

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA,	:	
	:	
Plaintiff,	:	
	:	
v.	:	
	:	
MERCY DOUGLASS CENTER INC.	:	CIVIL ACTION NO.
d/b/a STEPHEN SMITH HOME FOR THE AGED:	:	
	:	
Defendant.	:	

CONSENT ORDER AND JUDGMENT

The United States of America ("United States") and defendant, Mercy Douglass Center Inc., d/b/a/ Stephen Smith Home for the Aged, ("Stephen Smith Home or defendant"), have consented to the issuance of the following order subject to the approval of the Court:

JURISDICTION AND VENUE

1. The United States and defendant agree that this Court has jurisdiction pursuant to 28 U.S.C.A. §§1331, 1345 and 31 U.S.C.A. § 3732; that venue lies in this judicial district pursuant to 28 U.S.C.A. § 1391 (b) and (c) and 31 U.S.C. § 3732; and that the parties will be bound by the terms of this Consent Order and Judgment.

FACTUAL BACKGROUND

2. The United States alleges that from May 1997 until February 1999, defendant submitted, or caused to be submitted,

claims for services rendered at Stephen Smith Home on behalf of nursing home residents, to the government in violation of the False Claims Act, 31 U.S.C. §3729 et seq.

3. The United States alleges that from May 1997 until February 1999, defendant submitted, or caused to be submitted, claims for services rendered to residents of Stephen Smith Home in deliberate ignorance and/or reckless disregard of the truth of those claims regarding their failure to provide adequate nutrition and hydration, adequate nursing care to residents with decubitus ulcers (pressure ulcers), adequate pain management, adequate incontinence care and adequate staffing, as required by state and federal law and regulations. The Health Care Financing Administration (HCFA) imposed civil money penalties against defendant based on deficiencies found at the nursing home.

4. The defendant believes that the claims submitted to the United States were appropriate and expressly denies any wrongdoing or liability with respect to those claims. Defendant has filed administrative appeals from HCFA's imposition of civil money penalties and the underlying findings of alleged deficiencies.

GENERAL PROVISIONS

5. In entering into this Consent Order and Judgment, defendant does not admit to any violation of law and the parties

agree that this Consent Order shall not be construed as an admission of any liability or wrongdoing by defendant.

6. The parties agree that the provisions of this Order are a lawful, fair and appropriate resolution of this case.

7. This Order is legally binding and judicially enforceable by the parties and it shall be applicable to and binding upon all of the parties, their officers, agents, employees, assigns, and successors unless upon proof to the satisfaction of the United States, that Mercy Douglass Center Inc.'s current ownership has wholly divested itself of any interest or involvement, direct or indirect, in the nursing home, that the successor is an independent entity unrelated in any manner to Mercy Douglass Center Inc., that the successor has acquired its interest at fair market value in an arms' length transaction, that the successor has policies, procedures and practices in effect to ensure its compliance with the requirements of Medicare, Medicaid and all other Federal health care programs and is a purchaser acceptable to the government from both a financial and quality of care perspective.

PAYMENT

8. The defendant agrees to pay the sum of Eighty Thousand Dollars (\$80,000) to the United States in settlement of this False Claims Act action and HCFA's civil money penalties. This settlement amount is based upon the defendant's ability to

pay and the truthful and accurate representations made by the defendant and its owner regarding the financial condition of the defendant to the Health Care Financing Administration. Payment of this amount to the United States Attorney's Office, 615 Chestnut Street, Suite 1250, Philadelphia, Pa. 19106, Attn.: David R. Hoffman, is to be made as follows:

(a) Upon entry of this Consent Order, the defendant shall remit the amount of Three Thousand Dollars (\$3,000) by certified check payable to the United States of America. Thereafter, defendant shall pay by certified check, Three Thousand Dollars (\$3,000) per month, on the first day of each month until and unless the Stephen Smith Home is sold. In that event, the total amount of the obligation to the government shall be paid in full by certified check on the settlement date of the sale of the defendant;

(b) Defendant agrees that it is in default of this Consent Order on the date of occurrence of any of the following events ("Events of Default"):

(1) Failure to Make Timely Payments: Failure by defendant to pay any amount provided for in this paragraph;

(2) Commencement of Bankruptcy or Reorganization Proceeding: If prior to making the full payment of the amount due under this paragraph, (i) defendant commences any case, proceeding, or other action (A) under any law relating to bankruptcy, insolvency, reorganization or relief of debtors,

seeking to have any order for relief of debtors, or seeking to adjudicate it as bankrupt or insolvent, or (B) seeking appointment of a receiver, trustee, custodian or other similar official for it or for all or any substantial part of its assets; or (ii) there shall be commenced against defendant any such case, proceeding or other action referred to in clause (i) that results in the entry of an order for relief and any such order remains undismissed, or undischarged or unbonded for a period of thirty (30) days; or (iii) defendant takes any action authorizing, or in furtherance of, or indicating its consent to, approval of, or acquiescence in, any of the acts set forth above in this subparagraph.

DEFENDANT'S POLICIES AND PROCEDURES

9. Defendant agrees to comply, and to cause all of its healthcare subsidiaries, officers, agents, employees, contractors, and/or subcontractors to comply with the Policies and Procedures attached hereto and incorporated herein as Exhibit A. Defendant will provide the United States with notice and a reasonable period of time to review and approve additional policies and procedures pertaining to resident care as they are created, modified or discontinued.

