

TIME AND DATE: April 24-25, 1985, 9:00 a.m.

PLACE: Federal Building, South Auditorium, 915 Second Avenue, Seattle, Washington.

MATTERS TO BE CONSIDERED:

- Council Decision on Draft Load Forecasts
- Staff Presentation on the Status of Resource Portfolio Analysis
- Staff Presentation on Institutional Arrangements Issue Paper
- Council Decision on Use of Non-Firm Power (Including the Interruptibility of the Direct Service Industries)
- Public Comment on Proposed Council Interim Access Policy Issue Paper
- Public Comment on Out-of-Region Imports/Exports Issue Paper
- Staff Presentation and Public Comment on Re-Evaluation of the Model Conservation Standards Issue Paper
- Staff Presentation on Potential and Achievable Conservation Issue Paper
- Council Decision on Cost and Availability of Generating Resources
- Staff Presentation on Lost Opportunity Resources
- Public Comment on Research, Development and Demonstration of Promising Resources
- Council Business

Public comment will follow each item.

FOR FURTHER INFORMATION CONTACT:

Ms. Bess Wong, (503) 222-5161.

Edward Sheets,

Executive Director.

[FR Doc. 85-9282 Filed 4-15-85; 8:45 am]

BILLING CODE 0000-00-M

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SECURITIES AND EXCHANGE COMMISSION

Notice is hereby given pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of April 22, 1985.

An open meeting will be held on Tuesday, April, 23, 1985, at 2:30 p.m., in Room 1C30, followed by a closed meeting.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, the items to be considered at the closed meeting may be considered pursuant to one or more to the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9) (A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10).

Commissioner Cox, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the open meeting scheduled for Tuesday, April 23, 1985, at 2:30 p.m., will be:

1. Consideration of whether to approve under section 210(b) of the Investment Advisers Act of 1940 a program to share information with state securities officials regarding Commission adviser examinations. For further information, please contact Gene A. Gohlke at (202) 272-2024.

2. Consideration of whether to propose for public comment a revised Form ADV under the Investment Advisers Act of 1940 which would make the investment adviser registration application form a uniform form for use by both the commission and the states. For further information, please contact Mary Podesta at (202) 272-2107.

3. Consideration of whether to issue a release proposing for public comment revisions to Form BD, other related technical changes, and amendments to the broker-dealer successor rules, to reduce the regulatory burden on broker-dealers by revising the disciplinary question to remove duplicative information requirements and narrow the scope of that question, by clarifying the information required to be disclosed on the schedules, by making the information requested under Rule 17a-3 of the Securities Exchange Act of 1934 conform to

that requiring in the revised Form U-4, and by amending the broker-dealer successor rules to allow a broker-dealer to file an amendment to Form BD rather than a complete Form BD. For further information, please contact Valerie Golden at (202) 272-2848.

4. Consideration of an amendment to Rule (b)(2) of the Commission's Conduct Regulation, 17 CFR 200.734-3(b)(2). For further information, please contact Myrna Siegel at (202) 272-2430.

5. Consideration of whether to adopt two new registration forms, Forms S-4 (for all registrants) and F-4 (for certain foreign private issuers) to be used for the registration of securities in connection with merger proxies and exchange Patricia B. Magee at (202) 272-2589 (re Form S-4) or Martin L. Meyrowitz at (202) 272-3250 (re Form F-4).

6. Consideration of whether to issue a release proposing technical amendments to Rule 3A-02 of Regulation S-X, "Consolidated financial statements of the registrant and its subsidiaries." For further information, please contact Dorothy Walker at (202) 272-7343.

(This item was previously noticed in 50 FR 14192, April 10, 1985)

The subject matter of the closed meeting scheduled for Tuesday, April 23, 1985, following the 2:30 p.m. open meeting, will be:

Formal orders of investigation.

Settlement of administrative proceedings of an enforcement nature.

Institution of administrative proceedings of an enforcement nature.

Institution of injunctive actions.

Opinion.

At times changes in commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Angela Hall at (202) 272-3085.

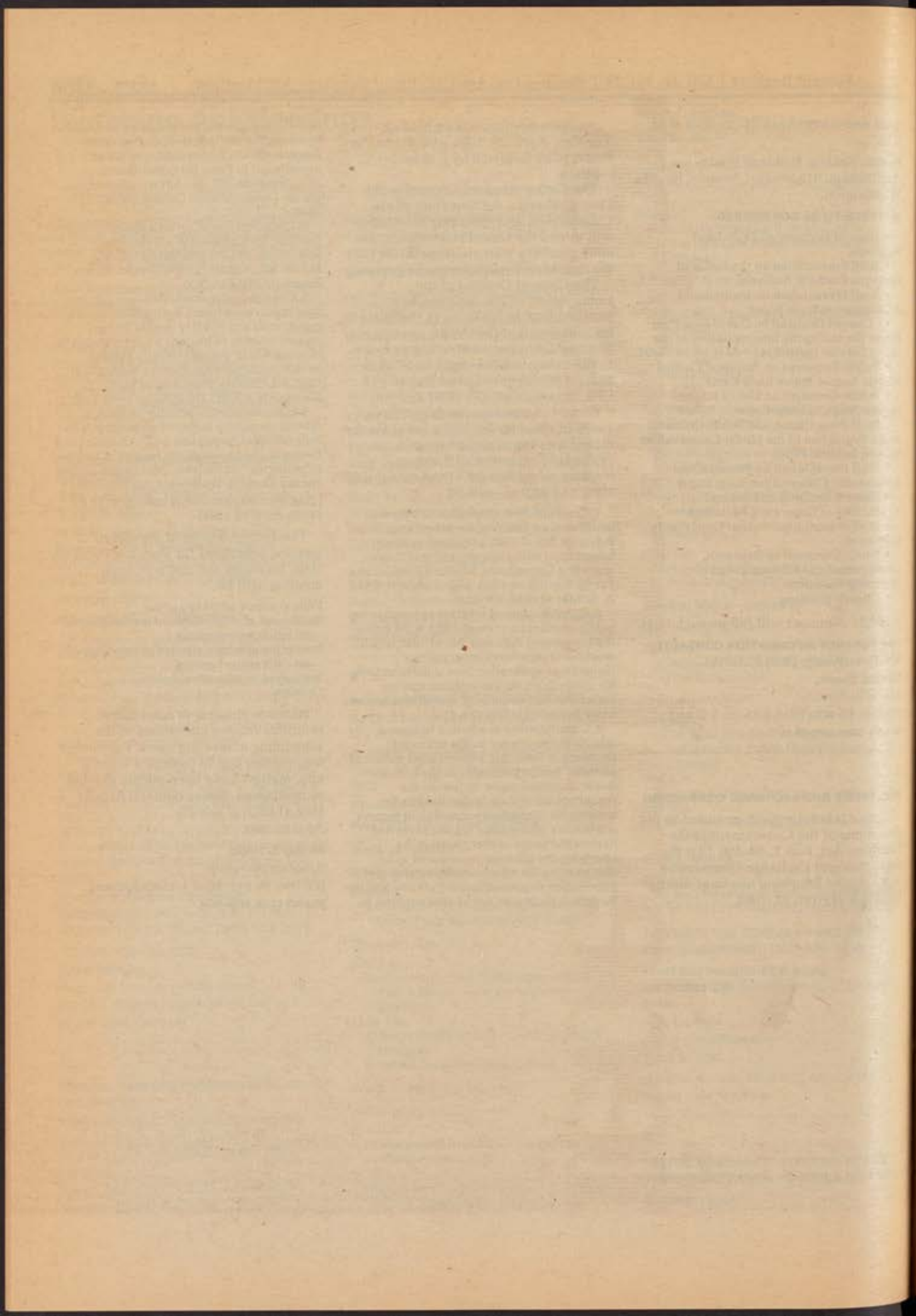
April 15, 1985.

Shirley E. Hollis,

Assistant Secretary.

[FR Doc. 85-9382 Filed 4-15-85 3:45 pm]

BILLING CODE 8010-10-M



Federal Register

**Wednesday
April 17, 1985**

Part II

Department of the Interior

Bureau of Indian Affairs

List of Indian Estates Affected by Old Age Assistance Claims; Notice

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

List of Indian Estates Affected by Old Age Assistance Claims

ACTION: Notice of Reimbursement.

This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Deputy Assistant Secretary—Indian Affairs by 209 DM 8.

SUMMARY: This notice lists all Indian trust estates identified by the Department of the Interior, from which unauthorized disbursements were made by the Secretary of the Interior to States, or political subdivisions thereof, as reimbursement for old age assistance provided to deceased Indians before death in violation of Federal laws. This notice is required by section 4(a) of the Old Age Assistance Claims Settlement Act of October 19, 1984, Pub. L. 98-500.

DATE: This notice establishes that tribes, bands, groups and individual Indians shall have until October 14, 1985, to submit to the Secretary of the Interior, through the proper Area Office, the names of any additional trust estates from which unauthorized disbursements were made and which are not contained in this list.

FOR FURTHER INFORMATION CONTACT:

Aberdeen Area Director, Bureau of Indian Affairs, 115 4th Avenue, S.E., Aberdeen, South Dakota 57401, Telephone: (605) 225-0250;

Albuquerque Area Director, Bureau of Indian Affairs, 5301 Central Avenue, N.E., P.O. Box 8327, Albuquerque, New Mexico 87198, Telephone: (505) 766-3170;

Anadarko Area Director, Bureau of Indian Affairs, Federal Building, P.O. Box 368, Anadarko, Oklahoma 73005, Telephone: (405) 247-6673;

Billings Area Director, Bureau of Indian Affairs, 316 North 26th Street, Billings, Montana 59101, Telephone: (406) 657-6315;

Eastern Area Director, Bureau of Indian Affairs, 1951 Constitution Avenue, N.W., Washington, D.C. 20245, Telephone: (703) 235-2571;

Juneau Area Director, Bureau of Indian Affairs, Federal Building, P.O. Box 3-8000, Juneau, Alaska 99802, Telephone: (907) 586-7177;

Minneapolis Area Director, Bureau of Indian Affairs, Chamber of Commerce Building, 15 South Fifth Street, 10th Floor, Minneapolis, Minnesota 55402, Telephone: (612) 349-3631;

Muskogee Area Director, Bureau of Indian Affairs, Old Federal Building, Muskogee, Oklahoma 74401, Telephone: (918) 687-2295;

Navajo Area Director, Bureau of Indian Affairs, P.O. Box M., Window Rock, Arizona 86515, Telephone: (602) 871-5151;

Phoenix Area Director, Bureau of Indian Affairs, 3030 North Central, P.O. Box 7007, Phoenix, Arizona 85011, Telephone: (602) 241-2305;

Portland Area Director, Bureau of Indian Affairs, 1425 Irving Street, N.E., Portland, Oregon 97208, Telephone: (503) 231-6702; and

Sacramento Area Director, Bureau of Indian Affairs, 2800 Cottage Way, Sacramento, California 95825, Telephone: (916) 484-4682.

SUPPLEMENTARY INFORMATION: The Old Age Assistance Claims Settlement Act, Pub. L. 98-500, authorizes and directs the Secretary of the Interior to pay entitled individuals their portions of any unauthorized disbursement made from the trust estate of a deceased Indian to a State, or a political subdivision thereof, as reimbursement for old age assistance provided to the deceased Indian before death in violation of Federal laws governing Indian trust property. The Secretary of the Interior is further directed to search the records of the Department of the Interior to identify individuals who are entitled to payment, and to ascertain the amount of the unauthorized disbursement to which each of the individuals would be entitled. Any payment under the Act shall include simple interest at a rate of five percent per annum from the date on which such unauthorized disbursement was made from the trust estate of the deceased Indian. No payments shall be made with respect to any unauthorized disbursement from the trust estate of a deceased Indian if the total amount of such unauthorized disbursement was less than \$50.

This notice lists all Indian trust estates, identified by the Department of the Interior, from which unauthorized disbursements were made for the purpose of reimbursement for old age assistance. Copies of the Old Age Assistance Claims Settlement Act, Pub. L. 98-500, and this document are being provided to all federally acknowledged Indian tribes.

Indian tribes, bands, groups and individual Indians have 180 days, or until October 14, 1985, to submit to the appropriate area Office, in writing, the names of any additional qualified estates not listed in this document. (See the **FOR FURTHER INFORMATION CONTACT** section of this document for the names, addresses and telephone numbers of the Area Offices.) The name of any additional qualified estate submitted to an Area Office must be accompanied

by: (1) The name and tribal affiliation of the Indian decedent, (2) the date and number of the Departmental probate order determining heirs of the trust estate, and (3) evidence that a payment was made from the trust estate of the decedent as reimbursement for old age assistance. Within 30 days after the expiration of the 180-day period, the Secretary of the Interior will publish in the *Federal Register* a supplemental list identifying those additional qualified estates submitted to Area Offices by tribes, bands, groups and individual Indians.

The payment and acceptance of any claim, after its determination in accordance with the Act, shall be a full discharge to the United States and any State, or political subdivision thereof, of all claims and demands touching any of the matters involved in the controversy.

Because of the numerous estates listed in the document, this notice may be subject to technical clarification or change.

John W. Fritz,

Deputy Assistant Secretary—Indian Affairs.

Instruction Sheet

Each estate from which an unauthorized payment was made has been assigned a nine or ten character issue number (a letter followed by eight or nine numbers). The first six characters identify a specific Bureau of Indian Affairs Area Office, Agency Office and tribe. The last three or four characters represent the specific numbers assigned to that estate from which an unauthorized payment was made. For example, A013400001 indicates:

A01—Aberdeen Area Office/Cheyenne River Agency

340—Cheyenne River Sioux Tribe

0001—Estate number one

To locate an estate, begin with the Table of Contents which lists each affected tribe (grouped by Area Office and Agency) and the pages where the estates for individuals affiliated with such tribe can be found. The list of estates has been reproduced by photographing two pages of the list to each *Federal Register* page. The page number referred to in the Table of Contents is located at the top center above the name of the Area Office and is not the five digit *Federal Register* page number located on the outer portion of each page.

If a tribe is not listed in the Table of Contents, no estate was identified for any individual affiliated with such tribe.

Each page of estates contains five columns of information under the

headings: Issue Number, Decedent Name, Decedent ID, \$ Allowed, \$ Paid.

Issue Number: The nine or ten character code (explained above) which identifies the Area Office/Agency/Tribe/and specific number assigned to that estate.

Decedent Name: The name of the deceased Indian whose Departmental records contain evidence that an unauthorized payment was made from his/her trust estate as reimbursement for old age assistance.

Decedent ID: The decedent's identification number. This number usually coincides with the decedent's allotment number, tribal enrollment number, or, in their absence, a number assigned by the Bureau of Indian Affairs.

\$ Allowed: The amount of money, cited in the decedent's probate order, which was allowed as a claim to be paid from the decedent's trust estate as

reimbursement to the State, or political subdivision thereof, for old age assistance. This figure appears in the list as an indication that the Departmental records contain evidence that some money was actually paid from the decedent's trust estate as reimbursement for old age assistance.

\$ Paid: The amount of money actually paid (the amount of the unauthorized disbursement) from the decedent's trust estate as reimbursement to the State, or political subdivision thereof, for old age assistance. This figure is supported by evidence appearing in Departmental records. Where the Departmental records contain evidence that money was paid from the decedent's trust estate as reimbursement for old age assistance, but the exact amount is not known, the word UNKNOWN appears in this column; further research is needed to ascertain such amount. Those amounts ascertained after this list is

published will appear on the supplementary list of estates to be published in the Federal Register 30 days after the expiration of the aforementioned 180-day period.

If, after locating an estate on the list, you desire further information, call or write the Area Office under which the estate is listed. The names, addresses, and telephone numbers for all Area Offices are contained in the **FOR FURTHER INFORMATION CONTACT** section of this document. Be sure to include the complete issue number in any correspondence with the Bureau of Indian Affairs Area or Agency Office. It is important to remember that additional qualified estates must be submitted in writing, together with evidence of the unauthorized disbursement, to the appropriate Area Office within 180 days of the publication of this document.

BILLING CODE 4310-02-M

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ASCENDING AREA

TRIBE CODE	AGENCY	TRIBE NAME	PAGE	ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	ALLOWED	#PAID
ARIZONA AREA								
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0004	JAMES ELLER (WILSON)	42	471.50	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0005	HANFAP L. NANCY (WEST)	36	671.50	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0011	THOMAS LOVEJOY	86137	2,454.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0012	JOHN A. LOVEJOY	0423	454.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0013	MINNIE LAMANCE	0249	27.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0014	CIRCLE EAGLE WILLIAM (FOUR)	1408	3,743.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0015	LONE HORSE PETER	1410	630.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0016	YELLOW SHIELD KNIFE NELLIE	2114	2,300.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0017	TOP OF THE LODGE JESSIE (EAGLE)	2022	2,347.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0018	LITTLE CROW GEORGE	1944	776.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0019	LEAR WELLS	1944	776.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0020	LITTLE WOUNDED JAMES	1441	569.50	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0021	LINDLEY LIZZIE N.	1244	82.50	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0022	WALKS RUNNING RATTLE CLARA	1236	21.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0023	WHITE WOLF THOMAS	1236	696.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0024	JAMES AFRID OF LIGHTENING	1239	650.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0025	DOG AR. ABRAHAM	1253	866.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0026	WAG SHAL THOMAS	1253	866.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0027	RICH LOUISE MARCELLE	1251	2,811.50	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0028	FIELDER TWO SPEARS ANNIE	1254	1,447.08	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0029	FOX LOUISE (BRIGET CURLEY)	1200	2,377.50	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0030	HAWK THAT DAVES SOLAMON	124	1,492.50	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0031	BLACK CHICKEN SAPHIA	544	3,508.50	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0032	RED HEAD NELLIE	2395	446.50	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0033	SETS OFF IDA	2351	446.50	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0034	BROWS AT A DISTANCE JESSIE	2386	4,000.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0035	COUNTING MARY	2357	1,133.00	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0036	CHAMBER MELLIE	2364	1,900.00	UNKNOWN
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A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0108	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0109	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0110	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0111	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0112	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0113	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0114	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0115	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0116	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0117	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0118	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0119	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0120	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0121	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0122	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0123	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0124	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0125	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0126	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0127	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0128	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0129	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0130	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0131	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0132	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0133	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0134	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAMBEAU	FLAMBEAU	1	A01-007-0135	FLORIAN GEORGE FLORA	195	18.44	UNKNOWN
A01-007	FLAM							

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	ALLOWED	PAID
AO1-00151	POOR ELK ANNIE	1322	1.50	1.50
AO1-00152	FOX THOMAS	3080	1.50	1.50
AO1-00153	LEE HENRY	401	1.50	1.50
AO1-00154	ALICE EDWARD	85	1.50	1.50
AO1-00155	MARSHALL TIA	877	1.50	1.50
AO1-00156	FRANKSIE ETIA	777	1.50	1.50
AO1-00157	BOTTOM SHOULDER JOHN	350	1.50	1.50
AO1-00158	FROM BIRD GEORGE	350	1.50	1.50
AO1-00159	ON THE TREE GEORGE	350	1.50	1.50
AO1-00160	HALF RED MAGGIE	350	1.50	1.50
AO1-00161	HARRY OAKES POWELL	2294	1.50	1.50
AO1-00162	HORSE WOMAN	2294	1.50	1.50
AO1-00163	ALBERT CML KING	2294	1.50	1.50
AO1-00164	JOHN DID NOT GO HOME	2294	1.50	1.50
AO1-00165	LOUIS POSEY MORAN	2294	1.50	1.50
AO1-00166	FRANK DUNN	2294	1.50	1.50
AO1-00167	FRANK IRON HAWK	2294	1.50	1.50
AO1-00168	MAGGIE SED HORSE	2294	1.50	1.50
AO1-00169	WELLIE KILLS THEM FIRST	2294	1.50	1.50
AO1-00170	ELMER WHITNEY	2294	1.50	1.50
AO1-00171	MORRIS TWO LANCE	2294	1.50	1.50
AO1-00172	GEORGE LANDREAU	2294	1.50	1.50
AO1-00173	ALBERT SAND	2294	1.50	1.50
AO1-00174	ROUSSEAU JULIA	2294	1.50	1.50
AO1-00175	LITTLE MOUNTAIN DELIA	2294	1.50	1.50
AO1-00176	KATIE CHARLES	2294	1.50	1.50
AO1-00177	MARSHALL ONE TRUD	2294	1.50	1.50
AO1-00178	BROWN WOLF PHILIP	2294	1.50	1.50
AO1-00179	SATTLING RIB LOUIS	2294	1.50	1.50
AO1-00180	MAS WATER ELIZABETH	2294	1.50	1.50
AO1-00181	MAYES IT LONG JOURNAL	2294	1.50	1.50
AO1-00182	CAGE KATE MRS	2294	1.50	1.50
AO1-00183	KITCHE SACK HARRY	2294	1.50	1.50
AO1-00184	JOHN SACK HARRY	2294	1.50	1.50
AO1-00185	JOHN SACK BULL	2294	1.50	1.50
AO1-00186	STAR MORAN (COW)	2294	1.50	1.50
AO1-00187	STAR MORAN (COW)	2294	1.50	1.50
AO1-00188	STAR MORAN (COW)	2294	1.50	1.50
AO1-00189	STAR MORAN (COW)	2294	1.50	1.50
AO1-00190	STAR MORAN (COW)	2294	1.50	1.50
AO1-00191	STAR MORAN (COW)	2294	1.50	1.50
AO1-00192	STAR MORAN (COW)	2294	1.50	1.50
AO1-00193	STAR MORAN (COW)	2294	1.50	1.50
AO1-00194	STAR MORAN (COW)	2294	1.50	1.50
AO1-00195	STAR MORAN (COW)	2294	1.50	1.50
AO1-00196	STAR MORAN (COW)	2294	1.50	1.50
AO1-00197	STAR MORAN (COW)	2294	1.50	1.50
AO1-00198	STAR MORAN (COW)	2294	1.50	1.50
AO1-00199	STAR MORAN (COW)	2294	1.50	1.50
AO1-00200	STAR MORAN (COW)	2294	1.50	1.50

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	ALLOWED	PAID
AO1-00201	POOR BUFFALO LUCY	2298	2.25	2.25
AO1-00202	FIRST BARK ALICE	2298	2.25	2.25
AO1-00203	COWLEY LOUISA	2298	2.25	2.25
AO1-00204	BEAR EAGLE GEORGE	1609	1.50	1.50
AO1-00205	WHITE LEATHER GEORGE	1609	1.50	1.50
AO1-00206	SPONT WOMAN BECCA	1609	1.50	1.50
AO1-00207	CREEK WALTER DANIEL	1609	1.50	1.50
AO1-00208	BRUGGER ANNE	1609	1.50	1.50
AO1-00209	SMITH BEAR THOMAS	1609	1.50	1.50
AO1-00210	ROBERTS JENNIE	1609	1.50	1.50
AO1-00211	WHITE EAGLE KATE	1609	1.50	1.50
AO1-00212	BLACK EAGLE KATE	1609	1.50	1.50
AO1-00213	ELK HEAD PHILIP	1609	1.50	1.50
AO1-00214	BULL HAN MARY	1609	1.50	1.50
AO1-00215	HIGH EAGLE ANNS	1609	1.50	1.50
AO1-00216	CARTER CATHERINE	1609	1.50	1.50
AO1-00217	AMIE BLACKDART	1609	1.50	1.50
AO1-00218	BLACKMAN NELLIE	1609	1.50	1.50
AO1-00219	SPOTTED HORSE MRS. JOHN	1609	1.50	1.50
AO1-00220	PETER ONE SHANK	1609	1.50	1.50
AO1-00221	MISS IN THE WOODS SOPHIA	1609	1.50	1.50
AO1-00222	BEAR EAGLE ANNIE	1609	1.50	1.50
AO1-00223	HOUSE RUNNING ANNIE	1609	1.50	1.50
AO1-00224	EAGLE BODY ANNIE	1609	1.50	1.50
AO1-00225	BLACK EAGLE LOUISE	1609	1.50	1.50
AO1-00226	WHITE HAWK JOHN	1609	1.50	1.50
AO1-00227	LONG LAG HARRY	1609	1.50	1.50
AO1-00228	LUPRIS EMILY	1609	1.50	1.50
AO1-00229	BUCHERMAUX VICTOR SR.	1609	1.50	1.50
AO1-00230	LAURELUX JOSEPHINE	1609	1.50	1.50
AO1-00231	STANDING ELK MATHEW	1609	1.50	1.50
AO1-00232	VEDO CHARLES	1609	1.50	1.50
AO1-00233	JEMETT LILLIE #2 (HIS HORSE)	1609	1.50	1.50
AO1-00234	TWO CROW MILLS	1609	1.50	1.50
AO1-00235	HIGH EAGLE ROSE	1609	1.50	1.50
AO1-00236	LIVERMONT WILLIE	1609	1.50	1.50
AO1-00237	MOUND PHILIP	1609	1.50	1.50
AO1-00238	RAISED HIM ABRAHAM	1609	1.50	1.50
AO1-00239	LARABER RICHARD	1609	1.50	1.50
AO1-00240	ROAN BEAR EDWARD	1609	1.50	1.50
AO1-00241	AFRAID OF THE BEAR MAGGIE	1609	1.50	1.50
AO1-00242	WOODS HARRY F.C.	1609	1.50	1.50
AO1-00243	HOWARD PHILIP F.C.	1609	1.50	1.50
AO1-00244	FIRST HAWK ALICE	1609	1.50	1.50
AO1-00245	WEST ALICE	1609	1.50	1.50
AO1-00246	MOLLY BILL PETER	1609	1.50	1.50
AO1-00247	HEAD OF BUCK ELK ELIAS	1609	1.50	1.50
AO1-00248	LENS HIS HORSE WALLACE	1609	1.50	1.50
AO1-00249	FIRST HAWK ALICE	1609	1.50	1.50
AO1-00250	CRAKE PRETTY VOICE	1609	1.50	1.50
AO1-00251	SPOTTER IRAD JESSE	1609	1.50	1.50
AO1-00252	BUCK BENTIS	1609	1.50	1.50
AO1-00253	CHUCKLING WALK HANNAH	1609	1.50	1.50
AO1-00254	BECKT CORA	1609	1.50	1.50
AO1-00255	RED IRON ISABELLE	1609	1.50	1.50
AO1-00256	BLUE IRON CHARLES	1609	1.50	1.50
AO1-00257	HAWK CRANE JACSEPH	1609	1.50	1.50
AO1-00258	ELK IRON WILLIE	1609	1.50	1.50
AO1-00259	UNITED IRON WILLIE	1609	1.50	1.50
AO1-00260	CRANE IRON WILLIE	1609	1.50	1.50
AO1-00261	IRON IRON WILLIE	1609	1.50	1.50
AO1-00262	IRON IRON WILLIE	1609	1.50	1.50
AO1-00263	IRON IRON WILLIE	1609	1.50	1.50
AO1-00264	IRON IRON WILLIE	1609	1.50	1.50
AO1-00265	IRON IRON WILLIE	1609	1.50	1.50
AO1-00266	IRON IRON WILLIE	1609	1.50	1.50
AO1-00267	IRON IRON WILLIE	1609	1.50	1.50
AO1-00268	IRON IRON WILLIE	1609	1.50	1.50
AO1-00269	IRON IRON WILLIE	1609	1.50	1.50
AO1-00270	IRON IRON WILLIE	1609	1.50	1.50

