

**UNITED STATES DISTRICT COURT  
FOR THE  
DISTRICT OF COLUMBIA**

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AMERICAN NURSES ASSOCIATION, )  
8515 Georgia Avenue Suite 400 )  
Silver Spring, MD 20910 )

and )

NEW YORK STATE NURSES ASSOCIATION, )  
11 Cornell Road )  
Latham, NY 12110 )

and )

WASHINGTON STATE )  
NURSES ASSOCIATION, )  
575 Andover Park West, Suite 101 )  
Seattle, WA 98188 )

Plaintiffs, )

v. )

MICHAEL O. LEAVITT , SECRETARY, )  
U.S. DEPARTMENT )  
OF HEALTH AND HUMAN SERVICES, )  
200 Independence Avenue, S.W. )  
Washington, D.C. 20201 )

and )

MARK MCCLELLAN, ADMINISTRATOR )  
CENTERS FOR MEDICARE )  
AND MEDICAID SERVICES, )  
7500 Security Boulevard )  
Baltimore, MD 21244 )

Defendants. )

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Civ. Action No. 06-1087 (HHK)

## SECOND AMENDED COMPLAINT

Plaintiffs American Nurses Association, New York State Nurses Association, and Washington State Nurses Association amend their first complaint and allege as follows:

1. This action seeks to remedy violations of law that pertain to the minimum standards for participation in the federal Medicare program. Plaintiffs bring this action under the judicial review provisions of the Administrative Procedure Act, 5 U.S.C. § 706 (the “APA”), based on the Defendants’ failure to act in following their regulations, which set forth specific requirements with regard to nursing services, 42 C.F.R. 482.23. Plaintiffs seek a declaration from this Court that Defendant Department of Health and Human Services (“HHS”) has failed to establish a system to ensure adequate registered nurse staffing, in violation of 42 C.F.R. 482.23, which states in pertinent part:

(b) Standard: Staffing and delivery of care. The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient.

2. Plaintiffs further seek a declaratory judgment and appropriate injunctive relief necessary to prevent HHS from unlawfully delegating to a private party, the Joint Commission on Accreditation of Healthcare Organizations, the authority to determine the sufficiency of its standards when measured against the HHS Conditions of Participation. Given the profound impact on public health and welfare, HHS’s inattention to the conditions of participation and its own standards regarding registered nurse staffing cannot go unchecked.

### **JURISDICTION AND VENUE**

3. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331, as this action arises under the laws of the United States.
4. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a). This court may grant declaratory relief and additional relief including an injunction, pursuant to 28 U.S.C. §§ 2201, 2202, and 5 U.S.C. §§ 705, 706.
5. Defendant HHS's failure to require compliance with its own regulations constitutes a failure to act which is subject to judicial review. 5 U.S.C. § 706.
6. Plaintiffs need not exhaust administrative remedies, as there is no administrative process or agency appeal with respect to Defendants' failure to enforce their own regulations pertaining to requirements for adequate registered nurse staffing.
7. Venue lies in the District of Columbia pursuant to 28 U.S.C. § 1391(e) because the Defendant HHS is located within this District.
8. Venue lies in the District of Columbia because Plaintiff American Nurses Association (ANA) is incorporated and does business in the District of Columbia.

### **PARTIES**

9. Plaintiff ANA is a national nonprofit membership organization incorporated in the District of Columbia. Its headquarters are in Silver Spring, MD, and it retains an office in the District of Columbia. The ANA is the professional association that represents the interests of the nation's 2.9 million registered Nurses. The ANA is comprised of 54 constituent member associations, including one in every state of the United States, the District of Columbia, Guam, the U.S. Virgin Islands and federal military nurses, with over 150,000 members. The ANA not only develops

the Code of Ethics for Nurses and the standards of nursing practice, it actively promotes patient safety, workplace rights, appropriate staffing, workplace and environmental health and safety, and the public health, including national policy initiatives that affect Medicare and access to health services. ANA represents registered nurses whose practice is adversely affected by Defendants' actions and inactions. In addition, among ANA's members there are retired registered nurses who are age 65 and older; these members are health care consumers who receive Medicare reimbursement for services received in hospitals that are affected by Defendants' failure to act.

10. The New York State Nurses Association (NYSNA) is a constituent of the American Nurses Association and represents approximately 34,000 registered nurses who work in New York and whose ability to render safe patient care is adversely affected by the Defendants' actions and inactions. NYSNA's headquarters are in Latham, and it maintains offices in New York City and Buffalo. As the oldest state nurses association, NYSNA's mission is to represent the interests of registered nurses and nursing in New York State.
11. Washington State Nurses Association (WSNA) is a constituent of the American Nurses Association and represents approximately 13,000 registered nurses, who work in Washington state and whose ability to render safe patient care is adversely affected by the Defendants' actions and inactions. WSNA's headquarters are in Seattle. WSNA has served as the voice of registered nurses and the nursing profession in Washington for almost a century.