NUTRITION AND WOUND CARE STANDARDS

10. Defendant agrees to provide wound care (decubitus ulcer) treatment that meets or exceeds the Agency for Healthcare Research and Quality (formerly Agency for Health Care Policy and Research) Guidelines, attached hereto and incorporated herein as Exhibit B. Additionally, defendant agrees to provide nutrition for those with wounds as set forth in Exhibit C, attached hereto and incorporated herein.

11. Defendant agrees that Registered Dieticians will accurately calculate all residents' ideal body weight, compare current body weight to the residents' usual body weight in order to determine an appropriate healthy weight range for each resident on a regular and consistent basis and will clearly document such findings in the residents' charts.

12. Defendant agrees to identify and provide timely clinical responses to all "nutritionally at risk" and "nutritionally compromised" residents at the earliest possible time. Nutritionally at risk and nutritionally compromised residents are defined in Exhibit A.

13. Defendant agrees to obtain serum albumin levels for all residents at the time of admission for screening purposes, and as warranted thereafter to measure protein levels and will perform prealbumins in accordance with Exhibits A and C.

COMPLIANCE WITH FEDERAL LAW AND ATTACHED PROTOCOLS

14. In the operation and management of Stephen Smith Home and in providing services to the defendant's residents, the defendant shall comply fully with the particular provisions of the Nursing Home Reform Act and other relevant provisions as embodied in Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 et seq., and Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 et seq., all regulations and guidelines promulgated pursuant to these statutes and the American with Disabilities Act of 1990, 42 U.S.C. §§ 12101 et seq. See attached Exhibit D, 42 C.F.R. Part 483, Subparts B, C, D, and E, § 483.1 through § 483.206. The parties agree that the language in 42 C.F.R. § 483.1 through § 483.206 is incorporated by reference into this Consent Order and that the provisions of this Consent Order are to be construed consistent therewith. Defendant shall also comply fully with the particular provisions of the defendant's protocols attached to this Order and incorporated by reference herein. Defendant agrees that its obligation to comply fully with the language of the attached protocols does not limit its obligation to comply fully with federal law or with the provisions of this Order.

15. Defendant's submission of plans of correction and/or certification by the Health Care Financing Administration does not in and of itself constitute compliance with this Consent Order nor does a cited deficiency by state or federal surveyors conclusively establish non-compliance with this Consent Order.

16. If the defendant seeks to add a policy, procedure, or protocol which addresses resident care issues to this Consent Order or to modify a policy, procedure or protocol which has been attached to and incorporated into this Consent Order, the defendant shall first submit any proposed new or modified policy, procedure, or protocol to the United States and the Monitor(s) as defined in paragraph 50 for review.

17. The United States or the Monitor(s) may provide the defendant with comments or recommendations regarding the proposed new or modified protocol within 30 days of receipt of the proposed modification.

18. If the United States or the Monitor(s) do not submit any comments or recommendations, the defendant shall submit the new or modified policy, procedure, or protocol to the Court as an agreed-upon exhibit.

19. In the event that the United States or the Monitor(s) submit any comments or recommendations, the defendant shall consider the comments and recommendations. If the defendant declines to adopt the recommendations or comments of the United States or the Monitor(s), they shall so notify, in writing, the United States and the Monitor(s), and the parties and the Monitor(s) shall confer within 30 days.

20. If the parties reach agreement to add or to modify a protocol, the parties shall submit the new or modified policy, procedure or protocol as an agreed-upon exhibit. If the parties

do not reach agreement, defendant may seek addition or modification of the policy, procedure or protocol with the Court and the United States may present its objections.

21. A new or modified policy, procedure, or protocol may be implemented immediately, if necessary due to emergency conditions or to comply with a change in the law, and then submitted to the Court.

RESIDENT SAFETY

22. Defendant shall provide a safe and functional environment for the residents. Defendant shall ensure that all residents are free from mistreatment, verbal, sexual, physical, and mental abuse, corporal punishment, involuntary seclusion, neglect, and misappropriation of property.

23. Defendant shall adequately supervise, monitor and safeguard the residents, especially those with histories of exhibiting behaviors that cause injury to themselves or others. Residents shall be protected from being victimized by other aggressive residents.

24. Defendant shall promptly notify the United States and the Monitor of any resident death resulting from injuries, suicide, malnutrition, dehydration, pressure ulcers or complications thereof, any incident of staff abuse or neglect (as defined in the applicable federal guidelines) of a resident, transfer and admission to a hospital as a result of injury or

accident and any other incident involving a resident that prompts a full internal investigation, specifying for each death or incident, the full name and social security number of the resident, the date of death or incident, and, to the extent that such information is available to defendants, a brief description of the events surrounding the death or incident.

BASIC CARE

25. Defendant shall ensure that staff members provide residents with appropriate basic care services that meet the residents' individual needs. Among other things, defendant shall ensure that all residents are positioned properly, receive proper oral care and receive restorative care. Defendant shall care for the residents in a manner and in an environment that promotes maintenance or enhancement of each resident's quality of life.

COMPREHENSIVE ASSESSMENT AND CARE PLAN

26. Defendant shall ensure that there is a timely, complete, and accurate minimum data set (MDS) and a current, complete and accurate interdisciplinary care plan in each resident's chart. Defendant shall conduct, at the time of each resident's admission and periodically thereafter (at least annually and promptly after a significant change in the resident's physical or mental condition), a comprehensive, accurate, standardized assessment of each resident's functional capacity with input by all relevant disciplines.