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ABERDEEN AREA

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	\$ALLOWED	\$PAID
103-00336	BEAR LEO	18	95.00	95.00
103-00337	LANCER CERIA	18	12.00	12.00
103-00338	LANIER ANTHONY	18	12.00	12.00
103-00339	LEAF WILLIAM	18	12.00	12.00
103-00340	ABRAM JAMES	18	12.00	12.00
103-00341	ABRAM JAMES	18	12.00	12.00
103-00342	ABRAM JAMES	18	12.00	12.00
103-00343	ABRAM JAMES	18	12.00	12.00
103-00344	ABRAM JAMES	18	12.00	12.00
103-00345	ABRAM JAMES	18	12.00	12.00
103-00346	ABRAM JAMES	18	12.00	12.00
103-00347	ABRAM JAMES	18	12.00	12.00
103-00348	ABRAM JAMES	18	12.00	12.00
103-00349	ABRAM JAMES	18	12.00	12.00
103-00350	ABRAM JAMES	18	12.00	12.00
103-00351	ABRAM JAMES	18	12.00	12.00
103-00352	ABRAM JAMES	18	12.00	12.00
103-00353	ABRAM JAMES	18	12.00	12.00
103-00354	ABRAM JAMES	18	12.00	12.00
103-00355	ABRAM JAMES	18	12.00	12.00
103-00356	ABRAM JAMES	18	12.00	12.00
103-00357	ABRAM JAMES	18	12.00	12.00
103-00358	ABRAM JAMES	18	12.00	12.00
103-00359	ABRAM JAMES	18	12.00	12.00
103-00360	ABRAM JAMES	18	12.00	12.00
103-00361	ABRAM JAMES	18	12.00	12.00
103-00362	ABRAM JAMES	18	12.00	12.00
103-00363	ABRAM JAMES	18	12.00	12.00
103-00364	ABRAM JAMES	18	12.00	12.00
103-00365	ABRAM JAMES	18	12.00	12.00
103-00366	ABRAM JAMES	18	12.00	12.00
103-00367	ABRAM JAMES	18	12.00	12.00
103-00368	ABRAM JAMES	18	12.00	12.00
103-00369	ABRAM JAMES	18	12.00	12.00
103-00370	ABRAM JAMES	18	12.00	12.00
103-00371	ABRAM JAMES	18	12.00	12.00
103-00372	ABRAM JAMES	18	12.00	12.00
103-00373	ABRAM JAMES	18	12.00	12.00
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103-00378	ABRAM JAMES	18	12.00	12.00
103-00379	ABRAM JAMES	18	12.00	12.00
103-00380	ABRAM JAMES	18	12.00	12.00
103-00381	ABRAM JAMES	18	12.00	12.00
103-00382	ABRAM JAMES	18	12.00	12.00
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103-00394	ABRAM JAMES	18	12.00	12.00
103-00395	ABRAM JAMES	18	12.00	12.00
103-00396	ABRAM JAMES	18	12.00	12.00
103-00397	ABRAM JAMES	18	12.00	12.00
103-00398	ABRAM JAMES	18	12.00	12.00
103-00399	ABRAM JAMES	18	12.00	12.00
103-00400	ABRAM JAMES	18	12.00	12.00

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ABERDEEN AREA

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	\$ALLOWED	\$PAID
103-00401	ALKINICAP ANTHONY	193	425.99	425.99
103-00402	TURKING EAGLE (SIPTO JOHNSON)	90	425.99	425.99
103-00403	MERRICK LOUIS	149	585.00	585.00
103-00404	GRIND HEAD PHLOMENE	405	450.00	450.00
103-00405	HOPKINS ANTHONY	500-4	450.00	450.00
103-00406	TAMARACK THOMAS	509	450.00	450.00
103-00407	CASKE ALBERT	386	450.00	450.00
103-00408	YOUNG ADELE (LANDOR)	185	450.00	450.00
103-00409	BROWN JOSEPHINE	905	450.00	450.00
103-00410	HOLYARDHENA (FALLING GRAY)	856	450.00	450.00
103-00411	BROWN CLARA (MOON)	979	450.00	450.00
103-00412	TWO HEARTS MARY (KING)	1149	450.00	450.00
103-00413	STANDLING JAMES	1150	450.00	450.00
103-00414	HIGH ELK ANNIE	1042	450.00	450.00
103-00415	BLACKSMITH MARY	1159	450.00	450.00
103-00416	BLACKSMITH MARY	1159	450.00	450.00
103-00417	BLACKSMITH MARY	1159	450.00	450.00
103-00418	BLACKSMITH MARY	1159	450.00	450.00
103-00419	BLACKSMITH MARY	1159	450.00	450.00
103-00420	BLACKSMITH MARY	1159	450.00	450.00
103-00421	BLACKSMITH MARY	1159	450.00	450.00
103-00422	BLACKSMITH MARY	1159	450.00	450.00
103-00423	BLACKSMITH MARY	1159	450.00	450.00
103-00424	BLACKSMITH MARY	1159	450.00	450.00
103-00425	BLACKSMITH MARY	1159	450.00	450.00
103-00426	BLACKSMITH MARY	1159	450.00	450.00
103-00427	BLACKSMITH MARY	1159	450.00	450.00
103-00428	BLACKSMITH MARY	1159	450.00	450.00
103-00429	BLACKSMITH MARY	1159	450.00	450.00
103-00430	BLACKSMITH MARY	1159	450.00	450.00
103-00431	BLACKSMITH MARY	1159	450.00	450.00
103-00432	BLACKSMITH MARY	1159	450.00	450.00
103-00433	BLACKSMITH MARY	1159	450.00	450.00
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103-00435	BLACKSMITH MARY	1159	450.00	450.00
103-00436	BLACKSMITH MARY	1159	450.00	450.00
103-00437	BLACKSMITH MARY	1159	450.00	450.00
103-00438	BLACKSMITH MARY	1159	450.00	450.00
103-00439	BLACKSMITH MARY	1159	450.00	450.00
103-00440	BLACKSMITH MARY	1159	450.00	450.00
103-00441	BLACKSMITH MARY	1159	450.00	450.00
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103-00446	BLACKSMITH MARY	1159	450.00	450.00
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103-00450	BLACKSMITH MARY	1159	450.00	450.00
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103-00459	BLACKSMITH MARY	1159	450.00	450.00
103-00460	BLACKSMITH MARY	1159	450.00	450.00
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103-00469	BLACKSMITH MARY	1159	450.00	450.00
103-00470	BLACKSMITH MARY	1159	450.00	450.00
103-00471	BLACKSMITH MARY	1159	450.00	450.00
103-00472	BLACKSMITH MARY	1159	450.00	450.00
103-00473	BLACKSMITH MARY	1159	450.00	450.00
103-00474	BLACKSMITH MARY	1159	450.00	450.00
103-00475	BLACKSMITH MARY	1159	450.00	450.00
103-00476	BLACKSMITH MARY	1159	450.00	450.00
103-00477	BLACKSMITH MARY	1159	450.00	450.00
103-00478	BLACKSMITH MARY	1159	450.00	450.00
103-00479	BLACKSMITH MARY	1159	450.00	450.00
103-00480	BLACKSMITH MARY	1159	450.00	450.00
103-00481	BLACKSMITH MARY	1159	450.00	450.00
103-00482	BLACKSMITH MARY	1159	450.00	450.00
103-00483	BLACKSMITH MARY	1159	450.00	450.00
103-00484	BLACKSMITH MARY	1159	450.00	450.00
103-00485	BLACKSMITH MARY	1159	450.00	450.00
103-00486	BLACKSMITH MARY	1159	450.00	450.00
103-00487	BLACKSMITH MARY	1159	450.00	450.00
103-00488	BLACKSMITH MARY	1159	450.00	450.00
103-00489	BLACKSMITH MARY	1159	450.00	450.00
103-00490	BLACKSMITH MARY	1159	450.00	450.00
103-00491	BLACKSMITH MARY	1159	450.00	450.00
103-00492	BLACKSMITH MARY	1159	450.00	450.00
103-00493	BLACKSMITH MARY	1159	450.00	450.00
103-00494	BLACKSMITH MARY	1159	450.00	450.00
103-00495	BLACKSMITH MARY	1159	450.00	450.00
103-00496	BLACKSMITH MARY	1159	450.00	450.00
103-00497	BLACKSMITH MARY	1159	450.00	450.00
103-00498	BLACKSMITH MARY	1159	450.00	450.00
103-00499	BLACKSMITH MARY	1159	450.00	450.00
103-00500	BLACKSMITH MARY	1159	450.00	450.00

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A. BERGEM - ARCA

[illegible]

PAGE 8

ALGERDEEN AREA

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	\$ALLOWED	\$PAID
AD5-144-00466	MOOREN GUN ALBERT	4219	12.00	12.00
AD5-144-00467	YELLOW SHIRT STELLA	4219	592.80	592.80
AD5-144-00468	BACK SIMON	4219	192.00	192.00
AD5-144-00469	LITTLE MAR BONNETT PETER	4219	608.46	608.46
AD5-144-00470	SANAVITA JAMES	4219	277.40	277.40
AD5-144-00471	LOWE COMMANDER JOHN	4219	384.45	384.45
AD5-144-00472	USCS BOB JULIA	4219	321.00	321.00
AD5-144-00473	BLACK BEAR	4219	1,000.20	1,000.20
AD5-144-00474	LITTLE KELLER JOHN	4219	19.10	19.10
AD5-144-00475	CUTLER BEAR WILLIAM	4219	71.60	71.60
AD5-144-00476	RANDALL WILLIAM	4219	50.00	50.00
AD5-144-00477	SHORT BILL FESSIE	4219	48.25	48.25
AD5-144-00478	EAGLE EAVY MARCESE	4219	1,440.00	1,440.00
AD5-144-00479	LAST MARCESE JOSEPH	4219	582.50	582.50
AD5-144-00480	SWAN MARCESE IN WOODS	4219	2,018.20	2,018.20
AD5-144-00481	BLACK BEAR EMMA	4219	188.50	188.50
AD5-144-00482	SHOING INN	4219	50.00	50.00
AD5-144-00483	SHOING ROCK	4219	357.00	357.00
AD5-144-00484	SWISS ABELIA	4219	92.88	92.88
AD5-144-00485	BEAR JUNG LUNE	4219	95.40	95.40
AD5-144-00486	BEAR BEACH BEAR MILDRED	4219	50.00	50.00
AD5-144-00487	BEAR ALICE	4219	50.00	50.00
AD5-144-00488	FIRE THUNDER MARY	4219	6430.00	6430.00
AD5-144-00489	EAGLE PIPE	4219	224.60	224.60
AD5-144-00490	BULL MARY	4219	601.00	601.00
AD5-144-00491	BULL MARY ANNA	4219	111.60	111.60
AD5-144-00492	RAMSAND CHARLES	4219	100.00	100.00
AD5-144-00493	RANDALL SUSIE	4219	100.00	100.00
AD5-144-00494	JUNG BEAR RACHEL	4219	100.00	100.00
AD5-144-00495	SWALLOW HATTIE	4219	100.00	100.00
AD5-144-00496	POOR BEAR ALBERT	4219	100.00	100.00
AD5-144-00497	BLACK EYES ANITE	4219	100.00	100.00
AD5-144-00498	BEAR MOUND ROBERT	4219	100.00	100.00
AD5-144-00499	CLINGER LIZZIE	4219	100.00	100.00
AD5-144-00500	BEAT FRANK	4219	100.00	100.00
AD5-144-00501	KINLIE BEN	4219	100.00	100.00
AD5-144-00502	LITTLE BILL MABEL	4219	100.00	100.00
AD5-144-00503	SMITH ALICE	4219	100.00	100.00
AD5-144-00504	STANDING BEAR DAVID	4219	100.00	100.00
AD5-144-00505	GOODMAN JANICE	4219	100.00	100.00
AD5-144-00506	BIG HEAD BRAVE JOHN	4219	100.00	100.00
AD5-144-00507	SAY MARY	4219	100.00	100.00
AD5-144-00508	THE CHIEF JULIE	4219	100.00	100.00
AD5-144-00509	STANDS BELLE	4219	100.00	100.00
AD5-144-00510	SHILLER MARLENDINO SUSIE	4219	100.00	100.00
AD5-144-00511	CAGLE MARK AGNES	4219	100.00	100.00
AD5-144-00512	STANDING BEAR ADA	4219	100.00	100.00
AD5-144-00513	BEAR BEAR SUSIE	4219	100.00	100.00
AD5-144-00514	BEAR BEAR JOSEPH	4219	100.00	100.00
AD5-144-00515	BEAR BEAR LUCY	4219	100.00	100.00
AD5-144-00516	BEAR BEAR JULIA	4219	100.00	100.00
AD5-144-00517	BEAR BEAR JOSEPH	4219	100.00	100.00
AD5-144-00518	BEAR BEAR ALBERT	4219	100.00	100.00
AD5-144-00519	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00520	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00521	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00522	BEAR BEAR THEN DONALD	4219	100.00	100.00
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AD5-144-00526	BEAR BEAR THEN DONALD	4219	100.00	100.00
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AD5-144-00528	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00529	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00530	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00531	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00532	BEAR BEAR THEN DONALD	4219	100.00	100.00
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AD5-144-00538	BEAR BEAR THEN DONALD	4219	100.00	100.00
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AD5-144-00541	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00542	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00543	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00544	BEAR BEAR THEN DONALD	4219	100.00	100.00
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AD5-144-00546	BEAR BEAR THEN DONALD	4219	100.00	100.00
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AD5-144-00548	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00549	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00550	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00551	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00552	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00553	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00554	BEAR BEAR THEN DONALD	4219	100.00	100.00
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AD5-144-00557	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00558	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00559	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00560	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00561	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00562	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00563	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00564	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00565	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00566	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00567	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00568	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00569	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00570	BEAR BEAR THEN DONALD	4219	100.00	100.00
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AD5-144-00573	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00574	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00575	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00576	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00577	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00578	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00579	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00580	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00581	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00582	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00583	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00584	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00585	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00586	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00587	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00588	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00589	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00590	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00591	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00592	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00593	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00594	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00595	BEAR BEAR THEN DONALD	4219	100.00	100.00
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AD5-144-00597	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00598	BEAR BEAR THEN DONALD	4219	100.00	100.00
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AD5-144-00607	BEAR BEAR THEN DONALD	4219	100.00	100.00
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AD5-144-00611	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00612	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00613	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00614	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00615	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00616	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00617	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00618	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00619	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00620	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00621	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00622	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00623	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00624	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00625	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00626	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00627	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00628	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00629	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00630	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00631	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00632	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00633	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00634	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00635	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00636	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00637	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00638	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00639	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00640	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00641	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00642	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00643	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00644	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00645	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00646	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00647	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00648	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00649	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00650	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00651	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00652	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00653	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00654	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00655	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00656	BEAR BEAR THEN DONALD	4219	100.00	100.00
AD5-144-00657	BEAR BEAR THEN DONALD	4219	100.00	100.00

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ABSEDIEN AREA

ISSUE NUMBER	NAME OF DECEASED	DECEDENT ID	ALLOWED	PAID
AD-1	LONG HORN	720	1	1
AD-2	OLIVER THOMAS	721	1	1
AD-3	LONG STUNK MELLIE	722	1	1
AD-4	WARM CLIPS	723	1	1
AD-5	PLENTY WOUNDS IDA	724	1	1
AD-6	LITTLE BOY CECILIA	725	1	1
AD-7	BLACK LEAFER WASHINGTON	726	1	1
AD-8	CLARK CHES CUT	727	1	1
AD-9	RAMMALL ANTON	728	1	1
AD-10	SCOTT WILLIAM	729	1	1
AD-11	SCOTT WILLIAM	730	1	1
AD-12	SCOTT WILLIAM	731	1	1
AD-13	SCOTT WILLIAM	732	1	1
AD-14	SCOTT WILLIAM	733	1	1
AD-15	SCOTT WILLIAM	734	1	1
AD-16	SCOTT WILLIAM	735	1	1
AD-17	SCOTT WILLIAM	736	1	1
AD-18	SCOTT WILLIAM	737	1	1
AD-19	SCOTT WILLIAM	738	1	1
AD-20	SCOTT WILLIAM	739	1	1
AD-21	SCOTT WILLIAM	740	1	1
AD-22	SCOTT WILLIAM	741	1	1
AD-23	SCOTT WILLIAM	742	1	1
AD-24	SCOTT WILLIAM	743	1	1
AD-25	SCOTT WILLIAM	744	1	1
AD-26	SCOTT WILLIAM	745	1	1
AD-27	SCOTT WILLIAM	746	1	1
AD-28	SCOTT WILLIAM	747	1	1
AD-29	SCOTT WILLIAM	748	1	1
AD-30	SCOTT WILLIAM	749	1	1
AD-31	SCOTT WILLIAM	750	1	1
AD-32	SCOTT WILLIAM	751	1	1
AD-33	SCOTT WILLIAM	752	1	1
AD-34	SCOTT WILLIAM	753	1	1
AD-35	SCOTT WILLIAM	754	1	1
AD-36	SCOTT WILLIAM	755	1	1
AD-37	SCOTT WILLIAM	756	1	1
AD-38	SCOTT WILLIAM	757	1	1
AD-39	SCOTT WILLIAM	758	1	1
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AD-42	SCOTT WILLIAM	761	1	1
AD-43	SCOTT WILLIAM	762	1	1
AD-44	SCOTT WILLIAM	763	1	1
AD-45	SCOTT WILLIAM	764	1	1
AD-46	SCOTT WILLIAM	765	1	1
AD-47	SCOTT WILLIAM	766	1	1
AD-48	SCOTT WILLIAM	767	1	1
AD-49	SCOTT WILLIAM	768	1	1
AD-50	SCOTT WILLIAM	769	1	1
AD-51	SCOTT WILLIAM	770	1	1
AD-52	SCOTT WILLIAM	771	1	1
AD-53	SCOTT WILLIAM	772	1	1
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AD-65	SCOTT WILLIAM	784	1	1
AD-66	SCOTT WILLIAM	785	1	1
AD-67	SCOTT WILLIAM	786	1	1
AD-68	SCOTT WILLIAM	787	1	1
AD-69	SCOTT WILLIAM	788	1	1
AD-70	SCOTT WILLIAM	789	1	1
AD-71	SCOTT WILLIAM	790	1	1
AD-72	SCOTT WILLIAM	791	1	1
AD-73	SCOTT WILLIAM	792	1	1
AD-74	SCOTT WILLIAM	793	1	1
AD-75	SCOTT WILLIAM	794	1	1
AD-76	SCOTT WILLIAM	795	1	1
AD-77	SCOTT WILLIAM	796	1	1
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AD-79	SCOTT WILLIAM	798	1	1
AD-80	SCOTT WILLIAM	799	1	1
AD-81	SCOTT WILLIAM	800	1	1
AD-82	SCOTT WILLIAM	801	1	1
AD-83	SCOTT WILLIAM	802	1	1
AD-84	SCOTT WILLIAM	803	1	1
AD-85	SCOTT WILLIAM	804	1	1
AD-86	SCOTT WILLIAM	805	1	1
AD-87	SCOTT WILLIAM	806	1	1
AD-88	SCOTT WILLIAM	807	1	1
AD-89	SCOTT WILLIAM	808	1	1
AD-90	SCOTT WILLIAM	809	1	1
AD-91	SCOTT WILLIAM	810	1	1
AD-92	SCOTT WILLIAM	811	1	1
AD-93	SCOTT WILLIAM	812	1	1
AD-94	SCOTT WILLIAM	813	1	1
AD-95	SCOTT WILLIAM	814	1	1
AD-96	SCOTT WILLIAM	815	1	1
AD-97	SCOTT WILLIAM	816	1	1
AD-98	SCOTT WILLIAM	817	1	1
AD-99	SCOTT WILLIAM	818	1	1
AD-100	SCOTT WILLIAM	819	1	1

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ABSEDIEN AREA

ISSUE NUMBER	NAME OF DECEASED	DECEDENT ID	ALLOWED	PAID
AD-1	BAVENEART JOSEPH	720	1	1
AD-2	LONG BULL JOHN	721	1	1
AD-3	KLINGS WHITE	722	1	1
AD-4	WATY HOSE SUE	723	1	1
AD-5	WATY HOSE SUE	724	1	1
AD-6	WATY HOSE SUE	725	1	1
AD-7	WATY HOSE SUE	726	1	1
AD-8	WATY HOSE SUE	727	1	1
AD-9	WATY HOSE SUE	728	1	1
AD-10	WATY HOSE SUE	729	1	1
AD-11	WATY HOSE SUE	730	1	1
AD-12	WATY HOSE SUE	731	1	1
AD-13	WATY HOSE SUE	732	1	1
AD-14	WATY HOSE SUE	733	1	1
AD-15	WATY HOSE SUE	734	1	1
AD-16	WATY HOSE SUE	735	1	1
AD-17	WATY HOSE SUE	736	1	1
AD-18	WATY HOSE SUE	737	1	1
AD-19	WATY HOSE SUE	738	1	1
AD-20	WATY HOSE SUE	739	1	1
AD-21	WATY HOSE SUE	740	1	1
AD-22	WATY HOSE SUE	741	1	1
AD-23	WATY HOSE SUE	742	1	1
AD-24	WATY HOSE SUE	743	1	1
AD-25	WATY HOSE SUE	744	1	1
AD-26	WATY HOSE SUE	745	1	1
AD-27	WATY HOSE SUE	746	1	1
AD-28	WATY HOSE SUE	747	1	1
AD-29	WATY HOSE SUE	748	1	1
AD-30	WATY HOSE SUE	749	1	1
AD-31	WATY HOSE SUE	750	1	1
AD-32	WATY HOSE SUE	751	1	1
AD-33	WATY HOSE SUE	752	1	1
AD-34	WATY HOSE SUE	753	1	1
AD-35	WATY HOSE SUE	754	1	1
AD-36	WATY HOSE SUE	755	1	1
AD-37	WATY HOSE SUE	756	1	1
AD-38	WATY HOSE SUE	757	1	1
AD-39	WATY HOSE SUE	758	1	1
AD-40	WATY HOSE SUE	759	1	1
AD-41	WATY HOSE SUE	760	1	1
AD-42	WATY HOSE SUE	761	1	1
AD-43	WATY HOSE SUE	762	1	1
AD-44	WATY HOSE SUE	763	1	1
AD-45	WATY HOSE SUE	764	1	1
AD-46	WATY HOSE SUE	765	1	1
AD-47	WATY HOSE SUE	766	1	1
AD-48	WATY HOSE SUE	767	1	1
AD-49	WATY HOSE SUE	768	1	1
AD-50	WATY HOSE SUE	769	1	1
AD-51	WATY HOSE SUE	770	1	1
AD-52	WATY HOSE SUE	771	1	1
AD-53	WATY HOSE SUE	772	1	1
AD-54	WATY HOSE SUE	773	1	1
AD-55	WATY HOSE SUE	774	1	1
AD-56	WATY HOSE SUE	775	1	1
AD-57	WATY HOSE SUE	776	1	1
AD-58	WATY HOSE SUE	777	1	1
AD-59	WATY HOSE SUE	778	1	1
AD-60	WATY HOSE SUE	779	1	1
AD-61	WATY HOSE SUE	780	1	1
AD-62	WATY HOSE SUE	781	1	1
AD-63	WATY HOSE SUE	782	1	1
AD-64	WATY HOSE SUE	783	1	1
AD-65	WATY HOSE SUE	784	1	1
AD-66	WATY HOSE SUE	785	1	1
AD-67	WATY HOSE SUE	786	1	1
AD-68	WATY HOSE SUE	787	1	1
AD-69	WATY HOSE SUE	788	1	1
AD-70	WATY HOSE SUE	789	1	1
AD-71	WATY HOSE SUE	790	1	1
AD-72	WATY HOSE SUE	791	1	1
AD-73	WATY HOSE SUE	792	1	1
AD-74	WATY HOSE SUE	793	1	1
AD-75	WATY HOSE SUE	794	1	1
AD-76	WATY HOSE SUE	795	1	1
AD-77	WATY HOSE SUE	796	1	1
AD-78	WATY HOSE SUE	797	1	1
AD-79	WATY HOSE SUE	798	1	1
AD-80	WATY HOSE SUE	799	1	1
AD-81	WATY HOSE SUE	800	1	1
AD-82	WATY HOSE SUE	801	1	1
AD-83	WATY HOSE SUE	802	1	1
AD-84	WATY HOSE SUE	803	1	1
AD-85	WATY HOSE SUE	804	1	1
AD-86	WATY HOSE SUE	805	1	1
AD-87	WATY HOSE SUE	806	1	1
AD-88	WATY HOSE SUE	807	1	1
AD-89	WATY HOSE SUE	808	1	1
AD-90	WATY HOSE SUE	809	1	1
AD-91	WATY HOSE SUE	810	1	1
AD-92	WATY HOSE SUE	811	1	1
AD-93	WATY HOSE SUE	812	1	1
AD-94	WATY HOSE SUE	813	1	1
AD-95	WATY HOSE SUE	814	1	1
AD-96	WATY HOSE SUE	815	1	1
AD-97	WATY HOSE SUE	816	1	1
AD-98	WATY HOSE SUE	817	1	1
AD-99	WATY HOSE SUE	818	1	1
AD-100	WATY HOSE SUE	819	1	1

