - (a) seek specific performance of this Settlement Agreement and the prevailing party shall be entitled to an award of reasonable attorneys fees and costs in its favor; or
 - (b) exercise any other right granted by law; or
 - seek exclusion by the OIG for material breach pursuant to the procedures set forth in paragraph 24 below.

24. OIG Remedy of Exclusion for Material Breach of this Agreement

- a. Definition of Material Breach. A material breach of this Agreement means:
 - a failure to meet an obligation under the Agreement that has a material impact on the quality of care rendered to any residents or patients of Brighten;
 - (2) repeated or flagrant violations of the obligations under this Agreement; or
 - (3) a failure to retain, pay, or use the Monitor in accordance with paragraph 21.
- b. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this Agreement by Brighten constitutes an independent basis for Brighten's exclusion from participation in the Federal health care programs, as defined in 42 U.S.C. § 1320a-7b(f). Upon a determination by the OIG that Brighten has materially breached this Agreement and that exclusion should be imposed, the OIG shall notify Brighten by certified mail of: (1) Brighten's material breach; and (2) the OIG's intent to exercise its contractual right to impose exclusion (Notice of Material Breach and Intent to Exclude).
- c. Opportunity to cure. Brighten shall have 30 days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:
 - (1) Brighten is in full compliance with this Agreement;
 - (2) The alleged material breach has been cured; or

- (3) The alleged material breach cannot be cured within the 30 day period, but that: (A) Brighten has begun to take action to cure the material breach; (B) Brighten is pursuing such action with due diligence; and (C) Brighten has provided to the OIG a reasonable timetable for curing the material breach.
- d. Exclusion Letter. If at the conclusion of the 30 day period, Brighten fails to satisfy the requirements of Section C(2), OIG may exclude Brighten from participation in the Federal health care programs. OIG shall notify Brighten in writing of its determination to exclude Brighten (Exclusion Letter). Subject to the Dispute Resolution provisions in Section C, below, the exclusion shall go into effect 30 days after the date of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. If Brighten is excluded under the provisions of this Agreement, Brighten may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

e. Dispute Resolution

Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligation of this Agreement, Brighten shall be afforded certain review rights comparable to those set forth in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the exclusion sought pursuant to this Agreement. Specifically, an action for exclusion shall be subject to review by an ALJ and, in the event of an appeal, the Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. §§ 1005.2-1005.21.

Notwithstanding the language in 42 C.F.R. § 1005.2©, a request for a hearing involving exclusion shall be made within 30 days of the date of the Exclusion Letter.

United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be: (A) whether Brighten was in material breach of this Agreement; (B) whether such breach was continuing on the date of the Exclusion Letter; and (C) whether the alleged material breach cannot be cured within the 30 day period, but that (1) Brighten has begun to take action to cure the material breach, (2) Brighten has pursued and is pursuing such action with due diligence, and (3) Brighten has provided to OIG a reasonable timetable for curing the material breach and Brighten has complied with that timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Brighten, only after a DAB decision in favor of OIG. Brighten's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude Brighten upon the issuance of an ALJ's decision in favor of the OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Brighten may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Brighten shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Brighten, Brighten shall be reinstated effective on the date of the original exclusion.

(3) Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations.

Consequently, the parties to this Agreement agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this Agreement.

- f. Review by Other Agencies. Nothing in this Agreement shall affect the right of CMS or any other federal or state agency to enforce any statutory or regulatory authorities with respect to Brighten's compliance with applicable state and Federal health care program requirements.
- 25. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.
- 26. Brighten represents that this Agreement is freely and voluntarily entered into without any degree of duress or compulsion whatsoever.
- 27. 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 is the United States District Court for the Eastern District of Pennsylvania, except that disputes arising under the exclusion for breach provisions of paragraph 23 shall be resolved exclusively under the dispute resolution set forth therein.
- 28. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.
- 29. The individuals signing this Agreement on behalf of Brighten represent and warrant that they are authorized by Brighten to execute this Agreement. The United States signatories represent that they are signing this Agreement in their official capacities and that they are authorized to execute this Agreement.
- 30. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

- 31. This Agreement is binding on Brighten's successors, transferees, heirs, and assigns.
- 32. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
- 33. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

UNITED STATES OF AMERICA:

PATRICK L. MEEHAN United States Attorney MARILYN MAY Assistant U.S. Attorney
Dated:
GERALD SULLIVAN Assistant U.S. Attorney Dated: 1007
GREGORY E. DEMSKE Assistant Inspector General Office of Counsel of the Inspector General Department of Health and Human Services
Dated

UNITED STATES OF AMERICA:

PATRICK L. MEEHAN
United States Attorney
·
MARILYN MAY
Assistant U.S. Attorney
Dated:
GERALD SULLIVAN
Assistant U.S. Attorney
Assistant O.S. Attorney
Dated:
GREGORY E. DEMSKE
Assistant Inspector General
Office of Counsel of the Inspector General
Department of Health and Human Services
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Dated: 2/14/17

BRIGHTEN AT BROOMALL

By: James 7-0 Conner

Dated: 07 FLBNARY 07

DOREENA CRAIG SLOAN, Esq. STEVEN T. HANFORD Dated: 2.08.07