UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

OHIO HOSPITAL ASSOCIATION
155 EAST BROAD STREET
COLUMBUS, OHIO 43215

AND

AMERICAN HOSPITAL ASSOCIATION
ONE NORTH FRANKLIN
CHICAGO, ILLINOIS 60606

PLAINTIFFS,

-VS-

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES
200 INDEPENDENCE AVENUE, S.W.
HUBERT H. HUMPHREY BUILDING
SUITE 615F
WASHINGTON, D.C. 20201

DEFENDANT.

CASE NO. 1:96 CV 2165

JUDGE O'MALLEY

JUDGE _____

MAG. JUDGE HEMANN

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Now come Plaintiffs, Ohio Hospital Association ("OHA") and American Hospital Association ("AHA"), by and through counsel, and for their Complaint state as follows:

I. PARTIES

1. Plaintiff OHA is an Ohio non-profit trade association which represents over 200 hospitals in the State of Ohio with its principal place of business located in Columbus, Ohio.

2. Plaintiff AHA is a non-profit trade association which represents hospitals throughout the United States, including most hospitals in Ohio, with its principal place of business located in Chicago, Illinois.

3. Defendant Donna E. Shalala is the Secretary of the U.S. Department of Health & Human Services ("Secretary") whose responsibilities include implementing Title XVIII of the Social Security Act, as amended, 42 U.S.C. §§ 1395 *et seq.* (the "Medicare Program") through the Health Care Financing Administration ("HCFA").

4. The Secretary and HCFA contract with private organizations to act as fiscal intermediaries of the Medicare Program to, among other things, determine the amounts payable to health care providers for services provided to Medicare beneficiaries and to make payment.

5. OHA's members and AHA's members are health care providers and parties to agreements with the Secretary and HCFA to provide Medicare services to patients presenting themselves to the hospitals for medical services.

6. In their capacity as Medicare providers, hospitals are paid for all inpatient and outpatient Hospital services they provide to beneficiaries under the Medicare Program unless such services are specifically excluded from coverage under § 1862 of the Medicare Act.

II. JURISDICTION & VENUE

7. This Court has jurisdiction over the parties pursuant to 28 U.S.C. § 1331 (federal question jurisdiction) and 28 U.S.C. § 1361 (mandamus against a federal official).

8. Venue is proper pursuant to 28 U.S.C. § 1391. The actions which give rise to this cause of action occurred in Cuyahoga and Summit Counties, as well as other places.

III. STATEMENT OF FACTS

9. Beginning in June, 1995, the United States Attorney's office, on behalf of the Secretary and the United States Department of Justice, began notifying Ohio hospitals by letter that they had allegedly submitted claims for services to Medicare and Medicaid patients which were in violation of the False Claims Act, 18 U.S.C. §287 and/or 31 U.S.C. §3729. An example of such letter is attached hereto as Exhibit A.

10. To the best of OHA's and AHA's knowledge as of the date of this pleading, over 150 of the approximately 185 general acute care hospitals in the State of Ohio have received such letters from the U.S. Attorney's office. Similar (although not identical) letters were sent by the U.S. Attorney's office in the Northern District of Ohio as were sent by the U.S. Attorney's office in the Southern District of Ohio.

11. To the best of OHA's and AHA's information and belief, hospitals in other states are beginning to or will soon receive notification from the U.S. Attorney's offices in their respective districts of similar investigations under the authority of the False Claims Act, 18 U.S.C. §287 and/or 31 U.S.C. §3729. AHA believes such investigations are being patterned in whole or in part after the investigations already conducted or ongoing in Ohio.

12. The Medicare claims alleged to be in violation of the False Claims Act are bills for outpatient laboratory tests involving certain chemistry, hematology, and urinalysis tests, and organ and disease panels and/or profiles (collectively referred to as "Outpatient Laboratory Tests").

Outpatient Laboratory Tests - Generally

13. The need for Outpatient Laboratory Tests for patients is determined entirely by the physician treating the patient. The physician then orders that one or more tests be performed and communicates such orders in writing to laboratory personnel.