PAGE 17
ABERDEEN AREA

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	ALLOWED	PAID	ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	ALLOWED	PAID
AT-1	JOSEPH HORNED ANTELOPE	2127	372.50	372.50	AT-1	BASMAN SAMUEL	129	200.00	200.00
AT-2	FARRIE NIGHT CHARGE (STRANGER HORSE)	2128	372.50	372.50	AT-2	FLYING HAWK EDWARD	130	200.00	200.00
AT-3	RICHARD LARVIE	2129	372.50	372.50	AT-3	COOK MARY HANK EAGLE	131	200.00	200.00
AT-4	MARY LARVIE	2130	372.50	372.50	AT-4	FELIX CHARLES	132	200.00	200.00
AT-5	STELLA RING CLOSE TO VILLAGE	2131	372.50	372.50	AT-5	DRAYAU LOUIS	133	200.00	200.00
AT-6	SCOTIA WHITE HARE ROBERTS CLAMMENT	2132	372.50	372.50	AT-6	CHIN HENRY	134	200.00	200.00
AT-7	WILLIAM BROWN	2133	372.50	372.50	AT-7	BLAINE STEPHEN G.	135	200.00	200.00
AT-8	PAUL BEAR HELLS	2134	372.50	372.50	AT-8	RATES THOMAS M.	136	200.00	200.00
AT-9	ANDREW RED BLANET	2135	372.50	372.50	AT-9	PATERSON AMIE	137	200.00	200.00
AT-10	MAGGIE WHITE YELLOW CLOUD	2136	372.50	372.50	AT-10	BLACKMON MAGGIE	138	200.00	200.00
AT-11	ESTELLA GOOD DAY HAWK TRACK	2137	372.50	372.50	AT-11	SPOTTED EAGLE TIMA WILLIAM	139	200.00	200.00
AT-12	ESTER ACSS	2138	372.50	372.50	AT-12	KUMPEY ANNIE MARY HARE	140	200.00	200.00
AT-13	CLARETH ELZA GANS THE WAR	2139	372.50	372.50	AT-13	STILGER FRANK ROE	141	200.00	200.00
AT-14	LOUIS FORTY TAIL	2140	372.50	372.50	AT-14	KEEL ISAC	142	200.00	200.00
AT-15	ALCIVILLA BIG HEART	2141	372.50	372.50	AT-15	STANLEY THOMAS	143	200.00	200.00
AT-16	SUGAN RINGING SILEY BARBER ARM SPK	2142	372.50	372.50	AT-16	COBBLE ANOS	144	200.00	200.00
AT-17	ESTHER DARLAN BROWN ROE	2143	372.50	372.50	AT-17	PAUL HILL	145	200.00	200.00
AT-18	JOHN COOK	2144	372.50	372.50	AT-18	CECELIA HILL	146	200.00	200.00
AT-19	JOSEPH WHITE BUFFALO	2145	372.50	372.50	AT-19	CECELIA HILL	147	200.00	200.00
AT-20	JOSEPH BEAVALS JR	2146	372.50	372.50	AT-20	CECELIA HILL	148	200.00	200.00
AT-21	REXNA RED ROSE OR TURNING WALK	2147	372.50	372.50	AT-21	CECELIA HILL	149	200.00	200.00
AT-22	MAKARA NEER MISSA A SHOT	2148	372.50	372.50	AT-22	CECELIA HILL	150	200.00	200.00
AT-23	ALEXANDER TURNING HAWK	2149	372.50	372.50	AT-23	CECELIA HILL	151	200.00	200.00
AT-24	JOHN LAYS ON HIS BELLY	2150	372.50	372.50	AT-24	CECELIA HILL	152	200.00	200.00
AT-25	LUCY LITTLE TAIL	2151	372.50	372.50	AT-25	CECELIA HILL	153	200.00	200.00
AT-26	FRANK	2152	372.50	372.50	AT-26	CECELIA HILL	154	200.00	200.00
AT-27	ROBERT LIA	2153	372.50	372.50	AT-27	CECELIA HILL	155	200.00	200.00
AT-28	WILLIAM S. SAMUEL BAKER	2154	372.50	372.50	AT-28	CECELIA HILL	156	200.00	200.00
AT-29	WILLIAM BROWN CLE	2155	372.50	372.50	AT-29	CECELIA HILL	157	200.00	200.00
AT-30	WILLIAM BROWN CLE	2156	372.50	372.50	AT-30	CECELIA HILL	158	200.00	200.00
AT-31	WILLIAM BROWN CLE	2157	372.50	372.50	AT-31	CECELIA HILL	159	200.00	200.00
AT-32	WILLIAM BROWN CLE	2158	372.50	372.50	AT-32	CECELIA HILL	160	200.00	200.00
AT-33	WILLIAM BROWN CLE	2159	372.50	372.50	AT-33	CECELIA HILL	161	200.00	200.00
AT-34	WILLIAM BROWN CLE	2160	372.50	372.50	AT-34	CECELIA HILL	162	200.00	200.00
AT-35	WILLIAM BROWN CLE	2161	372.50	372.50	AT-35	CECELIA HILL	163	200.00	200.00
AT-36	WILLIAM BROWN CLE	2162	372.50	372.50	AT-36	CECELIA HILL	164	200.00	200.00
AT-37	WILLIAM BROWN CLE	2163	372.50	372.50	AT-37	CECELIA HILL	165	200.00	200.00
AT-38	WILLIAM BROWN CLE	2164	372.50	372.50	AT-38	CECELIA HILL	166	200.00	200.00
AT-39	WILLIAM BROWN CLE	2165	372.50	372.50	AT-39	CECELIA HILL	167	200.00	200.00
AT-40	WILLIAM BROWN CLE	2166	372.50	372.50	AT-40	CECELIA HILL	168	200.00	200.00
AT-41	WILLIAM BROWN CLE	2167	372.50	372.50	AT-41	CECELIA HILL	169	200.00	200.00
AT-42	WILLIAM BROWN CLE	2168	372.50	372.50	AT-42	CECELIA HILL	170	200.00	200.00
AT-43	WILLIAM BROWN CLE	2169	372.50	372.50	AT-43	CECELIA HILL	171	200.00	200.00
AT-44	WILLIAM BROWN CLE	2170	372.50	372.50	AT-44	CECELIA HILL	172	200.00	200.00
AT-45	WILLIAM BROWN CLE	2171	372.50	372.50	AT-45	CECELIA HILL	173	200.00	200.00
AT-46	WILLIAM BROWN CLE	2172	372.50	372.50	AT-46	CECELIA HILL	174	200.00	200.00
AT-47	WILLIAM BROWN CLE	2173	372.50	372.50	AT-47	CECELIA HILL	175	200.00	200.00
AT-48	WILLIAM BROWN CLE	2174	372.50	372.50	AT-48	CECELIA HILL	176	200.00	200.00
AT-49	WILLIAM BROWN CLE	2175	372.50	372.50	AT-49	CECELIA HILL	177	200.00	200.00
AT-50	WILLIAM BROWN CLE	2176	372.50	372.50	AT-50	CECELIA HILL	178	200.00	200.00
AT-51	WILLIAM BROWN CLE	2177	372.50	372.50	AT-51	CECELIA HILL	179	200.00	200.00
AT-52	WILLIAM BROWN CLE	2178	372.50	372.50	AT-52	CECELIA HILL	180	200.00	200.00
AT-53	WILLIAM BROWN CLE	2179	372.50	372.50	AT-53	CECELIA HILL	181	200.00	200.00
AT-54	WILLIAM BROWN CLE	2180	372.50	372.50	AT-54	CECELIA HILL	182	200.00	200.00
AT-55	WILLIAM BROWN CLE	2181	372.50	372.50	AT-55	CECELIA HILL	183	200.00	200.00
AT-56	WILLIAM BROWN CLE	2182	372.50	372.50	AT-56	CECELIA HILL	184	200.00	200.00
AT-57	WILLIAM BROWN CLE	2183	372.50	372.50	AT-57	CECELIA HILL	185	200.00	200.00
AT-58	WILLIAM BROWN CLE	2184	372.50	372.50	AT-58	CECELIA HILL	186	200.00	200.00
AT-59	WILLIAM BROWN CLE	2185	372.50	372.50	AT-59	CECELIA HILL	187	200.00	200.00
AT-60	WILLIAM BROWN CLE	2186	372.50	372.50	AT-60	CECELIA HILL	188	200.00	200.00
AT-61	WILLIAM BROWN CLE	2187	372.50	372.50	AT-61	CECELIA HILL	189	200.00	200.00
AT-62	WILLIAM BROWN CLE	2188	372.50	372.50	AT-62	CECELIA HILL	190	200.00	200.00
AT-63	WILLIAM BROWN CLE	2189	372.50	372.50	AT-63	CECELIA HILL	191	200.00	200.00
AT-64	WILLIAM BROWN CLE	2190	372.50	372.50	AT-64	CECELIA HILL	192	200.00	200.00
AT-65	WILLIAM BROWN CLE	2191	372.50	372.50	AT-65	CECELIA HILL	193	200.00	200.00
AT-66	WILLIAM BROWN CLE	2192	372.50	372.50	AT-66	CECELIA HILL	194	200.00	200.00
AT-67	WILLIAM BROWN CLE	2193	372.50	372.50	AT-67	CECELIA HILL	195	200.00	200.00
AT-68	WILLIAM BROWN CLE	2194	372.50	372.50	AT-68	CECELIA HILL	196	200.00	200.00
AT-69	WILLIAM BROWN CLE	2195	372.50	372.50	AT-69	CECELIA HILL	197	200.00	200.00
AT-70	WILLIAM BROWN CLE	2196	372.50	372.50	AT-70	CECELIA HILL	198	200.00	200.00
AT-71	WILLIAM BROWN CLE	2197	372.50	372.50	AT-71	CECELIA HILL	199	200.00	200.00
AT-72	WILLIAM BROWN CLE	2198	372.50	372.50	AT-72	CECELIA HILL	200	200.00	200.00
AT-73	WILLIAM BROWN CLE	2199	372.50	372.50	AT-73	CECELIA HILL	201	200.00	200.00
AT-74	WILLIAM BROWN CLE	2200	372.50	372.50	AT-74	CECELIA HILL	202	200.00	200.00
AT-75	WILLIAM BROWN CLE	2201	372.50	372.50	AT-75	CECELIA HILL	203	200.00	200.00
AT-76	WILLIAM BROWN CLE	2202	372.50	372.50	AT-76	CECELIA HILL	204	200.00	200.00
AT-77	WILLIAM BROWN CLE	2203	372.50	372.50	AT-77	CECELIA HILL	205	200.00	200.00
AT-78	WILLIAM BROWN CLE	2204	372.50	372.50	AT-78	CECELIA HILL	206	200.00	200.00
AT-79	WILLIAM BROWN CLE	2205	372.50	372.50	AT-79	CECELIA HILL	207	200.00	200.00
AT-80	WILLIAM BROWN CLE	2206	372.50	372.50	AT-80	CECELIA HILL	208	200.00	200.00
AT-81	WILLIAM BROWN CLE	2207	372.50	372.50	AT-81	CECELIA HILL	209	200.00	200.00
AT-82	WILLIAM BROWN CLE	2208	372.50	372.50	AT-82	CECELIA HILL	210	200.00	200.00
AT-83	WILLIAM BROWN CLE	2209	372.50	372.50	AT-83	CECELIA HILL	211	200.00	200.00
AT-84	WILLIAM BROWN CLE	2210	372.50	372.50	AT-84	CECELIA HILL	212	200.00	200.00
AT-85	WILLIAM BROWN CLE	2211	372.50	372.50	AT-85	CECELIA HILL	213	200.00	200.00
AT-86	WILLIAM BROWN CLE	2212	372.50	372.50	AT-86	CECELIA HILL	214	200.00	200.00
AT-87	WILLIAM BROWN CLE	2213	372.50	372.50	AT-87	CECELIA HILL	215	200.00	200.00
AT-88	WILLIAM BROWN CLE	2214	372.50	372.50	AT-88	CECELIA HILL	216	200.00	200.00
AT-89	WILLIAM BROWN CLE	2215	372.50	372.50	AT-89	CECELIA HILL	217	200.00	200.00
AT-90	WILLIAM BROWN CLE	2216	372.50	372.50	AT-90	CECELIA HILL	218	200.00	200.00
AT-91	WILLIAM BROWN CLE	2217	372.50	372.50	AT-91	CECELIA HILL	219	200.00	200.00
AT-92	WILLIAM BROWN CLE	2218	372.50	372.50	AT-92	CECELIA HILL	220	200.00	200.00
AT-93	WILLIAM BROWN CLE	2219	372.50	372.50	AT-93	CECELIA HILL	221	200.00	200.00
AT-94	WILLIAM BROWN CLE	2220	372.50	372.50	AT-94	CECELIA HILL	222	200.00	200.00
AT-95	WILLIAM BROWN CLE	2221	372.50	372.50	AT-95	CECELIA HILL	223	200.00	200.00
AT-96	WILLIAM BROWN CLE	2222	372.50	372.50	AT-96	CECELIA HILL	224	200.00	200.00
AT-97	WILLIAM BROWN CLE	2223	372.50	372.50	AT-97	CECELIA HILL	225	200.00	200.00
AT-98	WILLIAM BROWN CLE	2224	372.50	372.50	AT-98	CECELIA HILL	226	200.00	200.00
AT-99	WILLIAM BROWN CLE	2225	372.50	372.50	AT-99	CECELIA HILL	227	200.00	200.00
AT-100	WILLIAM BROWN CLE	2226	372.50	372.50	AT-100	CECELIA HILL	228	200.00	200.00

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ABERDEEN AREA

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ISSUE NUMBER	NAME OF RECENT	DEPENDENT ID	SALLOWED
1	LOUISA (LOWMAN)		
2	CECELIA (BULLHEAD)		
3	WILLIAM (WILK)		
4	JOHN (JOHN)		
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NAME OF DECEASED	AGE	SEX	DATE OF DEATH	PLACE OF DEATH	CAUSE OF DEATH	REPORTING AGENCY	STATUS
JOHN DOE	45	M	1980-01-15	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JANE DOE	32	F	1980-02-20	NEW YORK	ACCIDENT	STATE DEPT	DECEASED
JOHN DOE	55	M	1980-03-10	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JANE DOE	28	F	1980-04-05	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JOHN DOE	60	M	1980-05-12	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JANE DOE	40	F	1980-06-18	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JOHN DOE	35	M	1980-07-25	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JANE DOE	25	F	1980-08-30	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JOHN DOE	50	M	1980-09-15	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JANE DOE	30	F	1980-10-20	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JOHN DOE	45	M	1980-11-25	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED
JANE DOE	20	F	1980-12-30	NEW YORK	HEART DISEASE	STATE DEPT	DECEASED

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Agency: ASA

ISSUE NUMBER	NAME OF DECEDENT	DECEDENT ID	ALLOWED	SP-10
1	DICK JOSEPH	0		
2	STICKLAND JULIA (WHITE H.)	0		
3	SLACK JOHN	0		
4	WILLIAM WESLEY CAYOU	0		
5	SULLIVAN HARRY	0		
6	CANNON DAVID	0		
7	JOHNSON JOSEPH (HAINES)	0		
8	HORTMAN SIGAN	0		
9	RENNING MARY ALLEN	0		
10	CLARE ELIZABETH	0		
11	LANDRAU MARY (WEST)	0		
12	BAKER CHARLES	0		
13	LEIB JACQUETTE (RICE)	0		
14	WITTE LEO C	0		
15	BERNLEY MARTHA (HENRY)	0		
16	WITTE ARSON	0		
17	WITTE GROVER	0		
18	LAKE MARGUERITE (KITTLE)	0		
19	CLAY JOHN	0		
20	WAGGINS JARY (WRIGHTON)	0		
21	WAGGINS JARY	0		
22	WAGGINS JOHN SR.	0		
23	WAGGINS WALTER	0		
24	WAGGINS DANIEL	0		
25	WAGGINS LULA	0		
26	WAGGINS LUCINE	0		
27	WAGGINS WILLIAM	0		
28	WAGGINS THOMAS	0		
29	WAGGINS THOMAS	0		
30	WAGGINS GREGORY	0		
31	WAGGINS ELIZABETH (ASHLEY)	0		
32	WAGGINS JACQUELINE (LOOSE)	0		
33	WAGGINS PAUL	0		
34	WAGGINS PAUL	0		
35	WAGGINS KENNETH	0		
36	WAGGINS KENNETH	0		
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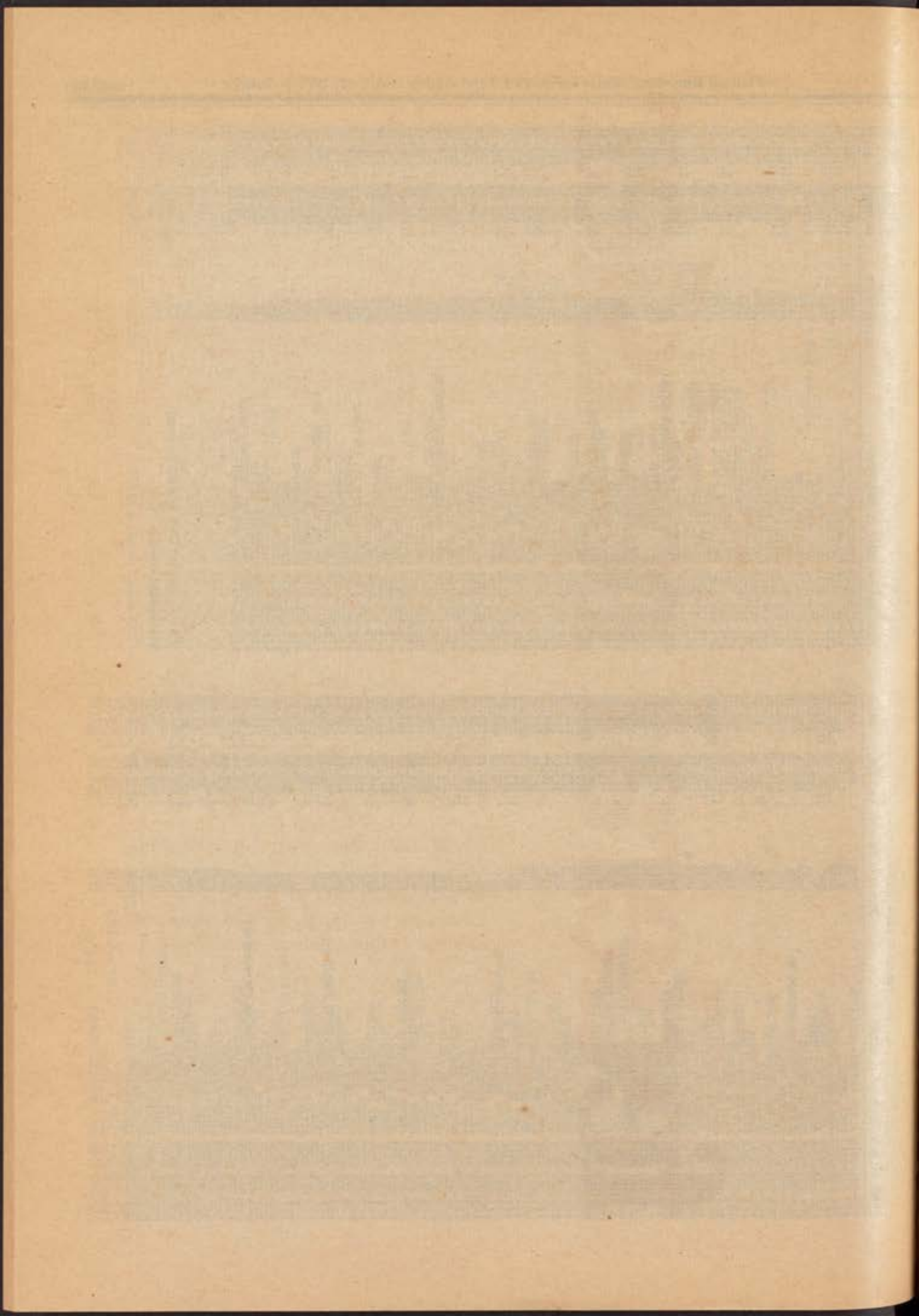
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PAGE 29
BILLINGS AREA

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1005	CHARLES J BUCKMAN	399	1000	1000
1006	ATTACKS	400	1000	1000
1007	TAKES PRISONER WARRIOR	401	1000	1000
1008	THE GIRL	402	1000	1000
1009	ANY BLACK-PEAR WHITE	403	1000	1000
1010	MRS J BARRITY	404	1000	1000
1011	GRANTING WITNESS	405	1000	1000
1012	BEHIND THE HUNTER	406	1000	1000
1013	MARK FISH GUTS	407	1000	1000
1014	HINAM FACING	408	1000	1000
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PAGE 28
BILLINGS AREA

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42 CFR Parts 400 et al.

Wednesday
April 17, 1985

Part III

Department of Health and Human Services

Health Care Financing Administration

42 CFR Parts 400 et al.

Medicare and Medicaid Programs; Peer
Review Organizations; Final Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400, 405, 412, 431, 433, 456, 460, 462, and 466

[HSQ-108-F]

Medicare and Medicaid Programs; Utilization and Quality Control Peer Review Organization (PRO): Assumption of Medicare Review Functions and Coordination With Medicaid

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

ACTION: Final rule.

SUMMARY: This rule describes the review functions to be performed by a utilization and quality control peer review organization (PRO). It outlines the relationships that will be established among PROs, Medicare fiscal intermediaries and carriers, providers, practitioners, and beneficiaries when a PRO assumes its review responsibilities. It also describes the relationship that should exist between PROs and State Medicaid agencies that contract with PROs to perform review.

This rule implements portions of the following statutes:

- Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. 97-248)
- Social Security Amendments of 1983 (Pub. L. 98-21)
- Deficit Reduction Act of 1984 (Pub. L. 98-369).

EFFECTIVE DATE: These regulations are effective May 17, 1985 except for the following:

(1) Section 466.78(a) that specifies that each hospital have a written contract with a PRO is effective June 17, 1985.

(2) Sections 412.44, 431.630, 456.654, 466.70, 466.72, 466.74, 466.78, 466.80 and 466.94 contain information collection requirements with which the public is not required to comply until the Executive Office of Management and Budget (EOMB) approves these requirements. See section VI of the preamble for a discussion of information collection.

FOR FURTHER INFORMATION CONTACT: Mary Kay Terry, (301) 594-7910.

SUPPLEMENTARY INFORMATION:

I. Background

The Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA), Pub. L. 97-248) amended Part

B of Title XI of the Social Security Act (Act) by establishing the Utilization and Quality Control Peer Review Organization (PRO) program. This program, when fully implemented, will replace the existing Professional Standards Review Organization (PSRO) program. The responsibilities that PROs are assuming are similar to those now exercised by PSROs. PROs will review health care services funded under Title XVIII of the Act (Medicare) to determine whether those services are reasonable, medically necessary, furnished in the appropriate setting, and are of a quality which meets professionally recognized standards. Congress created the PRO program in order to redirect, simplify and enhance the cost-effectiveness and efficiency of the peer review of services reimbursed by Medicare.

The Social Security Amendments of 1983 established a prospective payment system for Medicare and amended section 1866(a)(1)(F) of the Act to specify that hospitals seeking reimbursement under the prospective payment system must enter into agreements with PROs by specified dates to review the following:

- The validity of diagnostic and procedural information supplied by the provider.
- The completeness, adequacy, and quality of care provided.
- The appropriateness of admissions and discharges.
- The appropriateness of care provided or proposed to be provided for which payment is sought on an "outlier" basis under the prospective payment system.

In addition, the amendments added section 1866(f)(2) of the Act to specify that the Secretary may deny payment or require the hospital to take corrective action if a PRO provides the Secretary with documentation that a hospital has circumvented the prospective payment system through unnecessary admissions or other practices.

The Deficit Reduction Act of 1984 (DRA) revised the provisions of the Social Security Amendments to require that all hospitals, not just those receiving payment under the prospective payment system, must maintain an agreement with a PRO. Effective November 15, 1984, all hospitals must have an agreement with a PRO as a condition of payment under Medicare.

The DRA amendments permit the Secretary to enter into contracts with entities or affiliated entities (other than self-insured employers) that directly or indirectly make payments to a provider or practitioner on or after November 15, 1984 if there is no other available entity. Section 1153(b)(2)(A) of the Act, as

amended, clarifies that the Secretary can contract with this type of entity if the entity does not have more than one member of the governing board being affiliated through management, ownership or common control with a health maintenance organization or competitive medical plan which is an "eligible organization" as defined in section 1876(b) of the Act.

In addition, Congress modified the restriction in section 1153(b)(3) of the Act. The Secretary may now contract with an organization that has no more than 20 percent of the members of its governing board affiliated with health care facilities or associations of facilities through management, ownership or common control.

In June of 1984, HCFA began awarding contracts to PROs. On July 17, 1984, we published a proposed rule (NPRM) which describes the PROs' review responsibilities and the PROs' relationships with other PROs, fiscal intermediaries, carriers, providers, beneficiaries, and State Medicaid agencies (49 FR 29026). Seventy-eight items of correspondence were received from the public. The provisions of the proposed rule, the comments we received and the changes that we made in response to those comments, as well as additional changes, are discussed below.

II. Provisions of the Proposed Regulations

A. PRO Implementation and Functions Under Medicare

The NPRM specified that HCFA would award contracts to PROs and further specified the procedures for notifying facilities to be reviewed by the PRO, State survey agencies, Medicare fiscal intermediaries and carriers, and the public about the PRO contract and the schedule for the implementation of review. The NPRM proposed general requirements for a PRO's assumption of review.

The NPRM included the specific dates by which health care facilities would be required to enter into an agreement with a PRO. As discussed in section I, above, these requirements have been revised by DRA.

The proposed regulations would have required PROs to negotiate memoranda of understanding with Medicare fiscal intermediaries and carriers that delineate the responsibilities of each party and provide for the exchange of data, notification of review determinations, and any other pertinent procedures. The NPRM proposed that any of the duties and functions of a PRO

for which a PRO has not assumed responsibility under its contract with HCFA must be performed in the manner and to the extent otherwise provided for under the Act.

The proposal specified that a PRO determination under 42 CFR Part 466 would be an initial determination that is final and binding unless it is reconsidered or revised in accordance with appeal procedures in 42 CFR Part 473, Subpart B. Final regulations for Part 473 are included elsewhere in this issue of the *Federal Register*.

The proposal described the correlation of the Title XI and Title XVIII functions of the PRO. A PRO's review determination with regard to reasonableness, medical necessity, and appropriateness of placement at an acute level of care would replace the utilization review activities required of health care institutions under sections 1861(e)(6), 1861(j)(8) and (j)(12), 1861(k) and 1865 of the Act. However, a PRO's review determination would not supersede HCFA's authority to enforce the coverage provisions of the statute. For example, although a service may have been medically necessary, it might be a service that is not covered under Medicare.

In order for a PRO to carry out its review functions, we proposed that a PRO be authorized to examine the operations and records of facilities that are pertinent to services provided to Medicare beneficiaries. A PRO would be permitted to examine the records of non-Medicare patients only if authorized to do so by the facility or practitioner or by HCFA under sections 1815 and 1833 of the Act.

We proposed that PRO review would differ from the current PSRO review with regard to requirements for the annotation of claims. PSROs were required to annotate all Medicare claims from health care facilities under their review to indicate whether the claims are approved for payment or denied. Because that procedure has been administratively cumbersome and ineffective, we proposed that PROs would not annotate every claim, but only those made for additional payment for an "outlier" case, those cases subject to preadmission review and those other claims that are denied.

The proposed regulations described the procedures a PRO must follow in making an initial denial determination. Before a PRO issues an initial denial determination, the proposed regulations would have required that the PRO afford the provider and the patient's attending physician (or other attending health care practitioner) the opportunity to discuss with the PRO physician advisor any

proposed denial determination and the bases for that determination. The proposal also described the content of the notice and the procedures for notifying the patient or the patient's representative, the attending physician, the Medicare fiscal intermediary or carrier, and the facility.

The proposed rule specified that the PRO review period is generally within one year of the date that the claim containing the item or service was submitted to the Medicare fiscal intermediary or carrier. A PRO determination could be reopened and revised by the PRO within four years of the date that the claim was submitted to the Medicare fiscal intermediary or carrier if additional information is received on the patient's condition or if an error had been made. The proposed rule stated that a PRO determination could be reopened or revised at any time if it was obtained through fraud or a similar abusive practice.

The NPRM proposed qualifications for the PRO reviewers. Generally, the services ordered or furnished by a doctor of medicine, osteopathy or dentistry may be denied only by another doctor of medicine, osteopathy or dentistry, respectively, who has active admitting privileges at one or more hospitals in the PRO area.

The NPRM specified that a PRO would be required to negotiate with HCFA concerning the use of national or regional norms for conducting review to achieve the objectives set forth in the PRO contract. A PRO would also be required to establish written criteria and standards to be used in the conduct of review.

The NPRM proposed that a PRO, in order to achieve economical and efficient review, would be required to coordinate activities (including the exchange of information) among Medicare fiscal intermediaries and carriers, other PROs, and other public or private review organizations as appropriate.

B. PRO Relationships With Medicaid

The NPRM specified that, as with PSRO requirements, when a State contracts with a PRO for medical or utilization review, the State must submit a plan amendment to the Regional Office for approval. The proposed rule specified that the State plan would assure that the contract with the PRO satisfied certain requirements. Again, as with current PSRO policy, a State that contracts with a PRO will be eligible for Federal financial participation (FFP) at 75 percent for funds expended for the performance of medical and utilization review under the contract. If a State

fails to make a satisfactory showing that it has an effective utilization control program (42 CFR 456.650), the reduction in FFP would not apply to facilities where either PSRO or PRO review is being conducted under an approved contract.

Under the proposed regulations, if a State contracts with a PRO, the medical and utilization requirements would be deemed to be met. However, the physician certification requirements and plan of care requirements would not be deemed met through an approved PRO contract. The proposed regulations added the requirement that the State agency, in its quarterly report that indicates that the State meets utilization requirements, must include facilities in which a PRO is performing review. As specified in the NPRM, the State agency's report for a quarter would have to include the dates a PRO was responsible for review in a facility for which a showing that the State met utilization requirements for recipients would otherwise have had to been made. More specific details of the proposal can be found in the document published on July 17.

III. Discussion of Comments

Note: We have made references within this preamble and regulations text to prospective payment regulations (previously §§ 405.470 through 405.477) that were redesignated under a new Part 412 on March 29, 1985 (50 FR 12740). References to these sections in the preamble of this document give both old and new citations for the benefit of the reader.

The majority of the comments we received on the proposed rule were from PSROs, hospitals, hospital associations, business groups and national medical organizations. The comments and our responses are set forth below and are grouped by subject area:

A. Statutory Provisions (§ 466.70)

Comment: One commenter noted that the proposed § 466.70(c) that would allow PROs to make payment determinations based on the completeness, adequacy and quality of care is not consistent with the PRO statute that only allows PROs to review services, not deny payment, based on these issues. Another commenter believed the regulations should not require the PRO to perform any duties in addition to those imposed by the statute.

Response: We agree with the first comment and have revised § 466.70(c), now redesignated as paragraph (d), to remove the reference to a PRO making a payment determination based on the completeness, adequacy and quality of care. We have deleted the reference to a

PRO making payment determinations based on quality contained in the definition of "Review responsibility" (§ 466.1). We have also removed the reference to a PRO making a payment determination based on changes resulting from DRG validations. As revised, the section provides that PROs will make payment determinations based on the reasonableness and medical necessity of services and the appropriateness of the acute care setting. Regarding the second comment, the Secretary has the authority, under section 1154(a)(8) of the Act, to issue regulations to implement the PRO program. We believe that all of the PRO activities required by these regulations are required by statute (sections 1154, 1866(a)(1)(F), 1866(f)(2) of the Act) and are necessary for an effective peer review program.

B. Notification of Designation and Implementation of Review (§ 466.72)

Comment: One commenter suggested that the PRO's notification that it is assuming review should include a list of the facilities to be under review. Another commenter believed that facilities should get a detailed explanation of the review process within 10 days of the signing of the PRO contract.

Response: Section 466.72(b)(2) of the proposed regulations specifies that the PRO will publish a notice in at least one local newspaper listing each facility to be under review. HCFA has also published newspaper notices announcing the award of individual PRO contracts. However, PROs are still required to issue a more detailed newspaper notice listing each facility under review and stating when and where their review plan is available for public inspection. Regarding the second comment, the regulations at § 466.72(b)(1) require that the hospital receive written notification of the date and manner by which the PRO will implement review. In addition, regulations at § 466.76 require a PRO to discuss the PRO's review process with the hospital. Also, the PRO's review plan is available at the PRO office for public inspection (§ 466.72(b)(2)). Therefore, we believe that the regulations contain adequate provisions to assure that hospitals are fully aware of the PRO's review procedures.

C. General Requirements for PROs (§ 466.74)

Comment: Fifteen commenters disagreed with the proposed regulations that specify that a PRO must not subcontract with a facility to conduct review activities that would affect

payment. The commenters stated that this prohibition is unfair, inefficient, ineffective and costly and recommended deleting this section and replacing it with criteria for delegation. A national medical organization believed the PRO should be allowed to subcontract with members of the medical staff who are not employees of the hospital and who do not have an ownership interest in the hospital.

