

Eastern District of Kentucky
FILED

FEB 19 2004

AT LEXINGTON
LESLIE G WHITMER
CLERK U S DISTRICT COURT

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

UNITED STATES OF AMERICA)
)
Plaintiff,)
)
v.)
)
BREATHITT COUNTY, KENTUCKY,)
NIM HENSON GERIATRIC CENTER,)
and BREATHITT COUNTY)
GERIATRIC CORPORATION)
)
)
Defendants.)

CIVIL NO. 04-74-KSF

SETTLEMENT AGREEMENT

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I. INTRODUCTION

- A. On March 22, 2002, the United States notified Breathitt County officials of its intent to investigate conditions of confinement at Nim Henson Geriatric Center ("Nim Henson" or "the facility"), pursuant to the Civil Rights of Institutionalized Persons Act, 42 U.S.C. § 1997.
- B. On June 17-19, 2002, the United States toured the facility with consultants in the fields of geriatric medicine, geriatric psychiatry, and geriatric nursing.
- C. Throughout the course of the investigation, the United States received complete cooperation and access to the facility and documents from Breathitt County and the facility's administration.
- D. On March 6, 2003, the United States issued a findings letter pursuant to 42 U.S.C. § 1997(a)(1) which concluded that certain conditions at the facility violate federal constitutional and/or statutory rights of the facility's residents.
- E. Defendants in this action are Breathitt County, Kentucky, by and through the Breathitt County Fiscal Court; Nim Henson Geriatric Center; the Breathitt County Geriatric Corporation; and their successors, contractors, and agents.
- F. Defendants are legally responsible, in whole or in part, for the operation and conditions of Nim Henson.
- G. The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1345. The Attorney General has completed the prerequisites to filing suit as set forth in 42 U.S.C. §§ 1997a, 1997b, and 1997h. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b).
- H. Recognizing the interests of the residents of Nim Henson, and for purposes of avoiding protracted and adversarial litigation, the Parties enter into this Settlement Agreement.
- I. In entering into this Settlement Agreement, Defendants

do not admit any violation of law, and this Settlement Agreement may not be used as evidence of liability in any other proceeding.

- J. The United States acknowledges that Defendants have begun to implement measures addressing conditions of care at the facility.

II. DEFINITIONS

- A. "DOJ" or "the DOJ" shall refer to the United States Department of Justice, which represents the United States in this matter.
- B. "Nim Henson" or "the facility" shall refer to Nim Henson Geriatric Center, currently located in Jackson, Kentucky, as well as any facility that is built to replace or supplement Nim Henson.
- C. "Resident" or "residents" shall refer to one or more individuals confined at the facility.
- D. "Restrictive Controls" shall refer to any order, device, procedure, or medication that restricts, limits, or directs a person's freedom of movement, including, but not limited to, sedating medications.
- E. "Responsible party" shall refer to a person having authority to make health care decisions for a resident.

III. SUBSTANTIVE REMEDIAL MEASURES

A. General Medical Care

Effective upon the Court's entry of this settlement agreement as an order, Nim Henson residents shall be promptly assessed, diagnosed, treated, monitored, and, as monitoring indicates is necessary, reassessed, diagnosed, and treated, consistent with current, generally accepted standards of care, including with documentation adequate to withstand clinical scrutiny.

1. Medication Management

Effective upon the Court's entry of this settlement agreement as an order, Defendants shall ensure that every Nim Henson resident shall receive prescription medications only after first having been thoroughly evaluated or worked up and

diagnosed according to current, generally accepted standards of care, including with sufficient documentation to withstand clinical scrutiny, and ensure that each medication shall be clinically justified as an appropriate treatment for the diagnosed medical condition for which it is prescribed. Effective 90 days from the Court's entry of this settlement agreement as an order, Defendants shall:

- a. develop and implement adequate policies and protocols regarding:
 - (i) blood level monitoring for medications, including but not limited to medications such as anticonvulsants, lithium and digitalis;
 - (ii) medication side effect monitoring;
 - (iii) use and monitoring of medications that are problematic for the elderly, such as benzodiazepines and anticholinergic medications;
 - (iv) long-term use of medications for conditions when the relevant symptoms are unchanged over long periods of time; and
 - (v) use of as-needed (i.e., "PRN" or "pro re nata") sedatives and analgesics;
- b. complete a thorough evaluation/workup of all current residents and determine whether there is a clinically justifiable, current diagnosis supporting the use of each medication that each resident receives, and discontinue medications that are not clinically justified;
- c. ensure that all remaining medications are prescribed at appropriate therapeutic levels and that all polypharmacy is clinically justified;