27. Defendant shall ensure that within seven (7) days after the completion of the comprehensive assessment, the defendant's interdisciplinary team develops a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, mental and psychosocial needs that are identified in the comprehensive assessment. The care plan shall describe the services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being and must meet professional standards of quality. Defendant shall ensure that each resident's comprehensive care plan is implemented in a timely manner by appropriate and adequately trained staff. Defendant shall examine each resident no less than once every 3 months and as appropriate, revise the resident's assessment to assure the continued accuracy of the assessment.

ACTIVITIES

28. Defendant shall provide residents with sufficient, meaningful activities both during the week and on the weekends to ensure that the residents attain or maintain the highest practicable physical, mental, and psychosocial well-being. Defendant shall provide for an ongoing structured program of activities designed to meet the individual interests and physical, mental, and psychosocial well-being of each resident,

and defendants shall provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. Defendant shall ensure that unit-based activities are provided for those residents unable to attend activities elsewhere. Defendant shall evaluate the activities programs for effectiveness and modify their programs as warranted.

CHEMICAL AND PHYSICAL RESTRAINTS

29. Defendant shall ensure that physical and chemical restraints are used only pursuant to accepted professional standards and that they are never used as punishment or for the convenience of staff. Defendant shall assess, document, advocate and ensure that any restraints used, whether chemical or physical, are the least restrictive restraints appropriate for the resident and the situation. An interdisciplinary team will review and evaluate the need for restraints in all cases. Defendants recognize that they have an obligation to seek the least restrictive restraint for residents.

30. Defendant shall ensure that appropriate physicians' orders are obtained and followed before physical restraints are utilized and shall at all times seek the implementation of the least restrictive alternative for their residents.

31. Defendant shall ensure that residents are released from any physical restraints at least every two hours for at least 10 minutes under supervision by staff and are assessed at such time as to whether they need to remain in restraints. All residents who are restrained shall be appropriately repositioned and provided with adequate supervision, hydration, and circulation while in restraints.

32. Defendant shall only use psychotropic medication in accordance with accepted professional standards and where there is an appropriate psychiatric or neuropsychiatric diagnosis. Defendant must evaluate the availability of behavior analysis and management prior to the use of medication. Defendant must not use psychotropic medication as punishment, in lieu of a training program, for behavior control, in lieu of a psychiatric or neuropsychiatric diagnosis, or for the convenience of staff.

33. Absent emergency circumstances, defendant shall ensure that prior to using psychotropic medication, other less restrictive techniques have been systematically tried and have been demonstrated to be ineffective. Prior to using psychotropic medication, defendant will also ensure that:

(a) a psychiatrist reviews the current medication regimen of each individual to determine whether the type and dosage of the medication is appropriate and still necessary, and recommends any changes in the medication regimen;

(b) the psychiatrist consults with the resident's primary care physician, nurse, and other appropriate members of the resident's interdisciplinary team, to determine whether the harmful effects of the resident's mental illness clearly outweigh the possible harmful side effects of the psychotropic medication and whether reasonable alternate treatment strategies are likely to be less effective or potentially more dangerous than the medication.

PSYCHIATRIC AND RELATED SERVICES

34. Defendant agrees to develop and implement a professionally appropriate system to: (a) regularly monitor the progress of the defendants' residents with mental illness to ensure that staff members are continually taking whatever steps are necessary and appropriate to address the individual's mental health needs; (b) provide ongoing monitoring of the efficacy of treatment and make revisions in the treatment plan when warranted; (c) implement a protocol whereby a psychiatrist promptly sees any resident with a diagnosis of mental illness who has recently exhibited violent or threatening behaviors.

35. Defendant shall develop and implement an adequate and appropriate system, utilizing an interdisciplinary approach and based on generally accepted professional standards, for detecting, reporting, and responding to any drug-induced side effects of psychotropic medication in residents; shall take

special care to adequately and appropriately monitor involuntary movement side effects; shall implement gradual dose reductions, and behavioral interventions, unless clinically contraindicated, in an effort to discontinue these medications and shall adequately train and in-service appropriate nursing and direct care staff in how to properly monitor and document medication side effects.

MEDICAL CARE

36. Defendant shall ensure that residents receive adequate preventive, chronic, routine, acute, follow-up, and emergency medical care in accordance with generally accepted standards of care. Defendant shall provide the necessary health care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. To that end, defendant shall ensure that a physician is on-call, 7 days a week, 24 hours a day, to address changes in residents' medical conditions which warrant physician intervention.

37. Defendant shall take all reasonable steps, including intervention by their medical directors or revocation of physician privileges at Stephen Smith Home, to ensure that residents receive the care under paragraph 36, including that:

- a. Physicians promptly obtain and review all laboratory and test results, document the responses in the residents'

charts and take appropriate actions to address any abnormal results;

b. Physicians complete monthly notes in the residents' charts on a timely basis;

c. Physicians do not rely inappropriately on telephone orders in treating residents;

d. Physicians address promptly residents' significant or undesirable weight loss and personally provide continual follow-up until the situation is adequately addressed;

e. Health care of all diabetic residents comports with generally accepted medical practice;

f. All individuals with seizure disorders at defendants' facilities are provided with adequate and appropriate seizure management in accordance with accepted professional standards of care and with adequate and appropriate seizure documentation and with adequate and appropriate diagnostic techniques;

g. Residents currently receiving anticonvulsant medication, receive the type of medication(s) that is (are) appropriate and effective for the type of seizure and represents the fewest number of medications appropriate for effective seizure management;

h. There are a sufficient number of neurology consult hours, as determined by the defendant, to meet the needs of

the residents and to provide each resident with a seizure disorder with a neurology review every six (6) months;