Response: Although the PRO statute does not specifically prohibit PROs from subcontracting review responsibilities to facilities, we believe that subcontracting review responsibilities to hospitals would compromise the intent of Congress that there be no financial conflict of interest. Since 1981, Social Security Act legislation has reflected a clear departure from delegated hospital review. The Omnibus Reconciliation Act of 1981 removed the requirement that PSRO review be delegated and allowed PSROs discretion about whether or not to delegate review. TEFRA continued and strengthened this trend away from hospital delegation by limiting PRO subcontracting of review to those instances where the PRO finds that the provider will effectively and efficiently review itself. The Social Security Amendments of 1983 created the prospective payment system, where payment is based on a single review decision that affects payment for an entire hospital stay rather than multiple decisions that affect smaller units of payment over the course of a hospital stay. This, together with the Congressional concern expressed in the TEFRA legislation that there be no financial conflict of interest in PRO review, leads us to conclude that subcontracting any review that affects Medicare payment under the prospective payment system not be allowed. We also believe this prohibition should apply to non-PPS hospitals. The majority of PRO review is conducted retrospectively, after the patient has left the hospital. If a hospital were given the responsibility to conduct PRO review, it would therefore be asked to review and deny care, the cost of which it has already incurred. We consider this an extreme conflict of interest. Therefore, we are retaining the prohibition against subcontracting any review except quality review in this final rule.

Comment: Two commenters expressed concern about the requirement that the PRO make it contract primary to all other activities and believed this may interfere with PRO contracts for private review.

Response: Section 1154(b)(11) of the Act encourages PROs to engage in private review activities, but only to the extent feasible and appropriate. The intent of this provision of the regulations is that Medicare review not be compromised by any other PRO contract activities.

Comment: One commenter questioned whether PROs will compile statistics to determine a provider's favorable presumption status under section 1879 of the Act and whether the PRO will be required to notify the provider of its waiver status.

Response: We have included in § 466.74(e) provisions for circumstances when PROs are required to compile statistics to determine a provider's favorable presumption status using the criteria contained in § 405.332(b) and notify the provider of its status. Instructions concerning these compilations will be included in administrative guidelines.

Comment: One commenter believed the regulations should reflect the PRO's responsibility for confirming the accuracy of a hospital patient's discharge destination.

Response: We believe that the specific obligations of an individual PRO should be contained in that PRO's individual contract with HCFA rather than in regulations. Therefore, we are not revising the final rule as a result of this comment.

D. Cooperation with Health Care Facilities (§ 466.76)

Comment: Three commenters believed the 30 day timeframe for implementing review makes it very difficult for PROs to fully discuss their review plans with facilities. Another commenter requested that the regulations specify how a PRO must cooperate with facilities.

Response: We believe it is essential that a PRO begin its review activities as soon as possible after its contract is signed. In fact, we encouraged organizations that submitted proposals for PRO contracts to provide evidence that they had initiated discussions with facilities or associations of facilities in their area. Thus, we believe the 30 day timeframe is adequate for the discussion of review plans with facilities. Regarding the second comment, the individual agreements between PROs and facilities will detail the relationship between the two organizations.

E. Responsibilities of Health Care Facilities (§ 466.78)

Comment: A hospital representative questioned whether the hospital's Medicare payment would be in jeopardy

if the hospital did not have a contract with a PRO by October 1, 1984. The representative noted that there is no designated PRO for the area.

Response: As described in the preamble, the DRA amendments revised the date by which a hospital must have an agreement with a PRO. That date is now November 15, 1984. We note that there are now PROs in each geographic area.

Comments: Twenty-four commenters objected to the requirement in the proposed regulations (§ 466.78(b)(2)) that hospitals photocopy and deliver pertinent information to the PRO because it would increase hospitals' operating costs. The commenters further stated that the PRO should be required to conduct onsite reviews at the hospital whenever possible. The commenters also suggested that the regulations impose some limitations on the volume of material a PRO can request from a hospital and that they ensure the confidentiality of the records. Another commenter requested that the regulations specify that the PRO can request pre-admission records of tests in addition to the post-admission record.

Response: We believe it is important that PROs have adequate access to medical records to enable them to carry out required activities. This includes the right to request and receive copies as they deem necessary, including preadmission test records. In some cases, this will mean that the PRO will request hospitals to photocopy specific medical records and mail them to the PRO.

The prospective payment rates are computed according to the provisions of the law and are also based on the best available data at the time of computation.

Administrative costs are included in the Federal and hospital specific portions of prospective payments by virtue of their being incurred and reported by hospitals for the years that represent the data bases for the prospective payment system.

Prior to the use of PROs, review of inpatient hospital services was carried out either at the hospital or offsite. Offsite review sometimes required that the hospital mail patient records to Medicare fiscal intermediaries. These costs were subsumed in the hospital's administrative costs which in turn were reflected in Medicare cost reimbursement. Costs related to such activities are accounted for, in some measure, in the prospective payment base rates.

We also believe that the fiscal benefits of PRO review will compensate for any such increased costs. For

example, in many cases, PRO's preadmission review activities will protect hospitals from retrospective denials. Thus, there will be trade-offs between a hospital's cost of providing medical records to a PRO and the PRO's performance of review, that, in many cases, may assist hospitals in avoiding unnecessary expenditures.

We agree that the confidentiality of copied records is important and we plan to publish final regulations concerning PRO's protection of photocopied records as separate regulations.

Comment: One commenter questioned why the proposed rule did not contain provisions to satisfy the requirements under Section 1815(b) and 1861(w)(2) of the Act that specify that a hospital, as a condition of payment under Medicare, is obligated to pay a PRO an amount reasonably incurred by the PRO in conducting review activities at that hospital.

Response: Section 1153(c)(8) of the Act provides that reimbursement of PROs will be made in accordance with the terms of their contract with the Secretary. HCFA's policy in negotiating the terms of the PRO contracts has been that PROs will receive reimbursement directly from HCFA. This policy, which is in accordance with section 1153(c)(8) of the Act, eliminates the need for regulations that would specify that HCFA pay a hospital which in turn would pay a PRO for the conduct of review.

Comment: Many Commenters believed that hospitals should not be held financially liable for cases subject to preadmission review. The commenters believe that the PRO should be required to perform review in a timely manner and the beneficiary should be financially liable if the hospital notifies the beneficiary that services would not be covered. The commenters believed that the policy in the regulations is contrary to the limitation of liability provisions in section 1879 of the Act. Another commenter requested that we explain the difference between preadmission review and preadmission certification.

Response: We agree with the commenters that HCFA should not assign financial liability to providers in preadmission review cases in which both the patient and provider have knowledge that the proposed admission is medically unnecessary, unreasonable or inappropriate. Therefore, we have deleted this provision from § 466.78(b)(6) of the final rule. In accordance with section 1879(c) of the Act, if both the provider and beneficiary have knowledge that the proposed admission will not be covered by Medicare, HCFA

will not pay the bill and settlement will be between the hospital and the beneficiary. We are retaining the requirement that a facility agree to accept financial liability if (1) the facility has been notified by the PRO of the admission categories that are subject to preadmission review and certification; (2) the required PRO review has not been performed; (3) the facility admits the patient; and (4) subsequent PRO review finds the admission to be medically unnecessary, unreasonable or inappropriate. However, we are revising § 466.78(b)(6) to state that a hospital is not automatically liable if, in accordance with its agreement with the PRO, it makes a timely request for preadmission review and the PRO does not review the case. The agreements between the hospital and the PRO will contain specific details regarding the PRO preadmission review process including the timing of the request for PRO review and the PRO's response.

Regarding the request for clarification on the difference between preadmission review and preadmission certification, preadmission review is the process for determining, for payment purposes, the reasonableness, medical necessity and appropriateness of placement at an acute level of care. Preadmission certification is a favorable determination, transmitted to the hospital and the fiscal intermediary, approving of the patient's admission for payment purposes. We have included definitions of these two terms in § 466.1 of this final rule.

Comment: One State government suggested that the beneficiary should be informed of the reconsideration and appeals process at the time of admission. However, other commenters believed that we should eliminate the requirement that the beneficiary be informed by the hospital at the time of admission about PRO review because it would harm the patient and because the commenters believe it is the responsibility of the Government to inform the beneficiary.

Response: We believe it is important that Medicare beneficiaries be informed about the PRO review process at admission and the § 466.78 of these regulations adequately ensures that beneficiaries are aware of that process. We believe that the hospital can most effectively and efficiently provide this information to the beneficiary at the time of admission. Also, additional detailed information concerning PRO reconsiderations will be made available to beneficiaries by the PRO whenever a PRO denial determination is issued.

Comment: One commenter believed the regulations should specify that the hospital will provide space to the PRO for its review functions in accordance with other demands on the hospital for space.

Response: In their agreement, the PRO and the facility should work out an arrangement that provides the PRO with adequate space to perform its review functions while not placing a hardship on the facility.

F. Coordination with Medicare Fiscal Intermediaries and Carriers (§ 466.80)

Comment: Two commenters questioned whether the agreement between the PRO and the Medicare fiscal intermediaries or carriers has to be approved by HCFA before review can begin because this could delay implementation of review. The commenters believed that we should establish timeframes for submission of the agreements to HCFA and for approval by HCFA.

Response: The regulations require that the agreements must be approved by HCFA before the PRO begins to make review determinations. Because PRO contracts will be signed at different times, each PRO contract will contain a timeframe that is adequate for the PRO and the fiscal intermediary or carrier to reach an agreement. Therefore, we are retaining this provision in § 466.80(c) of the final regulations. We do not believe that more rigid timeframes would necessarily facilitate the negotiation process. Also, every organization that submitted a proposal for a PRO contract was asked to provide a draft agreement and to verify that it had initiated discussions with the appropriate fiscal intermediary. It is our intention that all PRO contracts be awarded in sufficient time for agreements to be signed by the November 15th deadline.

G. Continuation of Functions (§ 466.82)

Comment: One commenter asked who is responsible for certain review activities once a PRO contract is effective. Specifically, the commenter asked who is responsible for review activities not initiated or not completed by the fiscal intermediary or former PSRO for Medicare hospital admissions occurring before the effective date of the PRO contract. Another commenter believed that § 466.82 dealing with the continuation of functions is unnecessary because, as of November 15, all hospitals will have review contracts with PROs.

Response: The pro is responsible for all review activities specified in its contract with HCFA. In most cases, these contracts include the completion

of any PSRO activity. We believe that § 466.82 is still necessary because fiscal intermediaries must, in the unlikely event that a PRO contract terminates before a new contract is signed, be responsible for these review functions. The fiscal intermediary will also be responsible for any review function that the PRO has not yet assumed, but which it may assume at some future time.

Comment: Two commenters believed that the fiscal intermediaries should not be making determinations on medical necessity, reasonableness, or level of care. Another commenter believed that the PRO should use norms of care, not HCFA coverage policy, in making review determinations. One commenter believed the regulations appear to state that PRO review determinations are final and binding, but believed that all cases should be subject to appeal.

Response: In responses for the first comment, the regulations at § 466.85 provide that, if a PRO has assumed review responsibility, the PRO, in fact, is responsible for making determinations based on medical necessity, reasonableness and level of care. However, the fiscal intermediary will continue to make coverage determinations on other bases, including whether the service is a statutorily excluded service. It is bound, for payment purposes, by a PRO determination with respect to a medical necessity issue. Regarding the last comment, PRO initial denial determinations are final and binding, subject to appeal under 42 CFR Part 473. Final regulations for Part 473 are published elsewhere in this issue of the *Federal Register*.

Comment: One commenter believed that the regulations should state that the PRO's determination about whether outpatient or other inpatient care is appropriate must be consistent with medical care in the community and must take into consideration the availability and accessibility of care to the patient.

Response: Although we basically agree with the commenters, we do not believe the regulations should address these specific issues. In developing their review criteria, PROs must take into consideration the appropriate medical care in the community.

Comment: Two commenters objected to the need for hospitals to reinstate physician certification. The commenters believed that this will be an administrative burden on hospitals.

Response: The PRO statute does not contain the provision included in the PSRO statute at 1156(d)(1)(B) of the Act that permitted the use of PSRO review to meet the physician certification requirements of the Act. Therefore, to be

consistent with the PRO statute, we are retaining this provision for the final rule.

H. PRO Access to Non-Medicare Patient Records (§ 466.88)

Comment: Thirty-five commenters argued that the proposed regulations regarding a PRO's access to the medical records of non-Medicare patients (§ 466.88(b)) are contrary to the provisions of the statute. Section 1866(a)(1)(E) of the Act requires a hospital to release these records to a PRO for its conduct of review under a contract with a private or public agency. As written, the proposed regulations would allow a hospital to deny the PRO access to the medical records of non-Medicare patients. One commenter also questioned whether the working aged are considered Medicare patients when Medicare is not the primary payor.

Response: We agree with the commenters and are revising § 466.88(b) to provide that a PRO may obtain non-Medicare patient records relating to review performed under a non-Medicare PRO contract, if authorized by the patient under State law. This includes records of the working aged and beneficiaries who are dually entitled under Titles XVIII and XIX. However, when these beneficiaries are receiving Medicare services, all Medicare review rules apply. A PRO may also obtain non-Medicare patient records in accordance with its quality review responsibilities under the Act, only if authorized by the institution or practitioner.

Quality review is an integral and essential element of the PRO statute. Section 1154(a)(1)(B) of the Act specifies that any PRO must (in accordance with its contract with the Secretary) perform review to determine whether the quality of care provided to Medicare beneficiaries meets professionally recognized standards of health care. This PRO requirement represents the continuation of a peer review function mandated by the Medicare statute over the past ten years. In section 1154(a)(6), the Congress provides the same process for PROs as it had for earlier Medicare peer review for prescribing the way in which quality review would be performed by PROs, namely, regulations of the Secretary. Furthermore, the provisions of section 1154(a)(7)(D) and (a)(9) direct PROs, in a way similar to earlier peer review organizations, to inspect facilities and collect information necessary to carry out PRO review functions, including quality review. Section 1866(a)(1)(E) imposes a similar obligation on Medicare providers to release patient care data to PROs for

review purposes including the conduct of Medicare quality review. Taken together, these provisions give statutory authority to PROs to conduct quality review in the same manner as conducted by previous Medicare peer review organizations.

The quality review process consists of screening patient care information to identify and verify quality problems in addition to conducting quality review studies. A quality review study is an assessment conducted by or for a PRO of a patient care problem for the purpose of improving the patient care of some or all providers or practitioners in the PRO area through peer analysis, intervention, and resolution of the problem and follow-up.

While the problem studied must affect Medicare patients, it usually affects other patients as well, especially in the context of acute inpatient care. This is because quality problems relate to the way in which care is delivered (i.e., the behavior of a provider or practitioner). In some of these cases, a problem can be adequately addressed for Medicare patients only by addressing the problem for all patients in an acute care setting.

This means that in some quality review studies a PRO must review both Medicare and non-Medicare patient records in order to resolve the problem for Medicare patients. For example, a Medicare quality review study may seek to analyze and resolve a problem in the use of prophylactic antibiotics in certain operations which, when not used, increase the rate of infections post-operatively. However, for individual providers or specific practitioners, the frequency of certain operations for Medicare patients may be too low to draw reliable conclusions about the proper use of these antibiotics by that practitioner or in that provider on a timely basis (i.e., it may take a year of data collection for Medicare patients only). In contrast, the frequency for these operations performed on all patients may be adequate to permit timely and reliable assessment of the problem (i.e., within one to three months) and permit more rapid problem resolution for Medicare patients.

Also, physician and hospital-wide studies encourage general resolution of problems through the alteration of area practice patterns. This benefits both Medicare and non-Medicare patients and assures more substantive and longer lasting improvement in a problem than could have been achieved by focusing only on Medicare patients.

I. Examination of the Operation and Records of Facilities (§ 466.88)

Comment: Several commenters believed that PROs should only examine hospital information and charges for outlier cases and those other items required by law. Other commenters felt the language in § 466.88 is vague and requires PROs to duplicate fiscal intermediary efforts. Other commenters requested that we specify what aspects of a hospital's operation a PRO can examine and that PROs should be required to submit results of inspections in writing to the facility. Another commenter noted that the proposed regulations that allow a PRO to examine a hospital's operation in order to determine a hospital's capability to perform review should refer specifically to quality review, as this is the only review that may be delegated to a hospital. Another commenter questioned whether the facility may have access to PRO records.

Response: We believe that the regulations are consistent with the statute, which gives PROs the authority to inspect facilities and records of health care facilities and providers for the purpose of carrying out their responsibilities as specified in the Act. PROs may require hospital charge information for many types of review, such as ancillary services or quality review of inappropriate utilization. We have, however, deleted the reference to cost information from § 466.88(a) because we do not anticipate a need by PROs for this information in carrying out their statutory and contractual responsibilities. PRO review does not duplicate fiscal intermediary review because the functions of each are coordinated as described in § 466.88 of these regulations. For example, only PROs will make determinations based on medical necessity, reasonableness and appropriateness of inpatient care. Only fiscal intermediaries will make coverage determinations on services excluded by statute. The results of PRO review will be made known to hospitals in accordance with provisions that will be included in 42 CFR Part 476. We agree with the comment that the reference to the capability of the facility to perform review should refer specifically to quality review, and we have revised § 466.88(a)(3) accordingly.

J. Lack of Cooperation by a Health Care Facility or Practitioner (§ 466.90)

Comment: Some commenters questioned whether, if a PRO denies a claim because the hospital did not submit requested information, the hospital can then submit the information

and request a reconsideration. Two commenters believed that the proposed regulations at § 466.90 are vague and requested definitions and clarifications.

Response: If a PRO denies a claim because a hospital did not submit requested information, the hospital may request a reopening of the case after submitting the requested information in accordance with regulations in 42 CFR Part 473. Final regulations for Part 473 are also published in this issue of the **Federal Register**. We are not making any significant changes to § 466.90 because we believe that the terms used in the section have been defined or explained elsewhere in the text of the regulations.

K. Opportunity to Discuss Proposed Initial Denial Determination (§ 466.93)

Comment: Seven commenters recommended that we revise the proposed requirement that a PRO afford an opportunity for the provider and physician (or other attending health care practitioner) to discuss a proposed initial denial determination with the PRO physician advisor. The commenters believed that this requirement should not apply when a retrospective review is performed by the PRO after the patient is discharged from the hospital because it would result in an increased administrative burden to the PRO and would be impossible to implement. One commenter also suggested that if retrospective review is performed, an exit interview should be furnished to the hospital upon request. Another commenter questioned whether there is a need for both the provider and practitioner to discuss the proposed denial.

Response: Section 1154(a)(3) of the Act requires the PRO to afford an opportunity to the provider and practitioner to discuss any initial denial determination. In addition, our proposed rule would increase review flexibility and reduce the costs of issuing unnecessary denials or conducting reconsiderations by providing an opportunity for discussion to both provider and practitioner prior to issuing a denial. We believe this is a more efficient and less cumbersome procedure than exit interviews or retrospective denials alone.

Comment: A hospital association suggested that the PRO should be required to notify the provider and the physician of the proposed denial within 24 hours of the denial decision. Another commenter recommended that the provider and physician be given 24-hours to respond to the PRO's notification.

Response: We do not believe it would be appropriate for the regulations to require a 24-hour limit for notification of the provider and practitioner or for their response. However, in their individual agreements with PROs, hospitals may wish to negotiate these types of provisions.

L. Notice of PRO Initial Denial Determination (§ 466.94)

Comment: Several commenters objected to the proposed requirements that the content of a PRO's notification to a patient of an initial denial determination be the same as that used to notify the practitioner or provider. The commenter argued that, since in most cases the patient would not be liable for payment, it is inappropriate to include the same amount of detail that would be given to the practitioner or provider. Another commenter believed the notice to the patient should only be issued after all local appeals are completed.

Response: Section 1154(a)(3) of the Act specifically requires that the PRO promptly notify the practitioner, provider, patient and payment agency of the denial decision. The Act does not specify that the patient should receive a less detailed notice than the other parties. Therefore, we believe it appropriate that the patient be fully informed and receive the same notice as the other parties and at the same time. Also, in order to appeal a denial determination, a patient must receive timely notice of the denial.

Comment: Three commenters believed that the regulations should contain the specific requirements for the content and format of the denial notice in order to ensure that the notices are understandable, complete, written in plain English, and clearly represent the nature of the PRO's decision. The commenters believed the PRO and the hospital should negotiate the wording of the notice.

Response: We believe the wording of the denial notice is the responsibility of the PRO and should not be subject to negotiation with the hospital. We do agree with the commenters that the regulations should contain specific requirements for the content of the denial notices and we have included appropriate language in § 466.94 of the final rule. Also, we will be monitoring PRO denial notices to ensure that they can be understood by all parties and do not cause unnecessarily adverse reactions among the recipients.

Comment: One commenter believed the regulations should not limit when a patient's representative can be involved.

Response: We believe the regulations adequately provide for the protection of the patient and the inclusion of a patient representative, when appropriate.

Comment: One commenter pointed out that since Saturday and Sunday are not always working days, it might take three days for the delivery of a denial notice. The commenter also questioned what "prompt written notice" to the fiscal intermediary would be and suggested it be the same timeframe as the issuance of the notice to the other parties.

Response: We agree with the commenter and have revised the proposed § 466.94(c) (this is § 466.94(a)(2) in the final rule) to specify that the time periods for delivery of the notices are all in terms of "working" days, rather than calendar days. We have also revised the timeframe for the notice to the fiscal intermediary to be the same as the notice to the other parties. We have also added timeframes for the notice to the practitioner and provider regarding changes as a result of a PRO's DRG validation.

M. Review Period and Reopening of Denial Determinations (§ 466.96)

Comment: Three commenters suggested that a PRO should not have more than 120 days to deny payment, rather than the one year generally specified in the regulations. Another commenter suggested that the proposed § 466.96(b) that would allow denial determinations to be made within four years of the date of the claim for service should be deleted because all reviews should be completed within one year.

Response: We believe the timeframes specified in the regulations are appropriate because they are similar to other Medicare review time limits at § 405.750(b)(2). To assure the efficiency of the review process, we are limiting to one year the time period during which a PRO may on its own make or reopen an initial denial determination or a change as a result of a DRG validation. In addition, we are revising § 466.96 to allow up to four years for an initial determination change or a change as a result of a DRG validation to be made, reconsidered or revised as described in the regulations. We have deleted the proposed requirement that these actions first be approved by the HCFA Regional Administrator.

N. Reviewer Qualifications and Participation (§ 466.98)

Comment: Several commenters believed that doctors of medicine (M.D.s) and osteopathy (D.O.s) should be allowed to review each others' care. Other commenters suggested that specialists be able to request review by

another specialist in the same discipline. Another commenter was concerned that only appropriately qualified medical record personnel perform DRG validation. Another commenter believed the regulations should prohibit a person from performing review who is connected with a facility that is in competition with the facility under review. Also, one commenter suggested that any physician who receives compensation from a hospital should be prohibited from performing review. Another commenter believed the role of the non-physician in the review process should be detailed in the regulations.

Response: We believe it is the intent of the statute and the most effective method of peer review, for M.D.s to review M.D.s, and D.O.s to review D.O.s. We have, however, made an exception to this rule when the appropriate peer is not available to perform the review. Although the suggestions of the commenters regarding review by specialists may have merit, we do not believe these requirements should be included in regulations. However, we have revised the regulations to require that changes as a result of DRG validations be made by a physician and that individuals with training and experience in ICD-9-CM coding must review the technical coding issues. Additionally, the final regulations in Part 473 published elsewhere in this issue of the Federal Register do require that the reconsideration reviewer be a professional peer of the practitioner under review. Regarding the next two comments, we do not believe it is appropriate to include these limitations on the qualifications of reviewers. We believe that the regulations adequately protect against a conflict of interest and that further restrictions are not necessary. Regarding the last comment, we believe that § 466.102 adequately addresses the role of non-physicians in the review process.

O. Use of Norms and Criteria (§ 466.100)

Comment: Several commenters believed that the regulations do not reflect the Congressional intent that PROs use local norms, taking into consideration national norms. Other commenters expressed concern that the PRO may be discriminatory in applying different criteria to different locations and facilities. Other commenters suggested that the PRO be required to describe to the hospital how it arrived at the numbers of procedures selected for preadmission review. Another commenter believed the PRO should be required to make available to the

hospital the criteria, norms and standards used in review. Another commenter suggested that the regulations specify the body of knowledge to be used to determine national norms.

Response: Section 1153(c)(7) requires that negotiated PRO contracts include specifications for use of regional or national norms for setting contract objectives and performing review functions. Norms are statistical values used to establish standards of care and PRO objectives. In contrast to these norms, section 1154(a)(6) of the Act specifies that in their review PROs must use professionally developed norms based upon typical patterns of practice within the PRO area. These are in fact review criteria which are developed by each PRO. Criteria may reflect special circumstances in the PRO area. Regarding the last comment, the PRO agreement with the hospital should contain the specifics for exchange of data, including review criteria.

P. Coordination of Activities

Comment: One commenter suggested that PRO's should be allowed to exchange only aggregate data and that the regulations should preclude disclosure and redisclosure of unauthorized information. Another commenter suggested that the information should be exchanged only with those who have a financial interest in the case.

Response: The exchange of data is governed by the PROs review responsibilities as set forth in section 1154 of the Act. In some cases, the data may be aggregated, but in other cases may contain more detailed information. Regulations governing the acquisition, disclosure and redisclosure of PRO data will be contained in 42 CFR Part 476 and will be published in the Federal Register.

Q. HMOs

Comment: Two commenters suggested that HMO patients be exempted from review because the HMO receives a prospective payment and the HMO already has an incentive to provide efficient care.

Response: The statute does not exclude HMO patients from PRO medical review. We believe that PRO review is important because the quality of care is a critical issue for HMO and other patients treated on a capitated payment basis. Therefore, we are not revising the final rule to exempt HMO patients from PRO review.

R. Hospital Issued Denial Notice

Comment: One commenter suggested that the regulations provide that a patient be entitled to an expedited review of the hospital's denial notice and that the hospital be required to notify the patient of appeal rights before the notice is issued. Another commenter questioned whether the provisions of § 466.78(b)(4) are in conflict with a hospital's right to issue denials because that section would require that hospitals issue denials only in accordance with their agreement with the PRO.

Response: Regulations concerning the timing and review of hospital-issued denial notices are contained in § 412.42(c)(3) (previously § 405.472(b)(1)(iii)(C)). Therefore, we are revising § 466.78(b)(4) to specify that when a hospital has issued a written determination in accordance with § 412.42(c)(3) that a beneficiary no longer requires inpatient hospital care, it must submit a copy of its determination to the PRO within 3 working days.

S. Impact

Comment: Four commenters believed that the impact analysis that appeared in the NPRM was incorrect in stating that the regulations will not have an annual effect of \$100 million.

Response: In the Impact Analysis of this final rule, we have included a voluntary regulatory impact and regulatory flexibility analysis. The analysis acknowledges that a substantial number of facilities, practitioners and beneficiaries will be affected by implementing the PRO program. However, for the following reasons, we believe that the annual impact will not be significant, nor will it meet the \$100 million threshold criterion. The reasons we cite are: (1) The primary impact results from Congressional intent and from the individual PRO contracts; (2) the incremental differences between most PRO and previous peer review activities are not significant; and (3) the effect of PRO activities may not be the primary cause of these impacts. The influence of other factors like the prospective payment system and other third-party payor review efforts to reduce unnecessary admissions and procedures, may have a greater impact on costs than the effects of the PRO activity.

T. Objectives

Comment: Several commenters expressed concern that the objectives are, in fact, quotas and that they could have a negative impact on quality. Another commenter was concerned that setting unrealistic objectives will erode

PRO credibility with the medical community. Some commenters were concerned that PROs would be held accountable for their contract objectives even though circumstances beyond their control prevented them from accomplishing their objectives.

Response: While PROs have negotiated specific contract objectives in accordance with requirements contained in section 1153(c)(7) of the Act, these objectives are targets, or quotas. We recognize that there are circumstances under which the objectives may need to be modified. For example, quality objectives would be modified if data developed during the course of the contract demonstrates that the problem targeted is not as severe as previously thought, or if the PRO identifies a different problem of greater importance. Utilization objectives would be modified as a result of demographic shifts (for example, an influx of Medicare beneficiaries into the PRO service area), the effects of new technology, etc.

This approach will allow us to be responsive should circumstances for the PRO change significantly, while also retaining the accountability and performance incentives built into a specified, outcome-oriented contract. In addition, we will periodically review all PRO required review activities to evaluate their appropriateness and cost effectiveness.