14. Based on the written orders of the physician, laboratory personnel perform the tests requested. Laboratory personnel then assign codes to the tests ordered and performed.

15. Based on the codes assigned to the tests, billing personnel of a hospital submit claims for reimbursement to the hospital's fiscal intermediary.

16. The fiscal intermediary is responsible for reviewing the claims submitted by hospitals, determining the allowability of the claims submitted, and reimbursing the hospital for the claims submitted when and as appropriate. In addition to its responsibilities for handling hospitals' claims, fiscal intermediaries have a statutory duty, as set forth in Section 1816(a) of the Social Security Act (42 U.S.C. 1395h(a)), to "serve as a center for and, communicate to providers, any information or instructions furnished to it by the Secretary, and serve as a channel of communication from providers to the Secretary."

17. In submitting claims for payment to the fiscal intermediary, hospitals rely upon instructions and guidance as provided in the Medicare law and regulations as well as notices from their

fiscal intermediary, from the Hospital Manual, and from the Provider Reimbursement Manual.

18. For purposes of the proper coding and billing of Outpatient Laboratory Tests, the Secretary and HCFA have instructed hospitals to use and rely upon the American Medical Association's Current Procedures Code, fourth edition ("CPT-4") Manual.

Chemistry Tests

19. At all times from at least 1989 until the present, neither the Medicare law and regulations nor the Provider's Reimbursement Manual provided any specific instructions as to the coding and billing of certain chemistry tests performed on automated multi-channel laboratory equipment ("AMC Tests").

20. At all times from at least 1989 until the present, the only guidance provided to hospitals from the Medicare Hospital Manual with respect to the coding and billing of AMC Tests was contained at Section 437(J) and stated as follows:

> J. Laboratory Tests Utilizing Automated Equipment. Clinical laboratory tests are covered under Medicare if they are reasonable and necessary for the diagnosis or treatment of an illness or injury. In the case of multi-channel automated and/or batch automated (e.g., SMAC, CHEMICAL PROFILES, ASTRA) laboratory determinations, however, the physician may not be free to specify the tests the patient needs and there is normally one charge for the battery of tests. The delivery of the services in this manner is much more economical than if the tests are performed individually. **National guidelines for contractors on what tests are available in automated batteries are being developed. Until completed, use codes found in CPT-4 or sent to you by your intermediary.** (emphasis added.)

21. At all times from at least 1989 until November, 1995, the only guidance provided to hospitals from the Medicare Intermediary's Manual with respect to the coding and billing of AMC Tests was contained at Section 3628(J). Except for the last sentence, the

Intermediary's Manual was virtually identical to Medicare Hospital Manual §437(J) and stated as follows:

> J. Laboratory Tests Utilizing Automated Equipment. Clinical laboratory tests are covered under Medicare if they are reasonable and necessary for the diagnosis or treatment of an illness or injury. In the case of multi-channel automated and/or batch automated (e.g., SMAC, CHEMICAL PROFILES, ASTRA) laboratory determinations, the physician may not be free to specify the tests the patient needs, however, there is normally only one charge for the battery of tests. The delivery of the service in this manner is much more economical than if the tests are performed individually. **Install edit procedures to identify situations where the provider bills individual tests where billing for the automated battery would be appropriate based upon carrier practices in your area.** (emphasis added.)

22. At all times from at least 1989 until the present, the CPT-4 Manual listed certain Outpatient Laboratory Tests which, when performed in combination and on automated multi-channel laboratory equipment, should be billed under the CPT code for a single AMC Test. At all times from at least 1989 until the present, the pertinent instructions for the coding and billing of AMC Tests as stated in the CPT-4 Manual read as follows:

> The following list contains those tests that can be and are frequently done as groups and combinations ("profiles") on automated multi-channel equipment. **For any combination of tests among those listed immediately below**, use the appropriate number 80002-80019. Groups of the tests listed here are distinguished from multiple tests performed individually for immediate or "stat" reporting. (emphasis added.)

