(1) The project fails under one of the automatic major capital investment project categories (§ 633.5(1) or (2) of this part); or

(2) UMTA makes a determination that a project is a major capital project, consistent with the definition of major capital project in § 633.5. This determination normally will be made during the grant review process. However, UMTA may make such determination after grant approval.

(b)(1) UMTA will notify the recipient when it must submit the PMP. Normally, UMTA will notify the recipient sometime during the grant review process. If UMTA determines the project is major under its discretionary authority after the grant has been approved, UMTA will inform the recipient of its determination as soon as possible.

(2) Once UMTA has notified the recipient that it must submit a plan, the recipient will have a minimum of 90 days to submit the plan.

§ 633.23 UMTA review of PMP.

Within 60 days of receipt of a project management plan, the Administrator will notify the recipient that:

(a) The plan is approved;

(b) The plan is disapproved, including the reasons for the disapproval;

(c) The plan will require modification, as specified, before approval; or

(d) The Administrator has not yet completed review of the plan, and state when it will be reviewed.

§ 633.25 Contents of a project management plan.

At a minimum, a recipient's project management plan shall include—

(a) A description of adequate recipient staff organization, complete with well-defined reporting relationships, statements of functional responsibilities, job descriptions, and job qualifications;

(b) A budget covering the project management organization, appropriate consultants, property acquisition, utility relocation, systems demonstration staff, audits, and such miscellaneous costs as the recipient may be prepared to justify;

(c) A construction schedule;

(d) A document control procedure and recordkeeping system;

(e) A change order procedure which includes a documented, systematic approach to the handling of construction change orders;

(f) A description of organizational structures, management skills, and staffing levels required throughout the construction phase;

(g) Quality control and quality assurance programs which define functions, procedures, and responsibilities for construction and for system installation and integration of system components;

(h) Material testing policies and procedures;

(i) Plan for internal reporting requirements including cost and schedule control procedures; and

(j) Criteria and procedures to be used for testing the operational system or its major components;

§ 633.27 Implementation of a project management plan.

(a) Upon approval of a project management plan by the Administrator the recipient shall begin implementing the plan.

(b) If a recipient must modify an approved project management plan, the recipient shall submit the proposed changes to the Administrator along with an explanation of the need for the changes.

(c) A recipient shall submit periodic updates of the project management plan to the Administrator. Such updates shall include, but not be limited to:

(1) Project budget;

(2) Project schedule;

(3) Financing, both capital and operating;

(4) Ridership estimates, including operating plan; and

(5) Where applicable, the status of local efforts to enhance ridership when estimates are contingent, in part, upon the success of such efforts.

(d) A recipient shall submit current data on a major capital project's budget and schedule to the Administrator on a monthly basis.

§ 633.29 PMP waivers.

A waiver will be considered upon initiation by the grantee or by the agency itself. The Administrator may, on a case-by-case basis, waive:

(a) Any of the PMP elements in § 633.25 of this part if the Administrator determines the element is not necessary for a particular plan; or

(b) The requirement of having a new project management plan submitted for a major capital project if a recipient seeks to manage the major capital project under a previously-approved project management plan.

Issued on: May 28, 1989.

Roland J. Mross,

Deputy Administrator.

[FR Doc. 89-20644 Filed 8-31-89; 8:45 am]

BILLING CODE 4910-57-M

federal register

Friday
September 1, 1989

Part VII

Department of Education

Student Literacy Corps Program; Invitation for Applications for New Awards for Fiscal Year 1990; Notice

DEPARTMENT OF EDUCATION

[CFDA No. 84.219]

Student Literacy Corps Program; Invitation for Applications for New Awards for Fiscal Year 1990

Note to Applicants: This notice is a complete application package. Together with the statute authorizing the program and applicable regulations governing the program, including the Education Department General Administrative Regulations (EDGAR), the notice contains information, application forms, and instructions needed to apply for a grant under this competition.

Purpose of Program: To promote student literacy corps projects operated by institutions of higher education (IHEs) where volunteer undergraduates will serve as unpaid literacy tutors in public community agencies.

Deadline for Transmittal of Applications: January 2, 1990.

Deadline for Intergovernmental Review: March 2, 1990.

Available Funds: $5,108,000.

Estimated Range of Awards: Up to $50,000.

Estimated Average Size of Awards: $45,000.

Estimated Number of Awards: 90–110.

Note: The Department is not bound by any estimate in this notice.

Project Period: 24 months.

Applicable Regulations: The Education Department General Administrative Regulations (EDGAR) in 34 CFR part 74 (Administration of Grants to Institutions of Higher Education, Hospitals and Nonprofit Organizations), part 75 (Direct Grant Programs), part 77 (Definitions that Apply to Department Regulations), part 79 (Intergovernmental Review of Department of Education Programs and Activities), and part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

Description of Program: The Secretary of Education will make two-year non-renewable grants to eligible institutions of higher education to support literacy training at public community agency facilities. No more than $25,000 can be expended by any IHE during the first year. To be eligible to receive a grant, an IHE must demonstrate that it has previously engaged in community service activities. Specifically, it must indicate that it has either used a portion of its allotment under part C of title IV of the Higher Education Act of 1965, as amended (HEA), for work study and community service learning under section 443(b)(2)(A), or conducted a cooperative education program.

Upon request of the IHE, the Secretary may grant a waiver of the prior community service requirement described above if the IHE provides assurances that: (a)(1) it has conducted some other significant program involving community outreach and service; or (2) if it has not conducted such a program, it can demonstrate that it currently has the ability to engage in outreach efforts necessary to carry out Student Literacy Corps requirements; and (b) in the event that it receives an allotment under part C of title IV of the HEA, that a portion of this allotment will be used for community service learning programs.

Each IHE applicant must provide assurances in its application for Student Literacy Corps Program funds that—

(a) Its grant will be used to cover an IHE's costs of participation in the Student Literacy Corps Program for which assistance is sought, including evaluation and stipends for student coordinators, and funds made available will not be used for the payment of stipends or salaries to tutors, in accordance with the USES OF FUNDS provision in the authorizing legislation (20 U.S.C. 1018b);

(b) It will provide literacy tutoring services in structured classroom settings supervised by qualified personnel in one or more public community agencies in the community in which it is located that serve educationally or economically disadvantaged individuals (the term "public community agency" means an established community agency with an established program of instruction such as elementary and secondary schools, Head Start Centers, prisons, agencies serving youth, and agencies serving the handicapped, including disabled veterans);

(c) It will offer one or more courses for academic credit (in such academic areas as the social sciences, economics or education) designed to combine formal study with undergraduates' experience as literacy tutors;

(d) As a condition of receiving credit for the courses of instruction referred to in paragraph (c) above, undergraduates will perform not less than six hours of voluntary, uncompensated service each week of the academic term in a public community agency as tutors in its educational or literacy programs;

(e) The tutoring service referred to in paragraph (d) above will be supplementary both to the IHE's regular academic program and the existing instructional services offered by the community service learning programs; and

(f) It will make arrangements for adequate training of volunteers, depending upon available resources, which may include the training of student coordinators to assist in the process of preparing and placing undergraduates as tutors in community service learning programs.

Selection Criteria:

(a)(1) The Secretary uses the following selection criteria to evaluate applications for new grants under this competition.

(2) The maximum score for all of these criteria is 100 points.

(3) The maximum score for each criterion is indicated in parentheses.

(b) *The criteria.*—(1) *Meeting the purposes of the authorizing statute.* (30 points) The Secretary reviews each application to determine how well the project will meet the purpose of Title I, part D of the Higher Education Act of 1965, as amended, including consideration of—

(i) The objectives of the project; and

(ii) How the objectives of the project further the purposes of Title I, part D of the Higher Education Act of 1965, as amended.

(2) *Extent of need for the project.* (20 points) The Secretary reviews each application to determine the extent to which the project meets specific needs recognized in Title I, part D of the higher Education Act of 1965, as amended, including consideration of—

(i) The needs addressed by the project;

(ii) How the applicant identified those needs;

(iii) How those needs will be met by the project; and

(iv) The benefits to be gained by meeting those needs.

(3) *Plan of operation.* (30 points) The Secretary reviews each application to determine the quality of the plan of operation for the project, including—

(i) The quality of the design of the project;

(ii) The extent to which the plan of management is effective and ensures proper and efficient administration of the project;

(iii) How well the objectives of the project relate to the purpose of the program;

(iv) The quality of the applicant's plan to use its resources and personnel to achieve each objective;

(v) How the applicant will ensure that project participants who are otherwise eligible to participate are selected without regard to race, color, national origin, gender, age, or handicapping condition; and

(vi) For grants under a program that requires the applicant to provide an opportunity for participation of students enrolled in private schools, the quality of the applicant's plan to provide that opportunity.

(4) *Quality of key personnel.* (7 points)

(i) The Secretary reviews each application to determine the quality of key personnel the applicant plans to use on the project, including—

(A) The qualifications of the project director (if one is to be used);

(B) The qualifications of each of the other key personnel to be used in the project;

(C) The time that each person referred to in paragraph (b)(4)(i) (A) and (B) will commit to the project; and

(D) How the applicant, as part of its nondiscriminatory employment practices, will ensure that its personnel are selected for employment without regard to race, color, national origin, gender, age, or handicapping condition.

(ii) To determine personnel qualifications under paragraphs (b)(4)(i) (A) and (B), the Secretary considers—

(A) Experience and training in fields related to the objectives of the project; and

(B) Any other qualifications that pertain to the quality of the project.

(5) *Budget and cost effectiveness.* (5 points) The Secretary reviews each application to determine the extent to which—

(i) The budget is adequate to support the project; and

(ii) Costs are reasonable in relation to the objectives of the project.

(6) *Evaluation plan.* (5 points) The Secretary reviews each application to determine the quality of the evaluation plan for the project, including the extent to which the applicant's methods of evaluation—

(i) Are appropriate to the project; and

(ii) To the extent possible, are objective and produce data that are quantifiable.

(Cross-reference: See 34 CFR 75.590 Evaluation by the grantee.)

(7) *Adequacy of resources.* (3 points) The Secretary reviews each application to determine the adequacy of the resources that the applicant plans to devote to the project, including facilities, equipment, and supplies.

Intergovernmental Review of Federal Programs

This program is subject to the requirements of Executive Order 12372 (Intergovernmental Review of Federal Programs) and the regulations in 34 CFR Part 79.

The objective of the Executive order is to foster an intergovernmental partnership and to strengthen federalism by relying on State and local processes for State and local government coordination and review of proposed Federal financial assistance.

Applicants must contact the appropriate State Single Point of Contact to find out about, and to comply with, the State's process under Executive Order 12372. Applicants proposing to perform activities in more than one State should immediately contact the Single Point of Contact for each of those States and follow the procedure established in each State under the Executive order. If you want to know the name and address of any State Single Point of Contact, see the list published in the **Federal Register** on November 18, 1987, pages 44338–44340.

In States that have not established a process or chosen a program for review, State, areawide, regional, and local entities may submit comments directly to the Department.

Any State Process Recommendation and other comments submitted by a State Single Point of Contact and any comments from State, areawide, regional, and local entities must be mailed or hand-delivered by the date indicated in this notice to the following address: The Secretary, E.O. 12372—CFDA # 84.219, U.S. Department of Education, Room 4161, 400 Maryland Avenue, SW., Washington, DC 20202–0125.

Proof of mailing will be determined on the same basis as applications (see 34 CFR 75.102). Recommendations or comments may be hand-delivered until 4:30 p.m. (Washington, DC time) on the date indicated in this notice.

Please note that this address is not the same address as the one to which the applicant submits its completed application. Do not send application to the above address.

Instructions for Transmittal of Applications

(a) If an applicant wants to apply for a grant, the applicant shall—

(1) Mail the original and two copies of the application on or before the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA # 84.219), Washington, DC 20202–4725.

or

(2) Hand deliver the original and two copies of the application by 4:30 p.m. (Washington, DC time) on the deadline date to: U.S. Department of Education, Application Control Center, Attention: (CFDA # 84.219), Room # 3633, Regional Office Building # 3, 7th and D Streets, SW., Washington, DC.

(b) An applicant must show one of the following as proof of mailing:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the Secretary.

(c) If an application is mailed through the U.S. Posal Service, the Secretary does not accept either of the following as proof of mailing:

(1) A private metered postmark.

(2) A mail receipt that is not dated by the U.S. Postal Service.

Notes: (1) The U.S. Postal Service does not uniformly provide a dated postmark. Before relying on this method, an applicant should check with its local post office.

(2) An applicant wishing to know that its application has been received by the Department must include with the application a stamped, self-addressed postcard containing the CFDA number and title of this program.

(3) The applicant must indicate on the envelope and—if not provided by the Department—in Item 10 of the Application for Federal Assistance (Standard Form 424) the CFDA number—and letter, if any—of the competition under which the application is being submitted.

Application Instructions and Forms

The appendix to this application is divided into three parts plus a statement regarding estimated public reporting burden and various assurances and certifications. These parts and additional materials are organized in the same manner that the submitted application should be organized. The parts and additional materials are as follows:

Part I: Application for Federal Assistance (Standard Form 424 (Rev. 4–88)) and instructions.