U. Medicaid Provisions

Comment: One commenter objected to the provision that reimburses a State at 75 percent when they contract with a PRO to perform medical and utilization review, but only 50 percent when they contract with any other organization. Another commenter questioned what the reimbursement will be for those States with superior utilization review systems waivers granted under 42 CFR 456.505, currently reimbursed at 75 percent.

Response: Sections 1903(a)(2) and (7) of the Act provide that States will be reimbursed at 75 percent for the cost of utilization review activities performed by a PRO under contract with a State or by State employees but only 50 percent for review performed by others under a contract. Under section 1903(a)(2) of the Act, States that have been granted superior systems waivers to perform utilization review activities can be reimbursed at 75 percent for those activities performed by State employees.

Comment: One commenter pointed out that we had an incorrect cross-reference in § 431.630(b).

Response: We agree and have corrected the cross-reference in the regulations text.

V. Definitions

Comment: One commenter pointed out that the definition of grace days conflicts with 42 CFR 405.472, which requires 2 grace days after termination of benefits.

Response: Grace days as used in our proposed definition at 42 CFR 466.1 and as defined in 42 CFR 405.330 refer to additional days of Medicare payment (not more than 2 days) that a PRO or fiscal intermediary may, at its discretion, provide to arrange for post discharge care. In contrast, the provisions at § 412.42(c) [previously § 405.472(b)] describe when a hospital may begin to charge a beneficiary for services provided during a stay otherwise covered by a DRG payment. These provisions do not provide for additional Medicare payment but do specify when a hospital may charge the beneficiary (i.e., the day after the second day after the issuance of a hospital denial notice). Therefore, we believe our explanation of grace days is appropriate. We note that we are deleting the definition of grace days that was in our proposed § 466.1 because we did not specifically refer to grace days elsewhere in the proposed rule. We have, however, included our explanation of the term at § 466.70(d). We also note that we are changing our explanation of grace days. We previously stated that PROs may grant grace days for the purpose of arranging for post discharge care when neither the provider nor the patient knew or could reasonably be expected to have known that Medicare payment for the service would not be made. In accordance with section 1154(a)(2)(B) of the Act, we have revised our explanation to refer only to the provider's lack of knowledge regarding coverage of services.

Comment: Two commenters believed that the definition of "active staff privileges" is unduly restrictive. Many practitioners, such as psychologists, have privileges to practice independently in the hospital, but do not have admitting privileges. One commenter suggested that the definition include practitioners who are authorized to perform diagnostic services in a facility on a regular basis.

Response: The PRO program is a medical peer review program. To achieve true peer review, we believe it is essential that any PRO reviewing physician be actively practicing his or her profession which includes admitting patients to acute care hospitals.

Comment: One commenter questioned why the definitions of "length of stay norms" and "length of stay projections" only refer to PSROs. The commenter believes these definitions should also apply to PRO outlier reviews.

Response: We have revised these definitions to apply to both PSROs and PROs. PROs will be performing length-of-stay review in both non-PPs and specialty hospitals.

Comment: One commenter suggested that the definition of "quality review study" should include the element of follow-up to the problems identified to ensure that they are corrected.

Response: We agree with the commenter, and have added the element of follow-up to the definition of "quality review study".

Comment: One commenter suggested that the regulations should include a definition of "criteria".

Response: The definition of "criteria" is already contained in § 466.1. The definition did not appear in the July 17th Federal Register publication because the definition is unchanged from that contained in current regulations.

IV. Final Regulations

Based on the comments received and other considerations, we are making the following changes to the proposed rule. We also have made technical changes to the proposed regulations to correct drafting errors and to simplify and clarify certain sections.

A. Statutory Provisions

In the proposed § 466.70(a), we are replacing the reference to specific legislation with the important statutory cites relating to PRO review responsibilities. We are revising the proposed § 466.70(b) that is redesignated as § 466.70(c) to include the requirement that PROs make determinations as to whether a hospital has misrepresented admission or discharge information or has unnecessarily admitted patients to a hospital. This conforms to existing regulations at § 412.48 [previously § 405.472(e)]. We are revising the proposed § 466.70(c) that is redesignated as § 466.70(d) to conform to section 1154 of the Act that specifies that a PRO cannot make payment determinations based on the quality of care. Additionally, in § 466.70(d), we are specifying that PROs may grant grace days. In accordance with section 1154(a)(2)(B) of the Act, we refer only to the provider's (and not the patient's) lack of knowledge regarding coverage of services.

B. General Requirements for the Assumption of Review

We are revising § 466.74(e) to require that PROs compile statistics to determine a provider's favorable presumption status and notify the provider of its status.

C. Responsibilities of Health Care Facilities

We are revising § 466.78(a) to conform to section 1866(a)(1)(F) of the Act as revised by the DRA to require that effective November 15, 1984, all hospitals seeking payment under Medicare must maintain an agreement with a PRO. We also are specifying that the agreement must be in writing. In order to allow time for these agreements to be established, we are specifying that this provision is effective June 17, 1985 rather than May 17, 1985 which is the effective date for the other provisions of this rule.

We are revising the proposed § 466.78(b) to specify that when a health care facility has issued a written determination in accordance with regulations at § 412.42(c)(3) [previously § 405.472(b)(1)(iii)(C)], it must submit a copy of its determination to the PRO within 3 working days. We are revising § 466.78(b)(5) that requires a facility to assure that each case subject to preadmission review has been approved by the PRO before admission. We are adding the alternative that the facility assure that a timely request for the PRO preadmission review has been made. In § 466.78(b)(6), we have deleted the proposed provisions that would have assigned financial liability to a hospital in cases in which both the patient and the provider had knowledge that a proposed admission was medically unnecessary, unreasonable or inappropriate. We are also adding a provision to state that a facility is not automatically liable if, in accordance with its agreement with the PRO, it makes a timely request for preadmission review and the PRO does not review the case. This type of case is subject to retrospective prepayment review.

D. Coordination with Medicare Fiscal Intermediaries and Carriers

For consistency, we are changing the references to an "MOU" in this section to "agreement". We are also adding language in § 466.80(b) to provide that the PRO inform intermediaries and carriers of changes that result from DRG validations and the revisions that result from the review of these changes. In § 466.80(e) that specifies that an intermediary will not make payment unit it receives notice that the PRO has

approved the admission, we are specifying that the PRO's approval will be after a preadmission or retrospective review.

E. Initial Denial Determinations

We are revising the proposed § 466.83 to include a clarification of what constitutes an initial denial determination. We are redesignating the proposed § 466.84 as § 466.85 and adding a new § 466.84 to explain that changes as a result of DRG validations may be reviewed by a PRO in accordance with 42 CFR Part 473. The newly designated § 466.85 is revised to specify that both PRO initial denial determinations and changes as a result of DRG validations are final and binding unless reconsidered, reviewed and revised in accordance with Part 473. We note that we have made changes in several other sections of the proposed regulations in order to include the PRO review activity regarding DRG validation.

F. Correlation of Functions

We are revising the format of the proposed § 466.86 for clarity. In some cases, we are changing the citations of the statute to the appropriate citations of the regulations. In § 466.86(a)(1)(iv), we are clarifying that PRO determinations regarding the appropriateness of the setting are conclusive for payment purposes. Additionally, we are revising and adding the proposed § 466.92(b) to § 466.86 of the final rule because both sections concern coverage determinations.

G. Examination of the Operation and Records of Facilities

We are revising § 466.88(a) and (c) to delete the requirement that facilities permit a PRO to examine their cost information. We are revising § 466.88(a)(1) that lists certain PRO functions for which a facility must provide the PRO access to its records and operations. We are specifying that PRO access is not limited to the functions listed. We also are revising the proposed § 466.88(a)(3) to specify that a facility must permit a PRO to examine its operation and records to evaluate the facility's capability to perform quality review. We are revising the proposed § 466.88(b) that previously permitted a PRO to have access to non-Medicare records only if authorized by a facility or practitioner. We are now stating that a PRO may examine these records if: (1) The records relate to review performed under a non-Medicare contract and if authorized by the patient in accordance with State law, or (2) necessary to

perform quality review functions and if authorized by the facility or practitioner.

H. General Requirements for PRO Review

We are deleting the proposed § 466.92(a) regarding certain coverage issues that are involved in making a determination of the appropriateness of care. We are deleting this provision because the regulations contain a similar statement in § 466.86(c) that the Medicare fiscal intermediaries and carriers are not precluded from applying Medicare coverage policy rules. Additionally, we are adding the language contained in the proposed § 466.92(b) to § 466.86(c) since these sections are related and should be grouped together.

I. Notice of PRO Initial Denial Determination or Changes as a Result of a DRG Validation

We are revising the format of the proposed § 466.94 for clarity. In § 466.94(a) of this final rule, we discuss specific requirements for initial denial determination notices, including the parties to be notified and the timing of the notice. We are adding a requirement to this paragraph that PROs must document that the patient and facility receive notice of the initial denial determination in cases of preadmission review. We are clarifying that the time periods for the delivery of the notices are in terms of "working" days.

Also, we are adding a new paragraph (b) to include specific requirements for notice of changes as a result of DRG validations. We are including in this final rule at § 466.94(c) a requirement that PRO determination and DRG change notices be understandable and written in plain English.

Finally, we are revising § 466.94(d) and (e) to require that PROs notify payors of changes as a result of DRG validations and to expand the record retention requirements to include a record of these changes.

J. Review Period and Reopening of Determinations

We are revising the proposed § 466.96 for clarity and to include requirements for the review and reopening of changes as a result of DRG validations. We are limiting the time period to one year in which a PRO may make an initial denial determination or a change resulting from a DRG validation on its own. We are deleting the requirement in the proposed § 466.96(b) that denial determinations made after one year but within 4 years be approved by the HCFA Regional Administrator. Instead, we are requiring that HCFA evaluate on a case-by-case

basis whether the PRO will be permitted to make an initial denial determination or change as a result of DRG validation after the one year review period but within 4 years. In evaluating whether the PRO may make an initial denial determination or change DRGs, within the 4 year period, HCFA will assess whether the potential benefits of the review activity are justified in terms of the administrative burden on HCFA. We are also adding a provision stating that if there is an error on the face of the evidence, an initial denial determination or change as a result of a DRG validation may be reopened after one year but within four years. We inadvertently omitted this in our proposed rule but had included it in the proposed regulations for 42 CFR Part 473 concerning PRO reconsiderations and appeals (49 FR 29041). We note that the provision allowing PROs to review, at anytime, claims involving fraud or abuse, includes claims that may not have been previously reviewed by the PRO or those that were reviewed but were not denied by the PRO.

K. Reviewer Qualification and Participation

In § 466.98, we are adding a new paragraph (c) and redesignating the proposed paragraph (c) as (d). The new provision clarifies that decisions about procedural and diagnostic information must be made by physicians. However, (OIG) technical coding issues must be reviewed by individuals with training and experience in ICD-9-CM coding. This change conforms to regulations in Part 473 that are published elsewhere in this issue of the Federal Register.

L. Definitions

We are making several changes to the definitions located at § 466.1 as follows:

- We are deleting the proposed definition of "annotation" because we had previously deleted the reference to this term in the regulations text.
- We are revising and moving the definition of "area" to § 400.200 that contains definitions for terms used throughout 42 CFR Chapter IV.
- We are deleting the reference to PSROs in the definition of "concurrent review" so that the definition applies to both PSROs and PROs.
- We are deleting the definition of "denial" because we have added further explanations of denials in §§ 466.84 and 466.85.
- We are revising the definition of "DRG" for clarity.
- We are deleting the definition of "grace days" because we did not specifically refer to grace days in the

proposed rule. We note, however, that we are adding a provision at § 466.70(d) that states that PROs may grant grace days and explain the term.

- We are deleting the definition of "health care service" because this term is self-explanatory.

- We are deleting the reference to PSROs in the definitions of "length-of-stay norms" and "length-of-stay projections" so that the definitions apply to both PSROs and PROs.

- We are revising the definition of "non-facility organization" for purposes of clarity and to specify that it does not include entities that are owned by one or more associations of health care facilities. This requirement is specified in section 1153(b)(3) of the Act and we inadvertently omitted it from our proposal.

- We are adding the definitions of "preadmission certification", "preadmission review" and "preprocedure review".

- We are deleting the definition of "PRO" because it appears in § 400.200 that contains definitions that are used throughout 42 CFR Chapter IV.

- We are deleting the proposed definition of "provider" because this term has been defined in § 400.202. Since the definition we proposed included suppliers, we are making specific reference to suppliers where applicable in the regulations text.

- We are revising the definition of "quality review study" to limit it to the quality review studies conducted by or for a PRO for a patient care problem. We are also including an element of follow-up to the definition.

- We are revising the definition of "review responsibility" to delete an incorrect reference to a PRO's payment determination based on the quality of health care. We are also adding language to clarify that PRO decisions regarding changes as a result of DRG validations are conclusive.

- We are deleting the definition of "Utilization and Quality Control Peer Review Organization" because it is being added to the definitions in § 400.200 by another final rule published elsewhere in this issue of the *Federal Register* regarding the acquisition, protection and disclosure of PRO information.

We also are deleting the definitions of "area" and "PRO" in § 460.1. We are also deleting the definition of "PRO" in § 462.2 (that we are redesignating as § 462.1). These definitions are being deleted because they appear in 42 CFR Part 400 that is the general definition section for 42 CFR Chapter IV.

We are revising the definition of "payor organization" in the newly

redesignated § 462.1 to conform with section 1153(b)(2)(A) as amended by DRA.

M. Other Technical and Conforming Changes

We are revising Part 405, Subpart G that contains the reconsideration and appeals procedures for Medicare Part A services. Specifically, we are revising § 405.704 that lists actions that are initial determinations to cross-reference Parts 466 and 473 regarding initial and reconsidered determinations made by a PSRO or PRO.

We are revising § 412.44 (previously § 405.472(c)) regarding medical review requirements for hospitals under the prospective payment system to more accurately reflect a PRO's review responsibilities. As revised, this section is consistent with the description of PROs' responsibilities in § 466.70(c)(4), (5), (6), and (7).

We are revising § 412.82(b) (previously § 405.475(c)(2)) to provide that a medical review entity (for example, a PRO) grants grace days for day outliers under the prospective payment system for inpatient hospital care.

We are deleting references to PSROs in § 431.630 regarding the coordination of Medicaid with peer review organizations to conform to section 1902(d) of the Act.

In § 456.2 concerning States contracting with PSROs, we are deleting a cross-reference to § 431.630 since we are no longer referring to PSROs in that section in accordance with section 1902(D) of the Act.

Again, in accordance with section 1902(d) of the Act, we are deleting the cross-reference to § 431.630 in § 456.650. We also are revising the language in the proposed § 456.650(c)(3) for consistency with paragraph (c)(2). We are deleting the proposed § 456.652(d) that would have implemented a penalty provision for States, contracting with PSROs or PROs, if the State failed to submit a quarterly showing that it met physician certification, recertification and plan of care requirements. The DRA amendments which deleted sections 1903(g)(1)(A) and (B) of the Act, removed the penalty provision for those States not meeting these patient care requirements. Instead, the patient care requirements are now included under the State plan requirements located at section 1902(a)(44) of the Act.

We will not require that States, after they have entered into a contract with a PSRO or PRO, to submit quarterly showings that they meet the patient care requirements except for the first quarter following the effective date of the

contract. This will serve as notification to us to exclude that State or those particular facilities from our validation reviews. As specified in the proposed § 456.654(a)(5) and now in § 456.654(a)(4), if a facility is being reviewed by a PRO, the State need only list the date the PRO assumed review authority on the quarterly showing for that facility. However, a quarterly showing will continue to be required for any facility not being reviewed by a PRO or for any level of care that is still being reviewed by the State.

We are amending 42 CFR Part 462 regarding peer review organizations to establish a new Subpart A to include the definitions located at § 462.2. We are redesignating this section as § 462.1. Also in Part 462, we are making changes to §§ 462.102, 462.103 and 462.105 for clarity. We are revising § 462.105 to conform to section 1153(b)(3)(B) of the Act that defines an entity affiliated with a health care facility or association of facilities. We are further revising §§ 462.105 and 462.106 to conform to section 1153(b)(2)(A) that permits Medicare fiscal intermediaries to serve as PROs effective November 15, 1984. We are deleting the text at § 462.107(d)(2) because it duplicates the provisions contained in § 462.106.

V. Impact Analyses

A. Introduction

Executive Order 12291 requires us to prepare and publish a regulatory impact analysis for any regulations that are likely to have an annual effect on the economy of \$100 million or more, cause a major increase in costs or prices, or have a significant adverse effect on competition, employment, investment, productivity, or innovation. In addition, the Regulatory Flexibility Act, Pub. L. 96-354, requires us to prepare and publish a regulatory flexibility analysis for regulations unless the Secretary certifies that the regulations will not have a significant economic impact on a substantial number of small entities. Under both the Executive Order and the Regulatory Flexibility Act, such analyses must, when prepared, show that the agency issuing the regulations has examined alternatives that might minimize an unnecessary burden or otherwise ensure that the regulations are cost-effective.

In the Impact Analysis section of the proposed rule published on July 17, 1984, we stated that the effects of the regulation were not significant to the point of requiring a regulatory impact analysis or a regulatory flexibility analysis. However, after further review

of our proposed policies and as a result of substantive issues raised by the public commenters, we have decided to include a voluntary regulatory impact and regulatory flexibility analysis in this final rule. This analysis focuses primarily on the nature of the incremental differences between the PRO and PSRO programs and also on the impact of these differences on certain affected parties (e.g., the Federal government, hospitals, physicians, beneficiaries and recipients). Together with several specific comments noted in the preamble, the following discussion constitutes a voluntary analysis of this final rule.

B. Background

Since the inception of the Medicare program in 1965, and the Medicaid program in 1967, Utilization review has been an ongoing activity to assure that Federally reimbursed health care was furnished only when medically necessary. The Social Security Amendments of 1972 established the PSRO program to assure that the health services and items for which Federal payment is made conformed to appropriate professional standards and were delivered in the most efficient and economical manner possible. The Peer Review Improvement Act of 1982 focused on "... promoting effective, efficient, economical delivery of health care services and promoting the quality of services of the type for which payment may be made under this title ..." (Congressional Record—August 17, 1982, page H6185). Thus, throughout the history of the Medicare and Medicaid programs, utilization and peer review strategies have been maintained to safeguard program expenditures and the quality of services and items provided to programs beneficiaries.

C. PROs and PSROs—Differences and Similarities

As noted in the background discussion in the NPRM, there are differences and similarities between the PSRO and PRO programs. A general discussion of these points will focus on significant distinctions between these programs and the effect these differences have on affected parties.

There are notable differences between the two programs. They include:

- PROs are expected to achieve specific, outcome oriented measurable objectives. PSROs emphasized the process of review.
- The funding mechanism (PRO contracts vs. PSRO grants) and length of the agreement (2-year PRO contracts vs. 1-year PSRO grants).

- The responsibilities of PROs to monitor potential utilization and quality problems inherent in the prospective payment system (increased admissions, multiple transfers, early discharges, procedure coding abuse). PSRO review was not strongly focused on outcomes or system impact.

The similarities between the PRO and PSRO programs include:

- Safeguarding Medicare and Medicaid funds from unnecessary and inappropriate expenditures.
- Using various initiatives to educate physician and hospital staff regarding more effective, efficient and economical ways to provide health care services to program beneficiaries.
- Conducting medical reviews by peers.

In this analysis, we are focusing on the impact of the provisions in the rule that are new or modifications to the current peer review effort. In particular, we will examine the effects of the PROs' assumption of review on hospitals under the prospective payment system and for all other facilities, practitioners, and beneficiaries.

D. The Nature of Estimated Impacts Resulting from this Final Rule

In discussing the expected impacts (benefits, costs and behavioral changes) resulting from the final rule, several constraints limit our ability to determine the nature and extent of the impacts. First, PRO efforts are related to the purpose and goals of the prospective payment system. The prospective payment system endeavors to change hospital behavior through financial incentives under Medicare. The PROs act as a safeguard to assure that, as certain behavioral changes occur in response to prospective payment system incentives, program abuses do not occur to adversely affect beneficiaries or the Medicare program. Therefore, it will be difficult to differentiate clearly the impact of PRO efforts from those of the prospective payment system.

A second consideration is that States, other third-party payors and numerous business health care coalitions are also examining the behavior of hospitals and practitioners in hopes of reducing unnecessary and inappropriate expenditures and services. Their efforts, which in some case are the result of PROs' initiatives through private contractual arrangements, will also serve to reduce unnecessary and inappropriate admissions and services. While we view these efforts as beneficial in nature, they must be considered in determining the nature and extent of the effect of this final rule.

Finally, we believe that much of the impact of the PRO program results from the intent of Congress, as expressed in the statute, rather than from this final rule.

For these reasons we believe that the impact of these regulations, as distinct from the total impact of the PRO program, will not be singularly significant. However, apart from these considerations, it is certain that a substantial number of hospitals, practitioners, beneficiaries, recipients and other parties, including the Federal government, will be directly or indirectly affected by this final rule.

E. Impacts on Affected Parties

1. Medicare and Medicaid Programs.

As discussed in the Background section of this analysis, utilization and peer review programs have long been an integral part of both the Medicare and Medicaid programs. These medical review efforts have been safeguards over Federal expenditures for health care services and items furnished to Medicare and Medicaid beneficiaries. We believe that the PRO program will continue to assure that Federal funds will be spent only for necessary, reasonable and appropriate services and items and that beneficiaries will receive quality care.

To realize the continued safeguarding of Federal program expenditures and the provision of quality care, \$339 million will be spent on the two-year PRO contracts for the period from the fourth quarter FY 1984 through the third quarter of FY 1986. Investing these Federal funds will enable the PROs to meet their individual contract objectives (admission, quality of care and utilization goals), and will result in certain dollar benefits to the government in excess of total contract costs. Also, we believe that by reducing inappropriate utilization, more Federal funds would be freed to provide needed care for a greater number of beneficiaries and recipients. Furthermore, reducing unnecessary utilization will lessen possible health complications and deaths that at times result from unnecessary admissions and inappropriate procedures. Thus, we believe that the Federal government will realize benefits of greater value than its expenditures in its effort to safeguard Federal Medicare and Medicaid program expenditures.

2. Beneficiaries and Recipients.

Two issues of concern for Medicare beneficiaries and Medicaid recipients are the cost of health care, particularly out-of-pocket expenses, and the quality of care received from providers.

suppliers, and practitioners. As a result of PROs achieving their contractual objectives, we believe that beneficiaries and recipients will continue to receive necessary, reasonable and appropriate services and items. Beneficiaries, in particular, will be protected by PRO review from potential abuses that may result from the actions some providers may take in response to the incentives established by the prospective payment system (unnecessary increased admissions, inappropriate readmissions and unnecessary transfers to providers and units excluded from the prospective payment system.) Recipients in States operating under a cost reimbursement methodology will also benefit from the review activities of the PROs that will prevent unnecessary admissions and shortening lengths of stay. In both cases, individuals should save the out-of-pocket expenses (deductibles and coinsurance payment) related to unnecessary admissions, readmissions, transfers and lengths of stay.

In some instances, the impact of PRO review will be to change the site of service from inpatient to outpatient care. In these cases, the beneficiary would avoid paying the inpatient deductible amount (\$400 in 1985), but would pay the amount of the outpatient deductible and coinsurance. To the extent that the sum of the out-of-pocket expense for the Part B services is less than the Part A deductible, the beneficiary will incur less personal liability than if the service was performed in an inpatient setting.

Regarding the quality of care issue, we believe that beneficiaries and recipients will benefit from the peer review efforts of the PROs. In particular, we note that individual beneficiaries and recipients will be advantaged by the reduction in the number of inappropriate or unnecessary admissions or procedures; by the anticipated outcomes of certain required review activities; and by the achievement of overall PRO objectives aimed at significant improvement in patient quality care. For example, we expect PROs will reduce avoidable deaths and complications after surgery. To the extent that PROs can achieve these quality goals, beneficiaries will benefit from the PROs' efforts.

Therefore, in summary, beneficiaries and recipients can anticipate beneficial outcomes in several respects, especially reduced personal expenditures, avoidance of unnecessary or inappropriate health services, and avoidance of unnecessary death and complications. We qualify this conclusion by noting that some beneficiaries could incur additional

personal expenses under Part B if the site of care is changed from inpatient to an outpatient setting.

3. Health Care Facilities. Many of the public comments received on the proposed rule were from hospitals raising issues related to the impact of this rule on their operations. We are responding to many of these issues in the comment and response portion of the preamble. We also address in the preamble issues raised about other responsibilities and functions of health care facilities.

Earlier in this analysis, we discussed the difficulties encountered in estimating precisely the impact of this rule. We noted that the requirements of the PRO statute itself have an impact on facilities; that in many respects the incremental differences between the impact of the PSRO program and the PRO program are not significant; and that the influence of the prospective payment system and the efforts of other third-party payors will also affect facilities.

However, even given these qualifications, we can identify several areas of potential impact that may result from implementing the PRO program. In summary, they include:

- A potential increase in reporting, recordkeeping and photocopying burdens that were not specifically part of the prospective payment rate calculations. As explained earlier in the preamble, collection of this information is necessary for PROs to make determinations that the items and services provided by a facility are necessary and appropriate.

- A reduction in expected Medicare payments to health care facilities. Some facilities, especially hospitals, can minimize the impact of potential payment denials, by ensuring that admissions are medically necessary and appropriate.

- Changes in behavior regarding the numbers and types of admissions. We believe that these changes will result from reductions in unnecessary and inappropriate admissions and procedures. Many other behavioral changes will result from the financial incentives of the prospective payment system that will be reinforced by PRO activity.

We believe that many of these costs and additional burdens will be offset by identifiable benefits to the facilities. For example, by providing PROs with needed medical record information for the PROs' conduct of preadmission review, in many cases hospitals will avoid the more burdensome retrospective denial process.

In summation, we believe that all health care facilities will benefit from PRO activity, particularly in light of the increasing fiscal constraints that are affecting many facilities. We believe that PRO initiatives will be effective in reducing some operating expenses that would otherwise be spent on unnecessary or inappropriate services.

4. Physicians. In recent years, variations in physicians' hospital admission and procedure rates have come under particular examination for their influence on the cost and quality of health care. Recent studies identify several primary causes for these variations and conclude that they may occur because of "practice style" (Wennberg, *HEALTH AFFAIRS*, Summer 1984), "reliance on the opinions of peers" (Eddy, *HEALTH AFFAIRS*, Summer 1984), or "provider efficiency" (McClure, *HEALTH AFFAIRS*, Summer 1984).

The conclusion reached from these and other investigations is that variations in physician behavior may unnecessarily drive up health care costs and cause needless complications and even deaths. Historically, PSROs provided a peer review mechanism to examine the impact of physician decisions related to items in the general course of treatment, the appropriateness of the setting, and the length of an inpatient's stay. In many respects, PRO activities will also focus on similar concerns.

We received a number of public comments concerning the impact of PRO initiatives on physicians. In our responses, we consider some of the potential impacts resulting from provisions like the examination of practitioner records and the necessity for the cooperation of practitioners in the conduct of PRO reviews. However, it is difficult to isolate the impact of PRO activities alone on affected physicians. One reason is that the prospective payment system itself is causing significant direct and indirect changes in physician practice styles and behaviors (for example, in terms of admissions and decisions about elective surgery). Also, other third-party payor activities seek to influence physicians' practice styles. The combined effect of these initiatives is to provide physicians with economic incentives to alter their practice styles in order to reduce unnecessary expenditures while preserving the quality of health care.

However, we can cite several examples of potential impacts on affected physicians resulting from the PRO program. First, the change from local peer review (PSRO) to statewide

peer review (PRO) by expanding the geographic scope of reviewers, may contribute to a decrease in local practice variations within a State. Second, physicians may realize some reduction in Medicare revenues as the result of a PRO's decision concerning the necessity of an admission or the efficacy of a procedure. However, we believe that in most cases, overall reductions in physician income will not be significant because the majority will practice in accordance with accepted norms thereby avoiding the risk of payment denials.

In summary, we believe that PRO activities will affect many physicians. However, through the educational efforts of individual PROs, we believe that unnecessary admissions and procedures will be reduced. This in turn would lead to reduction in the number of denials for submitted claims and the accompanying administrative burdens associated with processing denied claims.