23. From 1989 through 1992, the CPT-4 Manual listed twenty-one (21) chemistry tests which are to be billed as AMC Tests pursuant to the instructions cited in the preceding paragraph. From 1993 to the present, the CPT-4 Manual listed nineteen (19) chemistry tests which are to be billed as AMC Tests pursuant to the instructions cited in the preceding paragraph.

24. At no time from at least 1989 to the present did the list of AMC Tests in the CPT-4 Manual include the following chemistry tests: Creatine kinase ("CPK"), Gammaglutamyltransferase ("GGT") or Triglycerides.

25. Prior to June, 1994, Ohio hospitals received no instructions which contradicted those set forth in the CPT-4 Manual as to the coding and billing of AMC Tests. Consequently, chemistry tests which were not included in the list of AMC Tests, including CPK, GGT and Triglycerides, were customarily coded and billed as ordered according to the CPT code(s) that most accurately described the service performed. Hospitals had no instructions to bundle and bill CPK, GGT and/or Triglycerides as an AMC Test.

26. In June, 1994, the fiscal intermediary issued Intermediary's Letter 94-14 ("IL 94-14") which notified Ohio hospitals that, effective July 1, 1994, edits would be installed in the fiscal intermediary's review procedures that would automatically amend any claims submitted by hospitals in which AMC Tests were billed individually. However, IL 94-14 also indicated that three tests not included in the list of AMC Tests in the CPT-4 Manual — CPK, GGT and Triglycerides — would also be bundled and billed as an AMC Test.

27. From at least 1989 until June, 1994, the fiscal intermediary knew that hospitals in Ohio were billing for individual chemistry tests under the individual code(s) in the CPT-4 Manual and the fiscal intermediary continued to reimburse hospitals for these individual chemistry tests without comment or disallowance. At no time did the fiscal intermediary inform hospitals that this billing practice was improper.

28. Beginning in June, 1995, hospitals in Ohio were informed through the U.S. Attorney's office that the Secretary has taken the position that at all times since 1989, CPK, GGT and Triglycerides were supposed to have been bundled and billed as AMC Tests.

29. There has never been any authority in the CPT-4 Manual or otherwise for the Secretary's position nor had the hospitals' fiscal intermediary ever instructed Ohio's hospitals prior to June, 1994 to treat CPK, GGT and Triglycerides as if they were AMC Tests. To the contrary, prior to June, 1994, the fiscal intermediary specifically instructed hospitals that "if tests other than those listed [as AMC tests in the CPT-4 Manual] are also performed on the specimen, they may be billed and reimbursed separately."

30. Despite the fact that Ohio hospitals were never put on notice prior to June, 1994 of the need to change their coding and billing for CPK, GGT, and Triglycerides, the Secretary, through the U.S. Attorney's Office and the U.S. Department of Justice, is requiring audits of Ohio hospitals' billings for all CPK, GGT and Triglycerides tests since 1989.

31. Despite the fact that Ohio hospitals were never put on notice prior to June, 1994 of the need to change their coding and billing for CPK, GGT, and Triglycerides, the Secretary, through the U.S. Attorney's Office and the U.S. Department of Justice, is accusing Ohio hospitals that they are in violation of the False Claims Act and that they should enter into settlement agreements with the Secretary. These settlement agreements obligate the hospitals to not only pay back any overpayments as a result of the prior billings, but also in many situations, to pay additional penalties. As a result, hospitals are being forced to repay the Secretary and pay penalties based on an interpretation of billing rules which were not in existence at the time of the original billings by the hospital.

Hematology Tests

32. Hematology tests are ordered, performed, coded and billed in the same manner as other Outpatient Laboratory Tests as described in paragraphs 13 through 18 above.

33. Unlike AMC Tests which at least had the instructions discussed in paragraphs 20, 21 and 22 above, to date, Ohio hospitals have received no specific instructions as to the selection of codes for billing hematology tests. Ohio hospitals have followed the general instruction given with respect to all procedures: bill the most appropriate CPT code.