Part II: Budget Information—Non-Construction Programs (Standard Form 424A) and instructions.

Part III: Application Narrative.

Additional Materials:

Estimated Public Reporting Burden.

Assurances—Non-Construction Programs (Standard Form 424B).

Certification regarding Debarment, Suspension, and Other Responsibility Matters: Primary Covered Transactions (ED Form GCS–008) and instructions.

Certification regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion: Lower Tier Covered Transactions (ED Form GCS–009) and instructions. (**Note:** ED Form GCS–009 is intended for the use of grantees and

should not be transmitted to the Department.)

Certification Regarding Drug-Free Workplace Requirements: Grantees, Other than Individuals (ED 80-0004).

An applicant may submit information on a photostatic copy of the application and budget forms, the assurances, and the certifications. However, the application form, the assurances, and the certifications must each have an original signature. No grant may be awarded unless a completed application form has been received.

FOR FURTHER INFORMATION CONTACT: Dr. Donald N. Bigelow, Office of Higher Education Programs, U.S. Department of Education, Room 3082, (202) 732-5596, ROB-3, Mail Station 5131, 400 Maryland Avenue, SW., Washington, DC 20202.

Program Authority: 20 U.S.C. 1018-1018f.

Dated: August 28, 1989.

James B. Williams,

Acting Assistant Secretary for Postsecondary Education.

BILLING CODE 4000-01-M

Appendix

APPLICATION FOR FEDERAL ASSISTANCE

OMB Approval No. 0348-0043

1. TYPE OF SUBMISSION: *Application* ☐ Construction ☐ Non-Construction; *Preapplication* ☐ Construction ☐ Non-Construction	2. DATE SUBMITTED	Applicant Identifier
	3. DATE RECEIVED BY STATE	State Application Identifier
	4. DATE RECEIVED BY FEDERAL AGENCY	Federal Identifier

5. APPLICANT INFORMATION

Legal Name:	Organizational Unit:
Address *(give city, county, state, and zip code)*:	Name and telephone number of the person to be contacted on matters involving this application *(give area code)*

6. EMPLOYER IDENTIFICATION NUMBER (EIN):

☐☐ – ☐☐☐☐☐☐☐

7. TYPE OF APPLICANT: *(enter appropriate letter in box)* ☐

A. State
B. County
C. Municipal
D. Township
E. Interstate
F. Intermunicipal
G. Special District
H. Independent School Dist.
I. State Controlled Institution of Higher Learning
J. Private University
K. Indian Tribe
L. Individual
M. Profit Organization
N. Other (Specify): _____

8. TYPE OF APPLICATION:

☐ New ☐ Continuation ☐ Revision

If Revision, enter appropriate letter(s) in box(es): ☐ ☐

A. Increase Award B. Decrease Award C. Increase Duration
D. Decrease Duration Other *(specify)*:

_____

9. NAME OF FEDERAL AGENCY:

10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: ☐☐ ■ ☐☐☐

TITLE:

11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:

12. AREAS AFFECTED BY PROJECT *(cities, counties, states, etc.)*:

13. PROPOSED PROJECT: Start Date	Ending Date	14. CONGRESSIONAL DISTRICTS OF: a. Applicant	b. Project

15. ESTIMATED FUNDING:

a. Federal	$	.00
b. Applicant	$	.00
c. State	$	.00
d. Local	$	.00
e. Other	$	.00
f. Program Income	$	.00
g. TOTAL	$	.00

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES. THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:

DATE _____

b. NO. ☐ PROGRAM IS NOT COVERED BY E.O. 12372

☐ OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?

☐ Yes If "Yes," attach an explanation. ☐ No

18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED

a. Typed Name of Authorized Representative	b. Title	c. Telephone number
d. Signature of Authorized Representative		e. Date Signed

Previous Editions Not Usable

Standard Form 424 (REV 4-88)
Prescribed by OMB Circular A-102

Authorized for Local Reproduction

INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

Item: Entry:

1. Self-explanatory.
2. Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable).
3. State use only (if applicable).
4. If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank.
5. Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application.
6. Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service.
7. Enter the appropriate letter in the space provided.
8. Check appropriate box and enter appropriate letter(s) in the space(s) provided:
   - "New" means a new assistance award.
   - "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.
   - "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation.
9. Name of Federal agency from which assistance is being requested with this application.
10. Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested.
11. Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project.

Item: Entry:

12. List only the largest political entities affected (e.g., State, counties, cities).
13. Self-explanatory.
14. List the applicant's Congressional District and any District(s) affected by the program or project.
15. Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate *only* the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15.
16. Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process.
17. This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes.
18. To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.)

BUDGET INFORMATION — Non-Construction Programs

OMB Approval No. 0348-0044

SECTION A – BUDGET SUMMARY

Grant Program Function or Activity (a)	Catalog of Federal Domestic Assistance Number (b)	Estimated Unobligated Funds		New or Revised Budget		
		Federal (c)	Non-Federal (d)	Federal (e)	Non-Federal (f)	Total (g)
1.		$	$	$	$	$
2.						
3.						
4.						
5. TOTALS		$	$	$	$	$

SECTION B – BUDGET CATEGORIES

6 Object Class Categories	GRANT PROGRAM, FUNCTION OR ACTIVITY (1)	(2)	(3)	(4)	Total (5)
a. Personnel	$	$	$	$	$
b. Fringe Benefits					
c. Travel					
d. Equipment					
e. Supplies					
f. Contractual					
g. Construction					
h. Other					
i. Total Direct Charges (sum of 6a - 6h)					
j. Indirect Charges					
k. TOTALS (sum of 6i and 6j)	$	$	$	$	$
7. Program Income	$	$	$	$	$

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Standard Form 424A (4-88)
Prescribed by OMB Circular A-102

SECTION C - NON-FEDERAL RESOURCES

(a) Grant Program	(b) Applicant	(c) State	(d) Other Sources	(e) TOTALS
8.	$	$	$	$
9.				
10.				
11.				
12. TOTALS (sum of lines 8 and 11)	$	$	$	$

SECTION D - FORECASTED CASH NEEDS

	Total for 1st Year	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
13. Federal	$	$	$	$	$
14. NonFederal					
15. TOTAL (sum of lines 13 and 14)	$	$	$	$	$

SECTION E - BUDGET ESTIMATES OF FEDERAL FUNDS NEEDED FOR BALANCE OF THE PROJECT

(a) Grant Program	FUTURE FUNDING PERIODS (Years)			
	(b) First	(c) Second	(d) Third	(e) Fourth
16.	$	$	$	$
17.				
18.				
19.				
20. TOTALS (sum of lines 16 -19)	$	$	$	$

SECTION F - OTHER BUDGET INFORMATION

(Attach additional Sheets if Necessary)

21. Direct Charges:	22. Indirect Charges:
23. Remarks	

SF 424A (4-88) Page 2
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INSTRUCTIONS FOR THE SF-424A

General Instructions

This form is designed so that application can be made for funds from one or more grant programs. In preparing the budget, adhere to any existing Federal grantor agency guidelines which prescribe how and whether budgeted amounts should be separately shown for different functions or activities within the program. For some programs, grantor agencies may require budgets to be separately shown by function or activity. For other programs, grantor agencies may require a breakdown by function or activity. Sections A,B,C, and D should include budget estimates for the whole project except when applying for assistance which requires Federal authorization in annual or other funding period increments. In the latter case, Sections A,B, C, and D should provide the budget for the first budget period (usually a year) and Section E should present the need for Federal assistance in the subsequent budget periods. All applications should contain a breakdown by the object class categories shown in Lines a-k of Section B.

Section A. Budget Summary
Lines 1-4, Columns (a) and (b)

For applications pertaining to a *single* Federal grant program (Federal Domestic Assistance Catalog number) and *not requiring* a functional or activity breakdown, enter on Line 1 under Column (a) the catalog program title and the catalog number in Column (b).

For applications pertaining to a *single* program *requiring* budget amounts by multiple functions or activities, enter the name of each activity or function on each line in Column (a), and enter the catalog number in Column (b). For applications pertaining to multiple programs where none of the programs require a breakdown by function or activity, enter the catalog program title on each line in *Column* (a) and the respective catalog number on each line in Column (b).

For applications pertaining to *multiple* programs where one or more programs *require* a breakdown by function or activity, prepare a separate sheet for each program requiring the breakdown. Additional sheets should be used when one form does not provide adequate space for all breakdown of data required. However, when more than one sheet is used, the first page should provide the summary totals by programs.

Lines 1-4, Columns (c) through (g.)

For new applications, leave Columns (c) and (d) blank. For each line entry in Columns (a) and (b), enter in Columns (e), (f), and (g) the appropriate amounts of funds needed to support the project for the first funding period (usually a year).

Lines 1-4, Columns (c) through (g.) (continued)

For continuing grant program applications, submit these forms before the end of each funding period as required by the grantor agency. Enter in Columns (c) and (d) the estimated amounts of funds which will remain unobligated at the end of the grant funding period only if the Federal grantor agency instructions provide for this. Otherwise, leave these columns blank. Enter in columns (e) and (f) the amounts of funds needed for the upcoming period. The amount(s) in Column (g) should be the sum of amounts in Columns (e) and (f).

For supplemental grants and changes to existing grants, do not use Columns (c) and (d). Enter in Column (e) the amount of the increase or decrease of Federal funds and enter in Column (f) the amount of the increase or decrease of non-Federal funds. In Column (g) enter the new total budgeted amount (Federal and non-Federal) which includes the total previous authorized budgeted amounts plus or minus, as appropriate, the amounts shown in Columns (e) and (f). The amount(s) in Column (g) should not equal the sum of amounts in Columns (e) and (f).

Line 5 — Show the totals for all columns used.

Section B Budget Categories

In the column headings (1) through (4), enter the titles of the same programs, functions, and activities shown on Lines 1-4, Column (a), Section A. When additional sheets are prepared for Section A, provide similar column headings on each sheet. For each program, function or activity, fill in the total requirements for funds (both Federal and non-Federal) by object class categories.

Lines 6a-i — Show the totals of Lines 6a to 6h in each column.

Line 6j – Show the amount of indirect cost.

Line 6k – Enter the total of amounts on Lines 6i and 6j. For all applications for new grants and continuation grants the total amount in column (5), Line 6k, should be the same as the total amount shown in Section A, Column (g), Line 5. For supplemental grants and changes to grants, the total amount of the increase or decrease as shown in Columns (1)-(4), Line 6k should be the same as the sum of the amounts in Section A, Columns (e) and (f) on Line 5.

INSTRUCTIONS FOR THE SF-424A *(continued)*

Line 7 – Enter the estimated amount of income, if any, expected to be generated from this project. Do not add or subtract this amount from the total project amount. Show under the program narrative statement the nature and source of income. The estimated amount of program income may be considered by the federal grantor agency in determining the total amount of the grant.

Section C. Non-Federal-Resources

Lines 8-11 – Enter amounts of non-Federal resources that will be used on the grant. If in-kind contributions are included, provide a brief explanation on a separate sheet.

Column (a) – Enter the program titles identical to Column (a), Section A. A breakdown by function or activity is not necessary.

Column (b) – Enter the contribution to be made by the applicant.

Column (c) – Enter the amount of the State's cash and in-kind contribution if the applicant is not a State or State agency. Applicants which are a State or State agencies should leave this column blank.

Column (d) – Enter the amount of cash and in-kind contributions to be made from all other sources.

Column (e) – Enter totals of Columns (b), (c), and (d).

Line 12 — Enter the total for each of Columns (b)-(e). The amount in Column (e) should be equal to the amount on Line 5, Column (f), Section A.

Section D. Forecasted Cash Needs

Line 13 – Enter the amount of cash needed by quarter from the grantor agency during the first year.

Line 14 – Enter the amount of cash from all other sources needed by quarter during the first year.

Line 15 – Enter the totals of amounts on Lines 13 and 14.

Section E. Budget Estimates of Federal Funds Needed for Balance of the Project

Lines 16 - 19 – Enter in Column (a) the same grant program titles shown in Column (a), Section A. A breakdown by function or activity is not necessary. For new applications and continuation grant applications, enter in the proper columns amounts of Federal funds which will be needed to complete the program or project over the succeeding funding periods (usually in years). This section need not be completed for revisions (amendments, changes, or supplements) to funds for the current year of existing grants.

If more than four lines are needed to list the program titles, submit additional schedules as necessary.

Line 20 – Enter the total for each of the Columns (b)-(e). When additional schedules are prepared for this Section, annotate accordingly and show the overall totals on this line.

Section F. Other Budget Information

Line 21 – Use this space to explain amounts for individual direct object-class cost categories that may appear to be out of the ordinary or to explain the details as required by the Federal grantor agency.

Line 22 – Enter the type of indirect rate (provisional, predetermined, final or fixed) that will be in effect during the funding period, the estimated amount of the base to which the rate is applied, and the total indirect expense.

Line 23 – Provide any other explanations or comments deemed necessary.