F. Conclusion

In the introduction to this analysis, we stated that we are performing a voluntary regulatory impact and flexibility analysis. This decision results from a further examination of the effects of our proposed policies and because of the number of public comments received on several substantive issues. We conclude that a substantial number of health care facilities, beneficiaries, recipients and physicians are affected by the PRO program. However, we believe that the impact directly attributable to these final regulations is not significant for three reasons:

- The primary impact results from the requirements of the PRO statute itself.
- The incremental differences between most PRO and previous peer review activities are not significant.
- The effect of PRO activities may not be the primary cause of these impacts. Other factors, such as the prospective payment system and other third-party payor review efforts, may have a greater impact than the PRO activities.

For the reasons noted above, we have determined that this final rule does not meet the threshold criteria set forth in Executive Order 12291. Furthermore, we have determined, and the Secretary certifies, that this final rule will not have a significant effect on a substantial number of small entities under the Regulatory Flexibility Act of 1980.

VI. Information Collection Requirements

Sections 412.44 (previously 405.472), 431.630, 456.654, 466.70, 466.72, 466.74, 466.78, 466.80 and 466.94 of this rule

contain information collection requirements. They are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). The public is not required to comply with the information collection requirements until OMB approves these requirements under section 3507 of the Paperwork Reduction Act of 1980. Comments on this requirement should be sent directly to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Washington, D.C., Attention: Faye Ludicello. A notice will be published in the *Federal Register* when approval is obtained.

VII. Waiver of Proposed Rulemaking

The Administrative Procedure Act (5 U.S.C. 553) requires us to publish a general notice of proposed rulemaking in the *Federal Register*, and afford prior public comment on proposed rules. Such notice includes a statement of the time, place, and nature of rulemaking proceedings, reference to the legal authority under which the rule is proposed, and the terms or substance of the proposed rule or a description of the subjects and issues involved. However, this requirement does not apply when an agency finds good cause that such a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and its reasons in the rules issued.

These final rules include revisions to conform the regulations to sections 2315(d), 2334 and 2347 of the Deficit Reduction Act of 1984. Because these conforming changes do not involve significant discretion or the addition of significant procedure or detail for implementation, we believe that there is good cause to waive a proposed rulemaking as unnecessary. Furthermore, the changes made to conform the regulations to the DRA amendments are less stringent than existing regulations. Therefore, it is also in the public interest to waive the proposed rulemaking.

VIII. List of Subjects

42 CFR Part 400

Definitions, OMB control numbers.

42 CFR Part 405

Administrative practice and procedure, Certification of compliance, Clinics, Contracts (Agreements), End-Stage Renal Disease (ESRD), Health care, Health facilities, Health maintenance organizations (HMO), Health professions, Health suppliers,

Home health agencies, Hospitals, Inpatients, Kidney diseases, Laboratories, Medicare, Nursing homes, Onsite surveys, Outpatient providers, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 431

Administrative practice and procedure, Contracts (Agreements), Fair hearings, Federal financial participation, Grant-in-Aid program—health, Health facilities, Health maintenance organizations (HMO), Indians, Information (Disclosure), Medicaid, Mental health centers, Prepaid health plans, Privacy, Quality control, Reporting and recordkeeping requirements.

42 CFR Part 433

Administrative practice and procedure, Assignment of Rights, Claims, Contracts (Agreements), Cost allocation, Federal financial participation, Federal matching provision, Grant-in-Aid program—health, Mechanized Claims Processing and Information Retrieval Systems, Medicaid, State fiscal administration, Third party liability.

42 CFR Part 456

Administrative practice and procedure, Grant-in-Aid program—health, Health facilities, Medicaid, Mental health centers, Nursing homes, Penalties, Reporting and recordkeeping requirements, Utilization control, Utilization review.

42 CFR Part 460

Health care, Health professions, Hospitals, Physicians, Professional Standards Review Organizations (PSRO).

42 CFR Part 462

Grant-in-Aid program—health, Health care, Professional Standards Review Organizations (PSRO).

42 CFR Part 466

Appeals, Delegation, Denials, Grant-in-Aid program—health, Health care, Health facilities, Health professions, Hospitals, Hospital review, Norms/criteria/standards, Physicians, Professional Standards Review Organizations (PSRO), Reconsiderations, Utilization and Quality Control Peer Review Organizations (PRO).

42 CFR Chapter IV is amended as set forth below:

I. The table of contents is amended by revising the title of Part 466 as follows:

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER D—PEER REVIEW ORGANIZATIONS

Part 466—Utilization and Quality Control Review

PART 400—INTRODUCTIONS; DEFINITIONS

The authority citation for Part 400 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

II. Section 400.200 is amended by adding in alphabetical order, the definition of "Area" to read as follows:

§ 400.200 General definitions.

"Area" means the geographical area within the boundaries of a State or a State or other jurisdiction designated as constitution an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

III. Part 405 is amended as follows:

A. The authority citation for Subpart C is revised to read as follows:

Authority: Secs. 1102, 1154(a)(2)(B), 1815, 1833, 1842, 1862, 1866, 1870, 1871, and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c-3(a)(2)(B), 1395g, 1395l, 1395u, 1395y, 1395cc, 1395gg, 1395hh, 1395pp), and 31 U.S.C. 3711.

B. In Subpart C, § 405.330 is amended by revising paragraph (b) to read as follows:

§ 405.330 Payment for certain nonreimbursable expenses.

(b) Payment may be made under this provision for not more than 2 days for inpatient hospital services, post-hospital, SNF care, or home health services (as defined in §§ 409.10, 409.20, and 409.40, respectively) when the fiscal intermediary or PRO determines that additional time is required in order to arrange for post discharge care, and when the additional care is furnished after whichever of the following days is the earlier:

(1) The day on which the individual to whom the services were furnished, has been determined, under § 405.332(a), to have knowledge, actual or imputed, that those services were excluded from coverage by reason of § 405.310(g) or § 405.310(k); or

(2) The day on which the provider of the services, has been determined, under § 405.332(b), to have knowledge, actual or imputed, that the services were excluded from coverage as custodial care (§ 405.310(g)) or as not reasonable and necessary (§ 405.310(k)).

C. The authority citation for Subpart G continues to read as follows:

Authority: Secs. 1102, 1154, 1155, 1869(b), 1871, 1872 and 1879 of the Social Security Act (42 U.S.C. 1302, 1320c, 1395ff(b), 1395hh, 1395ii and 1395pp).

In § 405.704(b), the introductory paragraph is reprinted, and paragraphs (b)(11) and (b)(12) are revised to read as follows:

§ 405.704 Actions which are initial determinations.

(b) *Requests for payment by or on behalf of individuals.* An initial determination with respect to an individual includes any determination made on the basis of a request for payment by or on behalf of the individual under Part A of Medicare, including a determination with respect to:

(11) The medical necessity of services (See Parts 466 and 473 of this chapter for provisions pertaining to initial and reconsidered determinations made by a PSRO or PRO);

(12) When services are excluded from coverage as custodial care (§ 405.310(g)) or as not reasonable and necessary (§ 405.310(k)), whether the individual or the provider of services who furnished the services, or both, knew or could reasonably have been expected to know that the services were excluded from coverage (see § 405.332); and

PART 412—PROSPECTIVE PAYMENT SYSTEM FOR INPATIENT HOSPITAL SERVICES

The authority citation for Part 412 continues to read as follows:

Authority: Secs. 1102, 1871 and 1886 of the Social Security Act (42 U.S.C. 1302, 1395hh, 1395ww).

IV. Part 412 is amended as follows:

A. In § 412.44, the introductory language is reprinted without change for the convenience of the reader, paragraph (a) is revised and

redesignated as paragraph (b), a new paragraph (a) is added, paragraphs (b) and (c) are redesignated as (c) and (d), and a new paragraph (e) is added. As revised § 412.44 reads as follows:

§ 412.44 Medical review requirements: Admissions and quality review.

Beginning on November 15, 1984, a hospital must have an agreement with a Utilization and Quality Control Peer Review Organization (PRO) to have the PRO review, on an ongoing basis, the following:

(a) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges.

(b) The medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§ 412.82 and 412.84 of this chapter.

(c) The validity of the hospital's diagnostic and procedural information.

(d) The completeness, adequacy, and quality of the services furnished in the hospital.

(e) Other medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

B. Section 412.82 is amended by revising paragraph (b) to read as follows:

§ 412.82 Payment for extended length of stay cases (day outliers).

(b) The medical review entity (that is, a PSRO, PRO, or intermediary) must review and approve to the extent required by HCFA—

(1) The medical necessity and appropriateness of the admission and outlier services in the context of the entire stay;

(2) The validity of the diagnostic and procedural coding; and

(3) The granting of grace days.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

The authority citation for Part 431 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, (42 U.S.C. 1302), unless otherwise noted.

V. Part 431 is amended as follows:

A. The table of contents for Part 431 is amended by revising the title of § 431.630 to read as follows:

Suppart M—Relations With Other Agencies

431.630 Coordination of Medicaid with PROs.

B. In § 431.630, the editorial note is removed and the section is revised to read as follows:

§ 431.630 Coordination of Medicaid with PROs.

(a) The State plan may provide for the review of Medicaid services through a contract with a PRO designated under Part 462 of this chapter. Medicaid requirements for medical and utilization review are deemed to be met for those services or providers subject to review under the contract.

(b) The State plan must provide that the contract with the PRO—

(1) Meets the requirements of § 434.6(a) of this part;

(2) Includes a monitoring and evaluation plan by which the State ensures satisfactory performance by the PRO;

(3) Identifies the services and providers subject to PRO review;

(4) Ensures that the review activities performed by the PRO are not inconsistent with PRO review activities of Medicare services and includes a description of whether and to what extent PRO determinations will be considered conclusive for Medicaid payment purposes.

PART 433—STATE FISCAL ADMINISTRATION

VI. Part 433 is amended as follows:

A. The authority citation for Part 433 is revised to read as follows:

Authority: Secs. 1102, 1902(a)(25), 1903(a)(3), 1903(d)(2), 1903(d)(5), 1903(o), 1903(p), and 1912 of the Social Security Act (42 U.S.C. 1302, 1396a(a)(25), 1396b(a)(3), 1396b(d)(2), 1396b(d)(5), 1396b(o), 1396b(p), and 1396(k), unless otherwise noted.

B. Section 433.15 is amended by revising paragraph (b)(6)(i) to read as follows:

§ 433.15 Rates of FFP for administration.

(b) *Activities and rates.*

(6)(i) Funds expended for the performance of medical and utilization review by a PRO under a contract entered into under section 1902(d) of the Act; 75 percent (section 1903(a)(3)(C) of the Act).

PART 456—UTILIZATION CONTROL

The authority citation for Part 456 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, 49 Stat. 647 (42 U.S.C. 1302).

VII. Part 456 is amended as follows:

A. Section 456.2 is amended by revising paragraph (b) to read as follows:

§ 456.2 State plan requirements.

(b) These requirements may be met by the agency by:

(1) Assuming direct responsibility for assuring that the requirements of this Part are met;

(2) Deeming, if the agency contracts with a PSRO designated under Part 462 of this chapter; or

(3) Deeming of medical and utilization review requirements if the agency contracts with a PRO to perform that review, which in the case of inpatient acute care review will also serve as the initial determination for PRO medical necessity and appropriateness review for patients who are dually entitled to benefits under Medicare and Medicaid.

B. Section 456.650(c) is revised to read as follows:

§ 456.650 Basis, purpose and scope.

(c) *Scope.* The reductions required by this subpart do not apply to—

(1) Services provided under a contract with a health maintenance organization;

(2) Facilities in which a PSRO is performing review under contract with the Medicaid agency, but only until a contract is awarded in the area to a PRO; or

(3) Facilities in which a PRO is performing medical and utilization reviews under contract with the Medicaid agency in accordance with § 431.630 of this chapter.

C. In § 456.654(a), the introductory language is reprinted; paragraph (a)(4) is revised to include requirements for PRO reviews; paragraph (a)(6) is amended to change "as" to "an" and "provided" to "provider"; and paragraph (a)(7) is amended to change "facility and" to "facility that". The revised § 456.654(a)(4) reads as follows:

§ 456.654 Requirements for content of showings and procedures for submittal.

(a) An agency's showing for a quarter must—

(4) If review has been contracted to a PRO under § 431.630 of this chapter or to a PSRO, list the date the PRO or PSRO contracted for review.

PART 460—AREA DESIGNATIONS

The authority citation for Part 460 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act, 42 U.S.C. 1302. Subpart A is also issued under sec. 150 of Pub. L. 97-248, 42 U.S.C. 1320c note. Subpart B is also issued under secs. 1151 and 1153 of the Social Security Act, 42 U.S.C. 1320c and 1320c-2.

§ 460.1 [Amended]

VIII. Section 460.1 is amended by removing the definitions of "Area" and "PRO".

IX. Part 462 is amended as follows:

A. The table of contents is revised to reflect the establishment of a new Subpart A—General Provisions, to include the current § 462.2 which is redesignated as § 462.1; the redesignation of the current Subpart A as Subpart B to include the current § 462.1 which is redesignated as § 462.2 and the current §§ 462.3–462.16; the redesignation of the current Subpart B as Subpart C to include the current §§ 462.100–462.107; and the revision of the authority citation to read as follows:

PART 462—PEER REVIEW ORGANIZATIONS

Subpart A—General Provisions

Sec.

462.1 Definitions.

Subpart B—PSRO

462.2 Scope and applicability.

462.3 Eligibility for grants.

462.4 Requirements for designation as a priority PSRO.

462.5 Requirements for designation as an alternate PSRO.

462.6 Application requirements for conditional designation.

462.7 [Reserved]

462.8 Conditional designation as a PSRO.

462.9 [Reserved]

462.10 Limitation on period of conditional designation.

462.11 Duration, renewal and voluntary termination or nonrenewal of grants.

462.12 Involuntary termination of non-renewal or grants.

462.13 Use of grant funds.

462.14 Publications and copyrights.

462.15 Applicability of 45 CFR Part 74.

462.16 Additional terms and conditions.

Subpart C—Utilization and Quality Control Peer Review Organizations

462.100 Scope and applicability.

462.101 Eligibility requirements for PRO contracts.

462.102 Eligibility of physician-sponsored organizations.

462.103 Eligibility of physician-access organizations.

462.104 Requirements for demonstrating ability to perform review.

462.105 Prohibition against contracting with health care facilities.

462.106 Prohibition against contracting with payor organizations.

462.107 PRO contract award.

Authority: Sec. 1102 of the Social Security Act, 42 U.S.C. 1302. Subpart B is also issued under sec. 150 of Pub. L. 97-248 U.S.C. 1320c note, Subpart C is also issued under secs. 1152 and 1153 of the Social Security Act, U.S.C. 1320c and 1320-2.

B. The current Subparts A and B are redesignated as Subparts B and C, respectively.

C. 1. A new Subpart A—General Provisions is established to include the current § 462.2 which is redesignated as § 462.1.

2. The newly designated § 462.1 is amended by removing the definition of "PRO" and by revising the definition of "Payor organization" to read as follows:

§ 462.1 Definitions.

"Payor organization" means any organization, other than a self-insured employer, which makes payments directly or indirectly to health care practitioners or providers whose health care services are reviewed by the organization or would be reviewed by the organization if it entered into a PRO contract. "Payor organization" also means any organization which is affiliated with any entity which makes payments as described above, by virtue of the organization having two or more governing body members who are also either governing body members, officers, partners, 5 percent or more owners or managing employees in a health maintenance organization or competitive medical plan.

§ 462.1 [Redesignated as § 462.2]

D. The newly designated Subpart B is amended by redesignating the current § 462.1 as § 462.2.

E. The newly designated Subpart C is amended as follows:

1. Section 462.102 is amended by revising paragraph (a) to read as follows:

§ 462.102 Eligibility of physician-sponsored organizations.

(a) In order to be eligible for designation as a physician-sponsored PRO, an organization must meet the following conditions:

(1) Be composed of a substantial number of the licensed doctors of medicine and osteopathy practicing medicine or surgery in the review area and who are representative of the physicians practicing in the area.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in § 462.105.

2. Sections 462.103, 462.105, and 462.106 are revised to read as follows:

§ 462.103 Eligibility of physician-access organizations.

(a) In order to be eligible for designation as a physician-access PRO, an organization must meet the following conditions:

(1) Have available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy practicing medicine or surgery in the review area to assure adequate peer review of the services provided by the various medical specialties and subspecialties.

(2) Not be a health care facility, health care facility association, or health care facility affiliate, as specified in § 462.105.

(b) An organization meets the requirements of paragraph (a)(1) of this section if it demonstrates—

(1) That it has available to it at least one physician in every generally recognized specialty; and

(2) The existence of an arrangement or arrangements with physicians under which the physicians would conduct review for the organization.

§ 462.105 Prohibition against contracting with health care facilities.

(a) *Basic rule.* Except as permitted under paragraph (b) of this section, the following are not eligible for PRO contracts:

(1) A health care facility in the PRO area.

(2) An association of health care facilities in the PRO area.

(3) A health care facility affiliate; that is, an organization in which more than 20 percent of the members of the governing body are also either a governing body member, officer, partner, five percent or more owner, or managing employee in a health care facility or association of health care facilities in the PRO area.

(b) *Exceptions.* Effective November 15, 1984, the prohibition stated in paragraph (a) of this section will not apply to a payor organization if HCFA determines under § 462.106 that there is no other eligible organization available.

(c) *Subcontracting.* A PRO must not subcontract with a facility to conduct any review activities except for the review of the quality of care.

§ 462.106 Prohibition against contracting with payor organizations.

Payor organizations are not eligible to become PROs for the area in which they make payments until November 15, 1984.

If no PRO contract for an area is awarded before November 15, 1984, a payor organization will be determined eligible by HCFA, if an eligible organization that is not a payor organization is unavailable at that time. HCFA may determine the unavailability of nonpayor organizations based on the lack of response to an appropriate Request for Proposal.

3. In § 462.107, the introductory language is reprinted, and paragraph (d) is revised to read as follows:

§ 462.107 PRO contract award.

HCFA, in awarding PRO contracts, will take the following actions—

(d) Subject to the limitations established by §§ 462.105 and 462.106, award the contract for the given PRO area to the selected organization for a period of two years.

X. Part 466 is amended as set forth below:

A. The title of Part 466 is revised to read as set forth below.

B. The table of contents is amended to reflect the revision of Subpart A—"General Provisions" to include only current § 466.2, which is redesignated as § 466.1, the revision of the title and contents of Subpart B—PSRO Review, to include current § 466.1 which is redesignated as § 466.2 and current §§ 466.3 through 466.63 with center headings, the removal of the headings of Subparts D and E and the revision of the heading of Subpart C. As revised, the table of contents reads as follows:

PART 466—UTILIZATION AND QUALITY CONTROL REVIEW

Subpart A—General Provisions

Sec.
466.1 Definitions.

Subpart B—PSRO Review

General

- 466.2 Statutory provisions and applicability.
- 466.3 Review objectives.
- 466.4 Examination of the operation and records of hospitals.
- 466.5 Refusal of hospital to allow PSRO entry and performance of review.
- 466.6 Reports to HCFA.
- 466.10 General requirements for concurrent review.
- 466.11 Admission review.
- 466.12 Continued stay review.
- 466.13 Elective procedures review.
- 466.14 Preadmission review.
- 466.15 Modifications of review activities.
- 466.16 Notice of adverse determination.
- 466.17 Informing discharge planners.
- 466.18 Medical care evaluation (MCE) studies.
- 466.19 Profile analysis.

- 466.20 Involvement of health care practitioners other than physicians.
466.21 Reviewer qualifications and participation.
466.22 Alternative review methods.

Delegated Review

- 466.30 Opportunity for hospitals to seek delegation.
466.31 Letter of interest.
466.32 Details of delegated review plan.
466.33 Determination and notice of hospital capability.
466.34 Delegation of review activities.
466.35 Agreement with delegated hospitals.
466.36 PSRO monitoring and reassessment of hospital capability.
466.37 Reconsiderations.
466.38 Monitoring by HCFA.
466.39 PSRO responsibilities when delegation is denied, withdrawn, or disapproved.

Norms, Criteria, and Standards for Review

- 466.50 Basic requirement for PSRO area norms, criteria, and standards.
466.51 Establishment of norms, criteria, and standards.
466.52 Dissemination of norms, criteria, and standards.
466.53 Use of norms, criteria, and standards.
466.54 Revisions.
466.55 Regional norms, criteria, and standards.
466.56 Review of PSRO norms, criteria, and standards.

Financing of Review Activities

- 466.60 Applicability and scope.
466.61 Areawide budget.
466.62 Reimbursement to delegated hospitals.
466.63 Reimbursement for nondelegated hospitals.

Subpart C—Review Responsibilities of Utilization and Quality Control Peer Review Organizations (PROs)

General Provisions

- 466.70 Statutory bases, applicability and provisions.
466.72 Notification of PRO designation and implementation of review.
466.74 General requirements for assumption of review.
466.76 Cooperation with health care facilities.
466.78 Responsibilities of health care facilities.
466.80 Coordination with Medicare fiscal intermediaries and carriers.
466.82 Continuation of functions not assumed by PROs.

PRO Review Functions

- 466.83 Initial denial determinations.
466.84 Changes as a result of DRG validations.
466.85 Conclusive effect of PRO initial denial determinations and changes as a result of DRG validations.
466.86 Correlation of Title XI functions with Title XVIII functions.
466.88 Examination of the operations and records of health care facilities.

- 466.90 Lack of cooperation by a health care facility or practitioner.
466.92 General requirements for PRO review.
466.93 Opportunity to discuss proposed initial denial determination and changes as a result of a DRG validation.
466.94 Notice of PRO initial denial determination and changes as a result of a DRG validation.
466.96 Review period and reopening of initial denial determinations and changes as a result of DRG validations.
466.98 Reviewer qualifications and participation.
466.100 Use of norms and criteria.
466.102 Involvement of health care practitioners other than physicians.
466.104 Coordination of activities.

Authority: Sec. 1102 of the Social Security Act, 42 U.S.C. 1302. Subpart B is also issued under sec. 150 of Pub. L. 97-248, 42 U.S.C. 1320c note. Subpart C is also issued under secs. 1151-1163, and 1868(a) of the Social Security Act, 42 U.S.C. 1320c-1320-12, and 1395cc(a).

C. Section 466.1 is redesignated as § 466.3 and § 466.2 is redesignated as § 466.1.

D. Newly designated § 466.1 is amended by removing definitions of "Act", "HCFA", "Health care service", "National Council", "Other Attending Health Care Practitioner" and "Secretary" and revising the definitions of "Active staff privileges", "Admission review", "Concurrent quality assurance", "Concurrent review", "Continued stay review", "Delegated Hospital", "Length-of-stay norms", "Length-of-stay projection", "Non-delegated hospital", "Norm", "Physician", "Quality Review Study", "Skilled nursing facility (SNF)", "Working day", and adding in alphabetical order, the definitions of "Diagnosis-Related Group (DRG)", "DRG Validation", "Five Percent or more owner", "Health care facility or facility", "Non-facility organization", "Outliers", "Practitioner", "Preadmission certification", "Preadmission review", "Preprocedure review", "PRO review", "Retrospective review", "Review responsibility", "State survey agency," and "Subcontractor" as follows:

§ 466.1 Definitions.

Active staff privileges means: (a) That a physician is authorized on a regular, rather than infrequent or courtesy, basis: (1) To order the admission of patients to a facility; (2) to perform diagnostic services in a facility; or (3) to care for and treat patients in a facility; or (b) that a health care practitioner other than a physician is authorized on a regular, rather than infrequent or courtesy, basis to order the admission of patients to a facility.

Admission review means a review and determination by a PSRO or a PRO of the medical necessity and appropriateness of a patient's admission to a specific facility.

Concurrent quality assurance means a form of PSRO review that focuses on the quality of health services furnished to individual patients, and is performed while the patient is in the hospital.

Concurrent review means a review and determination that is focused on the necessity and appropriateness of inpatient hospital services and is performed while the patient is in the hospital. It includes admission review, continued stay review and, when appropriate, procedure review.

Continued stay review means PSRO or PRO review that is performed after admission review and during a patient's hospitalization to determine the medical necessity and appropriateness of continuing the patient's stay at a hospital level of care.

Delegated hospital means a hospital to which PSRO review functions are delegated under Subpart B.

Diagnosis related group (DRG) means a system for classifying inpatient hospital discharges. DRGs are used for purposes of determining payment to hospitals for inpatient hospital services under the Medicare prospective payment system.

DRG validation means a part of the prospective payment system in which a PRO validates that DRG assignments are based on the correct diagnostic and procedural information.

Five percent or more owner means a person (including, where appropriate, a corporation) who:

- Has an ownership interest of 5 percent or more;
- Has an indirect ownership interest equal to 5 percent or more;
- Has a combination of direct and indirect ownership interests (the possession of equity in the capital, the stock, or the profits of an entity) equal to five percent or more; or
- Is the owner of an interest of five percent or more in any obligation secured by an entity, if the interest equals at least five percent of the value of the property or assets of the entity.

Health care facility or facility means an organization involved in the delivery of health care services for which reimbursement may be made in whole or in part under Title XVIII of the Act.

Length-of-stay norms means established statistical measures of average lengths of stay for patients of similar age and diagnosis or condition.

Length-of-stay projection means a criterion that defines the time at which patients of similar age and diagnosis or condition would be expected to be ready for discharge.

Non-facility organization means a corporate entity that (1) is not a health care facility; (2) is not a 5 percent or more owner of a facility; and (3) is not owned by one or more health care facilities or association of facilities in the PRO area.

Nondelegated hospital means a hospital in which the PSRO conducts review activities using its own review procedures, and to which it has not delegated review activities under Part 466, Subpart B of this chapter.

Norm means a pattern of performance in the delivery of health care services that is typical for a specified group.

Outliers means those cases that have either an extremely long length of stay or extraordinarily high costs when compared to most discharges classified in the same DRG.

Physician means a doctor of medicine or osteopathy or another individual who is authorized under State or Federal law to practice medicine and surgery, or osteopathy. This includes medical officers in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Practitioner means an individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

Preadmission certification means a favorable determination, transmitted to the hospital and the fiscal intermediary, approving the patient's admission for payment purposes.

Preadmission review means review prior to a patient's admission to a hospital to determine, for payment purposes, the reasonableness, medical necessity and appropriateness of placement at an acute level of care.

Preprocedure review means review of a surgical or other invasive procedure prior to the conduct of the procedure.

PRO review means review performed in fulfillment of a contract with HCFA, either by the PRO or its subcontractors.

Quality review study means an assessment conducted by or for a PRO of a patient care problem for the purpose of improving patient care

through peer analysis, intervention, resolution of the problem and follow-up.

Retrospective review means review that is conducted after services are provided to a patient. The review is focused on determining the appropriateness, necessity, quality, and reasonableness of health care services provided.

Review responsibility means (1) the responsibility of the PRO to perform review functions prescribed under Part B of Title XI of the Act and the Social Security Amendments of 1983 (Pub. L. No. 98-21) and the regulations of this part; (2) the responsibility to fulfill the terms and meet the objectives set forth in the negotiated contract between HCFA and the PRO; and (3) the authority of a PRO to make conclusive initial denial determinations regarding the medical necessity and appropriateness of health care and changes as a result of DRG validations.

Skilled nursing facility (SNF) means a health care institution or distinct part of an institution that (a) is primarily engaged in providing skilled nursing care or rehabilitative services to injured, disabled, or sick persons, and (b) has an agreement to participate in Medicare or Medicaid or both, and (c) is not a Christian Science sanatorium operated or listed and certified by the First Church of Christ Scientist, Boston, Massachusetts.

State survey agency means an agency performing provider surveys in accordance with an agreement under § 405.685 of this chapter.

"Subcontractor" means a facility or a non-facility organization under contract with a PRO to perform PRO review functions.

Working day means any one of at least five days of each week (excluding, at the option of each PSRO or PRO, legal holidays) on which the necessary personnel are available to perform review.

Subparts B through E—[Amended]

E. The headings for Subparts C, D, and E are removed, and §§ 466.30 through 466.63 are incorporated into Subpart B. Subpart B is amended by revising the title to read "PSRO Review", including the newly redesignated § 466.2 and incorporating therein current §§ 466.3 through 466.63, and adding center headings as follows: Center heading "Delegated Review" is added immediately before § 466.30, center heading "Norms, Criteria, and Standards for Review" is added immediately before § 466.50 and center

heading "Financing of Review Activities" is added immediately before § 466.60.

F. Subpart C consisting of §§ 466.70 through 466.104 is added to read as follows:

Subpart C—Review Responsibilities of Utilization and Quality Control Peer Review Organizations (PROs)

General Provisions

§ 466.70 Statutory bases, applicability and provisions.