i. As indicated by accepted professional standards of care, in the event of a medical emergency involving a resident, including status epilepticus, facility staff will immediately call an ambulance, and will initiate appropriate emergency interventions while awaiting arrival of the ambulance prior to transport of the resident to the closest tertiary care facility;

j. Physicians conduct comprehensive health care evaluations of all residents;

k. Physicians determine what specialized medical services are required for the residents and ensure that such services are timely provided whenever necessary to evaluate or treat the resident's medical problems;

l. An integrated medical plan of care for each resident exists;

m. Each resident's medical status and progress in response to the resident's medical plan of care is regularly and adequately reviewed and all changes appropriately documented;

n. Each resident's drug regimen is free from unnecessary drugs, i.e., any drug used in excessive dose, for excessive duration, without adequate monitoring, without adequate indications for its use, in the presence of adverse

consequences which indicate the dose should be reduced or discontinued, or any combinations of the reasons set forth herein;

o. Adequate and appropriate interdisciplinary communication among relevant professionals, especially between and among physicians and nurses;

p. Physicians communicate with the pharmacist pertaining to therapeutic responses by residents to prescribed medications.

q. Physicians ensure that an appropriate pain management protocol is implemented in accordance with Exhibit E.

NURSING CARE

38. Defendant shall ensure that residents receive adequate and appropriate nursing care, and that nurses perform their responsibilities in keeping with accepted professional standards of care by adequately identifying health care problems, notifying physicians of health care problems, monitoring and intervening to ameliorate such problems, and keeping appropriate records of residents' health care status. Defendant shall provide the necessary nursing care and services to attain or maintain the residents' highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

Defendant shall take, at a minimum, the following measures:

a. Conduct adequate, comprehensive nursing assessments, with quarterly updates, of the nursing care needs of the residents;

b. Develop nursing protocols and develop and implement adequate and appropriate comprehensive interdisciplinary care plans to address each resident's health care needs;

c. Routinely perform ongoing monitoring of serious medical conditions, including such basic procedures as taking vital signs (including pain assessment when appropriate), measuring weights, monitoring intake and output of fluids; all of these functions are to occur at appropriate intervals based upon the resident's clinical condition;

d. Implement a system for recording important information about a resident's status to monitor changes;

e. Regularly monitor the progress of residents to ensure that staff members are continually taking whatever nursing steps are necessary for the health care of the individual;

f. Communicate essential information to physicians;

g. Follow physicians' orders or document fully why a physician's order was not expressly followed;

h. Administer medications in a timely manner consistent with accepted nursing practice and provide the necessary supervision and training to minimize medication errors and if a medication error occurs, promptly investigate the error, properly document it and take appropriate corrective action;

i. Ensure that residents are provided with adequate skin care, nutrition, individualized turning and positioning to decrease the likelihood of skin breakdown; perform skin care assessments and ongoing treatments and therapy to prevent skin breakdown; comply fully with the particular provisions of Exhibit A and utilize the Clinical Practice Guidelines for the Prediction, Prevention and Treatment of Pressure Ulcers promulgated by the Agency for Healthcare Research and Quality (formerly AHCPR), as the basis to establish defendant's individualized care plan for skin and wound care;

j. Follow standard infection control procedures, maintain aseptic technique and conditions at treatment sites; require staff to wash their hands after each direct resident contact for which hand washing is indicated by accepted professional practice; establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection;

k. Ensure that residents' nutritional intake is adequate, that weights are routinely and accurately recorded, and that residents receive appropriate diets, adequate amounts of food, ensure that residents are provided with proper mealtime assistance and supervision and with appropriate eating assistive devices and adaptive equipment where necessary; ensure that residents with significant or undesirable weight gains or losses are promptly seen by nursing and dietary staff and provided with continual follow-up until the situation is adequately addressed; ensure that each resident receives food prepared by methods that conserve nutritive value, flavor, and appearance, food that is palatable, attractive, and at the proper temperature, prepared in a form designed to meet individual needs; offer substitutes of similar nutritive value to residents who refuse food served;

l. Ensure nurses provide adequate and acceptable health care to residents with diabetes, including properly evaluating blood sugars and providing appropriate treatment when necessary;

m. Utilize an interdisciplinary approach to properly assess and appropriately treat residents with swallowing problems and residents who are unable to eat orally in accordance with accepted professional procedures. To this end, defendant agrees to:(1) provide adequate care for those

residents at risk of aspiration, take any appropriate steps to ameliorate the individual's aspiration risk, and develop and implement an individualized feeding and positioning plan for each resident identified as at risk of aspiration; and (2) train staff in how to properly implement the feeding and positioning plans, and shall develop and implement a system to regularly monitor the progress of the residents who are at risk of aspirating to ensure that the staff is continually taking whatever assessment, diagnostic, supervision and treatment steps are necessary to ameliorate the resident's risk;

n. Ensure that residents have adequate fluid intake needed to prevent dehydration by identifying risk factors for dehydration such as fluid loss and increased need for fluids (e.g., diarrhea, fever etc.) and take steps to immediately address resident hydration problems;

o. Ensure that appropriate incontinence care is provided to all residents;

p. Ensure that fecal impactions do not occur through timely and appropriate revisions of the residents' diet and/or medication regimen or other appropriate interventions.

q. Ensure that residents receive appropriate pain management in accordance with the protocol attached hereto as Exhibit E.

THERAPY SERVICES

39. Defendant shall provide each resident in need of such services with adequate and appropriate physical therapy and occupational therapy services.