Instruction for Part III—Application Narrative

Before preparing the Application Narrative, an applicant should read carefully the description of the program and the selection criteria the Secretary uses to evaluate applications.

The Narrative should encompass each function or activity for which funds are being requested and should—

1. Begin with an Abstract; that is, a single page summary of the proposed project;

2. Describe the project in terms of each of the selection criteria in the order in which they are listed; and

3. Include in the Narrative, information that will assist the Secretary in reviewing the application by indicating as fully as possible how the relevant "assurances" (a) to (f) in the Description of the Program will be carried out. Clearly describe the course(s) to be offered, the related training for undergraduate tutors and the duties of student coordinators, if any; explain which community agencies will be cooperating and why, with information about their programs and their clients; finally, describe the management and logistics of the proposed project, whether or not it is new, and, if it is new, how it will be combined with pre-existing projects.

Please limit the Application Narrative to no more than 15 double-spaced, typed pages (on one side only).

Estimated Public Reporting Burden

Under terms of the Paperwork Reduction Act of 1980, as amended, and the regulations implementing that Act, the Department of Education invites comment on the public reporting burden in this collection of information. Public reporting burden for this collection of information is estimated to average four hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. You may send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the U.S. Department of Education, Information Management and Compliance Division, Washington, DC 20202–4651; and to the Office of Management and Budget, Paperwork Reduction Project 1840–0618, Washington, DC 20503.

(Information collection approved under OMB control number 1840–0618. Expiration date: 3/31/1992.)

BILLING CODE 4000-01-M

Student Literacy Corps Program
Program Assurances

As the duly authorized representative of the IHE applicant, I certify that the applicant will comply with all statutory and regulatory requirements applicable to this program and provide specific program assurances that:

a. Its grant will be used to cover an IHE's costs of participation in the Student Literacy Corps Program for which assistance is sought, including evaluation and stipends for student coordinators, and funds made available will not be used for the payment of stipends or salaries to tutors, in accordance with the USES OF FUNDS provision in the authorizing legislation (20 U.S.C. 1018b);

b. It will provide literacy tutoring services in structured classroom settings supervised by qualified personnel in one or more public community agencies in the community in which it is located which serve educationally or economically disadvantaged individuals (the term "public community agency" means an established community agency with an established program of instruction such as elementary and secondary schools, Head Start Centers, prisons, agencies serving youth, and agencies serving the handicapped, including disabled veterans).

c. It will offer one or more courses for academic credit (in such academic areas as the social sciences, economics or education) designed to combine formal study with undergraduates' experience as literacy tutors;

d. As a condition of receiving credit for the courses of instruction referred to in paragraph (c) above, undergraduates will perform not less than six hours or voluntary, uncompensated service each week of the academic term in a public community agency as tutors in its educational or literacy programs;

e. The tutoring service referred to in paragraph (d) above will be supplementary both to the IHE's regular academic program and the existing instructional services offered by the community service learning programs; and

f. It will make arrangements for adequate training of volunteers, depending upon available resources, which may include the training of student coordinators to assist in the process of preparing and placing undergraduate as tutors in community service learning programs.

Signature or Authorized Certifying Official	Title
Applicant Organization	Date Submitted

OMB Approval No. 0348-0040

ASSURANCES — NON-CONSTRUCTION PROGRAMS

Note: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:

1. Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.
2. Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.
3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.
4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.
5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728-4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).
6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C.§§ 6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. § 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.
7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.
8. Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.
9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a-7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. §§ 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327-333), regarding labor standards for federally assisted construction subagreements.

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10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program andto purchase flood insurance if the total cost of insurable construction and acquisition is $10,000 or more.

11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clear Air Act of 1955, as amended (42 U.S.C. § 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, (P.L. 93-523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 93-205).

12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.

13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a-1 et seq.).

14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.

15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.

16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.

17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.

18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	DATE SUBMITTED

SF 424B (4-88) Back

Certification Regarding Debarment, Suspension, and Other Responsibility Matters Primary Covered Transactions

This certification is required by the regulations implementing Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, Section 85.510, Participants' responsibilities. The regulations were published as Part VII of the May 26, 1988 Federal Register (pages 19160-19211). Copies of the regulations may be obtained by contacting the U.S. Department of Education, Grants and Contracts Service, 400 Maryland Avenue, S.W. (Room 3633 GSA Regional Office Building No. 3), Washington, D.C. 20202-4725, telephone (202) 732-2505.

(BEFORE COMPLETING CERTIFICATION, READ INSTRUCTIONS ON REVERSE)

(1) The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;

(b) Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicted for or otherwise criminally or civilly charged by a governmental entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or local) terminated for cause or default.

(2) Where the prospective primary participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Organization Name PR/Award Number or Project Name

Name and Title of Authorized Representative

Signature Date

ED Form GCS-008, (REV.12/88)

Instructions for Certification

1. By signing and submitting this proposal, the prospective primary participant is providing the certification set out below.

2. The inability of a person to provide the certification required below will not necessarily result in denial of participation in this covered transaction. The prospective participant shall submit an explanation of why it cannot provide the certification set out below. The certification or explanation will be considered in connection with the department or agency's determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

3. The certification in this clause is a material representation of fact upon which reliance was placed when the department or agency determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

4. The prospective primary participant shall provide immediate written notice to the department or agency to whom this proposal is submitted if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

5. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of the rules implementing Executive Order 12549. You may contact the department or agency to which this proposal is being submitted for assistance in obtaining a copy of those regulations.

6. The prospective primary participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency entering into this transaction.

7. The prospective primary participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion--Lower Tier Covered Transactions," provided by the department or agency entering into this covered transaction, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

8. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List.

9. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

10. Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion Lower Tier Covered Transactions

This certification is required by the regulations implementing Executive Order 12549, Debarment and Suspension, 34 CFR Part 85, Section 85.510, Participants' responsibilities. The regulations were published as Part VII of the May 26, 1988 Federal Register (pages 19160-19211). Copies of the regulations may be obtained by contacting the person to which this proposal is submitted.

(BEFORE COMPLETING CERTIFICATION, READ INSTRUCTIONS ON REVERSE)

(1) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

(2) Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

Organization Name PR/Award Number or Project Name

Name and Title of Authorized Representative

Signature Date

ED Form GCS-009, (REV. 12/88)

Instructions for Certification

1. By signing and submitting this proposal, the prospective lower tier participant is providing the certification set out below.

2. The certification in this clause is a material representation of fact upon which reliance was placed when this transaction was entered into. If it is later determined that the prospective lower tier participant knowingly rendered an erroneous certification, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

3. The prospective lower tier participant shall provide immediate written notice to the person to which this proposal is submitted if at any time the prospective lower tier participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

4. The terms "covered transaction," "debarred," "suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of rules implementing Executive Order 12549. You may contact the person to which this proposal is submitted for assistance in obtaining a copy of those regulations.

5. The prospective lower tier participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency with which this transaction originated.

6. The prospective lower tier participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility, and Voluntary Exclusion–Lower Tier Covered Transactions," without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

7. A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the method and frequency by which it determines the eligibility of its principals. Each participant may, but is not required to, check the Nonprocurement List.

8. Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

9. Except for transactions authorized under paragraph 5 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency with which this transaction originated may pursue available remedies, including suspension and/or debarment.

Certification Regarding Drug-Free Workplace Requirements Grantees Other Than Individuals

This certification is required by the regulations implementing the Drug-Free Workplace Act of 1988, 34 CFR Part 85, Subpart F. The regulations, published in the January 31, 1989 Federal Register, require certification by grantees, prior to award, that they will maintain a drug-free workplace. The certification set out below is a material representation of fact upon which reliance will be placed when the agency determines to award the grant. False certification or violation of the certification shall be grounds for suspension of payments, suspension or termination of grants, or governmentwide suspension or debarment (see 34 CFR Part 85, Sections 85.615 and 85.620).

The grantee certifies that it will provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing a drug-free awareness program to inform employees about--

(1) The dangers of drug abuse in the workplace;
(2) The grantee's policy of maintaining a drug-free workplace;
(3) Any available drug counseling, rehabilitation, and employee assistance programs; and
(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will--

(1) Abide by the terms of the statement; and
(2) Notify the employer of any criminal drug statute conviction for a violation occurring in the workplace no later than five days after such conviction;

(e) Notifying the agency within ten days after receiving notice under subparagraph (d)(2) from an employee or otherwise receiving actual notice of such conviction;

(f) Taking one of the following actions, within 30 days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted--

(1) Taking appropriate personnel action against such an employee, up to and including termination; or
(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

Organization Name PR/Award Number or Project Name

Name and Title of Authorized Representative

Signature Date

ED 80-0004

[FR Doc. 89-20584 Filed 8-31-89; 8:45 am]
BILLING CODE 4000-01-C

Federal Register

Friday
September 1, 1989

Part VIII

Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 405, et al.

Medicare Program; Medicare Coverage of Screening Mammography; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 410, 413, and 494

[BERC-619-P]

RIN 0938-AD88

Medicare Program; Medicare Coverage of Screening Mammography

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement section 204 of the Medicare Catastrophic Coverage Act of 1988, which provides limited coverage for screening mammography services. The rule would amend current Medicare regulations to set forth payment limitations and conditions for coverage of screening mammography. The conditions would consist of quality standards to assure the safety and accuracy of screening mammography services performed by qualified physicians and other suppliers of these services.

DATE: To be considered, comments must be mailed or delivered to the appropriate address, as provided below, and must be received by 5:00 p.m. on October 31, 1989.

ADDRESSES: Mail comments to the following address:

Health Care Financing Administration, Department of Health and Human Services, Attention: BERC-619-P, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC, or,

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments.

If comments concern information collection or recordkeeping requirements, please address a copy of comments to:

Office of Management and Budget, Office of Information and Regulatory Affairs, Room 3206, New Executive Office Building, Washington, DC 20503, Attention: Allison Herron.

In commenting, please refer to file code BERC-619-P. Comments received timely will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in Room 309-G of the Department's offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION CONTACT:

William Larson (Conditions for Coverage) (301) 966-4640

William Morse (Payment Limits) (301) 966-4520

SUPPLEMENTARY INFORMATION:

I. Background

Section 1862(a) of the Social Security Act (the Act) lists items and services excluded from Medicare coverage. Paragraph (a)(7) of that section identifies routine physical checkups as excluded services, and it is on this basis that screening mammography has been excluded from Medicare coverage. This policy is reflected in Medicare regulations at 42 CFR 405.310(a), which implement the statute by excluding coverage for routine physical checkups. In addition, current coverage instructions setting forth the routine physical checkup exclusion are found in the Medicare Carriers Manual (HCFA Pub. 14), the part A Intermediary Manual (HCFA Pub. 13), the Hospital Manual (HCFA Pub. 10), the Skilled Nursing Facility Manual (HCFA Pub. 12), and the Home Health Agency Manual (HCFA Pub. 11). Current coverage instructions on payment for diagnostic mammograms (as distinguished from screening mammograms) are included in section 50-21 of the Medicare Coverage Issues Manual (HCFA Pub. 6).

Section 204 of the Medicare Catastrophic Coverage Act of 1988 (Pub. L. 100-360, enacted on July 1, 1988) amended sections 1833, 1834, 1861, 1862, 1863, 1864, 1865, 1902, and 1915 of the Act to provide coverage of screening mammography (including a physician's interpretation of the images or films produced by the radiologic procedure) effective January 1, 1990, subject to frequency limitations, quality standards, and special payment rules.

In the legislative history of Public Law 100-360, Congress expressed strong concern that steps be taken to ensure the quality of screening mammography services. In the opening statement of the hearing on Medicare coverage for mammography, Representative Fortney H. Stark said, "To assure that Medicare beneficiaries receive the highest quality of care, my bill requires the Secretary to establish conditions of participation for facilities offering mammography procedures" (Report of the Subcommittee on Health of the Committee on Ways and Means, House of Representatives, H.R. Rep. No. 100-47, 100th Congress, 1st Session 7 (1987)). In testimony before the committee, other individuals and professional organizations in the health care community (the American College of Radiology, the American Cancer Society, and the National Women's Health Network, among others) also expressed concern regarding the quality of mammography services. For example, Alan C. Sartorelli, Ph.D., Alfred Gilman Professor of Pharmacology and Director of the Yale Comprehensive Cancer Center of the Yale University School of Medicine, and also President of the Association of American Cancer Institutes, testified that in constructing a Medicare screening mammography program that will be successful in the early detection of breast cancer, "* * * it is critical that quality control of the examinations be included". At the request of the Congress, the Office of Technology Assessment (OTA) published a report on the subject ("Breast Cancer Screening for Medicare Beneficiaries: Effectiveness, Costs to Medicare and Medical Resources Required", p. 11, November 1987). In this report, OTA identifies "the need to monitor the quality of screening service * * * if Medicare expects to restrict the amount to be reimbursed to providers of screening services", and says that "the rapid rise in new freestanding breast screening facilities is likely to raise concerns about the quality of the services provided" (p. 12). This concern about the quality of screening mammography has been strengthened by the May 1989 report of the U.S. Preventive Services Task Force to the Secretary, entitled "Guide to Clinical Preventive Services". Citing four studies, it concluded that, "Wide variation is found in the quality and consistency of mammography, as well as in the accuracy of interpretation, radiation exposure and cost" (p. 29).