34. In billing for hematology tests, Ohio hospitals typically selected the CPT code or codes which most accurately described the tests ordered by the physician and performed by the laboratory. In selecting the CPT code or codes, Ohio hospitals relied upon the descriptions for such codes as contained in the CPT-4 Manual.

35. Since at least 1989, the fiscal intermediary knew that hospitals in Ohio were billing for hematology tests in the manner described in paragraph 34 and the fiscal intermediary continued to reimburse hospitals for these hematology tests without comment or disallowance. At no time did the fiscal intermediary inform hospitals that this billing practice was improper.

36. Beginning in June, 1995, hospitals in Ohio were informed through the U.S. Attorney's office that the Secretary has taken the position that at all times since 1989, certain hematology CPT codes were more appropriate than others. The Secretary arbitrarily determined that in certain situations a single hematology CPT code was more appropriate than a combination of two, more descriptive CPT codes, and that CPT codes for certain hematology tests are encompassed in CPT codes for more comprehensive hematology

tests, even though not expressly included in the CPT-4 Manual description for the more comprehensive test.

37. There has never been any authority in the CPT-4 Manual or otherwise for the Secretary's position nor has the hospitals' fiscal intermediary ever instructed Ohio's hospitals to bill hematology tests in the manner now being required.

38. Despite the fact that Ohio hospitals were never put on notice of the need to change their coding and billing for hematology tests, the Secretary, through the U.S. Attorney's Office and the U.S. Department of Justice, is requiring audits of Ohio hospitals' billings for all hematology tests since 1989.

39. Despite the fact that Ohio hospitals were never put on notice of the need to change their coding and billing for hematology tests, the Secretary, through the U.S. Attorney's Office and the U.S. Department of Justice, is accusing Ohio hospitals that they are in violation of the False Claims Act and that they should enter into settlement agreements with the Secretary. These settlement agreements obligate the hospitals to not only pay back any overpayments as a result of the prior billings, but also in many situations, to pay additional penalties. As a result, hospitals are being forced to repay the Secretary and pay penalties based on an interpretation of billing rules which were not in existence at the time of the original billings by the hospital.

Urinalysis Tests

40. Urinalysis tests are ordered, performed, coded and billed in the same manner as other Outpatient Laboratory Tests as described in paragraphs 13 through 18 above.

41. Unlike AMC Tests which at least had the instructions discussed in paragraphs 20, 21 and 22 above, to date, Ohio hospitals have received no specific instructions as to the selection of codes for billing urinalysis tests. Ohio hospitals have followed the general instruction given with respect to all procedures: bill the most appropriate CPT code.

42. In billing for urinalysis tests, Ohio hospitals typically selected the CPT code or codes which most accurately described the tests ordered by the physician and performed by the laboratory. In selecting the CPT code or codes, Ohio hospitals relied upon the descriptions for such codes as contained in the CPT-4 Manual.

43. In ordering a urinalysis test for a patient, physicians routinely order a standard examination and, only if the results are positive, that a microscopic examination be performed. If the results of the urinalysis are negative, a microscopic examination was not needed and, therefore, was not ordered. This practice for the use of urinalysis tests represents generally accepted medical practice for most if not all physicians in Ohio hospitals.

44. For most if not all Ohio hospitals, laboratory billing systems require that the hospital-assigned code and/or its CPT code equivalent must be assigned at the time that the laboratory test is ordered and/or performed. In the case of urinalysis tests, then, the code for a urinalysis test without microscopic examination is used when that test is ordered and/or performed. Depending on whether the microscopic examination is non-automated or automated, the CPT code description for this procedure is stated as follows:

> **81002** — Urinalysis, by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; **without microscopy**, non-automated (emphasis added)

> **81003** — Urinalysis, by dip stick or tablet reagent for . . .; **without microscopy**, automated (emphasis added)

When a microscopic examination is subsequently determined necessary due to a positive result, and is ordered and performed, the appropriate code for that procedure is used by hospitals. The CPT code description for this procedure is stated as follows:

81015 — Microscopic only

45. Since at least 1989, the fiscal intermediary knew that hospitals in Ohio were billing for urinalysis tests in the manner described in paragraph 44 above and the fiscal intermediary continued to reimburse hospitals for these urinalysis tests without comment or disallowance. At no time did the fiscal intermediary inform hospitals that this billing practice was improper.