- d. monitor all medications for efficacy, side effects and continued appropriateness; and modify medication usage as monitoring warrants;
- e. conduct chart reviews to ensure that, on an ongoing basis, all medications are clinically justified and are prescribed consistent with applicable facility policies and protocols;
- f. ensure that the facility's Pharmacy and Therapeutics Committee ("P&T Committee"), with input from its medical director, pharmacist, pharmacy consultant, and administration, promptly provides guidance to its physicians regarding the use of polypharmacy and the use of medications contraindicated in the elderly; and
- g. ensure that, either through the P&T Committee or otherwise, the pharmacist, pharmacy consultant, and physicians communicate directly and regularly regarding the appropriateness of medications used, alone or in combination, on facility residents, and regarding developments in medications.

2. Medical Notes and Documentation

Effective upon the Court's entry of this settlement agreement as an order, Defendants shall ensure that medical notes and documentation are accurate, current, complete, and organized in a manner allowing relevant information to be quickly identified.

3. Oversight and Management of Medical Care

Effective 90 days from the Court's entry of this settlement agreement as an order, Defendants shall retain a well-qualified medical director who shall be responsible for maintaining a consistent level of adequate medical care throughout the facility. Defendants shall ensure that, within 90 days from the Court's entry of this settlement agreement as an order, the medical director:

- a. dedicates sufficient time to the facility to provide adequate oversight and management of

- medical care at the facility;
- b. establishes a medical quality assurance program that:
 - (i) actively collects data relating to the quality of medical services;
 - (ii) assesses these data for trends;
 - (iii) initiates inquiries regarding problematic trends and possible deficiencies;
 - (iv) identifies corrective action; and
 - (v) monitors to ensure that appropriate remedies are achieved;
 - c. establishes a system to track errors in the administration of medicine;
 - d. establishes uniform medical care policies and protocols, particularly regarding medication usage, nutrition and wound care, to ensure the consistent provision of medical care;
 - e. in a documented fashion, performs chart reviews and quality assurance reviews of medical documentation;
 - f. ensures the provision of appropriate specialized medical services, such as psychiatric, neurologic, ophthalmologic, podiatric, and dental care; and
 - g. takes an active role in staff education regarding critical issues such as psychiatric symptoms, medication side effects, nutrition, infection control, and wound care.

B. Chemical Restraints

Effective upon the Court's entry of this settlement agreement as an order, Restrictive Controls shall be used only

when less restrictive measures have been unsuccessfully attempted and not as a substitute for treatment of the underlying causes of the condition provoking the Restrictive Controls. Effective upon the Court's entry of this settlement agreement as an order, Defendants shall:

1. comply with 42 C.F.R. § 483.13 and other federal regulations that prohibit the use of physical or chemical restraints not required to treat a resident's medical condition;
2. provide meaningful activities, restorative care, and psychosocial supports to minimize the occurrence of disruptive or dangerous behavior;
3. eliminate use of all Restrictive Controls except:
 - a. when less restrictive measures have been used appropriately and have been adequately documented (including the reason for the procedure(s), the procedure(s) used, and the outcome(s)) and would not protect the person or others from harm; and
 - b. as a temporary, planned intervention in a plan of care, in which the underlying cause of the condition leading to Restrictive Controls has been clinically determined, or on an emergency basis, when an unexpected crisis situation occurs in which a person poses an immediate risk of harm to self or others; and
4. develop and implement a policy on Restrictive Controls that comports with federal regulations and current, generally accepted standards of care.