In response to this concern for the quality of screening mammography services, as well as to the congressional mandate for quality standards contained in section 1834(e)(3) of the Act, we are proposing comprehensive standards regarding equipment specifications, the qualifications of supervising and interpreting physicians and other personnel, safety measures, compliance with Federal, State, and local laws and regulations, the preservation and disposition of examination results and other records, and the need for an ongoing equipment quality assurance program.

We recognize that this approach to assuring the quality of screening mammography is not entirely consistent with our recent emphasis on using "outcome" or "performance" standards to assure the quality of provider services paid for under the Medicare program. Such as approach would be desirable in the screening mammography area, but it does not appear to be feasible at this time. An outcome oriented approach requires that certain methodologies such as a valid proficiency test be available to evaluate how well the goals established by regulation are being met. Some progress has been made in the development of a proficiency test for the performance of screening mammography examinations, primarily in the use of phantoms to evaluate the quality of the images being produced and in the development of other physics tests. However, we do not yet have a test for technologist positioning accuracy or for radiologist interpretative skills. Neither do we have a carefully evaluated clinical comparison for the physics tests now in use. Some research, sponsored by the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA), is now under way that may contribute to the development of some of the missing elements. This research and efforts by professional groups may eventually lead to a comprehensive valid proficiency test that will permit use of an outcome oriented approach in screening mammography. For the present, however, we believe that it will be necessary to require facilities to meet specific requirements that are known to contribute to effective mammography examinations and their interpretations. The proposed standards reflect this approach. However, we request comments on the availability and accuracy of proficiency testing for the elements noted above.

II. Provisions of the Regulations

This proposed rule would implement section 204 of Public Law 100–360 by setting forth payment limitations and establishing conditions for coverage of screening mammography to ensure the safety and accuracy of the screening process.

Thus, we would specify an exception to the list of examples of routine physical checkups excluded from coverage at 42 CFR 405.310(a)(1). The exception would be for screening mammography (including a physician's interpretation of the results) that is consistent with the payment requirements proposed at § 410.34 and that meets the conditions for coverage that we would specify under subpart B of a new 42 CFR part 494.

Coverage of screening mammography would be provided under Medicare Part B only; a reasonable interpretation of the law does not support Part A coverage of the procedure.

A. Payment Limitations

We would add a new § 405.534 to set forth limitations on payment for screening mammography services. There would be three categories of billing for mammography services, as is the case with other radiological services. Bills may be for the professional component of mammography services (that is, for the physician's interpretation of the results of the examination), for the technical component (all other services), or for both (global). This new section would establish payment limits for each of those categories. For purposes of payment for screening mammography services, we propose to weight the professional and technical components in the same manner that we did in establishing fee schedules for radiologists' services that were published in the **Federal Register** on March 2, 1989 (54 FR 8994–9024). Thus, we propose that, at this time, the professional component would represent 37 percent of the total amount for the complete service and the technical component would represent 63 percent. If the relationship between these values changes at a later date, we would modify § 405.534 to reflect the change.

Billing for screening mammography services would be in accordance with general Medicare payment policy for radiology services furnished by physicians in providers (§§ 405.554 through 405.555) and with policy governing payment under the fee schedule for radiologist services furnished in all settings (§§ 405.530 through 405.533). That is, a global charge may be made for services furnished in settings other than hospitals or the technical and professional components may be billed separately. However, global billing is not permitted for services furnished in hospital outpatient departments. Furthermore, the technical component of screening mammography services furnished in hospital outpatient departments would not be paid through the special methodology set forth in § 413.122, which is the generally applicable policy for payment of hospital outpatient radiology services. We propose that screening mammography services be excluded from the provision. Proposed payment for these services is discussed below.

Section 405.534(a) would set the limitations for payment of both the professional and technical components through global billing for services furnished in all settings. As discussed above, global fees may not be billed for screening mammography services furnished in hospitals. For screening mammography services furnished in all settings when a global charge is appropriate, the amount of payment subject to the deductible would be equal to 80 percent of the least of the—

- Actual charge for the service;
- Amount determined with respect to the professional and technical components for the service under §§ 405.530 through 405.533, which set forth the methodology for computing payments for radiologist services; or
- Limit for the procedure. For services furnished in calendar year 1990, the limit would be $50. On January 1 of each subsequent year, the limit would be updated by the percentage increase in the Medicare Economic Index (MEI).

In paragraph (b) of proposed § 405.534, we would set forth the limits for payment of the professional component. For services furnished in all settings in which the professional component is billed separately, the amount of payment for that professional component subject to the deductible would be equal to 80 percent of the least of the—

- Actual charge for the professional component of the service;
- Amount determined with respect to the professional component for the service under §§ 405.530 through 405.533, which set forth the methodology for computing payments for radiologist services; or
- Professional portion of the screening mammography limit. This amount is determined by multiplying the screening mammography limit (that is, $50 in calendar year 1990) by the same percentage that the professional relative value for screening mammography bears to the global relative value for screening mammography under §§ 405.530 through 405.533, or 37 percent. On January 1 of each subsequent year, the screening mammography limit would be updated by the percentage increase in the MEI.

In paragraph (c) of the proposed § 405.534, we would set forth the limitations for payment of the technical component. We propose the following:

- For services furnished in all settings in which the technical component is billed separately, the limit for that technical component subject to the deductible would be equal to 80 percent of the least of the—

—Actual charge for the technical component of the service;

—Amount determined with respect to the technical component for the service under §§ 405.530 through 405.533; or

—Technical portion of the screening mammography limit. This amount is determined by multiplying the screening mammography limit (that is, $50 in calendar year 1990) by the same percentage that the technical relative value for screening mammography bears to the global relative value for screening mammography under §§ 405.530 through 405.533, or 63 percent. On January 1 of each subsequent year, the overall limit would be updated by the percentage increase in the MEI.

• For services furnished in the outpatient departments of hospitals, the limit for that technical component subject to the deductible would be the same as described above.

We would also add a new § 405.535 to stipulate that, if screening mammography services are furnished to a beneficiary by a nonparticipating physician or supplier, a special limiting charge applies to the charges made to the beneficiary. The limiting charge would be the lesser of the amount determined using § 405.533 (rules for nonparticipating physicians furnishing radiology services) or the limit for nonparticipating suppliers set forth in section 204 of Public Law 100–360. In 1990, this limit would be 125 percent of the payment limit; in 1991, 120 percent; and, beginning January 1, 1992, 115 percent of the payment limit.

B. Coverage Limitations and Conditions

We would revise § 410.1(a), which sets forth the statutory basis for part B benefits, by adding section 1834 of the Act. Section 1834 provides for part B coverage of screening mammography services. We would revise § 410.10 to add a paragraph (t) reading "Screening mammography services". This would add screening mammography services to the listing of "medical and other health services" that part B covers.

We would redesignate the current § 410.34 as § 410.35. The new § 410.34 would set forth conditions for coverage for and limitations on coverage for screening mammography services. It would define screening mammography as a radiologic procedure furnished to a woman for the purpose of early detection of breast cancer, including a physician's interpretation of the results of the procedure. Section 410.34(a) would explicitly state that coverage is available for screening mammography services only if furnished by a screening mammography supplier that meets the conditions for coverage of screening mammography proposed in subpart B of part 494.

According to the Report of the Committee of Conference that accompanied Public Law 100–360 (H.R. Rep. No. 100–661, 100th Congress, 2d Session 171 (1988)), the conferees "understand that a bilateral four-view procedure is currently considered to be the standard of care in the United States for screening mammography * * * [and] therefore anticipate that this would be initially included in the quality standards to be developed by the Secretary as a requirement for coverage". Accordingly, § 410.34(b)(1) would specify that the service must be a bilateral four-view exposure (that is, a cranio-caudal and a medial lateral oblique view of each breast) furnished by a supplier that meets the conditions for coverage of screening mammography services.

Additionally, § 410.34 would set forth the following restrictions imposed by section 1834(e)(2) of the Act:

• No payment may be made for screening mammography performed on an asymptomatic woman under 35 years of age (§ 410.34(b)(2)).

• Payment may be made for only 1 screening mammography performed on an asymptomatic woman over 34 years of age, but under 40 years of age (§ 410.34(b)(3)).

• For an asymptomatic woman over 39 years of age, but under 50 years of age, the following coverage guidelines apply:

—Payment may be made for a screening mammography performed after at least 11 months have passed since the last screening mammography, if the woman has a high risk of developing breast cancer, that is, if she has—

—A personal history of breast cancer;

—A personal history of biopsy-proven benign breast disease;

—A mother, sister, or daughter who has had breast cancer; or

—Not given birth prior to age 30.

—Payment may not be made for a screening mammography performed within the 23 months after the previous screening mammography if the above criteria do not apply (that is, the woman is not at a high risk of developing breast cancer) (§ 410.34(b)(4)).

• For an asymptomatic woman over 49 years of age, but under 65 years of age, payment may not be made for screening mammography performed within 11 months after a previous screening mammography (§ 410.34(b)(5)).

• For an asymptomatic woman over 64 years of age, payment may not be made for screening mammography performed within 23 months after a previous screening mammography (§ 410.34(b)(6)).

These proposed guidelines reflect the mandated provisions of the law, except that the factors indicating a high risk of developing breast cancer were identified based upon advice we received from the National Cancer Institute of the National Institutes of Health. The proposed guidelines do not include a requirement that the screen mammography radiologic procedure (as distinguished from the physician's interpretation) must be prescribed by a physician for a particular beneficiary in order for it to be covered under the benefit. The law does not specify it, and the legislative history is also silent as to the need for physician referral. As provided in section 1834(e)(2)(B) of the Act, added by section 204(b)(2) of Public Law 100–360, the guidelines may be revised by the Secretary on the basis of consultation with the National Cancer Institute, but not before January 1, 1992.

We intend to publish a separate regulation concerning current payment methods for hospital outpatient radiology services and other diagnostic procedures. We are proposing to exclude screening mammography services as described in § 410.34 from those payment methods.

We would add a new § 413.123 that would specify the payment method for screening mammography performed by hospitals on an outpatient basis.

We would add a new Part 494 entitled "Conditions for Coverage of Particular Services". Subpart A would be reserved for future use as "General Provisions", and Subpart B would specify "Conditions for Coverage of Screening Mammography". In proposing the conditions for coverage of screening mammography, we used part 405, subpart N (Conditions for Coverage of Portable X-ray Services) as a model. Because of the similarity of services furnished and based on our experience with the portable X-ray benefit, we believe that some of the conditions for coverage of portable X-ray services furnish a sound basis upon which to develop similar conditions for coverage of screening mammography. The first condition for coverage under subpart B would be a general condition at § 494.50. It would provide that in order to be approved for participation in the Medicare program, a supplier of screening mammography must meet all the conditions set forth in subpart B with respect to individuals entitled to Medicare part B. Section 1834(e)(3) of the Act authorizes the Secretary to

establish safety and accuracy standards "under this Part", that is, under Medicare part B. All facilities (including participating providers) would have to meet all the safety and accuracy standards specified in the proposed regulations to qualify as screening mammography suppliers. Medicare participating hospitals, for instance, would not be considered to meet the proposed requirements solely because they are certified as participating providers. The second condition for coverage would be located at § 494.51. Using language similar to that used in § 405.1411 of subpart N, we would require compliance with Federal, State, and local laws and regulations by the supplier of screening mammography services. (Section 405.1411 requires compliance with Federal, State, and local laws as a condition for coverage of portable X-ray services.)

At a new § 494.52, we would establish a condition requiring supervision by a qualified physician. The language we would use is similar to that used in § 405.1412(a), which sets forth a physician supervision standard for coverage for portable X-ray services. We would establish a standard at § 494.52(a) to require that the screening mammography services must be supervised by a physician. Additionally, section 494.52(a), using language similar to that used in § 405.1412(b), would set forth the required qualifications of the physician supervisor. The new section would state that he or she must be a licensed doctor of medicine or licensed doctor of osteopathy who meets the requirements for the interpretation of the results of screening mammograms as specified in § 494.54. We would consider adequate supervision to be provided if the supervising physician meets the requirement proposed at § 494.52(b). Specifically, the supervising physician must certify annually that he or she has checked the procedural manuals and has observed monthly the operators' performance, that he or she has verified that the equipment and personnel meet applicable Federal, State, and local licensure and registration requirements, that safe operating procedures are used, and that all other requirements of part 494, subpart B are being met.