12. The U.S. Department of Health and Human Services is a federal agency with its headquarters located in Washington, D.C. HHS is responsible for the Medicare and Medicaid programs. Michael O. Leavitt is the Secretary of HHS and is named in his official capacity.
13. As a component of HHS, the Centers for Medicare and Medicaid manage the operations of the Medicare and Medicaid programs, including review of the Joint Commission on Accreditation of Healthcare Organization's ("JCAHO") evaluations of participating hospitals. Mark McClellan is the Administrator and is named in his official capacity.

## **FACTS**

### **BACKGROUND OF THE MEDICARE PROGRAM**

14. The Medicare Act was adopted by Congress in 1965. A key purpose was to provide a hospital insurance program for the elderly under the Social Security Act, with a supplementary health benefits program.
15. Part E of the Medicare Act, the Miscellaneous Provisions, references nursing services in the definition section. 42 U.S.C. § 1395x. "Inpatient hospital services" means "the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital -- (1) bed and board; (2) such *nursing services* and other related services, such as use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients...." 42 U.S.C. § 1395x(b) (emphasis added).
16. A "hospital" is defined as an institution which "provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed

practical nurse or registered professional nurse on duty at all times...” 42 U.S.C. § 1395x(e)(5), except for certain small, rural hospitals for which certain nursing service requirements are waived. 42 U.S.C. § 1395x(e)(5)(A).

17. A “hospital” is also defined as an institution which “meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.” 42 U.S.C. § 1395x(e)(9).

18. Since amendments passed by Congress in 1972, HHS has been empowered to set standards higher than those imposed by the industry through JCAHO.

### **CONDITIONS OF PARTICIPATION IN THE MEDICARE PROGRAM**

19. The Department of Health and Human Services has established a baseline requirement for registered nurse staffing of hospitals that receive Medicare payments for services rendered to patients.

20. The statutory bases for the regulations setting forth the Conditions of Participation that include the nurse staffing requirements, in the Medicare Program are 42 U.S.C. § 1395hh and 42 U.S.C. § 1302. The Social Security Act provides that the Secretary “shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title.” 42 U.S.C. § 1395hh.

21. The Social Security Act requires that the Secretary shall provide for notice of proposed regulations and a comment period of no less than 60 days. 42 U.S.C. § 1395hh(b)(1). This requirement applies when the Secretary is issuing any regulation in final form, with a few limited exceptions. *Id.*

22. As relevant hereto, the Secretary’s determination that additional requirements, over and above the statutory minimums of 42 U.S.C. § 1395x(e), are necessary for the

health and safety of Medicare patients, is discretionary in the first instance. The additional requirements, however, have the full force and effect of law upon finalization after publication and public comment.

23. The Conditions of Participation were first published in 1966. In 1980, the conditions were revised, and the Department published a notice of proposed rulemaking in the Federal Register. In 1983, as a result of substantial comments, the Department published a second notice of proposed rulemaking. Final Regulations were published on June 17, 1986. 51 FR 22010. The conditions of participation implement 42 U.S.C. § 1395x(e), among other sections of the Social Security Act. *Id.*, Section I (“Background”).
24. Conditions of Participation refer to the requirements that providers must meet in order to participate in the Medicare program. 42 C.F.R. 488.1. Federal regulations set forth specific requirements with regard to nursing services. 42 C.F.R. 482.23.
25. The current conditions of participation regarding nursing services state:

The hospital must have an organized nursing service that provides 24-hour nursing services. The nursing services must be furnished or supervised by a registered nurse.

(a) Standard: Organization. The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. The director of the nursing service must be a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

*(b) Standard: Staffing and delivery of care. The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a*

*registered nurse for bedside care of any patient.*

(1) The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse, and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under § 405.1910(c) of this chapter.

(2) The nursing service must have a procedure to ensure that hospital nursing personnel for whom licensure is required have valid and current licensure.

(3) A registered nurse must supervise and evaluate the nursing care for each patient.

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient.

(5) A registered nurse must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available.

(6) Non-employee licensed nurses who are working in the hospital must adhere to the policies and procedures of the hospital. The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of non-employee nursing personnel which occur within the responsibility of the nursing service.