C. Wound Care

Effective upon the Court's entry of this settlement agreement as an order, Defendants shall ensure that wounds are promptly detected, closely monitored and properly treated, consistent with current, generally accepted standards of care, including with documentation adequate to withstand clinical scrutiny. Effective 30 days from the Court's entry of this settlement agreement as an order, Defendants shall:

1. establish a facility-wide system for wound

tracking that shall include:

- a. timely and accurate wound statistics;
 - b. a master list, updated at least daily, of residents with wounds (including pressure ulcers, surgical wounds and skin tears), identifying preventative measures, sites, stages, and treatments; and
 - c. quality assurance evaluations of wound treatments and outcomes, including incidences of facility-acquired wounds and stages, wound statistics, and staff compliance with facility wound care policies and protocols; and
2. ensure that all staff responsible for resident care are competent in pressure ulcer prevention and staging;
 3. ensure that nursing staff know the current wound status of each resident in their care (i.e., the existence and stage (I, II, III or IV) of any wounds, the standard treatment interventions associated with any such wounds, whether those or other interventions have been applied correctly, and what changes have occurred in the wound status over the preceding 24 hours), promptly communicate changes in wound status to the resident's physician, and timely document the status of wounds, including changes in wound status; and
 4. establish a wound care formulary.

D. Nutrition

Effective upon the Court's entry of this settlement agreement as an order, Defendants shall ensure that residents' weight is properly monitored and that residents, especially those residents with swallowing difficulties, receive appropriate dietary and nutritional interventions. Effective 60 days from the Court's entry of this settlement agreement as an order, Defendants shall:

1. systemically track, through food intake records, residents who have sustained weight change;

2. consistently notify physicians and Responsible Parties of significant changes in weight; and
3. ensure that, for residents experiencing significant weight change:
 - a. a comprehensive investigation of the extent and cause of the resident's condition is performed that includes consideration of potentially reversible or treatable factors, such as medications, environmental conditions, disease state, sensory loss, cognitive status, and mood;
 - b. the considerations leading to use of feeding tubes, including the potential for improvement, be fully considered, in a documented manner, before a feeding tube is used;
 - c. staff responsible for resident care know the indications that justify the use of tube feeding;
 - d. appropriate interdisciplinary participation occurs in identifying interventions for the weight change, and particularly in the decision to insert a feeding tube into a resident, including participation from persons such as the resident, Responsible Parties, the resident's family, the physician, the nutritionist, the nurse, and the speech therapist;
 - e. residents with a feeding tube are reviewed on an ongoing basis to determine whether the tube can be discontinued;
 - f. care plans are reliably updated to describe interventions for the weight change;
 - g. direct care staff are competent in implementing the weight change interventions identified in the care plan; and
 - h. weight change interventions are monitored with sufficient frequency and, as necessary, revised.

E. Restorative Care

Effective upon the Court's entry of this settlement agreement as an order, Defendants shall assist facility residents to "attain or maintain the highest practicable physical, mental and psychosocial well-being," as required by 42 U.S.C. § 1395i-3(b)(4)(A). Effective 60 days from the Court's entry of this settlement agreement as an order, Defendants shall:

1. develop and implement restorative care plan policies and procedures that are consistent with federal regulations, including but not limited to 42 C.F.R. § 483.25, addressing change in resident condition;
2. develop and implement a plan for each resident to provide restorative care based on the resident's assessed needs, reassess those needs at appropriate intervals (especially as to: mobility, continence, and Activities of Daily Living ("ADL") support, activities that promote self care, seating supports, and meaningful activities), and update the plan based on such reassessment;
3. as appropriate, provide furniture and seating supports adequate to permit residents to transfer out of wheelchairs and so-called Geri-chairs (e.g., chairs on rollers, with side-arm and other supports, intended for use by a geriatric population) to facilitate resident physical functionality; and
4. ensure that nurses and Nim Henson staff responsible for resident care are competent in:
 - a. identifying significant age-related changes;
 - b. functional assessment and restorative care;
 - c. basic elements of common pathology and physical assessment;
 - d. medication effects and side effects; and
 - e. facility policies and procedures regarding change of condition.

F. Psychiatric Care

Effective upon the Court's entry of this settlement agreement as an order, Defendants shall provide Nim Henson residents with adequate psychiatric supports and services, as required under 42 U.S.C. § 1396r(b)(4)(A). Effective 90 days from the Court's entry of this settlement agreement as an order, Nim Henson residents shall receive psychotropic medications only after having been thoroughly evaluated and diagnosed according to current, generally accepted standards of care, including with sufficient documentation to withstand clinical scrutiny. Effective 90 days from the Court's entry of this settlement agreement as an order, Defendants shall:

1. obtain sufficient psychiatric services, consultative or otherwise, to meet the ongoing psychiatric needs of Nim Henson's residents;
2. develop or procure standard psychological and psychiatric assessment and interview protocols for reliably reaching a psychiatric diagnosis for individuals who are elderly and use these protocols to assess each person upon admission for possible psychiatric disorder(s);
3. ensure that all staff directly interacting with residents can competently provide appropriate supports for persons experiencing depression and/or dementia;
4. as to all residents receiving psychotropic medications, undertake a psychiatric consult to ensure that all such medications are appropriate and are specifically matched to current, clinically justifiable diagnoses; and
5. obtain informed consent or proper legal authorization prior to administering psychotropic medications and other invasive treatments.