We would add a new § 494.54 to set forth the requirements governing the interpretation of the results (that is, films or images) of screening mammography as a condition for Medicare coverage, in accordance with section 1834(e)(3)(C) of the Act. This section of the Act requires that mammography results be interpreted by either a physician "who is certified as qualified to interpret radiological procedures by such an appropriate board as the Secretary specifies" or "who is certified as qualified to interpret screening mammography procedures by such a program as the Secretary recognizes in regulation, as assuring the qualifications of the individual with respect to such interpretation". Thus, under § 494.54(a), we would require that the results of all screening mammography be interpreted by a physician who meets either of the following certification requirements that we developed as a result of consultation with the FDA, the American College of Radiology (ACR), and the National Cancer Institute (NCI):

- The interpreting physician is certified by the American Board of Radiology or by the American Osteophathic Board of Radiology (§ 494.54(a)(1)).
- The interpreting physician is certified as qualified to interpret the results of a screening mammography procedures by an appropriate program that assures the qualifications of the individual (§ 494.54(a)(2)).

We are specifically soliciting suggestions from the public concerning alternate sources of certification or other appropriate programs that may be used to meet this requirement, and we will revise proposed § 494.54(a)(2), as appropriate, based on those comments.

Additionally, on the basis of consultation with the FDA, ACR, and NCI, we would require in § 494.54(b) that the interpreting physician meet certain experience and continuing education standards to ensure that the special skills required to interpret the results (that is, films or images) of screening mammography accurately are kept up-to-date. The results of a screening mammography procedure are very difficult to interpret accurately and require a physician's special skills. These skills need to be kept up-to-date through special training and experience that is recognized by the ACR in its own accreditation program. We understand that neither certification by the American Board of Radiology nor by the American Osteopathic Board of Radiology includes any assurance that interpreting physicians are keeping their skills up-to-date through continuing training and experience. The experience and continuing education standards we would require in § 494.54(b) follow:

- A physician first meeting the board certification standards or meeting other equivalent certification qualifications as outlined above before January 1, 1990 must also—
  - —Have read the results of an average of 10 or more screening or diagnostic mammographies per work week in the 6 months prior to January 1, 1990 (the effective date of the final rule);
  - —Have successfully completed a minimum of 40 hours of post-graduate instruction in mammography interpretation in the 24 months prior to January 1, 1990; and
  - —Have successfully completed a minimum of 40 hours of post-graduate instruction in mammography interpretation every 24 months after January 1, 1990.
  - —Continued to read the results of an average of 10 or more screening or diagnostic mammographies per work week after he or she begins to read screening mammographies for Medicare beneficiaries.
- A physician first meeting the board certification standards or meeting other equivalent certification qualifications as outlined above on or after January 1, 1990, must also—
  - —Have read the results of an average of 10 or more screening or diagnostic mammographies per work week in the 6 months before the date that he or she begins reading screening mammographies for Medicare beneficiaries;
  - —Have successfully completed a minimum of 40 hours of post-graduate instruction in mammography interpretation in the 24 months before the date he or she begins reading screening mammographies for Medicare beneficiaries; and
  - —Have successfully completed a minimum of 40 hours of post-graduate instruction in mammography interpretation every 24 months after the date that he or she begins reading screening mammographies for Medicare beneficiaries.
  - —Continue to read an average of 10 or more screening or diagnostic mammographies per work week after he or she begins reading screening mammographies for Medicare beneficiaries.

We are interested in receiving comments regarding the appropriateness of these training and experience requirements.

Section 494.54(c) would require that the interpreting physician prepare and sign a written report on his or her interpretation of the results (that is, the images or films) of the screening mammography procedure and that a copy of that report and the original images or films be forwarded to the patient's screening mammography supplier for inclusion in the patient's

medical records. It would also require that the interpreting physician provide a written statement to the patient, in terms easily understood by a lay person. The statement would describe the importance of the screening mammography procedure to her ongoing health (including a description of the steps that should be taken if the results of the mammography procedure are positive), as well as her responsibility to share with any new physician or supplier of her next screening mammography, the date and place of her previous screening mammography. The statement must record the date of the procedure, the name of the facility providing the procedure, the physician (if any) to whom the woman wants a copy to be sent, and must indicate that the original images or films have been provided to the screening mammography supplier for inclusion in the woman's permanent medical record. This proposed requirement was also included as a result of our meetings with representatives of the FDA and the ACR.

We would add a new § 494.56 to set forth requirements concerning qualifications and orientation of technical personnel and the retention of employee records. Paragraphs (a) and (b) of this section were modeled after similar requirements at § 405.1413 concerning the conditions for coverage of portable X-ray services. Paragraph (a) would require that all operators of screening mammography equipment be licensed by the State to perform radiological procedures or, in States that have no licensing requirements, be certified in radiography by the American Registry of Radiologic Technologists, the American Registry of Clinical Radiographic Technologists, or possess equivalent certification qualifications.

In addition, on the basis of consultation with the FDA and ACR, we would require that all operators of screening mammography equipment meet certain formal and specialized training standards to ensure that a high level of quality is achieved in producing the results (that is, films or images) of the radiologic procedure. State licensure or other certificates in radiography normally mean that operators are only generally qualified to perform radiological procedures and not that they are specifically trained to perform screening mammography procedures that are especially difficult to do correctly. Accordingly, the operators would be required to successfully complete a program of not less than 24 months of formal training in X-ray technology in a school that meets the requirements of Appendix A (Standards for Accreditation of Educational Programs for Radiographers) of 42 CFR Part 75, or that is approved by the Council on Allied Health Education and Accreditation. Also, they would have to have successfully completed specialized training in mammographic positioning, compression, and technique factor settings in the 24 months prior to January 1, 1990 (or in the 24 months preceding the time he or she begins performing mammographies for Medicare beneficiaries), and every 24 months thereafter.

Paragraph (b) of proposed § 494.56 would require that a supplier of screening mammography services have an orientation program for operators based on a procedural manual that is available to all staff members and that includes instructions in all of the following areas:

- Precautions to protect the following individuals from unnecessary exposure to radiation—

—Patients;
—Individuals supporting a patient during a mammography procedure;
—Other individuals in the surrounding environment; and
—The operator of the screening mammography equipment.

- Determination of the area that will receive the primary beam (breast positioning).
- Pertinent information on compression, exposure levels, resolution, contrast, noise, examination identification, artifacts, and average glandular dose per view.
- Employee responsibilities concerning the proper use of personal radiation monitors.
- Proper use and maintenance of equipment, including a discussion of the image receptors appropriate for use with mammography and the kV(kilovoltage)-target-filter combination to be used with each image receptor.
- Proper maintenance of records.
- Possible technical problems and solutions.
- Protection against electrical hazards.
- Hazards of excessive exposure to radiation.

Paragraph (c) of § 494.56 provides alternative qualification criteria for people who furnish diagnostic X-ray physics support. The primary criteria are contained in (c)(1), which would require that those who furnish diagnostic X-ray physics support be certified by the American Board of Radiology as diagnostic medical physicists or possess qualifications that are recognized by the Secretary as equivalent to those required for certification. We are soliciting suggestions from the public for alternate sources of certification or registration for meeting this requirement. After consulting with the FDA, the ACR, and other health care organizations, we concluded that adoption of this certification requirement would be the best way to ensure that these individuals would be qualified to maintain a satisfactory quality assurance program. We were advised that the person furnishing diagnostic X-ray physics support is the technical expert with the overall responsibility of assuring that mammography equipment performance is consistently on the level required by the quality standards. He or she is a recognized expert in the physics involved in the operation of mammography equipment and the techniques used in monitoring equipment performance, and is capable of evaluating the monitoring results. Furthermore, he or she is specially qualified to carry out corrective actions as needed to ensure that the equipment continues to operate properly. Under this proposed rule, the person furnishing diagnostic X-ray physics support would establish and guide the quality assurance program. Specific duties would include conducting or training others to conduct equipment performance monitoring functions, analyzing the monitoring results to determine if there are problems requiring correction, and carrying out or arranging for the necessary corrective actions as well as the required calibrations and other preventive maintenance. Paragraph (c)(1) would also require that the person furnishing diagnostic X-ray physics support meet minimum training, experience, and continuing education requirements pertinent to screening mammography. We solicit suggestions regarding what these requirements should encompass.

Paragraph (c)(2) provides an alternate set of criteria, which has been included in recognition of the fact that in some parts of the country, especially in the rural regions, individuals meeting the qualifications set forth in (c)(1) may be unavailable to the screening mammography facility. In such cases, paragraph (c)(2) permits the State radiation control agency to recognize other individuals from the private sector as being qualified to provide guidance to the facility for the establishment and maintenance of a quality assurance program. This is a logical extension of the programs already in existence in several States in which the State program identifies "qualified experts" in

the private sector capable of performing a variety of diagnostic radiology physics tests and corrective actions. It is also in accordance with recommendations to the States contained in the "Suggested State Regulations for the Control of Radiation" (developed by the Conference of Radiation Control Program Directors) concerning the identification of those qualified to furnish diagnostic X-ray physics support. We are soliciting comments from the public on this alternative approach and suggestions for other ways of identifying individuals who are qualified to establish and maintain a satisfactory quality assurance program.

The proposed § 494.56(d) was adopted from the language used in § 405.1413(c). Section 494.56(d) would require that records be maintained for each current employee and that the records include evidence that each employee is qualified for his or her position by means of appropriate State licensure, other certification, training, and experience.

We would add a new § 494.58 to set forth a condition specifying the requirements for obtaining and preserving screening mammography records. It was modeled after § 405.1414, which specifies similar requirements for the preservation of portable X-ray records. The proposed condition states that all reasonable efforts be made to obtain any of the beneficiary's previous screening mammography records including original images or films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous screening mammographies that might be available from others, for comparison with the current screening mammography records. We would also require that records of previous screening mammographies obtained and current and subsequent screening mammographies produced by the supplier must be properly preserved and made available to other qualified mammography suppliers or others that submit a written request authorized by the beneficiary. The two specific standards that § 494.58 would set forth are as follows:

- The supplier must make, for each beneficiary, a record of the screening mammographies it performs, including: the date the screening mammogram was made and the date of the interpretation; the name of the beneficiary; the name of the equipment operator and the name of the interpretating physician; a description of the procedures performed; the name of the referring physician (if any), or other physician (if any) identified by the beneficiary to receive the interpreting physician's written report; and the date the physician's written report was sent to the appropriate physician or beneficiary.
- The supplier must provide satisfactory assurances (as documented in its medical records) that the images or films of the first and subsequent screening mammography procedures and the related written reports of the physicians' interpretations for each woman who is a Medicare beneficiary are either placed in her permanent medical records kept by the supplier or sent to another person (including the beneficiary) for placement in the women's permanent medical record as directed by the woman or by her physician. In the case of a participating supplier who holds the woman's medical records, the records of the mammography procedure must be retained for a period of at least 60 calendar months following the date of service (or longer if required by State law). Some concern has been expressed that these records should be retained indefinitely, but we believe that a reasonable limit must be placed on the retention of these records. Therefore, we have specified 60 calendar months, which is the longest period of time that any other participating provider or supplier is currently required to retain medical records. However, we specifically ask for comments on this issue.

Additionally, we would add a new § 494.60 to set forth the technical standards for mammography equipment. We have included in these proposed standards the requirements set forth at 21 CFR 1020.30 (FDA standards for diagnostic X-ray systems and their major components) and 21 CFR 1020.31 (FDA standards for radiographic equipment) and have also adopted suggestions from the FDA and the ACR. However, it is important to note that general purpose X-ray systems with special attachments for mammography, which are permitted under the FDA performance standards, would not meet the requirements for this standard. This is because section 1834(e)(3)(A) of the Act states that "the equipment used to perform the mammography must be specifically designed for mammography." General purpose units with special attachments for mammography are designed for a wide range of diagnostic and screening examinations and therefore do not meet the statutory requirement that they be specifically designed for mammography.

At the annual meeting of the Conference of Radiation Control Program Directors that was held in May 1986, a 1985–86 Nationwide Evaluation of X-ray Trends (NEXT) survey was discussed. This survey, which was conducted by the Conference of Radiation Control Program Directors, found that 30 percent of the xerography units were specifically designed for mammography while 82 percent of the film/screen units were so designed (Fred Rueter, NEXT 1985, (Mammography) Fall 1987, Newsletter of the Conference of Radiation Control Program Directors, Attachment No. 3). However, on the basis of analysis performed by the FDA there are about twice as many film/screen units as xerography units so overall about 70 percent of the mammography systems met the proposed requirement in 1985–86 and only about 30 percent did not. Furthermore, the percentage of systems specifically designed for mammography has been increasing rapidly; the newly purchased systems are almost entirely of that type.

The FDA fully expects that the data from the NEXT 1988 survey will show that the percentage of units that would meet this general requirement would be above 70 percent and that the use of only specifically designed units for mammography will continue to grow.

Thus, the specific standards proposed in § 494.60 follow:

- The equipment must be specifically designed for mammography and identified by the manufacturer as designed only for mammography.
- The equipment must meet the FDA performance standards for diagnostic X-ray systems and their major components at 21 CFR 1020.30 and FDA's standards for radiographic equipment at 21 CFR 1020.31. (However, the FDA standards include general requirements for any type of X-ray equipment; they do not specify requirements designed specifically for mammography equipment. In addition, the published FDA standards do not address the subject of image receptor systems, which are essential to the consistent performance of quality mammograms. Therefore, the requirements that follow must be added to explain what is meant by the statutory phase "specifically designed for mammography.")
- The image receptor systems and all their individual components must be designed appropriately for mammography.
- The equipment must be limited to providing kV(kilovoltage)-target-filter combinations appropriate to image receptors.
- The nominal focal spot size of the X-ray tube must not exceed 0.7 mm.