MOST INTEGRATED SETTING

40. Defendant shall ensure that appropriate professionals evaluate each resident to determine whether the resident is being served in the most integrated setting appropriate to the resident's needs. An initial evaluation shall occur within fourteen days of admission as part of a comprehensive assessment of each resident. Each resident shall be re-evaluated at least every three months or sooner if there is a significant change in the resident's physical or mental condition.

41. Defendant shall implement professional decisions that a resident can be served in a more integrated setting by transferring the resident to the alternative setting.

42. Defendant shall ensure that before any resident is transferred or discharged to a more integrated setting, the setting is capable of meeting the resident's needs and if transferred to a related entity, once transferred, the needs of the resident are being met.

RECORD KEEPING

43. Defendant shall ensure that it maintains medical records for each resident that comport with accepted professional standards and include current information with respect to the individual's care, medical treatment, and activities. Defendant shall maintain clinical records on each resident in accordance with accepted professional standards and practices that are complete, accurately documented, readily accessible, and systematically organized. Defendant recognizes that if clinical responses are not clearly documented, there is a rebuttable presumption in this proceeding that they did not, in fact, occur.

44. Defendant shall ensure that professional staff, including physicians, psychiatrists, therapists, and nurses, as well as direct care staff, make timely and appropriate notes in the residents' records detailing the residents' progress, status, condition, and detailing the steps needed to fully meet the residents' needs. Defendant shall ensure that all professional staff utilize such records in making care, medical treatment and training decisions.

QUALITY ASSURANCE

45. Defendant shall maintain a quality assessment and assurance committee that develops and implements appropriate plans of action to correct identified quality deficiencies. Defendant shall implement a system that reviews resident outcomes and improves upon those outcomes through analysis and

modification of care processes. Upon modification of care processes, defendant shall re-analyze the outcomes to ensure that care has been improved. Care protocols are a tool that may be used to attain improved outcomes but defendant shall ensure that residents' outcomes are determinative of the adequacy of the care rendered and not compliance with the protocol.

STAFFING

46. Defendant shall ensure that a sufficient number of professional and non-professional staff, especially nurses, are employed to fully meet the needs of the residents. To that end, defendant shall procure sufficient nursing staff to ensure adequate continuity of resident care so that the facility is not excessively reliant on temporary contract or agency nurses to a degree that impairs the level of quality of healthcare provided to the residents and shall employ sufficient nursing staff to provide nursing and related services on a 24-hour basis to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care.

STAFF TRAINING

47. Defendant shall provide a training program to ensure that all professional and direct care staff who provide services to residents are adequately trained to implement the requirements of this Consent Order and are thereafter provided

with in-service training on a regular basis. Defendant shall provide a training program for all personnel, including physicians, nurses and dieticians regarding, at a minimum: nutrition; wound care and infection control; abuse and neglect; appropriate drug therapies for the elderly; diabetes; behavior modification; renal disease; mental health needs of residents; pain management; and a coordinated interdisciplinary approach to providing care to residents. Defendant shall ensure that all nurse aides are appropriately trained and demonstrate competence in the performance of their duties. Defendant also agree to report all training sessions to the Monitors.

48. Defendant shall ensure that their medical staff regularly attends continuing medical education programs that address geriatrics, including but not limited to, medical therapies utilized in wound care, nutrition and diabetic care for long-term care residents.

RETENTION OF TECHNICAL ASSISTANCE

49. If and to the extent that the defendant requires additional outside technical assistance to comply with the provisions of this Order, it shall obtain such technical assistance and provide to the United States and the Monitor a list of the professionals providing the assistance and a list of topics addressed by the professionals.

MONITORS

50. Federal Monitors shall be appointed by July 10, 2000, and shall have full authority to oversee the defendant's compliance with the provisions of this Consent Order. The Monitors shall assess independently defendant's compliance with this Order, with the attached protocols, and with 42 C.F.R. § 483.1 through § 483.206 and guidelines as incorporated into this Order. The Monitors shall not be bound in their conclusions, in whole or in part, on the basis of any certification by the Health Care Financing Administration. In addition, the Monitors shall advise management and staff as to possible procedures that, in the Monitors' view, may be implemented to facilitate compliance with this Order. Defendant is not bound by the Monitors' conclusions and may contest the same.

51. Defendant agrees to allow the Monitors access to Stephen Smith Home at any time and without prior notice, to assess compliance with this Consent Order. The Monitors shall visit this long-term care facility at least monthly until this Order is terminated and shall have immediate access to all nursing home residents and their records. The Monitors shall also have access to relevant documents and records in the possession or control of defendant and to defendant's quality assurance reviews for purposes of ensuring coordination of responses to identified problems. Upon request, the Monitors will be promptly provided with access to and/or copies of incident reports, investigations, resident records, and any other records necessary

to enable the Monitors to fulfill their duties under this Order. Defendant shall assist in obtaining the full cooperation of its current employees, contractors and agents with the Monitors. The Monitors shall attempt to coordinate their activities with relevant personnel in order to minimize disruption in the day to day operations of the facility. At all times, the Monitors shall respect the privacy and dignity of all residents.

52. The Monitors shall create a report documenting any adverse findings relating to compliance with this Order and shall present the report within ten calendar days of the site visit to the defendant, the United States Attorney's Office, the U.S. Department of Health and Human Services, Office of Inspector General, and the Health Care Financing Administration. The Monitors shall submit to the parties a quarterly status report regarding the defendant's compliance with the terms of this Order. The Monitors may confer and correspond with the parties on an ex parte basis.

