

A. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *ABC Bancorp*, Moultrie, Georgia; to merge with First National Financial Corporation, Albany, Georgia, and thereby indirectly acquire First National Bank of South Georgia, Albany, Georgia.

Board of Governors of the Federal Reserve System, June 7, 1996.

Jennifer J. Johnson,

*Deputy Secretary of the Board.*

[FR Doc. 96-14999 Filed 6-12-96; 8:45 am]

BILLING CODE 6210-01-F

### Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.25 of Regulation Y (12 CFR 225.25) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act, including whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices" (12 U.S.C. 1843). Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 27, 1996.

A. Federal Reserve Bank of New York (Christopher J. McCurdy, Senior Vice President) 33 Liberty Street, New York, New York 10045:

1. *North Fork Bancorporation, Inc.*, Mattituck, New York; to acquire Haven Bancorp, Inc., Woodhaven, New York, and thereby indirectly acquire Columbia Federal Savings Bank, Woodhaven, New York, and thereby engage in operating a federal savings and loan association, pursuant to § 225.25(b)(9) of the Board's Regulation Y.

B. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Commercial Guaranty Bancshares, Inc.*, Shawnee Mission, Kansas; to engage *de novo* through its subsidiary, C.G. Capital Corporation, Overland Park, Kansas, in providing financial and investment advice, pursuant to § 225.25(b)(4) of the Board's Regulation Y; and in providing management consulting services to depository institutions, pursuant to § 225.25(b)(11) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, June 7, 1996.

Jennifer J. Johnson,

*Deputy Secretary of the Board.*

[FR Doc. 96-15000 Filed 6-12-96; 8:45 am]

BILLING CODE 6210-01-F

### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### Health Care Financing Administration [R-13]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated

burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Conditions of Coverage for Organ Procurement Organizations; *Form No.:* HCFA-R-13; *Use:* Organ procurement organizations are required to submit accurate data to HCFA concerning population and information on donors and organs on an annual basis in order to assure maximum effectiveness in the procurement and distribution of organs. *Frequency:* Annually; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 66; *Total Annual Responses:* 66; *Total Annual Hours Requested:* 1.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Louis Blank, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: June 5, 1996.

Kathleen B. Larson,

*Director, Management Planning and Analysis Staff, Office of Financial and Human Resources.*

[FR Doc. 96-15003 Filed 6-12-96; 8:45 am]

BILLING CODE 4120-03-P

#### [HSQ-231-N]

#### Medicare, Medicaid, and CLIA Programs; Clinical Laboratory Improvement Amendments of 1988 Exemption of Laboratories in the State of Oregon

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice.

**SUMMARY:** Section 353(p) of the Public Health Service Act provides for the exemption of laboratories from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) when the State in which they are located has requirements equal to or more stringent than those of CLIA. This

notice grants exemption from CLIA requirements and is applicable only to laboratories located within the State of Oregon that possess a valid State license.

**EFFECTIVE DATE:** The provisions of this notice are effective on June 13, 1996, through December 31, 1999.

**FOR FURTHER INFORMATION CALL:** Val Coppola, (410) 786-3354.

**SUPPLEMENTARY INFORMATION:**

**I. Background and Legislative Authority**

Section 353 of the Public Health Service Act, as amended by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), requires any laboratory that performs tests on human specimens to meet the requirements established by the Department of Health and Human Services. Under the provisions of the sentence following section 1861(s)(14) and paragraph (s)(16) of the Social Security Act, any laboratory that also requests to be paid for services furnished to Medicare beneficiaries must meet the requirements of section 353 of the Public Health Service Act. Subject to specified exceptions, laboratories must have a current and valid CLIA certificate to test human specimens to be eligible for payment from the Medicare or Medicaid program. Regulations implementing section 353 of the Public Health Service Act are contained in 42 CFR part 493, Laboratory Requirements.

Section 353(p) of the Public Health Service Act provides for the exemption of laboratories from CLIA requirements in a State that applies requirements that are equal to or more stringent than those of CLIA. The statute does not specifically require the promulgation of criteria for the exemption of laboratories in a State. The decision to grant CLIA exemption to laboratories within a State is at HCFA's discretion, acting on behalf of the Secretary of Health and Human Services.

Part 493, subpart E, Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program implements section 353(p) of the Public Health Service Act. Section 493.513 provides that we may exempt from CLIA requirements, for a period not to exceed 6 years, State licensed or approved laboratories in a State if the State meets specified conditions. Section 493.513(k) provides that we will publish a notice in the Federal Register announcing the names and basis for exemption of States whose laboratories are exempt from meeting the requirements of part 493.