• Devices parallel to the imaging plane must be available to immobilize and compress the breast.

• The equipment must have the capability for using anti-scatter grids.

• The equipment must have the capability of automatic exposure control.

• The equipment must have a control panel that includes a device (usually a milliammeter) or means for an audible signal to give positive indication of the production of X-rays whenever the X-ray tube is energized. The control panel must include appropriate indicators (labeled control settings or meters that show the physical factors such as kVp (kilovoltage potential), mAs (milliampere seconds), exposure time, or whether timing is automatic) used for exposure.

In a new § 494.62, we propose to set forth a condition concerning safety standards for mammography. In proposing this condition, we adapted the provisions of § 405.1415, which set the safety standards for portable X-rays. We would require that screening mammograms be conducted with equipment that is free from unnecessary hazards for patients, personnel, and other people in the immediate environment, and in accordance with procedures that provide minimum radiation exposure. These standards would include the following:

• Using proper safety precautions, including: adequate shielding for patients, personnel, and facilities. The equipment must be operable only from a shielded position.

• Use of exposure badges or other appropriate devices to measure the radiation exposure of personnel operating the equipment.

• Periodic inspection of equipment and shielding by a staff or consultant medical physicist or by a physicist approved by an appropriate State or local government agency as meeting the qualification requirements of § 494.56(c). Identified hazards must be promptly corrected.

• Use of shockproof and grounded equipment.

Finally, we would add a new § 494.64 to set forth quality assurance standards. These standards were written after consultation with representatives from the FDA and the ACR and, for the most part, incorporate the principles described in the FDA recommendations for quality assurance programs for diagnostic radiology facilities at 21 CFR 1000.55. Specifically, § 494.64 would require a supplier of mammography services to have an ongoing equipment quality assurance program specific to mammography imagery and covering all components of the X-ray system from X-ray generator to the image developer in order to ensure consistently high quality images with minimum patient exposure. We would specify that the supplier must conduct a general review of the program at least annually and employ (or hire on a consultative basis) a medical physicist who, under the direction of the supervising physician described in § 494.52, will be responsible for establishing and conducting the program. The specific standards set forth in proposed § 494.64 that follow are given to ensure that the level of quality assurance is consistent no matter which facility the patient visits:

• The medical physicist has the overall responsibility for establishing and conducting the ongoing equipment quality assurance program. The medical physicist's specific duties must include—

—Conducting or training others to conduct equipment performance monitoring functions;

—Analyzing the monitoring results to determine if there are problems requiring correction; and

—Carrying out or arranging for necessary corrective actions as well as calibrations and other preventive maintenance.

• All variable parameters of the equipment must be calibrated—

—When it is first installed;

—After any major changes or replacement of parts;

—At least annually during use; and

—When quality assurance tests indicate that calibration is needed.

• The supplier must routinely monitor the performance of the mammography system. The need to monitor the following parameters at the given frequencies is generally accepted by radiological experts.

—At a minimum, the parameters that must be monitored are—

Processor performance (through sensitometric-densitometric means);

Half value layer;

Output reproducibility and linearity;

Automatic exposure control reproducibility, kVp response, and thickness response;

Adequacy of film storage (both before use and after exposure if processing does not occur immediately);

Darkroom integrity;

Availability and use of technique charts that must include an indication of the kV-target-filter combination to be used with each image receptor;

Image quality (using a testing device called a "phantom", which simulates the composition of the breast and indicators of disease conditions, allowing objective analysis of clinical image quality); and

Dose.

—The equipment must be monitored frequently.

Processor performance and the use of a kV-target-filter combination appropriate to the image receptor must be monitored daily before patient irradiation.

Image quality must be monitored before patient irradiation with a phantom every time the unit is moved, altered in any major way including the replacement of parts, and at least monthly between movements or alterations.

The frequency of monitoring of all other parameters must be proportional to the expected variability of each parameter, but, at a minimum, monitoring must be conducted at least annually.

• *Standard—monitor evaluation.* Monitoring must be evaluated on a regular basis.

—Standards of image quality giving acceptable ranges of values for each of the parameters tested must be established to aid in the evaluation. The standards of image quality related to dose must include a requirement that the mean glandular dose for one craniocaudal view of a 4.5 cm compressed breast (50 per cent adipose/50 per cent glandular) must not exceed 100, 300, and 400 mrad (millirad) for film/screen units without grids, film/screen units with grids, and xerography units respectively. These dose values reflect generally accepted standards of practice.

—The monitoring results must be compared routinely to the standards of image quality. If the results fall outside the acceptable range, the test must be repeated. If the results continue to be unacceptable, the source of the problem must be identified and corrected before further examinations are conducted.

• A program to analyze retakes must be established as a further aid in detecting and correcting problems affecting image quality or exposure.

• Responsibility for each standard, from monitoring through the annual review, must be assigned to qualified personnel. These assignments must be documented in the supplier's record.

III. Regulatory Impact Analysis

A. Executive Order 12291 and Regulatory Flexibility Act

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any proposed rule that meets one of the E.O. criteria for a "major rule"; that is, that would be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a proposed rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all physicians and suppliers of screening mammography services and equipment are treated as small entities.

This proposed rule would implement section 204 of Public Law 100–360 to provide Medicare coverage of screening mammography. We anticipate that Medicare coverage of screening mammography would result in the following costs:

TABLE I.—PROJECTED COSTS AS A RESULT OF MEDICARE COVERAGE OF SCREENING MAMMOGRAPHY

[In millions] [1]

Fiscal year—				
1990	FY 1991	FY 1992	FY 1993	FY 1994
$150	$275	$325	$375	$425

[1] Rounded to the nearest 25 million.

Our projected costs are based on the following assumptions:

- An effective date of January 1, 1990.
- A 50-percent utilization rate across all age groups in calendar year 1990 rising five percent annually to reach 75 percent in calendar year 1995.

Below are estimates of the number of incurred screening mammographies.

TABLE II.—PROJECTED NUMBER OF INCURRED SCREENING MAMMOGRAPHIES AS A RESULT OF MEDICARE COVERAGE OF SCREENING MAMMOGRAPHIES

[In millions]

	Calendar year—				
	1990	1991	1992	1993	1994
Total	4.9	5.5	6.1	6.7	7.4

We estimate that in FY 1990 there would be 7,000 screening mammography facilities increasing to 9,000 in FY 1991. The total cost of surveying and certifying these 9,000 facilities would be approximately $3.5 million.

We believe that any effects of these provisions on the economy and public would primarily be the result of the statute and not this proposed rule. This is because we have proposed to implement the statute exercising administrative discretion in only the following four areas: the equipment standards for screening mammography; the safety standards for screening mammography; specifying who we consider to be a high risk individual for the purpose of determining the frequency of screening mammography for an asymptomatic woman over 39 years of age, but under 50; and the Board certification we would accept. In section II of this preamble, we discuss our rationale for choosing specific provisions. As discussed in the analyses below, with one exception, we do not believe these provisions would result in effects that meet E.O. 12291 or Regulatory Flexibility Act criteria. That exception is the proposed equipment standards for screening mammography of Medicare beneficiaries. The equipment must be specifically designed for mammography and identified by the manufacturer as designed only for mammography. We are not able to determine the costs associated with this exception. For that reason, and because Medicare coverage of screening mammography represents a significant expansion of Medicare benefits, we are providing voluntary regulatory impact and regulatory flexibility analyses.

1. Background

Congressional hearings held in 1986 projected that in 1987 approximately 110,000 women would be diagnosed as having new primary cases of breast cancer, and approximately 47,000 deaths from breast cancer would occur (Medicare Coverage for Mammography Examinations: Hearings Before the Subcommittee on Health of the House Committee on Ways and Means, 100th Cong., 1st Sess. 6 (1987)). Furthermore, it was estimated that one out of every ten women would develop the disease in her lifetime (ibid. note 1, at 66).

Additionally, the Subcommittee report stated that women 65 and older are about one and one-half times as likely as women in the 40–64 age group to develop breast cancer. It was projected that in 1987 about 48,000 (44 percent) of the new primary cases and about 24,000 of breast cancer deaths would occur in women over age 65 ("The Feasibility of Breast Cancer Screening," Health Technology, 1:26–37, 1987).

Some medical experts believe that appropriate use of screening mammography, in conjunction with clinical examination and breast self examination, can enable health care suppliers to detect many breast cancers at their earliest stage (op. cit. note 1, at 66).

2. Effects on Physicians and Other Healthcare Suppliers

We believe that a great number of the supervising physicians and most of the interpreting physicians who perform screening mammographies are radiologists. As of December 31, 1986, there were 8,345 radiologists practicing in the United States with 6,365 being certified by their corresponding board (Physician Characteristics and Distribution in the U.S., 1986. Department of Data Release Services, Division of Survey and Data Resources, American Medical Association, 1987). Radiologists, as a group, had a physician participation rate of 40 percent in 1987 and a Medicare assignment rate of 73 percent in 1986.

We believe that Medicare coverage of screening mammography would result in increased utilization over current levels on the part of Medicare eligible women. A logical outgrowth of this increased utilization would be an increase in demand for those who provide the services and supplies that constitute the screening mammography field, namely: supervising physicians, interpreting physicians, medical physicists, radiological technologists, and suppliers of screening mammography services and equipment.

The effect of this proposed rule on an individual radiologist, physician, or other health care supplier would depend on the percentage of their business that involves Medicare eligible women and the percentage of their business that involves performing screening mammographies. Clearly, this would vary among practicing radiologists, physicians, and other healthcare suppliers. Additionally, we believe that

suppliers of screening mammography equipment would experience increased demand for their equipment.

The upper limit for a screening mammography service performed in 1990 would be $50. In subsequent years, the upper limit would be increased by the percentage increase in the Medicare Economic Index (MEI) for that subsequent year.

Nonparticipating physicians would be affected by this proposed rule. Section 1834(e)(5)(B) of the Act, with respect to screening mammography performed by a nonparticipating physician, places an upper limit on the amount that a nonparticipating physician or supplier can charge beneficiaries. In 1990, the first year of implementation, the upper charge limit would be 125 percent of the payment limit, which would be $62.50. In 1991, the upper charge limit would be 120 percent of the payment limit, and in subsequent years, the upper charge limit would be 115 percent of the payment limit.

Below is a discussion of several areas in which we are using administrative discretion with respect to physicians and other health care suppliers and a discussion of why we believe, with the exception of the proposed equipment standards, their effects on these entities would be negligible.

First, in developing the equipment standards for screening mammography, we have incorporated FDA requirements and have also adopted suggestions from the FDA and ACR. Although in certain respects the proposed equipment standards go beyond what is currently required by the FDA for diagnostic X-ray systems and radiographic equipment, we believe that the majority of physicians and healthcare suppliers would be able to meet them. This belief is based on the 1985–86 NEXT survey discussed in section II.B. of the preamble. This survey, conducted by the Conference of Radiation Control Program Directors, found that approximately 70 percent of currently existing mammography systems would meet the equipment standards we are proposing and about 30 percent would not.

Those physicians that possess mammography systems that would not meet the proposed equipment standards would incur additional expenses if they choose to meet these standards. One major factor in their decision as to whether to purchase this equipment might be the percentage of their patient population that are Medicare beneficiaries. We are unable to determine this percentage or the percentage of physicians who currently do not meet these proposed standards and would choose to comply with them. Thus, we cannot estimate the cost of compliance.

Second, in developing safety standards for screening mammography, we adapted the safety standards currently in use for portable X-ray equipment. Thus, for the most part the equipment and safety standards we are proposing are drawn from currently used standards and, therefore, would place little if any additional burden on most healthcare suppliers.

Third, the statute allows the Secretary to specify in regulations the appropriate organization to certify that an individual is qualified to perform radiological procedures and the appropriate board to certify that an individual is qualified to interpret radiological procedures, or be board eligible, or meet equivalent qualifications. We are proposing the use of two board certifying organizations—the American Board of Radiology and the American Osteopathic Board of Radiology. Use of these particular board certifying organizations poses no additional burden on radiologists since those organizations' board certification requirements are no more restrictive than current Medicare requirements that radiologists must meet in order to perform radiological services other than screening mammographies for Medicare beneficiaries.

Furthermore, as stated in section II.B. of the preamble, in consultation with the FDA, ACR, and NCI, we would require in § 494.54(b) that the interpreting physician meet several experience and continuing education standards specifically related to mammogram reading and interpretation. We believe that it is necessary to have these standards in order to implement the intent of Congress with regard to the safety and accuracy of screening mammography for Medicare beneficiaries.

We believe it is reasonable to expect physicians who perform screening mammographies for Medicare beneficiaries to have the experience and training in this area required by these proposed standards. Moreover, we do not believe that these proposed standards are onerous.