42 C.F.R. 482.23 (emphasis added).

26. HHS interpretive guidelines provide that:

The nursing service must ensure that patient needs are met by ongoing assessments of patients' needs and providing nursing staff to meet those needs. There must be sufficient numbers, types, and qualifications of supervisory and staff nursing personnel to respond to the appropriate nursing needs and care of the patient population of each department or nursing unit.

There must be a [sic] RN physically present on the premises and on duty at all times. Every inpatient unit/department/location within the hospital-wide nursing service must have adequate numbers of RNs physically present at each location to ensure the immediate availability of a RN for the bedside care of any patient.

A RN would not be considered immediately available if the RN were working on more than one unit, building, floor in a building, or provider at the same time.

Staffing schedules must be reviewed and revised as necessary to meet the patient care needs and to make adjustments for nursing staff absenteeism.

Appendix A, Regulations and Interpretive Guidelines for Hospitals, § 482.23(b) at 39 (April 2004).

### **HOSPITAL PARTICIPATION IN THE MEDICARE PROGRAM**

27. A hospital may participate in the Medicare program in one of two ways. First, the appropriate state agency may conduct a survey of a hospital and certify whether the hospital is, or is not, in compliance with the conditions of participation. 42 C.F.R. 488.12. The agency's certification is based on an evaluation of the hospital site. 42 C.F.R. 488.26(b). In the alternative, a hospital may allow JCAHO to release its accreditation report to CMS. 42 C.F.R. 488.10(b)(2).
28. JCAHO is a private, non-profit accrediting organization controlled by its sponsors, the American Medical Association, the American Hospital Association, the American College of Physicians-American Society of Internal Medicine, and the American Dental Association. JCAHO receives its funding through fees, paid by hospitals to receive accreditation review and through fees paid by hospitals to JCAHO's consulting arm that assists hospitals in trying to obtain JCAHO accreditation. JCAHO's accreditation is equivalent to approval for participation in the Medicare program, provided that the JCAHO standards are as high as those set by HHS pursuant to 42 U.S.C. § 1395x(e)(9). *See* 42 U.S.C. § 1395bb(a)(4).

29. If a provider is found to be noncompliant with one or more of the conditions of participation, it may still participate in Medicare so long as (1) it has submitted a plan of correction which will take place in a reasonable amount of time, and (2) the deficiencies do not jeopardize the health and safety of patients. 42 C.F.R. 488.28.
30. According to the Government Accounting Office, in 2002, JCAHO accredited 4,211 of Medicare participating hospitals, which is equivalent to 82%. These hospitals received Medicare payments of approximately \$98 billion. GAO-04-850 at p. 7.
31. JCAHO's nursing service standards are as follows:

NR.1.10. A nurse executive directs the hospital's nursing services.

NR.2.10. The nurse executive is a licensed professional registered nurse qualified by advanced education and management experience.

NR.3.10. The nurse executive establishes nursing policies and procedures, nursing standards of patient care, treatment, and services, standards of nursing practice and a nurse staffing plan(s).

- JCAHO Comprehensive Accreditation Manual for Hospitals: The Official Handbook* at p. NR-2 (2006).
32. The elements of performance for JCAHO standard 3.10 regarding a hospital's nurse staffing plan are as follows:

1. The nurse executive, registered nurses, and other designated nursing staff members write nursing policies and procedures; nursing standards of patient care, treatment and services; standards of nursing practice; a nurse staffing plan(s); and standards to measure, assess, and improve patient outcomes.

2. The nurse executive is responsible for ensuring that nursing policies, procedures, and standards describe and guide how the nursing staff provides the nursing care, treatment, and services required by all patients

and patient populations served by the hospital and as defined in the hospital's plan(s) for providing nursing care, treatment, and services.

3. All nursing policies, procedures, and standards are defined, documented, and accessible to the nursing staff in written or electronic format.

4. The nurse executive or a designee(s) exercises final authority over those associated with providing nursing care, treatment, and services.

*JCAHO Comprehensive Accreditation Manual for Hospitals: The Official*

*Handbook* at p. NR-8 (2006).

33. JCAHO's nursing standards are totally devoid of standards and requirements concerning the immediate availability of a registered nurse to render bedside care to the patients. Instead, the JCAHO standards focus only on the role of the nurse executive and his or her adoption of policies and procedures. The JCAHO nursing standards do not specify the nature of the staffing plans that are required of accredited hospitals and therefore these JCAHO standards are not an equivalent or higher standard than that of HHS, which calls for staffing plans that "ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient." 42 C.F.R. 482.23.

34. JCAHO's general human resource standards include:

HR.1.10. The hospital provides an adequate number and mix of staff that are consistent with the hospital's staffing plan.