(a) **Statutory basis.** Sections 1154, 1896(a)(1)(F) and 1886(f)(2) of the Act require that a PRO review those services furnished by physicians, other health care professionals, providers and suppliers as specified in its contract with the Secretary.

(b) **Applicability.** The regulations in this subpart apply to review conducted by a PRO and its subcontractors.

(c) **Scope of PRO review.** In its review, the PRO must determine (in accordance with the terms of its contract)—

(1) Whether the services are or were reasonable and medically necessary for the diagnosis and treatment of illness or injury or to improve functioning of a malformed body member, or (with respect to pneumococcal vaccine) for prevention of illness or (in the case of hospice care) for the palliation and management of terminal illness;

(2) Whether the quality of the services meets professionally recognized standards of health care;

(3) Whether those services furnished or proposed to be furnished on an inpatient basis could, consistent with the provisions of appropriate medical care, be effectively furnished more economically on an outpatient basis or in an inpatient health care facility of a different type;

(4) Through DRG validation, the validity of diagnostic and procedural information supplied by the hospital;

(5) The completeness, adequacy and quality of hospital care provided;

(6) The medical necessity, reasonableness and appropriateness of hospital admissions and discharges;

(7) The medical necessity, reasonableness and appropriateness of inpatient hospital care for which additional payment is sought under the outlier provisions of §§ 412.82 and 412.84 of this chapter; and

(8) Whether a hospital has misrepresented admission or discharge information or has taken an action that results in—

(i) The unnecessary admission of an individual entitled to benefits under Part A;

(ii) Unnecessary multiple admissions of an individual; or

(iii) Other inappropriate medical or other practices with respect to beneficiaries or billing for services furnished to beneficiaries.

(d) *Payment determinations.* On the basis of the review specified under paragraphs (c) (1), (3), (6) and (7), and (8) of this section, the PRO must determine whether payment may be made for these services. A PRO may grant a period of not more than two days (grace days) for the purpose of arranging post discharge care when the provider did not know or could not reasonably be expected to have known that payment for the service(s) would not be made under the Medicare program as specified in § 405.330(b).

(e) *Other duties and functions.* (1) The PRO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary or carrier if it determines that the information submitted by the hospital was incorrect.

(2) The PRO must also perform other duties, functions, and responsibilities as required by HCFA.

§ 466.72 Notification of PRO designation and implementation of review.

(a) *Notice of HCFA's decision.* HCFA sends written notification of a PRO contract award to the State survey agency and Medicare fiscal intermediaries and carriers. The notification includes the effective dates of the PRO contract and specifies the area and types of health care facilities to be reviewed by the PRO. The PRO must make a similar notification when review responsibilities are subcontracted.

(b) *Notification to health care facilities and the public.* As specified in its contract with HCFA, the PRO must—

(1) Provide to each health care facility scheduled to come under review, a timely written notice that specifies the date and manner in which the PRO proposes to implement review, and the information to be furnished by the facility to each Medicare beneficiary upon admission as specified in § 466.78(b)(3) of this part.

(2) Publish, in at least one local newspaper of general circulation in the PRO area, a notice that states the date the PRO will assume review responsibilities and lists each area health care facility to be under review. The PRO must indicate that its plan for the review of health care services as approved in its contract with HCFA is available for public inspection in the PRO's business office and give the

address, telephone number and usual hours of business.

§ 466.74 General requirements for the assumption of review.

(a) A PRO must assume review responsibility in accordance with the schedule, functions and negotiated objectives specified in its contract with HCFA.

(b) A PRO must notify the appropriate Medicare fiscal intermediary or carrier of its assumption of review in specific health care facilities no later than five working days after the day that review is assumed in the facility.

(c) A PRO must maintain and make available for public inspection at its principal business office—

(1) A copy of each agreement with Medicare fiscal intermediaries and carrier;

(2) A copy of its currently approved review plan that includes the PRO's method for implementing review; and

(3) Copies of all subcontracts for the conduct of review.

(d) A PRO must not subcontract with a facility to conduct any review activities except for the review of the quality of care. The PRO may subcontract with a non-facility organization to conduct review in a facility.

(e) If required by HCFA, a PRO is responsible for compiling statistics based on the criteria contained in § 405.332 of this chapter and making limitation of liability determinations on excluded coverage of certain services that are made under section 1879 of the Act. If required by HCFA, PROs must also notify a provider of these determinations. These determinations and further appeals are governed by the reconsideration and appeals procedures in Part 405, Subpart G of this chapter for Medicare Part A related determinations and Part 405, Subpart H of this chapter for Medicare Part B related determinations.

(f) A PRO must make its responsibilities under its contract with HCFA, primary to all other interests and activities that the PRO undertakes.

§ 466.76 Cooperation with health care facilities.

Before implementation of review, a PRO must make a good faith effort to discuss the PRO's administrative and review procedures with each involved health care facility.

§ 466.78 Responsibilities of health care facilities.

(a) Beginning November 15, 1984, every hospital seeking payment for services provided to Medicare beneficiaries must maintain a written

agreement with a PRO operating in the area in which the hospital is located. These agreements must provide for the PRO review specified in § 466.70(c).

(b) *Cooperation with PROs.* Health care facilities that submit Medicare claims must cooperate in the assumption and conduct of PRO review. Facilities must—

(1) Allocate adequate space to the PRO for its conduct of review at the times the PRO is conducting review.

(2) Provide patient care data and other pertinent data to the PRO at the time the PRO is collecting review information that is required for the PRO to make its determinations. When review is performed away from the facility, the facility must photocopy and deliver to the PRO, without charge, all required information within 30 days of a request. When the PRO does post-admission, preprocedure review, the facility must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis.

(3) Inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to PRO review and indicate the potential outcomes of that review. Furnishing this information to the patient does not constitute notice, under § 405.332(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered.

(4) When the facility has issued a written determination in accordance with § 412.42(c)(3) of this chapter that a beneficiary no longer requires inpatient hospital care, it must submit a copy of its determination to the PRO within 3 working days.

(5) Assure, in accordance with the provisions of its agreement with the PRO, that each case subject to preadmission review has been reviewed and approved by the PRO before admission to the hospital or a timely request has been made for PRO review.

(6)(i) Agree to accept financial liability for any admission subject to preadmission review that was not reviewed by the PRO and is subsequently determined to be inappropriate or not medically necessary.

(ii) The provisions of paragraph (b)(6)(i) of this section do not apply if a facility, in accordance with its agreement with a PRO, makes a timely request for preadmission review and the PRO does not review the case timely. Cases of this type are subject to retrospective prepayment review under paragraph (b)(7) of this section.

(7) Agree that, if the hospital admits a case subject to preadmission review without certification, the case must receive retrospective prepayment review, according to the review priority established by the PRO.

§ 466.80 Coordination with Medicare fiscal intermediaries and carriers.

(a) *Procedures for agreements.* The Medicare fiscal intermediary or carrier must have a written agreement with the PRO. The PRO must take the initiative with the fiscal intermediary or carrier in developing the agreement. The following steps must be taken in developing the agreement.

(1) The PRO and the fiscal intermediary or carrier must negotiate in good faith in an effort to reach written agreement. If they cannot reach agreement, HCFA will assist them in resolving matters in dispute.

(2) The PRO must incorporate its administrative procedures into an agreement with the fiscal intermediary or carrier and obtain approval from HCFA, before it makes conclusive determinations for the Medicare program, unless HCFA finds that the fiscal intermediary or carrier has—

(i) Refused to negotiate in good faith or in a timely manner, or

(ii) Insisted on including in the agreement, provisions that are outside the scope of its authority under the Act.

(b) *Content of agreement.* The agreement must include procedures for—

(1) Informing the appropriate Medicare fiscal intermediaries and carriers of—

(i) Changes as a result of DRG validations and revisions as a result of the review of these changes; and

(ii) Initial denial determinations and revisions of these determinations as a result of ——— reconsideration and all approvals and denials with respect to cases subject to preadmission review and outlier claims in hospitals under a prospective payment system for health care services and items;

(2) Exchanging data or information;

(3) Modifying the procedures when additional review responsibility is authorized by HCFA; and

(4) Any other matters that are necessary for the coordination of functions.

(c) *Action of HCFA.* (1) Within the time specified in its contract, the PRO must submit to HCFA for approval its agreement with the Medicare fiscal intermediaries carriers, and if an agreement has not been established, the PRO's proposed administrative procedures, including any comments by

the Medicare fiscal intermediaries and carriers.

(2) If HCFA approves the agreement or the administrative procedures (after a finding by HCFA as specified in paragraph (a)(2) of this section), the PRO may begin to make determinations under its contract with HCFA.

(3) If HCFA disapproves the agreement or procedures, it will—

(i) Notify the PRO and the appropriate fiscal agents in writing, stating the reasons for disapproval; and

(ii) Require the PRO and fiscal intermediary or carrier to revise its agreements or procedures.

(d) *Modification of agreements.* Agreements or procedures may be modified, with HCFA's approval—

(1) Through a revised agreement with the fiscal intermediary or carrier, or

(2) In the case of procedures, by the PRO, after providing opportunity for comment by the fiscal intermediary or carrier.

(e) *Role of the fiscal intermediary.* (1) The fiscal intermediary will not pay any claims for those cases which are subject to preadmission review by the PRO, until it receives notice that the PRO has approved the admission after preadmission or retrospective review.

(2) A PRO's determination that an admission is medically necessary is not a guarantee of payment by the fiscal intermediary. Medicare coverage requirements must also be applied.

§ 466.82 Continuation of functions not assumed by PROs.

Any of the duties and functions under Part B of Title XI of the Act for which a PRO has not assumed responsibility under its contract with HCFA must be performed in the manner and to the extent otherwise provided for under the Act or in regulations.

§ 466.83 Initial denial determinations.

A determination by a PRO that the health care services furnished or proposed to be furnished to a patient are not medically necessary, are not reasonable, or are not at the appropriate level of care, is an initial denial determination and is appealable under Part 473 of this chapter.

§ 466.84 Changes as a result of DRG validation.

A provider or practitioner may obtain a review by a PRO under Part 473 of this chapter for changes in diagnostic and procedural coding that resulted in a change in DRG assignment as a result of PRO validation activities.

§ 466.85 Conclusive effect of PRO initial denial determinations and changes as a result of DRG validations.

A PRO initial denial determination or change as a result of DRG validation is final and binding unless, in accordance with the procedures in Part 473—

(a) The initial denial determination is reconsidered and revised; or

(b) The change as a result of DRG validation is reviewed and revised.

§ 466.86 Correlation of Title XI functions with Title XVIII functions.

(a) *Payment determinations.*

(1) PRO initial denial determinations under this part with regard to the reasonableness, medical necessity, and appropriateness of placement at an acute level of patient care as are also conclusive for payment purposes with regard to the following medical issues:

(i) Whether inpatient care furnished in a psychiatric or tuberculosis hospital meets the requirements of § 405.1629 of this chapter.

(ii) Whether payment for inpatient hospital or SNF care beyond 20 consecutive days is precluded under § 489.50 of this chapter because of failure to perform review of long-stay cases.

(iii) Whether the care furnished was custodial care or care not reasonable and necessary and, as such, excluded under § 405.310(g) or § 405.310(k) of this chapter.

(iv) Whether the care was appropriately furnished in the inpatient or outpatient setting.

(2) Reviews with respect to determinations listed in paragraph (a)(1) of this section must not be conducted, for purposes of payment, by Medicare fiscal intermediaries or carriers except as outlined in paragraph (c) of this section.

(3) PROs make determinations as to the appropriateness of the location in which procedures are performed. A procedure may be medically necessary but denied if the PRO determines that it could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

(4) PRO determinations as to whether the provider and the beneficiary knew or could reasonably be expected to have known that the services described in paragraph (a)(1) of this section were excluded are also conclusive for payment purposes.

(b) *Utilization review activities.* PRO review activities to determine whether inpatient hospital or SNF care services

are reasonable and medically necessary and are furnished at the appropriate level of care fulfill the utilization review requirements set forth in §§ 405.1035, 405.1042, and 405.1137 of this chapter.

(c) *Coverage.* Nothing in paragraphs (a) (1) and (3) of this section will be construed as precluding HCFA or a Medicare fiscal intermediary or carrier, in the proper exercise of its duties and functions, from reviewing claims to determine:

(1) In the case of items or services not reviewed by a PRO, whether they meet coverage requirements of Title XVIII relating to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care. However, if a coverage determination pertains to medical necessity, reasonableness, or appropriateness of placement at an acute level of patient care, the fiscal intermediary or carrier must use a PRO to make a determination on those issues if a PRO is conducting review in the area and must abide by the PRO's determination.

(2) Whether any claim meets coverage requirements of Title XVIII relating to issues other than medical necessity, reasonableness or appropriateness of placement at an acute level of patient care.

(d) *Payment.* Medicare fiscal intermediaries and carriers are not precluded from making payment determinations with regard to coverage determinations made under paragraph (c) of this section.

(e) *Survey, compliance and assistance activities.* PRO review and monitoring activities fulfill the requirements for compliance and assistance activities of State survey agencies under section 1864(a) with respect to sections 1861(e)(6), 1861(j)(8), 1861(j)(12), and 1861(k) of the Act, and activities required of intermediaries and carriers under §§ 421.100(d) and 421.200(f) of this chapter.

(f) *Appeals.* The requirements and procedures for PRO review of changes as a result of DRG validation and the reconsideration, hearing and judicial review of PRO initial denial determinations are set forth in Part 473 of this chapter.

§ 466.88 Examination of the operation and records of health care facilities and practitioners.

(a) *Authorization to examine records.* A facility claiming Medicare payment must permit a PRO or its subcontractor to examine its operation and records (including information on charges) that are pertinent to health care services furnished to Medicare beneficiaries and

are necessary for the PRO or its subcontractor to—

(1) Perform review functions including, but not limited to—

(i) DRG validation;

(ii) Outlier review in facilities under a prospective payment system; and

(iii) Implementation of corrective action and fraud and abuse prevention activities;

(2) Evaluate cases that have been identified as deviating from the PRO norms and criteria, or standards; and

(3) Evaluate the capability of the facility to perform quality review functions under a subcontract with the PRO.

(b) *Limitations on access to records.* A PRO has access to the records of non-Medicare patients if—

(1) The records relate to review performed under a non-Medicare PRO contract and if authorized by those patients in accordance with State law; or

(2) The PRO needs the records to perform its quality review responsibilities under the Act and receives authorization from the facility or practitioner.

(c) *Conditions of examination.* When examining a facility's operation or records the PRO must—

(1) Examine only those operations and records (including information on charges) required to fulfill the purposes of paragraph (a) of this section;

(2) Cooperate with agencies responsible for other examination functions under Federal or Federally assisted programs in order to minimize duplication of effort;

(3) Conduct the examinations during reasonable hours; and

(4) Maintain in its principal office written records of the results of the examination of the facility.

§ 466.90 Lack of cooperation by a health care facility or practitioner.

(a) If a health care facility or practitioner refuses to allow a PRO to enter and perform the duties and functions required under its contract with HCFA, the PRO may—

(1) Determine that the health care facility or practitioner has failed to comply with the requirements of § 474.30(c) of this chapter and report the matter to the HHS Inspector General; or

(2) Issue initial denial determinations for those claims it is unable to review, make the determination that financial liability will be assigned to the health care facility, and report the matter to the HHS Inspector General.

(b) If a PRO provides a facility with sufficient notice and a reasonable amount of time to respond to a request

for information about a claim, and if the facility does not respond in a timely manner, PRO will deny the claim.

§ 466.93 Opportunity to discuss proposed initial denial determination and changes as a result of a DRG validation.

Before a PRO reaches an initial denial determination or makes a change as a result of a DRG validation, it must—

(a) Promptly notify the provider or supplier and the patient's attending physician (or other attending health care practitioner) of the proposed determination or DRG change; and

(b) Afford an opportunity for the provider or supplier and the physician (or other attending health care practitioner) to discuss the matter with the PRO physician advisor and to explain the nature of the patient's need for health care services, including all factors which preclude treatment of the patient as an outpatient or in an alternative level of inpatient care.

§ 466.94 Notice of PRO initial denial determination and changes as a result of a DRG validation.

(a) *Notice of initial denial determination—(1) Parties to be notified.* A PRO must provide written notice of an initial denial determination to—

(i) The patient, or if the patient is expected to be unable to comprehend the notice, the patient's next of kin, guardian or other representative or sponsor;

(ii) The attending physician, or other attending health care practitioner;

(iii) The facility; and

(iv) The fiscal intermediary or carrier.

(2) *Timing of the notice.* The notice must be delivered to beneficiaries in the facility or mailed to those no longer in the facility, within the following time periods—

(i) For admission, on the first working day after the initial denial determination;

(ii) For continued stay (e.g., outliers in facilities under a prospective payment system), by the first working day after the initial denial determination if the beneficiary is still in the facility, and within 3 working days if the beneficiary has been discharged;

(iii) For preprocedure review, before the procedure is performed;

(iv) For preadmission review, before admission;

(v) If identification as a Medicare program patient has been delayed, within three working days of identification;

(vi) For retrospective review, (excluding DRG validation and post procedure review), within 3 working

days of the initial denial determination; and

(vii) For post-procedure review, within 3 working days of the initial denial determination.

(3) *Preadmission review.* In the case of preadmission review, the PRO must document that the patient and the facility received notice of the initial denial determination.

(b) *Notice of changes as a result of a DRG validation.* The PRO must notify the provider and practitioner of changes to procedural and diagnostic information that result in a change of DRG assignment, within 30 days of the PRO's decision.

(c) *Content of the notice.* The notice must be understandable and written in plain English and must contain—

(1) The reason for the initial denial determination or change as a result of the DRG validation;

(2) For day outliers in hospitals, the date on which the stay or services in the facility will not be approved as being reasonable and medically necessary or appropriate to the patients' health care needs;

(3) A statement informing each party or his or her representative of the right to request in accordance with the provisions of Part 473, Subpart B of this chapter—

(i) Review of a change resulting from DRG validation; or

(ii) Reconsideration of the initial denial determination;

(4) The locations for filing a request for reconsideration or review and the time period within which a request must be filed;

(5) A statement about who is liable for payment of the denied services under section 1879 of the Act; and

(6) A statement concerning the duties and functions of the PRO under the Act.

(d) *Notice to payers.* The PRO must provide prompt written notice of an initial denial determination or changes as a result of a DRG validation to the Medicare fiscal intermediary or carrier within the same time periods as the notices to the other parties.

(e) *Record of initial denial determination and changes as a result of a DRG validation.* (1) The PRO must document and preserve a record of all initial denial determinations and changes as a result of DRG validations for six years from the date the services in question were provided.

(2) The documentary record must include—

(i) The detailed basis for the initial denial determination or changes as a result of a DRG validation; and

(ii) A copy of the determination or change in DRG notices sent to all parties

and identification of each party and the date on which the notice was mailed or delivered.

§ 466.96 Review period and reopening of initial denial determinations and changes as a result of DRG validation.

(a) *General timeframe.* A PRO or its subcontractor—

(1) Within one year of the date of the claim containing the service in question, may review and deny payment; and

(2) Within one year of the date of its decision, may reopen an initial denial determination or a change as a result of a DRG validation.

(b) *Extended timeframes.* (1) An initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the claim containing the service in question, if HCFA approves.

(2) A reopening of an initial denial determination or change as a result of a DRG validation may be made after one year but within four years of the date of the PRO's decision if—

(i) Additional information is received on the patient's condition;

(ii) Reviewer error occurred in interpretation or application of Medicare coverage policy or review criteria;

(iii) There is an error apparent on the face of the evidence upon which the initial denial or DRG validation was based; or

(iv) There is a clerical error in the statement of the initial denial determination or change as a result of a DRG validation.

(c) *Fraud and abuse.* (i) A PRO or its subcontractor may review and deny payment anytime there is a finding that the claim for service involves fraud or a similar abusive practice that does not support a finding of fraud.

(ii) An initial denial determination or change as a result of a DRG validation may be reopened and revised anytime there is a finding that it was obtained through fraud or a similar abusive practice that does not support a finding of fraud.

§ 466.98 Reviewer qualifications and participation.

(a) *Peer review by physician.* (1) Except as provided in paragraph (a)(2) of this section, each person who makes an initial denial determination about services furnished or proposed to be furnished by a licensed doctor of medicine or osteopathy or by a doctor of dentistry must be respectively another licensed doctor of medicine or osteopathy or of dentistry with active staff privileges in one or more hospitals in the PRO area.

(2) If a PRO determines that peers are not available to make initial denial determinations, a doctor of medicine or osteopathy may make denial determinations for services ordered or performed by a doctor in any of the three specialties.

(3) For purposes of paragraph (a)(1) of this section, individuals authorized to practice medicine in American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands as "medical officers" may make determinations on care ordered or furnished by their peers but not on care ordered or furnished by licensed doctors of medicine or osteopathy.

(b) *Peer review by health care practitioners other than physicians.* Health care practitioners other than physicians may review services furnished by other practitioners in the same professional field.

(c) *DRG validation review.* Decisions about procedural and diagnostic information must be made by physicians. Technical coding issues must be reviewed by individuals with training and experience in ICD-9-CM coding.

(d) *Persons excluded from review.* (1) A person may not review health care services or make initial denial determinations or changes as a result of DRG validations if he or she, or a member of his or her family—

(i) Participated in developing or executing the beneficiary's treatment plan;

(ii) Is a member of the beneficiary's family; or

(iii) Is a governing body member, officer, partner, 5 percent or more owner, or managing employee in the health care facility where the services were or are to be furnished.

(2) A member of a reviewer's family is a spouse (other than a spouse who is legally separated under a decree of divorce or separate maintenance), child (including a legally adopted child), grandchild, parent, or grandparent.

§ 466.100 Use of norms and criteria.

(a) *Use of norms.* As specified in its contract, a PRO must use national, or where appropriate, regional norms in conducting review to achieve PRO contract objectives. However, with regard to determining the number of procedures selected for preadmission review, a PRO must use national admission norms.

(b) *Use of criteria.* In assessing the need for and appropriateness of an inpatient health care facility stay, a PRO must apply criteria to determine—

(1) The necessity for facility admission and continued stay (in cases of day outliers in hospitals under prospective payment);

(2) The necessity for surgery and other invasive diagnostic and therapeutic procedures; or

(3) The appropriateness of providing services at a particular health care facility or at a particular level of care. The PRO must determine whether the beneficiary requires the level of care received or whether a lower and less costly level of care would be equally effective.

(c) *Establishment of criteria and standards.* For the conduct of review a PRO must—

(1) Establish written criteria based upon typical patterns of practice in the PRO area, or use national criteria where appropriate; and

(2) Establish written criteria and standards to be used in conducting quality review studies.

(d) *Variant criteria and standards.* A PRO may establish specific criteria and standards to be applied to certain locations and facilities in the PRO area if the PRO determines that—

(1) The patterns of practice in those locations and facilities are substantially different from patterns in the remainder of the PRO area; and

(2) There is a reasonable basis for the difference which makes the variation appropriate.

§ 466.102 Involvement of health care practitioners other than physicians.

(a) *Basic requirement.* Except as provided in paragraph (b) of this section, a PRO must meet the following requirements:

(1) Consult with the peers of the practitioners who furnish the services under review of the PRO review care and services delivered by health care practitioners other than physicians.

(2) Assure that in determinations regarding medical necessity of services or the quality of the services they furnish, these practitioners are involved in—

(i) Developing PRO criteria and standards;

(ii) Selecting norms to be used; and

(iii) Developing review mechanisms for care furnished by their peers.

(3) Ensure that an initial denial determination or a change as a result of DRG validation of services provided by a health care practitioner other than a physician is made by a physician only after consultation with a peer of that practitioner. Initial denial determinations and changes as a result of DRG validations must be made only by a physician or dentist.

(b) *Exception.* The requirements of paragraph (a) of this section do not apply if—

(i) The PRO has been unable to obtain a roster of peer practitioners available to perform review; or

(ii) The practitioners are precluded from performing review because they participated in the treatment of the patient, the patient is a relative, or the practitioners have a financial interest in the health care facility as described in § 466.98(d).

(c) *Peer involvement in quality review studies.* Practitioners must be involved in the design of quality review studies, development of criteria, and actual conduct of studies involving their peers.

(d) *Consultation with practitioners other than physicians.* To the extent practicable, a PRO must consult with nurses and other professional health care practitioners (other than physicians defined in 1861(r) (1) and (2) of the Act) and with representatives of institutional and noninstitutional providers and suppliers with respect to the PRO's responsibility for review.

§ 466.104 Coordination of activities.

In order to achieve efficient and economical review, a PRO must coordinate its activities (including information exchanges) with the activities of—

(a) Medicare fiscal intermediaries and carriers;

(b) Other PROs; and

(c) Other public or private review organizations as may be appropriate.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program; No. 13.773, Medical—Hospital Insurance; No. 13.774, Medicare—Supplementary Medical Insurance)

Dated: December 17, 1984.

Carolyn K. Davis,
Administrator, Health Care Financing Administration.

Approved: January 28, 1985.

Margaret M. Heckler,
Secretary.

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42 CFR Parts 405, 420, 474 and 489

[HSQ-109-F]

Medicare Program; Utilization and Quality Control Peer Review Organizations—Imposition of Sanctions on Health Care Practitioners and Providers of Health Care Services

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

ACTION: Final rule.

SUMMARY: This final rule implements the portion of the Peer Review Improvement Act of 1982 that imposes certain obligations on health care practitioners and other persons who provide health care services to Medicare beneficiaries. The rule also: (1) Establishes sanctions that the Secretary may impose for violations of the obligations; (2) imposes certain responsibilities on utilization and quality control peer review organizations; and (3) provides that an exclusion sanction will automatically become effective if the Secretary fails to act within a 120-day review period.

EFFECTIVE DATE: May 17, 1985. However, peer review organizations are not required to comply with the information collection requirements contained in §§ 474.36(b), 474.38(b), 474.38(c), 474.39(b), 474.40(b), and 474.40(c) until they are approved by the Office of Management and Budget. (See section VI.C. of the preamble for a discussion of the information collection requirements.)

FOR FURTHER INFORMATION CONTACT:

Anthony J. Tirone (HCFA)—(PRO process), (301) 594-9208.

William M. Libercci (OIG)—

(Department process), (301) 594-5035.

SUPPLEMENTARY INFORMATION:

I. Background

The Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA, Pub. L. 97-248)) amended Part B of Title XI of the Social Security Act by establishing the Utilization and Quality Control Peer Review Organization (PRO) program. The PRO legislation, enacted on September 3, 1982, seeks to redirect, simplify, and enhance the cost-effectiveness of the peer review program under Medicare.

Section 143 of TEFRA amends sections 1151 through 1163 of the Social Security Act (the Act). As amended, section 1156 of the Act imposes certain obligations upon health care practitioners and other persons who furnish or order services under Medicare. Section 1156 of the Act also provides for sanctions if the Secretary determines that the obligations were not met. These sanctions are recommended to the Secretary by PROs that contract with the Secretary. PROs have the responsibility to determine whether practitioners and other persons are complying with their obligations under the statute. Based upon the PRO recommendations, the Secretary is authorized, by statute, to exclude practitioners or other persons from the

Medicare program or, in lieu of exclusion, require payment of a monetary penalty as a condition of continued eligibility to receive reimbursement under the program.

II. Discussion of Proposed Rule

On April 18, 1984, we published a proposed rule to implement section 1156 of the Act (49 FR 15233). Briefly, the major provisions of the proposal were as follows:

A. PRO Review Process

We proposed to require PROs to review activities of practitioners and other persons who furnish or order health care services or items and, when warranted, make determinations that obligations were violated and that corrective action is needed.

Under the proposal, when a practitioner or other person fails to comply substantially with an obligation in a substantial number of cases, or violates an obligation in a gross and flagrant manner, the PRO must report the violation to the Secretary. The Office of the Inspector General (OIG), Department of Health and Human Services, would act as the Secretary's designee.

The proposal detailed the procedures the PRO must follow in giving notice to the practitioner or other person and providing an opportunity for discussion before making a final determination that a practitioner or other person has violated an obligation. If, after following those procedures, the PRO still determines that a violation has occurred, the PRO would send its report and recommendations to the OIG.

The OIG would review the PRO report and either agree or disagree with the PRO's recommendations. If the OIG agrees with the PRO determination, it could exclude the practitioner or other person from the Medicare program, or in lieu of exclusion, require payment of a monetary penalty as a condition for continued participation in the program.

As provided in section 1156(b)(1) of the Act and our proposal, an exclusion would automatically become effective 120 days after a PRO recommendation for exclusion is received by the OIG, unless the OIG specifically rejects the recommendation. This provision would not apply to recommendations for a monetary penalty.