Lastly, at a new § 494.52, we would establish a condition requiring supervision of screening mammography by a qualified physician. As stated in section II.B. of the preamble, the physician supervisor must be a licensed doctor of medicine or licensed doctor of osteopathy who meets the requirements for the interpretation of screening mammograms as specified in § 494.54. The language we would use is similar to that used in 42 CFR 405.1412(a) which sets forth a supervising physician standard for coverage for portable X-ray services and 42 CFR 405.1412(b) which sets forth the required qualifications of the supervising physician. Because the supervising physician coverage standards we are proposing are drawn from currently used standards, we believe they would place little if any additional burden on most supervising physicians.

3. Effect on Beneficiaries

We believe that the effect of this proposed rule on beneficiaries would be a positive one. After meeting the $75 part B deductible, the only expense a beneficiary would incur for a covered screening mammography would be the 20 percent coinsurance if the physician performing the service is a participating physician. For calendar year 1990, this would be no more than $10 (20 percent coinsurance × $50 limit). (If a nonparticipating physician is used, the physician is limited in what he or she can charge.)

There is an area in which we are using administrative discretion with respect to beneficiaries. The statute allows us to specify who we consider to be a high risk individual for the purpose of determining the frequency of screening mammography for an asymptomatic woman over 39 years of age, but under 50. The guidelines we proposed are ones we received from the National Cancer Institute of the National Institutes of Health. We believe they are broad enough to capture those asymptomatic women who have a demonstrable need for a screening mammography.

B. Rural Hospital Impact Statement

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital with fewer than 50 beds located outside of a Metropolitan Statistical Area.

We are not preparing a rural impact statement since we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on the operations of a substantial number of small rural hospitals.

IV. Information Collection Requirements

Proposed regulations at §§ 494.52, 494.54, 494.56, 494.58, and 494.64 contain

information collection and recordkeeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C 3501 *et seq.*). The information collection requirements concern written reports on examination results, interpretations, and employee records. The respondents who would provide the information are suppliers of mammography services. Public reporting burden for this collection of information is estimated to be [estimate to be provided before final publication] minutes/hours per response. A notice will be published in the **Federal Register** after approval is obtained. Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the OMB official whose name appears in the "ADDRESS" section of this preamble.

V. Response to Comments

Because of the large number of items of correspondence we normally receive on a proposed rule, we are not able to acknowledge or respond to them individually. However, we will consider all comments that we receive by the date and time specified in the "DATE" section of this preamble, and, if we proceed with a final rule, we will respond to the comments in the preamble of that rule.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 413

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 494

Mammography, X-rays, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR chapter IV would be amended as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Part 405, subpart C is amended as set forth below:

Subpart C—Exclusions, Recovery of Overpayment, Liability of a Certifying Officer, and Suspension of Payment

1. The authority citation for subpart C is amended to read as follows:

Authority: Secs. 1102, 1815, 1833, 1834, 1842, 1861, 1862, 1866, 1870, 1871 and 1879 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395l, 1395m, 1395u, 1395x, 1395y, 1395cc, 1395gg, 1395hh, and 1395pp) and 31 U.S.C. 3711.

2. In Section 405.310 the introductory text of the section and the introductory text of paragraph (a) are reprinted and (a)(1) is revised to read as follows:

§ 405.310 Particular services excluded from coverage.

The following services are excluded from coverage.

(a) *Routine physical checkups such as*—

(1) Examinations performed for a purpose other than treatment or diagnosis of a specific illness, symptom, complaint, or injury, except for screening mammography (including a physician's interpretation of the results) that meets the payment requirements specified at § 410.34 of this chapter and the conditions for coverage at subpart B, part 494 of this chapter.

* * * * *

B. Part 405, subpart E is amended as set forth below:

Subpart E—Criteria for Determination of Reasonable Charges; Radiology Fee Schedules; and Reimbursement for Services of Hospital Interns, Residents, and Supervising Physicians

1. The authority citation for subpart E continues to read as follows:

Authority: Secs. 1102, 1814(b), 1832, 1833(a), 1834 (b) and (e), 1842 (b) and (h), 1861 (b) and (v), 1862(a)(14), 1866(a), 1871, 1881, 1886, 1887, and 1889 of the Social Security Act as amended (42 U.S.C. 1302, 1395f(b), 1395k, 1395l(a), 1395m (b) and (e), 1395u (b) and (h), 1395x (b) and (v), 1395y(a)(14), 1395cc(a), 1395hh, 1395rr, 1395ww, 1395xx, and 1395zz).

2. A new § 405.534 is added to read as follows:

§ 405.534 Limitation on payment for screening mammography services.

This section implements section 1834(e) of the Act by establishing a limit on payment for screening mammography examinations. There are three categories of billing for screening mammography services. Those categories and the payment limitations on each follow:

(a) *Global or complete service billing representing both the professional and technical components of the procedure.* When a global service fee is billed, the amount of payment subject to the deductible is equal to 80 percent of the least of the—

(1) Actual charge for the service;

(2) Amount determined with respect to the professional and technical components for the service under §§ 405.530 through 405.533; or

(3) Limit for the procedure. For services furnished in calendar year 1990, the limit is $50. On January 1 of each subsequent year, the limit will be updated by the percentage increase in the Medicare Economic Index (MEI).

(b) *Professional component billing representing only the physician's interpretation for the procedure.* When the professional component of screening mammography services is billed separately, the amount of payment for that professional component subject to the deductible is equal to 80 percent of the least of the—

(1) Actual charge for the professional component of the service;

(2) Amount determined with respect to the professional component for the service under §§ 405.530 through 405.533, which set forth the methodology for computing payments for radiologist services; or

(3) Professional portion of the screening mammography limit. This amount is determined by multiplying the screening mammography limit described in paragraph (a)(3) of this section by 37 percent.

(c) *Technical component billing representing other resources involved in furnishing the procedure.* When the technical component of screening mammography services is billed separately, the amount of payment subject to the deductible is equal to 80 percent of the least of the—

(1) Actual charge for the technical component of the service;

(2) Amount determined with respect to the technical component for the service under §§ 405.530 through 405.533; or

(3) Technical portion of the screening mammography limit. This amount is determined by multiplying the screening mammography limit described in paragraph (a)(3) of this section by 63 percent.

3. A new § 405.535 is added to read as follows:

§ 405.535 Special rules for nonparticipating physicians furnishing screening mammography services.

If screening mammography services are furnished to a beneficiary by a nonparticipating physician or supplier who does not accept assignment, a special limiting charge applies to the charges made to the beneficiary. The limiting charge is the lesser of—

(a) The amount determined using § 405.533 (special rules for nonparticipating physicians furnishing radiology services); or

(b) A percentage of the payment limit for screening mammograms as follows:

(1) 125 percent of the payment limit in 1990;

(2) 120 percent of the payment limit in 1991; and

(3) 115 percent of the payment limit beginning January 1, 1992.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

C. Part 410, Subpart B is amended as set forth below:

1. The authority citation for part 410 is revised to read as follows:

Authority: Secs. 1102, 1832, 1833, 1834, 1835, 1861, (r), (s) and (cc), 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395k, 1395l, 1395m, 1395n, 1395x, (r), (s) and (cc), 1395hh, and 1395rr).

2. Section 410.1 is amended by revising paragraph (a) to read as follows:

§ 410.1 Basis and scope.

(a) *Statutory basis.* Section 1832 of the Social Security Act establishes the scope of benefits provided under the Medicare Part B supplementary medical insurance (SMI) program. Sections 1833, 1834, 1835, and 1862 set forth the amounts of payment for SMI services, the conditions for payment, and the exclusions from coverage. Section 1861 defines the kinds of services that may be covered.

* * * * * * *

Subpart B—Medical and Other Health Services

3. In § 410.10, the introductory text is reprinted and paragraph (t) is added to read as follows:

§ 410.10 Medical and other health services: Included services.

Subject to the conditions and limitations specified in § 410.12, "medical and other health services" includes the following services:

* * * * *

(t) Screening mammography services.

§ 410.35 [Redesignated from § 410.34]

4. The current § 410.34 is redesignated as § 410.35, and a new § 410.34 is added to read as follows:

§ 410.34 Conditions for coverage for and limitations on coverage for screening mammography services.

Effective January 1, 1990, Medicare pays for screening mammography services (including physician interpretation of the results). Screening mammography is defined as a radiologic procedure furnished to a woman for the purpose of early detection of breast cancer and includes a physician's interpretation of the results of the procedure.

(a) Coverage is available for screening mammography services only if furnished by a screening mammography supplier that meets all the conditions for coverage of screening mammography specified in subpart B of part 494 of this chapter.

(b) The following limitations apply to coverage of screening mammography services:

(1) The service must be a four-view exposure (that is, a cranio-caudal and a medial lateral oblique view of each breast) furnished by a supplier that meets the conditions for coverage of screening mammography services specified in subpart B of part 494 of this chapter.

(2) Payment may not be made for screening mammography performed on an asymptomatic woman under 35 years of age.

(3) Payment may be made for only 1 screening mammography performed on an asymptomatic woman over 34 years of age, but under age 40.

(4) For an asymptomatic woman over 39 years of age, but under age 50, the following restrictions apply:

(i) Payment may be made for a screening mammography performed after at least 11 months have passed since the last screening mammography if the woman has—

(A) A personal history of breast cancer;

(B) A personal history of biopsy-proven benign breast disease;

(C) A mother, sister, or daughter who has had breast cancer; or

(D) Not given birth prior to age 30.

(ii) If the woman does not meet the conditions described in paragraph (b)(4)(i) of this section, payment may be made for a screening mammography performed after at least 23 months have passed since the last screening mammography.

(5) For an asymptomatic woman over 49 years of age, but under age 65, payment may be made for a screening mammography performed after at least 11 months have passed since the last screening mammography.

(6) For an asymptomatic woman over 64 years of age, payment may be made for a screening mammography performed after at least 23 months since the last screening mammography.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES

D. Part 413, subpart F is amended as set forth below:

1. The authority citation for Part 413 is revised to read as follows:

Authority: Secs. 1102, 1122, 1814(b), 1815, 1833(a), 1834(e), 1861(v), 1871, 1881, and 1886 of the Social Security Act as amended (42 U.S.C. 1302, 1320a–1, 1395f(b), 1395g, 1395l(a), 1395m(e), 1395x(v), 1395hh, 1395rr, and 1395ww).

Subpart F—Specific Categories of Costs

2. A new § 413.123 is added to read as follows:

§ 413.123 Payment for screening mammography performed by hospitals on an outpatient basis.

(a) *Basis and scope.* This section implements section 1834(e)(1)(C) of the Act and establishes the method for determining Medicare payment for screening mammographies performed by hospitals.

(b) *Payment to hospitals on an outpatient basis.* Payment to hospitals for screening mammography services performed on an outpatient basis (described in § 410.33 of this chapter) is determined in accordance with § 405.534(c) of this chapter.

E. A new part 494 is added to read as follows:

PART 494—CONDITIONS FOR COVERAGE OF PARTICULAR SERVICES

Subpart A—General Provisions [Reserved]

Subpart B—Conditions for Coverage of Screening Mammography

Sec.

494.50 Condition for coverage: General.

494.51 Conditions for coverage: Compliance with Federal, State, and local laws and regulations.

494.52 Condition for coverage: Supervision by a qualified physician.

494.54 Condition for coverage: Interpretation of the results of screening mammography procedures.

494.56 Condition for coverage: Qualifications and orientation of technical personnel, and retention of employee records.

Sec.

Authority: Secs. 1833(a)(2)(E), 1834, 1861, 1862(a), 1863, 1864(a), 1865(a), 1902(a)(9)(C), and 1915(a)(1)(B)(ii)(I) of the Social Security Act (42 U.S.C. 13951(a)(2)(E), 1395m, 1395x, 1395y(a), 1395z, 1395aa(a), 1395bb(a), 1396a(a)(9)(C), and 1396n(a)(1)(B)(ii)(I)).

Subpart A—General Provisions [Reserved]

Subpart B—Conditions for Coverage of Screening Mammography

§ 494.50 Condition for coverage: General.

To be approved for participation in the Medicare program a supplier of screening mammography services must meet all the conditions set forth in this subpart with respect to individuals entitled to Medicare part B.

§ 494.51 Conditions for coverage: Compliance with Federal, State, and local laws and regulations.

The supplier of screening mammography services must comply with all applicable Federal, State, and local laws and regulations pertaining to radiological services and screening mammography services. This includes—

(a) Licensure or registration of supplier;

(b) Licensure or registration of personnel;

(c) Licensure or registration of equipment;

(d) Compliance with safety laws.

§ 494.52 Condition for coverage: Supervision by a qualified physician.

(a) *Standard: Qualifications of the physician supervisor.* Screening mammography services must be furnished under the supervision of a licensed doctor of medicine or licensed doctor of osteopathy who meets the requirements for the interpretation of the results of the screening mammography procedure as specified in § 494.54.