G. Incident Management and Quality Assurance

Effective upon the Court's entry of this settlement agreement as an order, Defendants shall ensure that incidents involving injury and unusual incidents shall be reliably and accurately reported and investigated, with appropriate follow-up. Effective 30 days from the Court's entry of this settlement

agreement as an order, Defendants shall:

1. address the root causes of falls and other injuries to minimize their occurrence, and provide appropriate, individualized interventions;
2. replace unwarranted use of full side rails with less harmful interventions for falls;
3. ensure that incidents involving injury and unusual incidents are tracked and analyzed to identify root causes;
4. ensure that analyses are transmitted to the relevant disciplines and direct-care areas for responsive action, and responses are monitored to ensure that appropriate steps are taken; and
5. ensure that assessments are conducted to determine whether root causes have been addressed and, if not, ensure that appropriate feedback is provided to the responsible disciplines and direct-care areas.

H. Most Integrated Setting

Effective upon the Court's entry of this settlement agreement as an order, Defendants shall ensure that the facility's treatment professionals periodically and reliably assess its residents to determine whether community placement is appropriate for any of them. If treatment in a more integrated setting is determined to be appropriate, then such treatment shall be provided, if the affected person does not oppose such treatment, and the placement can be reasonably accommodated.

I. Compliant Policies, Procedures and Protocols

Effective 90 days from the Court's entry of this settlement agreement as an order, Defendants shall review and revise, as appropriate, all policies, protocols, and procedures as necessary to comply with and implement all of the provisions of this settlement agreement.

IV. REPORTING REQUIREMENTS AND RIGHT OF ACCESS

- A. Within 90 days from the Court's entry of this settlement agreement as an order, Defendants shall provide DOJ with an initial status report regarding

their compliance with this settlement agreement. Within 180 days from entry of this order, Defendants shall provide DOJ with a second status report regarding their compliance with this settlement agreement. Within one year of the Court's entry of this settlement agreement, and within every 180 days thereafter (so long as this agreement remains in effect), Defendants shall provide DOJ with a status report regarding their compliance with this settlement agreement.

- B. Each status report required by IV.A. shall provide:
1. a description of Defendants' status in complying with each and every provision of this settlement agreement and the steps taken to achieve compliance with each and every provision of this settlement agreement during the period since the last status report; and
 2. all relevant documents that demonstrate Defendants' compliance with this settlement agreement, including, but not limited to, policies, procedures, protocols, training materials, and curriculum vitae.
- C. Defendants shall provide DOJ, its staff, experts, and agents, with unrestricted access to:
1. all buildings and facilities at the facility;
 2. all current Nim Henson staff;
 3. all current residents; and
 4. any records relating to: the issues addressed in this agreement; the facility's staff; or facility residents.
- D. Within 30 days of receipt of written questions from DOJ concerning Defendants' compliance with this settlement agreement, Defendants shall provide DOJ with written answers and any requested documents regarding Defendants' compliance with the requirements of this settlement agreement.
- E. Defendants shall maintain sufficient records to document their compliance with all of the requirements of this settlement agreement. Defendants shall also

maintain (so long as the agreement remains in effect) any and all records required by or developed under this settlement agreement.