46. Beginning in June, 1995, hospitals in Ohio were informed through the U.S. Attorney's office that the Secretary has taken the position that at all times since 1989, urinalysis tests which ultimately required microscopic examinations were supposed to have been billed under a single CPT code as urinalysis tests with microscopic examinations rather than two CPT codes, as described in paragraph 44 above. The Secretary arbitrarily determined that in these situations it was more appropriate to bill CPT code 81000 which had the following description in the CPT-4 Manual:

> **81000** — Urinalysis by dip stick or tablet reagent for bilirubin, glucose, hemoglobin, ketones, leukocytes, nitrite, pH, protein, specific gravity, urobilinogen, any number of these constituents; **with microscopy** (emphasis added)

47. There has never been any authority in the CPT-4 Manual or otherwise for the Secretary's position nor has the hospitals' fiscal intermediary ever instructed Ohio's hospitals to bill urinalysis tests in the manner now being required.

48. Despite the fact that Ohio hospitals were never put on notice of the need to change their coding and billing for urinalysis tests, the Secretary, through the U.S. Attorney's Office and the U.S. Department of Justice, is requiring audits of Ohio hospitals' billings for all urinalysis tests since 1989.

49. Despite the fact that Ohio hospitals were never put on notice of the need to change their coding and billing for urinalysis tests, the Secretary, through the U.S. Attorney's Office and the U.S. Department of Justice, is accusing Ohio hospitals that they are in violation of the False Claims Act and that they should enter into settlement agreements with the Secretary. These settlement agreements obligate the hospitals to not only pay back any overpayments as a result of the prior billings, but also in many situations, to pay additional penalties. As a result, hospitals are being forced to repay the Secretary and pay penalties based on an interpretation of billing rules which were not in existence at the time of the original billings by the hospital.

Organ and Disease Panels

50. Organ and disease panels are ordered, performed, coded and billed in the same manner as other Outpatient Laboratory Tests as described in paragraphs 13 through 18 above. Organ and disease panels were developed in response to the increased use of organ and problem-oriented laboratory test combinations performed by laboratories.

51. Unlike AMC Tests which at least had the instructions discussed in paragraphs 20, 21 and 22 above, to date, Ohio hospitals have received no specific instructions as to the selection of codes for billing organ and disease panels. Ohio hospitals have followed the general instruction given with respect to all procedures: bill the most appropriate CPT code.

52. In billing for organ and disease panels, Ohio hospitals typically selected the CPT code or codes which most accurately described the tests ordered by the physician and performed by the laboratory. In selecting the CPT code or codes, Ohio hospitals relied upon the descriptions for such codes as contained in the CPT-4 Manual.

53. Prior to August, 1993, the CPT-4 Manual described CPT codes for organ and disease panels; however, no specific tests were required to be performed as a part of such panel. In fact, the prefatory instructions in the CPT-4 Manual stated as follows:

> Organ "panels" as an approach to diagnosis have been developed in response to the increased use of general screening programs that are now in use in physicians' offices, health centers, clinics, and hospitals. Also included here are profiles that combine laboratory tests together under a problem oriented classification. **The lack of an expanded list of laboratory tests under each number is deliberate. Because no two laboratories utilize the same array of tests in a particular panel, each laboratory should establish its own profile and accompany each reported panel by a listing of the components of that panel performed by the laboratory**. (emphasis added.)

54. Based on the CPT-4 Manual prior to August, 1993, hospitals could either bill each CPT code for each of the component tests within the panel or bill the CPT code for the appropriate panel. Moreover, hospitals were free to define what component tests comprised that particular panel.