(b) *Standard: Physician supervision.* The provision of all screening mammography services must be supervised by a physician who must document in writing annually that—

(1) He or she has checked the procedural manuals and has observed monthly the operators' performance;

(2) He or she has verified that equipment and personnel meet applicable Federal, State, and local licensure and registration requirements;

(3) Safe operating procedures are used; and

(4) All the other requirements of this subpart are being met.

§ 494.54 Condition for coverage: Interpretation of the results of screening mammography procedures.

The results of all screening mammography procedures must be interpreted by a physician who meets the following certification, experience, continuing education, and written report requirements:

(a) *Standard: Board certification.* The interpreting physician must—

(1) Be certified by the American Board of Radiology or by the American Osteopathic Board of Radiology; or

(2) Possess equivalent certification qualifications.

(b) *Standard: Experience and continuing education.* (1) For physicians first meeting the board certification requirements or meeting other equivalent certification requirements described in paragraph (a) of this section before January 1, 1990, the physician must also—

(i) Have been reading the results of an average of 10 or more screening or diagnostic mammographies per work week in the 6 months preceding January 1, 1990.

(ii) Have successfully completed a minimum of 40 hours of post-graduate instruction in mammography interpretation in the 24 months preceding January 1, 1990;

(iii) Have successfully completed a minimum of 40 hours of post-graduate work in mammography interpretation every 24 months after January 1, 1990; and

(iv) Continue to read the results of an average of 10 or more screening or diagnostic mammographies per work week after he or she begins to read screening mammographies for Medicare beneficiaries.

(2) For physicians first meeting the board certification requirement or meeting other equivalent certification qualifications described in paragraph (a) of this section on or after January 1, 1990, the physician must also—

(i) Have been reading the results of an average of 10 or more screening or diagnostic mammographies per work week in the 6 months preceding when he or she begins reading screening mammographies for Medicare beneficiaries;

(ii) Have successfully completed a minimum of 40 hours of post-graduate instruction in mammography interpretation in the 24 months preceding when he or she begins reading screening mammographies for Medicare beneficiaries.

(iii) Have successfully completed a minimum of 40 hours of post-graduate work in mammography interpretation every 24 months after the date he or she begins reading screening mammographies for Medicare beneficiaries; and

(iv) Continue to read the results of an average of 10 or more screening or diagnostic mammographies per work week after he or she begins to read screening mammographies for Medicare beneficiaries.

(c) *Standard: Written and signed report.* The interpreting physician must—

(1) Prepare and sign a written report on his or her interpretation of the results (that is, images or films) of the screening mammography procedure;

(2) Provide a copy of the written report and the original images or films to the patient's screening mammography supplier for inclusion in the patient's permanent medical record; and

(3) Provide a written statement to the patient, in terms easily understood by a lay person. The statement must describe the importance of the screening mammography to her ongoing health (including a description of the steps that should be taken if the results of the mammography procedure are positive), as well as her responsibility to share with any new physician or supplier of her next screening mammography procedure, the date and place of her previous screening mammography procedure. The statement must record the date of the procedure, the name of the facility providing the procedure, the physician (if any) to whom the woman wants a copy to be sent, and must indicate that the original images or films have been provided to the screening mammography supplier for inclusion in the woman's permanent medical record.

§ 494.56 Condition for coverage: Qualifications and orientation of technical personnel, and retention of employee records.

(a) *Standard: Qualifications of operators of screening mammography equipment.* Anyone operating screening mammography equipment must—

(1) Be licensed by the State to perform radiological procedures, or, in States that have no licensure requirements, be certified in radiography by the American Registry of Radiologic Technologists, the American Registry of Clinical Radiographic Technologists, or possess equivalent certification qualifications;

(2) Have successfully completed a program of formal training in radiologic

technology of not less than 24 months' duration in a school that meets the requirements of appendix A (Standards for Accreditation of Educational Programs for Radiographers) of 42 CFR part 75, or that is approved by the Council on Allied Health Education and Accreditation; and

(3) Have completed specialized training in mammographic positioning, compression, and technique factor settings in the 24 months preceding January 1, 1990 (or in the 24 months preceding the time he or she begins performing screening mammographies for Medicare beneficiaries), and complete this specialized training every 24 months thereafter.

(b) *Standard: Personnel orientation.* The supplier of screening mammography services must have an orientation program for operators of mammography equipment based on a procedures manual that is available to all members of the staff and that incorporates relevant documents, and instructions concerning the following:

(1) Precautions to protect the operator of the equipment, the patient and individuals in the surrounding area from unnecessary exposure to radiation.

(2) Determination of the area that will receive the primary beam (breast positioning).

(3) Pertinent information on compression, exposure levels, resolution, contrast, noise, examination identification, artifacts, and average glandular dose per view.

(4) Employee responsibilities concerning the proper use of personal radiation monitors.

(5) Proper use and maintenance of equipment, including a discussion of the image receptors appropriate for use with mammography and the kV-target-filter combination to be used with each image receptor.

(6) Proper maintenance of records.

(7) Possible technical problems and solutions.

(8) Protection against electrical hazards.

(9) Hazards of excessive exposure to radiation.

(c) *Standard: Qualifications of individuals furnishing diagnostic x-ray physics support.* Individuals furnishing diagnostic x-ray physics support must meet one of the following qualifications.

(1) The individual must be certified by the American Board of Radiology as a diagnostic medical physicist or possess equivalent qualifications. Additionally, the individual must meet minimum training, experience, and continuing education requirements pertinent to screening mammography.

(2) The individual must be recognized by a State radiation control agency as qualified to provide oversight of the establishment and conduct of the quality assurance program in § 494.64, which sets forth the standards of a quality assurance program for screening mammography required as a condition of coverage.

(d) *Standard: Employee records.* Records are maintained to show that each employee is qualified for his or her position by means of appropriate State licensure, other certification, training, and experience.

§ 494.58 Condition for coverage: Obtaining and preserving records.

All reasonable efforts must be made by the supplier of the current examination to obtain any of the beneficiary's previous screening mammography records, including original images and films, copies of written reports prepared by interpreting physicians, and other relevant information pertinent to previous screening mammographies that might be available from others, for comparison with the current screening mammography records. Records of previous screening mammographies obtained and of current and subsequent screening mammographies performed by the supplier must be properly preserved and made available to other qualified mammography suppliers or others that submit a written request authorized by the beneficiary.

(a) *Standard: Records of screening mammography services performed by the supplier.* The supplier must make, for each beneficiary, a record of the screening mammography services it provides, including—

(1) The date the screening mammography procedure was performed and the date of the interpretation;

(2) The name of the beneficiary;

(3) The name of the operator of the equipment and the name of the interpreting physician;

(4) A description of the procedures performed;

(5) The name of the referring physician (if any), or other physician (if any) identified by the beneficiary to receive the interpreting physician's written report; and

(6) The date the physician's written report was sent to the appropriate physician or beneficiary.

(b) *Standard: Preservation of records.* The supplier must provide satisfactory assurances (as documented in its medical records) that the images or films of the first and subsequent screening mammography procedures and the related written reports of the physicians' interpretations for each beneficiary are either placed in her permanent medical record kept by the supplier, or sent to another person (including the beneficiary) for placement in the beneficiary's permanent medical record as directed by her or by her physician. If the records of the examination must be retained by the supplier, they must be retained for a period of at least 60 calendar months following the date of service (or longer if required by State law).

§ 494.60 Condition for coverage: Equipment standards.

The equipment used to perform mammography must be specifically designed for mammography and must meet the following standards:

(a) *Standards: Equipment design.* The equipment must be specifically designed for mammography and identified by the manufacturer as designed only for mammography.

(b) *Standard: FDA standards.* The equipment must meet the FDA performance standards for diagnostic X-ray systems and their major components at 21 CFR 1020.30 and FDA's standards for radiographic equipment at 21 CFR 1020.31.

(c) *Standard: Image receptor systems.* The image receptor systems and all their individual components must be designed appropriately for mammography.

(d) *Standard: kV-target-filter combinations.* The equipment must be limited to providing kV-target-filter combinations appropriate to image receptors meeting the requirements of paragraph (c) of this section.

(e) *Standard: Focal spot size.* The nominal focal spot size of the X-ray tube must not exceed 0.7 mm.

(f) *Standard: Devices to immobilize and compress the breast.* Devices parallel to the imaging plane must be available to immobilize and compress the breast.

(g) *Standard: Anti-scatter grids.* The equipment must have the capability for using anti-scatter grids.

(h) *Standard: Automatic exposure control.* The equipment must have the capability of automatic exposure control.

(i) *Standard: Control panel indicators.* The equipment must have a control panel that includes a device (usually a milliammeter) or means for an audible signal to give positive indication of the production of X-rays whenever the X-ray tube is energized. The control panel must include appropriate indicators (labeled control settings of meters that show the physical factors such as

kilovoltage potential (kVp), milliampere seconds (mAs), exposure time, or whether timing is automatic) used for exposure.

§ 494.62 Condition for coverage: Safety standards.

Screening mammograms must be conducted using equipment and operating procedures free of unnecessary hazards and providing minimum radiation exposure to patients, personnel, and other persons in the immediate environment.

(a) *Standard: Safety precautions.* Proper safety precautions must be maintained. This includes adequate shielding for patients, personnel, and facilities. The equipment must be operable only from a shielded position.

(b) *Standard: Exposure badges.* Personnel operating the equipment must wear badges or other appropriate devices to measure their radiation exposure.

(c) *Standard: Equipment inspection.* Periodic inspection of equipment and shielding must be made by a staff or consultant medical physicist or by a physicist approved by an appropriate State or local government agency as meeting the qualification requirements of § 494.56(c). Identified hazards must be promptly corrected.

(d) *Standard: Protection against electrical hazards.* All equipment must be shockproof and grounded.

§ 494.64 Condition for coverage: Quality assurance.

The supplier must have an ongoing equipment quality assurance program specific to mammography imagery, and covering all components of the X-ray system, from the X-ray generator to the image developer, to ensure consistently high-quality images with minimum patient exposure. The supplier must conduct a general review of the program at least annually, and have available the services of a person qualified to furnish diagnostic X-ray physics support who, under the direction of the supervising physician described in § 494.52, is responsible for establishing and conducting the program.

(a) *Standard: Responsibility for the quality assurance program.* Under the direction of the supervising physician, the person furnishing diagnostic X-ray physics support has the overall responsibility for establishing and conducting the ongoing equipment quality assurance program. That individual's specific duties must include—

(1) Conducting or training others to conduct equipment performance monitoring functions;

(2) Analyzing the monitoring results to determine if there are any problems requiring correction; and

(3) Carrying out or arranging for the necessary corrective actions as well as for the calibrations and other preventive maintenance.

(b) *Standard: Calibration of equipment.* All variable parameters of the equipment must be calibrated—

(1) When the equipment is first installed;

(2) After any major changes or replacement of parts;

(3) At least annually during use; and

(4) When quality assurance tests indicate that calibration is needed.

(c) *Standard: Performance monitoring.* The supplier must routinely monitor the performance of the mammography system.

(1) At a minimum, the parameters that must be monitored are—

(i) Processor performance (through sensitometric-densitometric means);

(ii) Half value layer;

(iii) Output reproducibility and linearity;

(iv) Automatic exposure control reproducibility, kVp response, and thickness response;

(v) Adequacy of film storage (both before use and after exposure if processing does not occur immediately;

(vi) Availability and use of technique charts that must include an indication of the kV-target-filter combination to be used with each image receptor;

(vii) Darkroom integrity;

(viii) Image quality (using a testing device called a "phantom", which simulates the composition of the breast and indicators of disease conditions, allowing objective analysis of clinical image quality); and

(ix) Dose.

(2) The equipment must be monitored as follows:

(i) Processor performance and the use of a kV-target-filter combination appropriate to the image receptor must be monitored daily before patient irradiation.

(ii) Image quality must be monitored with a phantom every time the unit is moved, altered in any major way including the replacement of parts, and at least monthly between movements or alterations.

(iii) The frequency of monitoring all other parameters must be proportional to the expected variability of each parameter, but monitoring must be conducted at least annually.

(d) *Standard: Evaluation of monitoring results.* Monitoring must be evaluated on a regular basis.

(1) Standards of image quality giving acceptable ranges of values for each of the parameters tested must be established to aid in the evaluation. The standards of image quality related to dose must include a requirement that the mean glandular dose for one craniocaudal view of a 4.5 cm compressed breast (50 percent adipose/50 percent glandular) must not exceed 100, 300, and 400 mrad (millirad) for film/screen units without grids, film/screen units with grids, and xerography units, respectively.

(2) The monitoring results must be compared routinely to the standards of image quality. If the results fall outside the acceptable range, the test must be repeated. If the results continue to be unacceptable, the source of the problem must be identified and corrected before further examinations are conducted.

(e) *Standard: Retake analysis program.* A program to analyze retakes must be established as a further aid in detecting and correcting problems affecting image quality or exposure.

(f) *Standard: Responsible personnel.* Responsibility for each standard, from monitoring through the annual review, must be assigned to qualified personnel. These assignments must be documented in the supplier's records.

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Acting Administrator, Health Care Financing Administration.

Louis W. Sullivan,

Secretary.

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