**II. Notice of Approval of CLIA Exemption to Laboratories in the State of Oregon**

In this notice, we grant CLIA exemption for all specialties and subspecialties to all laboratories located in the State of Oregon that possess a valid license to perform laboratory testing effective June 13, 1996, through December 31, 1999.

**III. Evaluation of The Oregon State Laboratory Program**

The following describes the process we used to determine whether we should grant exemption from CLIA requirements to licensed Oregon laboratories.

**A. Requirements for Granting CLIA Exemption**

To determine whether we should grant a CLIA exemption to all laboratories within the State of Oregon, we conducted a detailed and indepth comparison of Oregon State's requirements for its laboratories to those of CLIA and evaluated whether Oregon State's standards meet the requirements at § 493.513. In summary, we evaluated whether the State of Oregon—

- Has laws in effect that provide for requirements that are equal to or more stringent than CLIA requirements;
- Has an agency that licenses or approves laboratories meeting State requirements that also meet or exceed CLIA requirements, and would, therefore, meet the condition level requirements of the CLIA regulations;
- Demonstrates that it has enforcement authority and administrative structures and resources adequate to enforce its laboratory requirements;
- Permits us or our agents to inspect laboratories within the State;
- Requires laboratories within the State to submit to inspections by us or our agents as a condition of licensure;
- Agrees to pay the cost of the validation program administered by us and the cost of the State's pro rata share of the general overhead to develop and implement CLIA as specified in §§ 493.645(a) Fee(s) applicable to accredited laboratories/approved State licensure programs and 493.646(b) Payment of fees; and
- Takes appropriate enforcement action against laboratories found by us or our agents not to be in compliance with requirements comparable to condition level requirements.

We also evaluated whether the State of Oregon laboratory program meets the requirements and licenses laboratories in accordance with § 493.515, Federal

review of laboratory requirements of State laboratory programs.

As specified in § 493.515, our review of a State laboratory program includes (but is not necessarily limited to) an evaluation of—

- Whether the State's requirements for laboratories are equivalent to or more stringent than the CLIA condition level requirements;
- The State's inspection process requirements to determine—
  - The comparability of the full inspection and complaint inspection procedures to our procedures;
  - The State's enforcement procedures for laboratories found to be out of compliance with its requirements; and
  - The ability of the State to provide us with electronic data and reports with the adverse or corrective actions resulting from proficiency testing results that constitute unsuccessful participation in HCFA-approved proficiency testing programs and with other data we determine to be necessary for validation and assessment of the State's inspection process requirements;
- The State's agreement to—
  - Notify us within 30 days of the action taken against any CLIA-exempt laboratory that has had its licensure or approval withdrawn or revoked or been in any way sanctioned;
  - Notify us within 10 days of any deficiency identified in a CLIA-exempt laboratory in cases when the deficiency poses an immediate jeopardy to the laboratory's patients or a hazard to the general public;
  - Notify each laboratory licensed by the State within 10 days of our withdrawal of the exemption;
  - Provide us with written notification of any changes in its licensure (or approval) and inspection requirements;
  - Disclose any laboratory's proficiency testing results in accordance with the State's confidentiality requirements;
  - Take the appropriate enforcement action against laboratories we find not to be in compliance with requirements comparable to condition level requirements and report these enforcement actions to us;
  - Notify us of all newly licensed laboratories, including the specialties and subspecialties for which any laboratory performs testing, within 30 days; and
  - Provide to us, as requested, inspection schedules for validation purposes.

### *B. Evaluation of the Oregon State Request for CLIA Exemption*

The State of Oregon has formally applied to us for an exemption from the CLIA requirements for laboratories located within the State that possess a valid State license.

We have evaluated the Oregon State's CLIA exemption application and all subsequent submissions for equivalency against the three major categories of CLIA rules: The implementing regulations, the enforcement regulations, and the deeming/exemption requirements. The statutory requirements pertaining to laboratories in Oregon are found at Chapter 438, Clinical Laboratories, in the Oregon Revised Statutes. We found the Laboratory Licensing Section of the Center for Public Health Laboratories, which issues, implements, and enforces regulations specified in the Oregon Administrative Rule, Division 24, Chapter 333, to administer a program that is equal to the CLIA program, taken as a whole. We performed an in-depth evaluation of the Oregon application to verify the State's assurance of compliance with the following subparts of part 493.