HR.1.20. The hospital has a process to ensure that a person's qualifications are consistent with his or her job responsibilities.

HR.1.30. The hospital uses data from clinical/service screening indicators and human resource screening indicators to assess and continuously improve staffing effectiveness.

*JCAHO Comprehensive Accreditation Manual for Hospitals: The Official*

*Handbook* at p. HR-2 (2006).

35. The JCAHO Element of Performance for HR. 1.10 is that “The hospital has an adequate number and mix of staff to meet the care, treatment, and service needs of the patients.” *JCAHO Comprehensive Accreditation Manual for Hospitals: The Official Handbook* at p. HR-7 (2006).

36. The element of performance for Standard 1.30 for testing the adequacy of staffing plans permits a hospital to bypass RN-specific data through allowing data review of “[a]ll nursing staff (including registered nurses, licensed practical nurses, and nursing assistants or aides)...,” leaving to hospitals the discretion on stratification of data by discipline. *JCAHO Comprehensive Accreditation Manual for Hospitals: The Official Handbook* at p. NR-8 (2006). Thus, specific information about RN staffing may go undetected.

37. The JCAHO standard for Human Resources staffing does not result in adequate registered nurse staffing, as it is applicable to all staff, and the self-assessment tools do not ensure compliance with the HHS nursing standard for registered nurse availability. *See* 42 C.F.R. 482.23(b). The JCAHO standard is thus a lower standard than the conditions of participation.

38. Among many other hospitals in the United States, JCAHO has accredited hospitals at which members of NYSNA and WSNA work and are adversely affected by the inadequate levels of RN staffing.

39. Those hospitals that are accredited by JCAHO are “deemed to meet” the conditions of participation, “except... any standard, promulgated by the Secretary pursuant to paragraph (9) thereof, which is higher than the

requirements prescribed for accreditation by such Commission.” 42 U.S.C. § 1395bb(a)(4). The Secretary remains ultimately responsible for ensuring safeguards in this process and has failed to do so.

40. Upon information and belief, the “deemed” status of hospitals participating in Medicare is assumed by HHS notwithstanding the higher requirements of HHS regarding nurse staffing.

41. There are hospitals in New York and Washington states, among other states, where due to the official neglect of HHS, the hospitals have consistently failed to provide sufficient registered nurse staffing to make a registered nurse immediately available when needed, yet those hospitals participate in and receive funds from the Medicare program.

#### **HARMS SUFFERED DUE TO INADEQUATE NURSE STAFFING**

42. NYSNA’s membership includes registered nurses who work for the New York City Health and Hospitals Corporation (HCC), which received JCAHO accreditation as follows: Bellevue Hospital Center on August 13, 2005, Coler-Goldwater Specialty Hospital and Nursing Facility on November 8, 2002, Coney Island Hospital on October 31, 2003, Elmhurst Hospital Center on October 30, 2004, Gouverneur Nursing Facility on August 14, 2004, Harlem Hospital Center on February 24, 2005, Jacobi Medical Center on May 27, 2005, Kings County Hospital Center on July 7, 2005, Lincoln Medical and Mental Health Center on October 18, 2003, Dr. Susan Smith McKinney Nursing/Rehabilitation Center on July 17, 2004, Metropolitan Hospital Center on August 21, 2004, North Central Bronx Hospital on October 19, 2002, Queens Hospital Center on May 6, 2005, Sea View Hospital Rehabilitation

Center and Home on May 15, 2004, Woodhull Medical and Mental Health Center on October 12, 2002.

43. Between September 2003 and September 2005, NYSNA members who work for HCC experienced at least 1,233 shifts where they were not able to complete patient care tasks in a manner that they felt was necessary and safe due to high caseloads per registered nurse resulting in inadequate numbers of personnel to provide nursing care as needed. Many of these instances involved patients who received Medicare benefits. For example, on one HCC Medical/Surgical Unit on January 6, 2004, there were only two RNs on duty for 23 patients, all over 65 years of age, which impeded the immediate availability of an RN for bedside care.
44. On January 16, 2005, in the Emergency Department of an HCC facility, only one RN was on duty, assigned to adult walk-in triage, with no patient care assistance. The RN saw 120 patients during a 10 hour period. The lack of adequate RN staffing impeded the immediate availability of an RN for bedside care.
45. On December 14, 2002 in the Med/Surg Observational Unit of an HCC facility, the one registered nurse assigned to a shift was required to do admission and medication administration on the regular floor outside of the Observational Unit, leaving no RN on the unit.
46. In the Intensive Care Unit on March 21, 2005, there were only two RNs for 12 patients, which impeded the immediate availability of an RN for bedside care as needed, and created a high risk of medication errors.
47. WSNA members work at Sacred Heart Medical Center, which was accredited by JCAHO on November 1, 2003. Throughout the period of 2002 through 2004, staffing

deficiencies including deficiencies in registered nurse staff levels and other health care staff levels directly resulted in the frequent inability of RNs to take necessary rest breaks, thereby creating physical and emotional stress on the registered nurses.