53. The parties agree that Susan Renz, MSN, RN,CS, and Marie Boltz, MSN, RN, NHA, shall serve as the Monitors and that they serve at the behest of the United States and may be removed from the Monitor position solely at the discretion of the United States. Defendant may request the replacement of either or both of the Monitors for good cause and the United States shall be required to consider, but not necessarily grant, such request. In the event that either of the Monitors is replaced, for any

reason, the United States shall submit the name(s) and curricula vitae of the new proposed Monitor(s) to the Court and the defendant shall have the opportunity to assess the proposed Monitor(s) and the right to present to the Court their position as to the new proposed Monitor(s).

54. The Monitors shall submit within thirty days of their designation an initial hourly rate for monitoring activities. The Monitors may retain independent consultants, as needed, to meet their obligations under this Order. Defendant shall bear all reasonable costs of the Monitors consistent with the hourly rate and the parties agree that the total annual budget for the monitoring program shall not exceed the amount of \$100,000, except in the event that unforeseen circumstances arise. Failure to pay the Monitors within 20 calendar days of submission of their invoices shall constitute contempt of court. Defendant agrees to fund the Monitors at the same annual rate until this Order is terminated.

TEMPORARY MANAGEMENT

55. The defendant has hired and installed Amcare Management Services, Inc., a Pennsylvania corporation headquartered in Bala Cynwyd, Pennsylvania, as temporary manager at Stephen Smith Home for the Aged. The parties agree that defendant's temporary manager shall have all of the regulatory authority set forth in 42 C.F.R. §488.415(a), including but not

limited to, the independent authority to hire, terminate or reassign staff, obligate facility funds, alter facility procedures, and manage the facility to correct deficiencies identified in Stephen Smith Home. The defendant shall employ the temporary manager until Stephen Smith Home is in substantial compliance with all Medicare requirements or an approved sale of the facility occurs in accordance with the provisions set forth in paragraph 7. The temporary manager may be removed from its position for cause with the assent of the United States. The temporary manager shall coordinate its activities with the Monitors to ensure that appropriate decisions are made pertaining to staffing and quality of care issues for those residents residing at Stephen Smith Home.

ACCESS TO DEFENDANT'S FACILITIES

56. The Monitors, the United States and its agents shall have the right to request, inspect, review and copy facility records, resident charts and any other documents necessary to assess compliance, including all reimbursement data pertaining to Stephen Smith Home/Mercy Douglass Center, Inc., conduct interviews with residents and any staff member, consultant or employee outside the presence of supervisory staff or counsel for defendants, and observe activities normally conducted at the various facilities to assess compliance with

this Order. The Monitors, the United States and its agents agree to respect the privacy and dignity of the residents.

CORPORATE COMPLIANCE PROGRAM

57. The defendant agrees to adopt a Corporate Compliance Program that sets forth the structure for reporting and addressing all components relevant to the provision of adequate care, e.g., medical, nursing, nutrition, wound care, dietary, housekeeping, laundry, infection control, plant operations and facility management services and shall incorporate the principles and policies set forth in the HHS-OIG's Compliance Program Guidance for Nursing Facilities. This Program shall be submitted for approval by the Office of Counsel to the Inspector General, Civil Recoveries Branch-Compliance Unit, Department of Health and Human Services. The Office of Counsel to the Inspector General shall have sixty (60) days from receipt of the defendants' Program within which to review and either accept or reject the Program. If, after reasonable attempts have been made to obtain an acceptable Compliance Program, and this Program is not approved by September 1, 2000, the United States may treat this failure as a material breach in paragraph 63(d) of this Order and as grounds for exclusion from the Medicare Program in accordance with the procedures set forth in paragraph 63.

This Corporate Compliance Program shall be binding on the successors, assigns and transferees of Stephen Smith Home.

However, on a case-by-case basis, OIG, in its sole discretion, will waive this successor liability provision upon proof that Stephen Smith Home has wholly divested itself of any interest or involvement, direct or indirect, in the entity, that the successor is an independent entity unrelated in any manner to Stephen Smith Home, that the successor has acquired its interest at fair market value to an arms' length transaction, and that the successor has policies, procedures and practices in effect to ensure its compliance with the requirements of Medicare, Medicaid and all other Federal health care programs.

TERMINATION OF CONSENT ORDER

58. The Court shall retain jurisdiction of this action for all purposes under this Consent Order until defendant shall have fully and faithfully implemented all provisions of the Order and until this action is dismissed or until the sale of Mercy Douglass Center Inc./Stephen Smith Home to a buyer approved by the United States in accordance with the provisions contained in paragraph 7 of this Order.

59. On or after the date on which the defendant shall have fully and faithfully implemented all provisions of this Consent Order or the date on which the defendant has completed an approved sale of the nursing home, the defendant or the United

States may move that the case be closed on the grounds that defendant has fully and faithfully implemented and maintained all provisions of this Order or that the case be dismissed due to the sale of the facility.

60. Subject to defendant's continuing payment obligations under this Consent Order, if any, dismissal shall be granted if the defendant is in material compliance with this Consent Order for a reasonable period of time or if there is a sale of the facility to an acceptable buyer as set forth in paragraph 7, unless, within 60 days after receipt of the defendant's motion, the United States objects to the motion. If the United States objects to the dismissal, the Court shall hold a hearing on the motion and the burden shall be on the defendant to demonstrate that it has fully and faithfully implemented all provisions of this Consent Order or that a sale has occurred to a buyer acceptable to the United States.