#### **Subpart E, Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program**

HCFA and the Centers for Disease Control and Prevention staff reviewers have examined the Oregon State application and all subsequent submissions against the exemption requirements that a State must meet in order to be granted CLIA-exempt status (§ 493.513 and the applicable parts of §§ 493.515, 493.517, 493.519, and 493.521, which concern General requirements for CLIA-exempt laboratories; Federal review of laboratory requirements of State laboratory programs; Validation inspections of CLIA-exempt laboratories; Continuing Federal oversight of an approved State laboratory program; and Removal of CLIA exemption and final determinations review). The State has complied with the applicable CLIA requirements for exemption under this subpart.

#### **Subpart H, Participation in Proficiency Testing for Laboratories Performing Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests**

The Oregon Administrative Rule requires licensed laboratories within Oregon to enroll and participate in a HCFA-approved proficiency testing program for all tests listed in Subpart I of the CLIA regulations. Oregon has adopted the requirements of Subpart H, Participation in proficiency testing for laboratories performing tests of moderate complexity (including the subcategory), high complexity, or any combination of these tests.

Therefore, the proficiency testing requirements of Oregon are equivalent to those of CLIA.

#### **Subpart J, Patient Test Management for Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests**

Oregon has modified its requirements for patient test management to be equal to those of the CLIA regulations.

#### **Subpart K, Quality Control for Tests of Moderate Complexity (Including the Subcategory), High Complexity, or Any Combination of These Tests**

The Oregon Administrative Rule recognizes the CLIA categorization of tests and stipulates quality control requirements for moderate complexity (including the subcategory of provider performed microscopy), and high complexity tests that are equivalent to the respective CLIA requirements, taken as a whole.

#### **Subpart M, Personnel for Moderate Complexity (Including the Subcategory) and High Complexity Testing**

The personnel requirements of the Oregon Administrative Rule are equivalent to those of CLIA for all levels of testing complexity.

#### **Subpart P, Quality Assurance for Moderate Complexity (Including the Subcategory) or High Complexity Testing, or Any Combination of These Tests**

The applicable standards of the Oregon Administrative Rule are equal to the CLIA requirements at §§ 493.1701 through 493.1721, which address quality assurance.

#### **Subpart Q, Inspection**

Oregon laboratories that possess a license for moderate or high complexity testing are routinely inspected on-site, biennially. Routine inspections are usually announced. All complaint inspections are unannounced. The Oregon State Laboratory Licensing Section implements inspection requirements and policies that are equal to those of CLIA.

#### **Subpart R, Enforcement Procedures**

We have reviewed documentation of Oregon State's enforcement authority, its administrative structure and the resources used to enforce its standards. The State appropriately applies limitations and revocations of its licenses for laboratories as well as other categories of penalties. Dependent upon probable circumstances, Oregon may impose a directed plan of correction, it may refuse to issue a license or permit, or, if necessary, it could initiate criminal penalties.

The State of Oregon has provided us with the mechanism it currently uses to monitor the proficiency testing performance of its laboratories. The initial action taken by Oregon State for unsuccessful proficiency testing performance requires the laboratory to determine the cause of the failure, document corrective actions and provide an assurance that patient testing is correctly performed. If no response or an inadequate response is received, procedures to remove the analyte, subspecialty, or specialty from the laboratory's license will be initiated. The State may perform an on-site inspection due to unsuccessful proficiency testing performance.

The State of Oregon has provided appropriate documentation demonstrating that its enforcement policies and procedures are equivalent to those of CLIA.

#### **IV. Federal Validation Inspections and Continuing Oversight**

The Federal validation inspections of CLIA-exempt laboratories, as specified in § 493.517, will be conducted on a representative sample basis as well as in response to substantial allegations of noncompliance (complaint inspections). The outcome of those validation inspections will be our principal means for verifying the appropriateness of the exemption given to laboratories in Oregon. This Federal monitoring is an on-going process. The State of Oregon will provide us with survey findings for each laboratory selected for validation.

#### V. Removal of Approval of Oregon State Exemption

We will remove the CLIA exemption of laboratories located in the State of Oregon that possess a valid license if we determine the outcome and comparability review of validation inspections are not acceptable as described under § 493.521 or if the State fails to pay the required fee as stated under § 493.645(a).

#### VI. Laboratory Data

In accordance with § 493.513(d)(2)(iii), Oregon State will provide us with changes to a laboratory's specialties or subspecialties based on the State's survey and with changes in a laboratory's licensure status.