48. At Yakima Regional Medical Center, which was accredited by JCAHO on May 27, 2005 three emergency department registered nurses were required to care for twenty-five patients, i.e., 8 patients per RN on July 15, 2005, which did not meet the standard of care guidelines.
49. At Yakima Regional Medical Center, on October 2, 2003, there were an insufficient number of registered nurses on duty in the emergency room to permit a registered nurse to be immediately available to provide timely care, including services to a chest pain patient.
50. On June 18, 2005, at Yakima Regional Medical Center, there was an inadequate number of staff to cover the care of three ventilated patients along with 8 or 9 other high acuity patients. At least one registered nurse member received no breaks, including no meal break during the shift.
51. During the period of 2002 – 2005, and to the present, JCAHO standards did not, and do not, require sufficient registered nurses and other staff to ensure the immediate availability of a registered nurse to render bedside care to numerous hospitalized patients as required by the HHS regulations.
52. The short staffing and injuries described in paragraphs 42 to 50 are attributable to Defendants' failure to enforce their own regulations thereby permitting JCAHO accreditation to qualify hospitals for participation in the Medicare program without

the necessary levels of registered nurses and other support staff to ensure the immediate availability of an RN to render bedside care when needed.

53. Given the profound impact on public health and welfare, HHS's inattention to the conditions of participation and its own standards regarding registered nurse staffing cannot go unchecked.

54. Plaintiffs are nurses associations who are concerned that the on-going neglect and failure of HHS seriously endanger the health and well-being of the patients who seek Medicare-reimbursed health care services. Further, the violations of law that are the subject of this complaint place registered nurses in the untenable position of providing health care services in a manner that does not comport with the high professional standards of the nurses who work for affected hospitals.

55. Plaintiffs and the public are harmed by a failure to require adequate staffing on medical/surgical units where registered nurse-to-patient staffing ratios of 1:8 result in patients being 28% more likely to die within 30 days than those in units with RN to patient ratios of 1:4, and complications such as urinary tract infections, pneumonia, shock and gastrointestinal bleeding are much more prevalent.

56. Plaintiffs' members, who are consumers of Medicare-reimbursed services in hospitals not meeting the RN staffing condition of participation, are adversely affected by the diminished level of care they receive as a result.

#### **CLAIMS AND REQUEST FOR RELIEF**

57. Paragraphs 1 through 56 are incorporated by reference.

58. Defendants HHS and CMS have failed to implement statutory and regulatory requirements that JCAHO standards be at least equivalent to requirements established by the Secretary of HHS as a prerequisite to having JCAHO accreditation be deemed approval to participate in the Medicare program.
59. Through its failure to require JCAHO to have an equivalent registered nurse staffing standard, as that which is stated in the regulatory conditions of participation, HHS has unlawfully delegated its authority to JCAHO.
60. Plaintiffs request a declaratory judgment that determines that the failure of HHS to assure that JCAHO imposes standards, at least equivalent to the standards promulgated by the Secretary, constitutes an action unlawfully withheld and results in the improper participation of hospitals in the Medicare program that do not have adequate nursing services that comply with the conditions of participation.
61. The Plaintiffs request a declaratory judgment that finds that through the failure of HHS to assure that JCAHO imposes standards, at least equivalent to the standards promulgated by the Secretary, while acknowledging the “deemed” status of JCAHO accredited hospitals as required by law, HHS is engaging in an unlawful *de facto* delegation of its responsibility to JCAHO.
62. Plaintiffs request an order of the Court to (1) set aside HHS acknowledgement of hospitals’ participation in the Medicare program if their accreditation from JCAHO forms the basis for such participation; (2) require HHS to provide these hospitals provisional approval for participation in Medicare to ensure

continuing access to health care services; and (3) require HHS to ensure that hospitals comply with the registered nurse staffing regulation.

63. Plaintiffs request an order of the Court to require HHS to establish a system to ensure that JCAHO standards are at least equivalent to those established by the Secretary of HHS.

64. Plaintiffs seek an award of attorneys' fees.

65. Plaintiffs seek such other relief as the Court finds appropriate.

Respectfully submitted,

/s/

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