61. In the event of any filing of a motion to terminate this Order, nothing in this Order precludes the parties from conducting discovery pursuant to the Federal Rules of Civil Procedure.

62. The parties reserve the right to withdraw consent to this Consent Order in the event that this Order is not approved by the Court in its entirety.

ENFORCEMENT OF CONSENT ORDER

63. In the event that defendant and/or its agents, employees, contractors and subcontractors fail to materially comply in good faith with the terms of this Consent Order, that is, fail to meet any obligation under this Consent Order that has a significant impact on the quality of care rendered to any resident or residents, or should any of defendant's representations be materially false, the United States may, at its sole discretion, exercise one or more of the following rights:

(a) seek contempt of court based on the failure of defendant and/or its agents, employees, contractors and subcontractors to materially comply with this Consent Order. The parties agree that, after a finding of civil contempt, a penalty of ten thousand dollars (\$10,000) per day may be assessed, beginning upon the finding of contempt and lasting until all defaults are cured. After curing all defaults, the defendant may petition the Court to lift its contempt order and to withdraw the imposition of any penalties;

(b) exercise any other right granted by law, including imposition of a temporary manager to manage the nursing homes;

(c) exercise any right recognizable at common law or equity including injunctive relief;

(d) seek exclusion by the OIG for material breach pursuant to the following procedures:

1. *Notice of Material Breach and Intent to Exclude.*

The parties agree, as a contractual remedy, that a material breach of this Order by defendant constitutes an independent basis for defendant's exclusion from participation in the Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)). Upon a determination by OIG that defendant has materially breached this Order and that exclusion should be imposed, the OIG shall notify defendant by certified mail of: (a) defendant's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion ("Notice of Material Breach and Intent to Exclude"). The exclusion may be directed at one or more facilities or corporate entities, depending upon the facts of the breach.

2. *Opportunity to cure.* Defendant shall have thirty five (35) days from the date of the Notice of Material Breach and Intent to Exclude Letter to demonstrate to the OIG's satisfaction that:

- a. Defendant is in full compliance with this Order;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the thirty five (35) day period, but that: (i) Defendant has begun to take action to cure the material breach; (ii) Defendant is pursuing such action with due diligence; and (iii) Defendant has provided to OIG a reasonable timetable for curing the material breach.

3. *Exclusion Letter.* If at the conclusion of the thirty five (35) day period, defendant fails to satisfy the requirements of this paragraph d, OIG may exclude defendant from participation in the Federal health care programs. OIG will notify defendant in writing of its determination to exclude defendants ("Exclusion Letter"). Subject to the provisions in this paragraph d, the exclusion shall go into effect thirty (30) days after the date of the Exclusion Letter. The exclusion shall have national effect and will also apply to all other federal procurement and non-procurement programs. If defendant is excluded under the provisions of the Consent Order, defendant may seek reinstatement pursuant to the provisions at 42 C.F.R. §§ 1001.3001-.3004.

4. *Review Rights.* Upon the OIG's delivery to defendant of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under the obligations of this Consent Order, defendant 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 for breach of this Order. 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(c), a request for a hearing involving exclusion for breach shall be made within thirty (30) days of the date of the Exclusion Letter.

5. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of the Consent Order shall be: (a) whether defendant was in material breach of this Consent Order; (b) whether such breach was continuing on the date of the Exclusion Letter; and (c) the alleged material breach cannot be cured within the 35 day period, but that (i) defendant has begun to take action to cure the material breach, (ii) defendant is pursuing such action with due diligence, and (iii) defendant has provided to OIG a reasonable timetable for curing the material breach.

6. For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision that is favorable to the OIG. Defendant's election of its contractual right to appeal to the DAB shall not abrogate the OIG's authority to exclude defendants upon the issuance of the ALJ's decision. If the ALJ sustains the determination of the OIG and determines that exclusion is authorized, such exclusion shall take effect twenty

(20) days after the ALJ issues such a decision, notwithstanding that defendant may request review of the ALJ decision by the DAB.

RELEASES

64. In consideration for such repose and on the terms and conditions contained herein, and upon payment in full of the amount due the United States as set forth in this Consent Order, and as expressly provided below, the United States fully and finally releases and forever discharges the defendants, their officers, directors and employees from any and all civil and administrative monetary claims, demands, damages, liabilities, losses and causes of action, including penalties and costs of investigation under the False Claims Act, 31 U.S.C. §§ 3729 et seq., the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, the Medicare and Medicaid Patient and Program Protection Act, 42 U.S.C. §1320a-7(b), or the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812, or the common law theories of payment by mistake, unjust enrichment, breach of contract, and fraud, for the billing for alleged inadequate care rendered to those residents of Stephen Smith Home identified in the OIG subpoena served on defendant on March 30, 1999 in violation of regulations governing standards of care applicable to long-term care facilities from May 1997 through February 1999.

65. The parties agree that the release given in the preceding paragraph specifically excludes the following:

a. Any civil or administrative disputes, adjustments, claims or HCFA enforcement action relating to matters other than the alleged violation of standards of care rendered to the subpoena-identified residents of Stephen Smith Home from May 1997 through February 1999.

b. Any disputes or claims arising under the Internal Revenue Code.

c. Any disputes or claims arising under any express or implied warranties relating to products or services.

d. Any disputes or claims arising under the criminal laws of the United States.

e. Any enforcement proceedings based upon the defendants' violations of this Agreement.

f. Except as explicitly stated herein, any administrative liability, including mandatory exclusion from federal health care programs pursuant to 42 U.S.C. §1320a-7(a).

g. Any intentional fraudulent conduct performed by the defendants and/or their agents or employees.