#### VII. Required Administrative Actions

CLIA is a user-fee funded program. The registration fee paid by the laboratories is used to cover the cost of the development and administration of the program. However, when a State's application for exemption is approved, we may not charge a fee to laboratories in the State that are covered by the exemption. The State's share of the costs associated with CLIA must be collected from the State. Section 493.645 specifies that Health and Human Services assesses fees that a State must pay for the following:

- Costs of Federal inspection of laboratories in the State to verify that standards are enforced in an appropriate manner. The average cost per validation survey nationally is multiplied by the number of surveys that will be conducted.
- Costs incurred for Federal investigations and surveys triggered by complaints that are substantiated. We bill the State for these costs. We anticipate that most of these surveys will be referred to the State and that there will be little Federal activity in this area.
- The State's proportionate share of general overhead costs for the items and services it benefits from and only for those paid for out of registration or certificate fees we collected.

In order to estimate Oregon State's proportionate share of the general overhead costs, we determined the ratio of laboratories in Oregon State to the total number of laboratories nationally. In that the general overhead costs apply equally to all laboratories, we determined the cumulative overhead costs that should be assumed by the State of Oregon.

The State of Oregon has agreed to pay us its pro rata share of the overhead

costs and anticipated costs of actual validation and complaint investigation surveys. A final reconciliation for all laboratories and all expenses will be made. We will reimburse the State for any overpayment or bill it for any balance.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: May 13, 1996.

Bruce C. Vladeck,

*Administrator, Health Care Financing Administration.*

[FR Doc. 96-14969 Filed 6-12-96; 8:45 am]

BILLING CODE 4120-01-P

#### Health Resources and Services Administration

##### Availability of Funds for the Community Scholarship Programs

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice of available funds.

**SUMMARY:** The Health Resources and Services Administration (HRSA) announces the availability of approximately \$100,000 under section 338L of the Public Health Service (PHS) Act for competing and project period renewal Grants to States for Community Scholarship Programs (CSP).

The purpose of the CSP is to enable States to increase the availability of primary health care in urban and rural federally designated health professional shortage areas (HPSAs) by assisting community organizations to provide scholarships for the education of individuals to serve as health professionals in these communities.

The PHS is committed to achieving the health promotion and disease prevention objectives of *Healthy People 2000*, a PHS-led national activity. This grant program is related to the objectives of improving access to and availability of primary health care services for all Americans, especially the underserved populations. Potential applicants may obtain a copy of *Healthy People 2000* (Full Report: Stock No. 017-001-00474-0) or *Healthy People 2000* (Summary Report; Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402-9325 (telephone number 202-783-3238).

PHS strongly encourages all grant recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public

Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children.

**DATES:** Applications are due July 15, 1996. Applications will be considered to have met the deadline if they are (1) received on or before the deadline date; or (2) postmarked on or before the established deadline date and received in time for orderly processing. Applicants should request a legibly dated U.S. Postal Service postmark or obtain a receipt from a commercial carrier. Private metered postmarks will not be acceptable as proof of timely mailing. Late applications not accepted for processing will be returned to the applicant.

**ADDRESSES:** Application materials may be obtained from, and completed applications should be returned to: Ms. Alice H. Thomas, Grants Management Officer, Bureau of Primary Health Care (BPHC), 4350 East-West Highway, 11th Floor, Bethesda, Maryland 20814, (301) 594-4250. The Grants Management staff is available to provide assistance on business management issues.

Applications for these grants will be made on PHS Form 5161-1 with revised face sheet DHHS Form 424, as approved by the Office of Management and Budget (OMB) under control number 0937-0189.

**FOR FURTHER INFORMATION CONTACT:** For general program information and technical assistance, please contact Sharley L. Chen, Division of Scholarships and Loan Repayments, BPHC, HRSA, 4350 East-West Highway, 10th Floor, Bethesda, Maryland 20814, at (301) 594-4400.

**SUPPLEMENTARY INFORMATION:** In FY 1996, approximately \$100,000 will be awarded for 3-5 new and project period renewal grants ranging from \$5,000 to \$75,000 for a 12-month budget period and up to a 3-year project period. Under this program, States enter into agreements with public or private nonprofit community organizations located in federally designated HPSAs. These organizations will recruit qualified residents of their communities and provide scholarships to them to become physicians, certified nurse practitioners, certified nurse midwives, or physician assistants based on the needs of the communities.

This grant program is intended to be consistent with the efforts of the National Health Service Corps (NHSC) Scholarship Program, NHSC Loan Repayment Program and NHSC State