55. In August, 1993, the CPT-4 Manual instructions for organ and disease panels changed to require certain tests which had to be performed in order to bill a particular organ or disease panel CPT code; however hospitals were free to perform and bill for additional tests. The prefatory instructions in the CPT-4 Manual stated as follows:

> These panels were developed for coding purposes only and should not be interpreted as clinical parameters. The tests listed with each panel identify the defined components of that panel. **These panel components are not intended to limit the performance of other tests. If one performs tests in additions to**

those specifically indicated for a particular panel, those tests should be reported separately in addition to the panel code. (emphasis added)

56. Based on the CPT-4 Manual after August, 1993, hospitals could either bill each CPT code for each of the component tests within the panel or bill the CPT code for the appropriate panel. However, in order to bill for the CPT code for a listed organ or disease panel, each of the component tests described in the CPT-4 Manual had to be performed.

57. Since at least 1989, the fiscal intermediary knew that hospitals in Ohio were billing for organ and disease panels in the manner described in paragraphs 54 and 56 and the fiscal intermediary continued to reimburse hospitals for these organ and disease panels without comment or disallowance. At no time did the fiscal intermediary inform hospitals that this billing practice was improper.

58. Beginning in November, 1995, certain hospitals in Ohio were informed through the U.S. Attorney's office that the Secretary has taken the position that at all times since 1989, certain CPT codes relating to lipid and thyroid organ and disease panels were more appropriate than others. The Secretary arbitrarily determined that in certain situations hospitals were required to use an organ or disease panel CPT code if the individual components of that panel were performed.

59. There has never been any authority in the CPT-4 Manual or otherwise for the Secretary's position nor has the hospitals' fiscal intermediary ever instructed Ohio's hospitals to bill lipid and thyroid panels in the manner now being required.

60. Despite the fact that Ohio hospitals were never put on notice of the need to change their coding and billing for organ and disease panels, the Secretary, through the U.S. Attorney's

Office and the U.S. Department of Justice, is requiring audits of certain Ohio hospitals' billings for all lipid and thyroid panels since 1989.

61. Despite the fact that Ohio hospitals were never put on notice of the need to change their coding and billing for organ and disease panels, the Secretary, through the U.S. Attorney's Office and the U.S. Department of Justice, is accusing certain Ohio hospitals that they are in violation of the False Claims Act and that they should enter into settlement agreements with the Secretary. These settlement agreements obligate the hospitals to not only pay back any overpayments as a result of the prior billings, but also in many situations, to pay additional penalties. As a result, hospitals are being forced to repay the Secretary and pay penalties based on an interpretation of billing rules which were not in existence at the time of the original billings by the hospital.

62. In light of the clear lack of guidance and instruction on the billing issues which are the subject of the Secretary's investigations, the Secretary, through the U.S. Attorney's Office and the U.S. Department of Justice, has proceeded with these investigations of Ohio hospitals under the guise of the False Claims Act knowing that the conduct of the subject hospitals does not satisfy the scienter requirement of the False Claims Act as set forth in 31 U.S.C. §3729(b).

63. Prior to involvement by the U.S. Attorney's office in June, 1995, errors with respect to the use of appropriate billing codes were resolved administratively by the fiscal intermediary with overpayments or underpayments adjusted as part of the hospitals' overall Medicare and Medicaid reimbursement. These adjustments are made to the annual cost reports filed by hospitals with the fiscal intermediary.

64. No adjustments for the laboratory billing issues which are the subject of the Secretary's investigations have been made to the cost reports for Ohio hospitals; thus, no administrative remedy is available. In addition, many of the cost reporting periods to which those adjustments would relate, even if they were made, are closed.

65. The Secretary's pervasive unconstitutional course of action has already detrimentally affected approximately fifteen (15) of OHA's and AHA's member hospitals and will affect the approximately 135 remaining Ohio hospitals under investigation if action is not taken by this Court.

66. OHA and AHA believe that the Secretary has begun or intends to begin similar investigations of the billing practices for Outpatient Laboratory Tests for hospitals in other states.