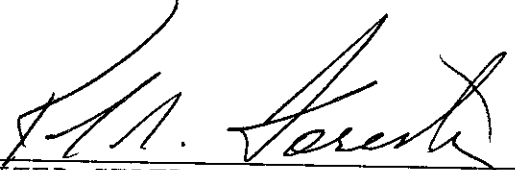
V. IMPLEMENTATION and TERMINATION

- A. Effective upon the Court's entry of this settlement agreement as an order, Defendants shall immediately ensure that all current and future employees at the facility understand the requirements of this settlement agreement and the necessity for compliance with it.
- B. This settlement agreement shall constitute the entire integrated agreement of the Parties. With the exception of DOJ's findings letter referenced in paragraph I.D., and any DOJ technical assistance recommendations regarding the issues raised herein, no prior drafts or prior or contemporaneous communications, oral or written, will be relevant or admissible for purposes of determining the meaning of any provisions in this agreement or in any other proceeding.
- C. Defendants shall appoint a person who shall devote sufficient time and resources to oversee adequately Defendants' compliance with this settlement agreement and to serve as Defendants' point of contact.
- D. If DOJ believes that Defendants have failed to fulfill any obligation under this settlement agreement, DOJ will, prior to initiating any court proceeding to remedy such failure, give written notice of the failure to Defendants. Defendants shall have 60 days from the date of such notice either to cure the failure and provide DOJ with sufficient proof of its cure or to demonstrate to DOJ that they are in compliance with this agreement. At the end of the 60-day period, in the event that DOJ determines that the failure has not been cured, DOJ may initiate a court proceeding to remedy the failure. However, in the event that DOJ determines that the failure poses an imminent and serious threat to the life or health of facility residents, it may initiate a court proceeding at any time.
- E. The Court shall retain jurisdiction of this action for all purposes during the term of this settlement agreement. One year from the date by which Defendants

shall have implemented all of their obligations under this agreement (i.e., the deadline which is the greatest number of days from the day of the Court's entry of this agreement, taking into account any mutually agreed deadline modifications) ("Completion Date"), the Parties shall meet and confer regarding whether Defendants are in compliance with each and every provision of this settlement agreement. At that time the Parties may agree to continue or terminate this settlement agreement. If the Parties do not agree, the burden shall be on DOJ to demonstrate that Defendants are not in compliance with some provision of this settlement agreement. Ninety days after the Completion Date, and in the absence of a motion to extend the term of, or otherwise modify, this agreement, this matter may be dismissed with prejudice by the Court upon its own motion. Notwithstanding the foregoing, the Parties at any time may jointly move the Court to dismiss this action with prejudice.

- F. The Parties agree to defend the provisions of this settlement agreement. The Parties shall notify each other of any court challenge to this settlement agreement. In the event any provision of this settlement agreement is challenged in any local or state court, removal to a federal court shall be sought.
- G. In the event any provision of this settlement agreement is declared invalid for any reason by a court of competent jurisdiction, said finding shall not affect the remaining provisions of this settlement agreement.

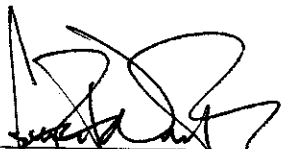
SO ORDERED:



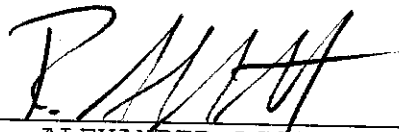
UNITED STATES DISTRICT JUDGE

2/19/04
DATE


FOR THE UNITED STATES:



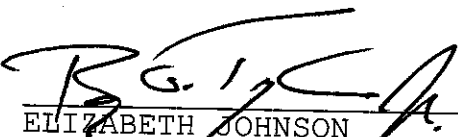
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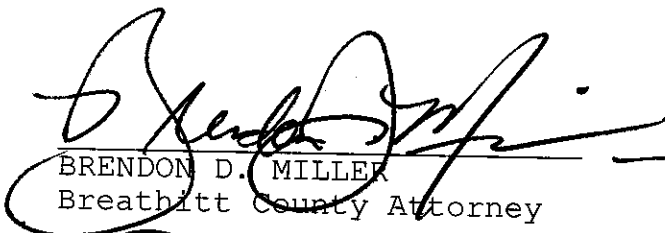
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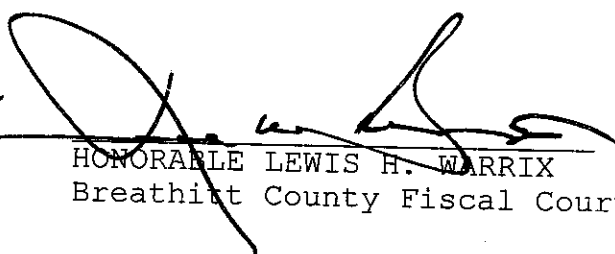
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