66. In consideration of the obligations of defendant as set forth in this Consent Order, conditioned upon defendant's payment in full of the settlement amount, and subject to paragraph 8, below, the OIG-HHS agrees to release and refrain from instituting, directing or maintaining any administrative claim or any action seeking exclusion from the Medicare, Medicaid or other Federal health care programs (as defined in 42 U.S.C.

§ 1320a-7b(f) against defendant under 42 U.S.C. § 1320a-7a (Civil Monetary Penalties Law), or 42 U.S.C. § 1320a-7(b)(permissive exclusion), for the released conduct, except as reserved in paragraph 65, and as reserved in this paragraph. Nothing in this paragraph precludes the OIG-HHS from taking action against entities or persons, or for conduct and practices, for which civil claims have been reserved in paragraph 65.

67. Defendant agrees that all costs (as defined in the Federal Acquisition Regulation ("FAR") § 31.205-47 and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395 et seq. and §§ 1396 et seq., and the regulations promulgated thereunder) incurred by or on behalf of defendant, in connection with: (a) the government's investigations, and defendant's investigations and defense of this False Claims Act proceeding, (b) the negotiation of this Order, (c) any corrective action undertaken by defendant for the released acts during the relevant period, and (d) the payments made to the United States pursuant to this Order, shall be unallowable costs for government contract accounting and for Medicare, Medicaid, CHAMPUS, VA and FEHBP reimbursement purposes. These amounts shall be separately estimated and accounted for by defendant, and defendant will not charge such costs directly or indirectly to any contracts with the United States or any State Medicaid program, or to any cost report, cost statement, or information statement submitted by defendants, CHAMPUS, VA or FEHBP programs. Defendant further

agrees that within 60 days they will identify to applicable Medicare and CHAMPUS fiscal intermediaries, carriers and/or contractors, and Medicaid fiscal agents any unallowable costs (as defined in this paragraph) included in payments sought in any cost reports, cost statements or information reports already submitted by defendant or any of its subsidiaries and will request that such cost reports, cost statements or information reports, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Any payments due after the adjustments have been made shall be paid to the United States at 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 defendants or any of its subsidiaries on the effect of inclusion of unallowable costs (as defined in this paragraph) on defendant's, or any of its subsidiaries' cost reports, cost statements or information reports. Nothing in this Agreement shall constitute a waiver of the rights of HHS, or any Medicare or CHAMPUS fiscal intermediary or contractor, or any Medicaid fiscal agent, to examine or re-examine the unallowable costs described in this paragraph.

68. In consideration for such repose and on the terms and conditions contained herein, defendants fully and finally release, dismiss, and forever discharge the United States, its agencies, employees, servants, and agents, from any and all

claims, causes of action, liabilities, losses, appeals of remedies imposed by HCFA, and damages, including attorney's fees, costs and expenses which defendant has asserted or could have asserted against the United States, its agencies, employees, servants, and agents, related to the billing for alleged inadequate care rendered to residents of Stephen Smith Home, in violation of regulations governing standards of care applicable to long-term care facilities from May 1997 through February 1999. Defendant agrees that within five (5) days of the entry of this Consent Order, it will notify the Administrative Law Judges presiding over all administrative appeals filed by defendant pertaining to remedies imposed by HCFA that the appeals are withdrawn with prejudice and that all requests for hearings are also withdrawn with prejudice.

69. The parties agree that the release set forth in paragraph 68 specifically excludes any dispute or appeal that defendant may assert in connection with any claim for reimbursement under the Medicare or Medicaid Programs for services other than those provided to the individuals which are the basis for this proceeding.

COSTS

70. All parties shall bear their own costs, including attorney fees.

RETALIATION

71. Defendant and its agents, employees, contractors, and/or subcontractors agree not to intimidate or take any retaliatory action against any individual or individuals who cooperated with this investigation and/or who cooperates with the United States or the Monitor throughout the pendency of this Consent Order.

SIGNATURES

72. All signatories to this Consent Order hereby warrant that they have the authority to and have entered into this Consent Order knowingly, voluntarily and of their own free will and without duress of any kind. This Consent Order may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

We, the undersigned, consent to the entry of the above Consent Order. We represent to the Court that this Consent Order contains a complete description of the agreement between the parties. All material representations, understandings and promises of the parties are contained in this Order. Any modifications must be set forth in writing and signed by all parties. The defendant represents that this Consent Order is entered into with knowledge of the events described herein, and that it is entered into knowingly and voluntarily, without any degree of duress or compulsion whatsoever.

UNITED STATES OF AMERICA:

DEFENDANT:

MICHAEL R. STILES
UNITED STATES ATTORNEY

JAMES G. SHEEHAN
ASSISTANT U.S. ATTORNEY
CHIEF, CIVIL DIVISION

DAVID R. HOFFMAN
ASSISTANT U.S. ATTORNEY

LEWIS MORRIS
ASSISTANT INSPECTOR GENERAL FOR LEGAL AFFAIRS
OFFICE OF COUNSEL TO THE INSPECTOR GENERAL
DEPARTMENT OF HEALTH AND HUMAN SERVICES

JAMES C. NEWMAN
CHIEF COUNSEL, REGION III

JAN M. LUNDELIUS
ASSISTANT REGIONAL COUNSEL
COUNSEL FOR HEALTH CARE FINANCING ADMINISTRATION

APPROVED AND SO ORDERED:

J.