67. OHA and AHA believe that the Secretary has begun or intends to begin similar investigations of Ohio hospitals into other Medicare billing issues using the same conduct described herein.

68. Section 1871(a)(1) of the Medicare Act, 42 U.S.C. § 1395hh(a)(1), requires the Secretary to prescribe such regulations as may be necessary to administer the Medicare Program.

69. Section 1871(a)(2) of the Medicare Act, 42 U.S.C. § 1395hh(a)(2), provides that "no rule, requirement, or other statement of policy, other than a national coverage determination, that establishes or changes a substantive legal standard governing the scope of benefits [or] the payment for services ... under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph 1."

70. In addition to the specific rulemaking obligations of Section 1871 of the Medicare Act, the Secretary has assumed responsibility for adhering to the rulemaking requirements of the

Administrative Procedure Act, 5 U.S.C. § 553, by expressly waiving the exceptions available for benefits and contracts under § 553(a)(2).

71. The position now being taken by the Secretary with respect to the coding and billing for certain Outpatient Laboratory Tests, as described herein, constitutes a rule, requirement, or other statement of policy, other than a national coverage determination, that establishes or changes a substantive legal standard governing the scope of benefits or the payment for services under the Medicare program.

72. At no time to the present did the Secretary ever properly promulgate a rule or regulation providing that CPK, GGT, and Triglycerides were to be treated as "AMC tests."

73. At no time to the present has the Secretary ever properly promulgated a rule or regulation providing that hematology, urinalysis and organ/disease panel testing are to be billed in the manner now being required, as described herein.

74. The Secretary is inappropriately using the Offices of the U.S. Attorney and the U.S. Department of Justice to coerce hospitals into making substantial payments to HCFA under threat of criminal prosecution and/or civil penalties.

75. Ohio hospitals are at imminent risk of overpayment claims being levied against them by the Secretary based upon the Secretary's inappropriate use of the Offices of the U.S. Attorney and U.S. Department of Justice to enforce invalid rules and regulations regarding billing for Outpatient Laboratory Tests.

76. Ohio hospitals are at imminent risk of prosecution by the Secretary, through use of the Offices of the U.S. Attorney and U.S. Department of Justice, for criminal and civil penalties, including exclusion from the Medicare and Medicaid programs, under the Social

Security Act, 42 U.S.C. §1320a-7b and 42 U.S.C. § 1320a-7a, and the Federal False Claims Act, 18 U.S.C. §287 and 31 U.S.C. § 3729 based upon the Secretary's invalid rules and regulations regarding billing for Outpatient Laboratory Tests.

COUNT I: MEDICARE RULEMAKING REQUIREMENTS

77. Plaintiff alleges, as if fully rewritten herein, each and every allegation as set forth in paragraphs 1 through 76 of this Complaint.

78. Defendant Secretary's mandate that Ohio's hospitals must treat chemistry tests for CPK, GGT, and Triglycerides as AMC Tests for the period 1989 through July 1, 1994 has been implemented in the absence of any rule or regulation supporting such position.

79. Defendant Secretary's mandate as to the manner in which Ohio's hospitals must bill hematology tests as described herein for the period 1989 to the present has been implemented in the absence of any rule or regulation supporting such position.

80. Defendant Secretary's mandate as to the manner in which Ohio's hospitals must bill urinalysis tests as described herein for the period 1989 to the present has been implemented in the absence of any rule or regulation supporting such position.

81. Defendant Secretary's mandate as to the manner in which Ohio's hospitals must bill organ and disease panel tests as described herein for the period 1989 to the present has been implemented in the absence of any rule or regulation supporting such position.

82. The Secretary's positions with respect to CPK, GGT, Triglycerides, hematology tests, urinalysis tests, and organ and disease panel tests, as described herein, constitute substantive rules which represent a change in existing law or policy and affects existing, substantive rights of Ohio hospitals.

83. The Secretary's actions are in violation of her statutory duty to promulgate, pursuant to 42 U.S.C. § 1395hh, regulations regarding billing for Outpatient Laboratory Testing.

COUNT II: ADMINISTRATIVE PROCEDURE ACT

84. Plaintiff alleges, as if fully rewritten herein, each and every allegation as set forth in paragraphs 1 through 83 of this Complaint.

85. The Secretary's actions are in violation of her statutory duty to promulgate, pursuant to 5 U.S.C. § 533 regulations regarding billing for Outpatient Laboratory Testing.

COUNT III: 5TH AMENDMENT

86. Plaintiff alleges, as if fully rewritten herein, each and every allegation as set forth in paragraphs 1 through 85 of this Complaint.

87. Defendant Secretary, through the U.S. Attorney's Office and the U.S. Department of Justice, has threatened and continues to threaten Ohio hospitals that charges will be brought against them under the False Claims Act for Outpatient Laboratory Testing charges unless the hospitals enter into settlements that impose penalties for violations of billing rules that were not in existence at the time the bills were submitted.

88. Defendant Secretary's inappropriate use of the U.S. Attorney's Office and the U.S. Department of Justice to coerce hospitals into making substantial payments to HCFA to avoid costly litigation based upon an arbitrary and capricious interpretation of the applicable standards of the False Claim Act, deprives hospitals of their property without due process of law in violation of the Fifth Amendment of the United States Constitution.

COUNT IV: FALSE CLAIMS ACT

89. Plaintiff alleges, as if fully rewritten herein, each and every allegation as set forth in paragraphs 1 through 88 of this Complaint.

90. Defendant Secretary's use of the False Claims Act in this manner is contrary to the purpose and intent standard of the False Claims Act, 18 U.S.C. § 287 and 31 U.S.C. § 3729.

WHEREFORE, Plaintiffs Ohio Hospital Association and American Hospital Association respectfully pray for the following:

A. A declaration that the Secretary's position with respect to the appropriate coding and billing for certain Outpatient Laboratory Tests is incorrect and without basis under existing law;

B. A declaration that the Secretary's position with respect to the appropriate coding and billing for certain Outpatient Laboratory Tests constitutes substantive rules which have not been properly promulgated pursuant to 42 U.S.C. § 1395hh and 5 U.S.C. §553.

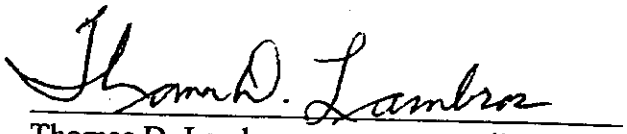
C. A declaration that the Secretary's actions to enforce her position with respect to the appropriate coding and billing for certain Outpatient Laboratory Tests for the period of 1989 to the present constitutes a violation of the Fifth Amendment of the United States Constitution.

D. A declaration that the Secretary's use and interpretation of the False Claims Act as a means to enforce her position with respect to the appropriate coding and billing for certain Outpatient Laboratory Tests for the period of 1989 to the present is improper as being contrary to the intent and language of the False Claims Act, 31 U.S.C. §3729.

E. That the Court enjoin the Secretary from enforcing the positions described herein as to hospitals in Ohio.

F. All other legal and equitable relief, including costs and attorneys' fees, to which the Plaintiff may be entitled.

Dated October 7, 1996 at
Cleveland, Ohio



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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF and a copy of the Summons have been served, by hand delivery upon Emily M. Sweeney, United States Attorney, Northern District of Ohio, 1800 Bank One Center, 600 Superior Avenue East, Cleveland, Ohio 44114, and by certified U.S. mail, return receipt requested, upon Janet Reno, Attorney General of the United States of America, 5111 Main Justice Building, Tenth Street and Constitution Avenue, N.W., Washington, D.C. 20530, and Donna E. Shalala, Secretary of Health and Human Services, 200 Independence Avenue, S.W., Hubert H. Humphrey Building, Suite 615-F, Washington, D.C. 20201, this 7th day of October, 1996.

Thomas D. Lambros (0049206)