B. Effect of an Exclusion

Under the proposed rule, payment under Medicare would not be made to a practitioner or other person who has been excluded from the program for services or items furnished on or after the effective date of the exclusion. Also,

payment would not be made for services or items ordered by an excluded practitioner or other person. Further details of our proposal, and the rationale for the proposed policies may be found in the preamble to the April 18 document.

III. Analysis and Response to Comments

We received comments on the proposed rule from 52 commenters including individuals, hospitals, medical societies, hospital and other professional associations, and professional standards review organizations (PSROs). These comments and our responses to them are discussed below.

A. Comment Period

Comment: Some commenters believe that the comment period for the proposed regulations was too short. They stated that 30 days was not enough to address all the issues and implications adequately. The commenters also suggested that the deadline for PRO contracts be revised from October 1, 1984 to January 1, 1985 to allow more time for review and comment.

Response: We believe 30 days was adequate time for commenters to address the proposal. The comment period was limited to 30 days to allow HCFA ample time to review, analyze, and incorporate pertinent comments into the final rule. The initial date mandated by Congress for the implementation of the PRO program was October 1, 1984. The implementation date was subsequently extended to November 15, 1984 by the Deficit Reduction Act of 1984 (Pub. L. 98-369).

B. Definitions (§ 474.0(b))

Comment: One of the obligations of a health care practitioner or other person who furnishes or orders health care services under Medicare, is to assure that those services are furnished economically (proposed § 474.30(a)). The proposed rule stated that *economically* meant that services were provided at the least expensive, medically appropriate type of setting or level of care.

A few commenters suggested revisions to the definition of the term *economically*, stating that although a physician may agree that services could be provided at a lower level of care, that lower level may not exist or be available. In addition, commenters stated that the longer and more complicated inpatient stays should not be arbitrarily terminated because less intensive services could be given in another setting. They believe that, in

many cases, the continuity and completion of the patient care plan would be disrupted by such a move.

Other related comments on termination of stays cited the serious stress a patient could suffer, time wasted in the patient's physical transfer and transfer of medical records, and the adjustment problems the patient could have becoming familiar with new staff for a very short period of time.

Some commenters also suggested that the definition of *economically* should require transfer of a patient to another setting only when the new setting can actually take care of the patient. These commenters recommended that the definition be related to the availability of alternative settings or levels of care.

Response: We agree with the recommendation to revise the definition of *economically* and have added the word *available* to the definition. Thus, the requirement at § 474.30(a) that the practitioner provide services *economically*, means that the services must be provided at the least expensive, medically appropriate type of setting or level of care available. "Available", for this purpose, relates to the availability of alternative settings or levels of care with certain limitations (§ 405.1827). For example, if a patient no longer requires acute hospital care but could receive treatment, covered under Medicare, in a skilled nursing facility and there is no bed available to the patient, that continued stay in the hospital would be considered covered care. However, if a patient no longer needs an acute inpatient level of care but requires home health care services, any continued inpatient stay would not be considered covered care even though the necessary home health care services are not available. Consideration of alternatives by the PROs in no way implies any modification of current coverage policy.

Comment: One commenter believes that the definition of *economically* ignores the special needs of patients in rehabilitation hospitals and that the interpretation of the term *least expensive, medically appropriate type of setting or level of care* could cause significant problems. Another commenter stated that the proposed definition of *economically* could create the impression that the PRO or the physician is to make a comparative cost determination between institutional and other types of services. The commenter believes that this aspect should be clarified.

Response: The term *least expensive, medically appropriate* does not imply that a patient should be placed in or transferred to a facility or level of care

because the cost of the services needed is lower than in another similar facility (or level of care). The definition of *economically* for the final rule reads "least expensive, medically appropriate type of setting or level of care available". We believe this modified definition also addresses concerns related to special needs of patients in all types of settings.

Comment: Several commenters noted that the regulations do not define the criteria that PROs will utilize when making a determination that a practitioner or other person has (1) failed substantially to comply with any obligation in a substantial number of cases, or (2) grossly and flagrantly violated any obligation in one or more instances (§ 474.34(c)). Some commenters also stated that no definitions were given for *substantial* or *gross and flagrant* in the proposed rule. The commenters stated that without definitions, the interpretations will vary from one locality to another and even within a particular PRO area. The commenters believe that this will lead to inconsistent application of sanctions.

Response: We are not specifying the criteria for determining violations of the statutory obligations contained in section 1156(a) of the Act and § 474.30 of these final regulations. The PROs have responsibility for the review of the professional activities of practitioners or other persons. In rendering medical judgments, the PROs must apply, as principal points of evaluation and review, professionally developed norms of care, diagnosis, and treatment based on typical patterns of practice within the geographic area served by the organization. We agree with part of the comments and have added definitions for what will be considered *gross and flagrant* and *substantial* violations (§ 474.0(b)).

We have differentiated between *substantial* violation and *gross and flagrant* by interpreting the language used by the statute. *Substantial* violation in a substantial number of cases means a pattern of care has been provided that is inappropriate, unnecessary or does not meet the recognized professional standards of care or is not supported by the necessary documentation of care as required by the PRO. *Gross and flagrant* violation means a violation of an obligation has occurred in one or more instances which presents an imminent danger to health, safety or well being of a Medicare beneficiary or places the beneficiary unnecessarily in high risk situations.

Comment: One commenter suggests that the definition for Statewide Council

be deleted because Statewide Councils do not apply to the PRO program and are no longer operational in the PSRO program.

Response: We agree and have deleted the definition for Statewide Council.

C. Obligations of Practitioners or Other Persons (§ 474.30)

Comment: One commenter believes that the practitioner's or other person's obligation to assure that services are of a quality that meet professionally recognized standards of health care (proposed § 474.30(b)) could be a problem. The commenter states that a PRO may not be qualified to define these standards. Similarly, one commenter states that the proposed sanction process imposes the judgment of non-professionals on medical professionals without due process of law. A third commenter wants us to ensure that the sanction process is objective. This commenter is concerned that the proposed regulations could result in reviewers who are not familiar with certain procedures making arbitrary determinations of violations.

Response: The requirements and criteria for determining the capability of a PRO to perform medical review were specified in the request for proposal for PRO contracts. As part of the requirements, a PRO must have sufficient physician resources to conduct all required review activities. This requirement assures adequate peer review. The process followed in developing a sanction case under this regulation is very similar to the process used under the PSRO program. These procedures have been tested in court and found to be constitutionally sound.

Comment: Proposed § 474.30(c) stated that practitioners or other persons who furnish or order health care services under Medicare would be obligated to assure that the services are supported by evidence of medical necessity and quality in the form and fashion that the reviewing PRO may reasonably require. Some commenters believe that § 474.30(c) is not consistent with the related provision in the statute (section 1156(a)(3) of the Act). These commenters stated that this paragraph would require a hospital to substantiate its compliance with pre-admission or pre-procedure review requirements. They noted, however, that the request for proposal for PROs sent out by HCFA indicates that no review function except quality review studies will be delegated to a hospital by the PRO. The commenters believe, in essence, that the proposed rule would require hospitals to develop a system to comply with a review

activity that only the PRO is supposed to conduct.

Some commenters believe that the practitioner's or other person's obligation to comply with pre-admission or pre-procedure review requirements allows PROs to exercise a broad authority not supported by statute. They recommend that the reference to pre-admission and pre-procedure reviews be deleted from § 474.30(c). One commenter suggested that the pre-admission and pre-procedure reviews cited in § 474.30(c) should be performed on a delegated basis because this method would be the most cost-effective.

Response: The commenters are correct when they point out that no pre-admission or pre-procedure review activity will be delegated to hospitals and only the PROs will conduct this type of review. However, the intent of the requirement was misunderstood by the commenters and only needs to be clarified here. A PRO may require that practitioners or other persons follow certain procedures to enable the PRO to conduct this type of review, and all practitioners or other persons must comply. Hospitals must develop procedures to ensure that categories of patients subject to pre-admission review are, in fact, reviewed before admission. A violation of these procedures could result in a sanction. At its discretion, a PRO could request evidence of compliance with its review procedures to assure that a practitioner or other person is meeting the obligations imposed by section 1156(a) of the Act. Therefore, we do not believe that any changes are required in § 474.30(c).

Comment: Many commenters believe that PROs should not be provided with copies of medical records at the expense of the practitioner or other person (§ 474.30(c)). They stated that this provision shifts substantial unreimbursed costs to the practitioner or other person, causing an undue financial burden. One commenter noted that under the prospective payment system, the high non-reimbursable costs for retrieving, copying, and transporting records will result in higher charges to private pay patients.

Response: We believe it is important that PROs have adequate access to medical records to enable them to carry out required activities. This includes the right to request and receive copies as they deem necessary. In some cases, this will mean that the PRO will request hospitals to photocopy specific medical records and mail them to PRO. However, the cost of photocopying records is a hospital operating cost and,

as such, is covered by the DRG prospective payments.

The prospective payment rates are computed according to the provisions of the law and are also based on the best available data at the time of the computation. Administrative costs are included in the Federal and hospital specific portions of prospective payments by virtue of being incurred and reported by hospitals for the years that represent the data bases for the prospective payment system.

Prior to the use of PROs, review of inpatient hospital services was carried out either at the hospital or offsite. Offsite review sometimes required that the hospital mail patient records to Medicare fiscal intermediaries. These costs were subsumed in the hospital's administrative costs that in turn were reflected in Medicare cost reimbursement calculations. Costs related to such activities are accounted for, in some measure, in the prospective payment base rates.

We also believe that the fiscal benefits of PRO review will compensate for any such increased costs. For example, in many cases, PROs' pre-admission review activities will protect hospitals from many retrospective denials. Thus, there will be trade-offs between hospitals' costs of providing medical records to PROs and PROs' performance of review that in many cases, may assist hospitals in avoiding unnecessary expenditures.

Accordingly, we are not changing this section of the regulations.

D. Sanctions (§ 474.32)

Comment: One commenter stated that § 474.32(b) does not completely reflect the Act's provisions and limitations in section 11256(b)(3). The commenter believes that although the proposed rule reflects the fact that monetary penalties are to be imposed in lieu of exclusion and are limited to an amount not in excess of the cost of improper or unnecessary services, the proposed rule does not indicate that monetary penalties can be imposed only when "such acts or conduct involved the provision or ordering . . . of health care services which were medically improper or unnecessary."

Response: We agree and have modified § 474.32(b) to specifically state that penalty is only available in cases of unnecessary or improper services.

Comment: One commenter recommends that the time for payment of a monetary assessment be extended from six months to one year since the amount of the penalty may be substantial.

Response: We believe six months is a sufficient period of time for payment of any monetary assessment. The practitioner or other person will have an option of taking six months to pay the monetary assessment or having it deducted from any sums the Federal Government owes the practitioner or other person. We believe the six month period is appropriate given the basis for determining the amount of the penalty and the need to adequately monitor its enforcement.

Comment: One commenter states that HCFA should promote a means of coordinating sanction activity between the Medicare and Medicaid programs.

Response: We agree and are coordinating sanction activity to the extent that legislation allows notification to State agencies when sanctions are being imposed on practitioners and other persons participating in the Medicare program.

E. PRO Responsibilities (§ 474.34)

Comment: A commenter recommends that the regulations be amended to provide a means of accommodating the practitioner's or other person's comments prior to the PRO's identification of a violation. The commenter stated that before a PRO identifies a violation, the PRO should be required to speak with the practitioner or other person to obtain his or her view of the facts and to see if a mutually satisfactory resolution could be reached.

Response: We agree with the comments but have not accepted the recommendation to revise the proposed rule because the requirements suggested are beyond the scope of the regulations and have already been included in the peer review plan of the PRO. A PRO must use all appropriate mechanisms of review and intervention to resolve adverse situations and assure compliance with the statutory obligations prior to using the sanction procedures specified in these final regulations. The sanction process is viewed as a measure of last resort in the peer review program. We believe that the broad scope of the basic responsibilities addressed in § 474.34(a) applies to the requirement of resolving situations before using the sanction procedures under this final rule.

Comment: Proposed § 474.34(e) requires the PRO to deny Medicare payment for services or items ordered by an excluded practitioner or other person when the PRO identifies such services or items and reports the findings to HCFA. One commenter stated that it will be almost impossible for a PRO to identify items or services ordered by an excluded practitioner

from another area or State, given the present state-of-the-art for tracking excluded practitioners. The commenter suggested that § 474.34(e) be modified to recognize this difficulty.

Response: We have not changed this section because we believe that the provisions requiring that notice of sanction be provided to the PRO who originated the sanction report and PROs in adjacent areas (as defined in § 474.52(e) (1) and (2)) reduce the potential difficulty that may be encountered by a PRO in identifying services or items ordered by an excluded practitioner. Section 474.34(e) does not require a tracking mechanism for an excluded practitioner outside the jurisdiction of a PRO. However, PROs are statewide organizations and are expected to conduct statewide monitoring. The OIG's internal procedures requiring monthly notice of sanctioned individuals to every State and PRO could facilitate the identification of an out-of-State practitioner who could be furnishing services in another State.

F. Action of Identification of a Violation (§ 474.36)

Comment: One commenter stated that § 474.36(b), concerning PRO action if the PRO determines that a violation is a substantial failure to comply in a substantial number of cases, should require the PRO to send the practitioner or other person a written initial notice when the PRO identifies the violation.

Response: We agree with this comment and have clarified the section to require the PRO to send a written notice when a substantial violation is identified.

Comment: One commenter believes that a summary of the information used by the PRO in arriving at its determination (which is supplied to the practitioner or other person at the time a violation is identified) is insufficient to support action by the PRO at that time. The commenter believes that the practitioner or other person would be unable to respond properly to the PRO's allegations, unless detailed supporting material were provided at the time of notice.

Response: We believe the summary information that the PRO provides with the written notice at the time a substantial violation is identified is adequate. This summary must be complete enough to advise the physician or other person of the issues involved and to identify the significant information on cases used in determining the violation. Section 474.38(b) requires the PRO to provide a

copy of all the material used by the PRO if it is determined that a violation has, in fact, occurred.

G. PRO Determination of a Violation (§ 474.39)

Comment: The proposed regulations allow a practitioner or other person 20 or 30 days to respond to PRO notices during different stages of the sanction process (§§ 474.36(b)(6), 474.38(b)(5), and 474.39(b)(2)). Various commenters stated that 20 or 30 days is not enough time for a reasonable reply. One commenter also noted that the failure of a PRO to release notices in a timely manner and potential delays in the postal system could limit the available time even more. The commenters suggested that: (1) The time frames be extended by 10 or 15 days, (2) practitioners or other persons be given 20 to 30 days to reply from the date the PRO notification is received, and (3) only work days be considered in the time frames.

Response: Sections 474.36(b)(6), 474.38(b)(5), and 474.39(b)(2) have been modified to incorporate the suggestion that practitioners or other persons be given 20 or 30 days, as specified, to reply from the date the PRO notification is received. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary. We are not further extending these timeframes for the final rule. These timeframes have been extended already from the time allowed under the previous sanction regulations. Extending the timeframes any longer would prolong an already lengthy process. We believe that the time allowed is adequate for a practitioner or other person to respond.

Comment: We proposed that if the issue concerning the PRO's determination of a violation is not resolved to the PRO's satisfaction, the PRO would submit its report and recommendation to the OIG, and the practitioner or other person would have 30 days to submit additional material to the OIG. One commenter recommends that the proposal be revised to allow the OIG to accept information beyond the proposed 30-day period if the practitioner or other person has exercised diligence in providing or obtaining information, and acceptance of the information could materially affect the outcome of the case.

Response: We believe the time limits specified in the regulations are sufficient for the practitioner or other person to submit additional material to the OIG. Additionally, in view of the statutory mandate that the Secretary act within

120 days of the receipt of a PRO recommendation for exclusion, the granting of any additional time in which to submit additional information would interfere with the OIG responsibility in this regard.

H. PRO Report to OIG (§ 474.40)

Comment: One commenter states that the language contained in § 474.40(c)(4) was merely repetitive of the language in the statute and requested a more thorough explanation as to how a "finding" could be made as to whether a practitioner or other person is unable or unwilling substantially to comply with his or her obligations.

Response: We have changed the word "finding" to "recommendation" in § 474.40(c)(4). Section 1156(b) of the Act requires the Secretary, rather than the PRO, to make the determination before invoking a sanction, that the practitioner or other person is unable or unwilling substantially to comply with the statutory obligations. We have not specified the information that the PRO must use in making its recommendation in the final regulation. The PROs are responsible for determining in each situation the information that would best support their recommendation. For example, the PRO could base its recommendation on the experience the PRO has had with the particular practitioner as well as any other information considered relevant by the PRO.

I. Basis for Recommended Sanction (§ 474.41)

Comment: Proposed § 474.41 contains the various considerations on which the PRO would base its recommendations for a specific type of sanction. A commenter stated that two of the listed considerations were duplicative, and that we should require consideration of the availability of alternative sources of services in the community.

Response: The repetition was due to a typographical error that has been corrected in these final regulations. The proposal should have required, in place of the duplication, a consideration of the deterrent value of the sanction. Also, the commenter's request concerning alternative sources of services in the community has been accepted. However, as discussed in section III.B. of this preamble, consideration of alternatives by the PROs in no way implies any modification of current coverage policy.

J. Review of PRO Report by the OIG (§ 474.42)

Comment: One commenter suggests that § 474.42(b) should be revised to

expand the bases for OIG review of a PRO's report and recommendations to include, in the case of evidentiary violations, whether the PRO's procedures and demands for documentation in the cases at issue were reasonable and necessary to performance of its duties under the Act.

Response: We believe the requirement contained at § 474.42(b)(1) that the OIG determine whether the PRO is following its procedures is sufficient to substantiate whether the PRO's actions were reasonable and necessary.

Comment: One commenter noted that paragraphs (d) through (f) of § 474.42 were incorrectly designated since paragraph (c) was omitted.

Response: Appropriate redesignations have been made to correct the typographical error.

Comment: One commenter stated that § 474.42(e) (2) and (3) [redesignated in this final rule as paragraphs (d) (2) and (3)] were not clear as to how the type and severity of offense would be classified and weighed in the OIG's sanction determination.

Response: We believe the present language adequately advises the reader of the manner in which the OIG determines the appropriateness of any sanction. Identical language was found in former § 474.10, relating to HCFA's deliberations concerning the imposition of a sanction following the receipt of a PSRO report.

Comment: Many commenters disagree with the automatic imposition of an exclusion if the OIG (acting as the Secretary's designee) does not act within the 120-day review period (proposed § 474.42(f)). These commenters believe that this is an arbitrary intrusion into the Secretary's discretionary role that fails to consider special circumstances that may arise. The commenters want some action required by the OIG before an exclusion could be effective. One commenter stated that the automatic exclusion is inappropriate because action by the OIG is required to reinstate a practitioner or other person in the Medicare program.

Response: We are unable to accept these comments because the 120-day provision for the automatic implementation of an exclusion is required by section 1156(b)(1)(B) of the Act. However, if an exclusion sanction becomes effective because a decision was not made within 120 days, the OIG will complete the review of the case and issue a notice to the practitioner or other person affirming or modifying the PRO recommendation. We would note that proposed § 474.42(f) has been

redesignated as § 474.42(e) in this final rule.

Comment: Several comments were received concerning the imposition of a monetary penalty in lieu of an exclusion. Specifically, the proposed rule states that the 120-day provision for automatic imposition does not apply to the recommendations for a monetary penalty. Commenters requested specific language to reflect the appropriate handling of monetary penalty recommendations, specifying the action that OIG will take in these cases.

Response: We have modified the section pertaining to the automatic imposition of an exclusion to accommodate the comments. We have also added a new paragraph (§ 474.42(f)) relating to monetary penalty recommendations to address the comments.

K. Notice of Sanction (§ 474.52)

Comment: In the case of an exclusion under the proposed rule, the OIG would specify the earliest date on which it would accept a request for reinstatement. One commenter believes that the OIG should consider reinstatement of a practitioner without inflexible time limits when to do so would serve the interest of patients and the program.

Response: Under current HCFA regulations in 42 CFR Part 420—Program Integrity, § 420.132, Criteria for Action on Request for Reinstatement, provides that reinstatement will not be granted unless it is reasonably certain that the violations that led to exclusion will not be repeated. Statutory authority is given to the Secretary to exclude either permanently or for such period as may be determined. By excluding for a specific period of time, the practitioner or other person will have sufficient time to improve his or her medical practice or services and to demonstrate to the Secretary that the violations that led to exclusion will not recur. Furthermore, allowing reinstatement prior to the period specified by the Secretary would mitigate against the effect of imposing a sanction. To permit the practitioner or other person to apply for reinstatement when the practitioner or other persons believes that he or she is ready to be reinstated would be totally unmanageable and would not be of benefit to the program. This could allow the person to apply one week after the effective date.

Comment: Many commenters are concerned that the new regulations do not adequately address the administrative appeals process available to a practitioner or other

person who receives a sanction notice from the OIG.

Response: Several modifications have been made to accommodate these concerns. We have added a new paragraph (g) to § 474.52 to specify that the OIG's determination and notice of sanction under these regulations constitute an "initial determination" and a "notice of initial determination" for purposes of the administrative appeals process. These initial determinations are not subject to reconsideration. Instead, if dissatisfied with an initial determination, a practitioner or other person must request a hearing. We have revised § 474.56 to clarify that the OIG's determination that the basis for the exclusion no longer exists and that there is reasonable assurance that the problems will not recur must be made in accordance with 42 CFR 420.130–420.136. We have also revised § 474.58 to clarify that a practitioner or other persons dissatisfied with the OIG's determination or an automatic exclusion sanction is entitled to a hearing before an Administrative Law Judge and may also request a review of that decision by the Appeals Council in accordance with 42 CFR 405.1530 through 405.1595 of this chapter.

Comment: Many commenters strongly believe that, since hospitals and other health care providers could potentially be held liable for services ordered by the sanctioned practitioner, the OIG should notify hospitals and other health care providers where the sanctioned practitioner may be practicing.

Response: We agree, in part, with these comments, and have added a requirement to § 474.52(e)(5) that notifications be given to the hospital where the sanctioned individual's case originated and where the individual currently has privileges, if known.

L. Effect of an Exclusion on Medicare Payments and Services (§ 474.54)

Comment: Many commenters noted that under § 474.54(a)(2) providers will not be paid for items or services ordered by the excluded practitioner or other person even though the provider may not be aware of the exclusion. These commenters believe that a provider (especially the institutions where the practitioner practices) must get adequate notice of sanction if the provider is going to be held liable in this manner. The commenters stated that the provision, as proposed, imposes an undue financial burden on providers because they will not be aware of particular sanctions.

Response: As previously noted, we will notify the hospital where the sanctioned individual's case originated

and where the individual currently has visiting privileges, if known.

Comment: We proposed to continue payment for inpatient hospital or skilled nursing services for 30 days after the effective date of an exclusion, for services furnished to a beneficiary who was admitted before the effective date of the exclusion. One commenter questioned why the length of stay should be determined by a sanction when a patient's admission is found to be medically necessary and appropriate (§ 474.54(b)(1)). This commenter noted that the prospective payment system already has sufficient remedies for lengths of stay and total costs that exceed the designated limits. The commenter believes that the hospitals should receive payment for items and services covered by the Medicare program and found by the PRO to be provided appropriately, regardless of the relationship of the length of stay to the effective date of the sanction.

Response: This is a statutory requirement contained in section 1866(b)(3) of the Act, and we cannot revise that policy in § 474.54(b)(1). Although we received no comments related to the payment exception for home health services or items, we have modified § 474.54(b)(2) to reflect a recent change to the Act that was contained in section 2348 of the Deficit Reduction Act of 1984 (Pub. L. 98-369). That statutory revision amended section 1866(b)(4) of the Act to permit payment for home health services or items furnished under a plan established before the effective date of exclusion to be available for services or items furnished up to 30 days after the effective date.

M. Hearings and Appeals (§ 474.58)

Many commenters are concerned about the hearings and appeals that would be available under the proposed regulations. The following comments illustrate these concerns.

Comments:

- The proposed sanction process deprives practitioners or other persons of their constitutionally guaranteed right to legal counsel and judicial proceedings prior to the imposition of a sanction.

- An individual practitioner's reputation in the community could be irreparably damaged by an incorrect finding and publication of a sanction. All alleged violators should be accorded the right to a full, fair, and impartial evidentiary hearing prior to the imposition of a sanction and public disclosure. Publication of a sanction should be postponed until appeals are

completed, or until the time to appeal has expired.

- There is no opportunity to appeal a substantive error during the period that the OIG is reviewing the PRO's determination.

- Sections 474.36 and 474.38 of the proposed regulations (PRO identification and determination of a violation) should be revised. The regulations do not provide for an evidentiary hearing, permit the alleged violator to cross-examine witnesses or call witnesses in its defense, nor provide for an objective forum to judge the PRO's determination. Under the proposed regulations, the PRO would determine that a violation exists and then would judge whether or not the determination is correct.

- The practitioner or other person should have at least as much time to develop its documentation as the PRO took in preparing the determination of a violation.

- The regulations preclude any meaningful administrative review. Proposed § 474.52 provides that a sanction would be effective 15 days after the practitioner or other person is notified. A sanction could be entered, imposed, publicized, and implemented before the practitioner or other person has had any hearing and before there has been any opportunity to be heard by an independent forum. The regulations should provide that a sanction will not go into effect before a provider has had an opportunity to exhaust administrative review rights and not until one month after any petition for judicial review is filed.

- The regulations should require the PRO to provide the practitioner or other person with the actual information used by the PRO to determine that a violation exists. The summary of information (§ 474.38(b)(7)) required in the proposed regulations is not sufficient for a practitioner or other person to prepare an adequate defense.

- The regulations do not provide the practitioner or other person with a hearing before the OIG. While § 474.39(b)(2) grants the right to submit additional material to the OIG, it does not allow critical activities such as the right to cross-examine and probe the data upon which the PRO has relied.

Response: We do not agree that a formal hearing is required before implementation of a sanction.

Section 1156(c) of the Act provides for a hearing and judicial review as provided in section 205(b) and (g) of the Act, respectively. In accordance with these sections, the hearing and judicial review of administrative determinations do not occur before the decision is implemented.

Provision has been made in the regulations for an opportunity for the practitioner or other person to submit additional documentary evidence or written argument to the OIG before any sanction is imposed. This information must be submitted within 30 days from the date of receipt of final notice of a violation (§ 474.39(b)). We believe that the two opportunities to meet with the PRO in the case of a substantial violation (one opportunity in a gross and flagrant situation) before a final determination of a violation is made, and the opportunity to submit additional written argument or evidence to the OIG prior to its determination, along with the opportunity for an evidentiary hearing and judicial review after the implementation of a sanction, fully satisfy the due process standards as set forth by the United States Supreme Court in *Matthews v. Eldridge*, 424 U.S. 319 (1976).

In the *Eldridge* case, the Supreme Court made clear that due process does not require a full evidentiary pretermination hearing. The Court in the *Eldridge* case set forth three factors to be evaluated in deriving specific requirements of due process for a given situation:

- (a) The private interest involved;
- (b) The reliability of the process in making correct determinations and the probable value of additional safeguards; and
- (c) The government's interest, including the fiscal and administrative burdens of additional safeguards (424 U.S. at 335).

The private interest here concerns practitioners' or providers' abilities to furnish services for which payment may be made under the Medicare program. Continued access to Medicare funds is not a prerequisite for the practitioner or provider continuing to furnish health care services to patients but concerns the physicians' access to one group of potential customers for their services. The government's interest, on the other hand, is not only fiscal but also the health and safety of individuals who are eligible for Medicare benefits.

In our view, the meeting with the PRO before it files a sanction report, and then the opportunity to provide additional written evidence or argument to the OIG before a determination is made, assures a high degree of reliability for the OIG's actions and safeguards against the erroneous imposition of a sanction.

We believe that requiring a full evidentiary hearing prior to the OIG's actions would not only be contrary to the Act but would adversely affect the health and safety of individuals. It also would add to the OIG's administrative

and fiscal burdens by precluding prompt action and by allowing the continuation of benefit payments pending a conclusion of the hearing, without adding significantly to the reliability of the OIG's decision.

IV. Summary of Changes to the Proposed Rule

The following summary of regulations changes is provided for the reader's reference.

1. Section 405.1502

- We have added a new paragraph (f) to specify that the determination and notice of sanction under the PRO program is one of the initial determinations made by the Secretary.

2. Section 405.1503

- This section has been revised to distinguish between the notification procedures for initial determinations under the PRO sanction process and the notification procedures for other types of initial determinations.

3. Section 420.115(c)

- This paragraph has been revised to reflect a recent statutory change contained in section 2348 of Pub. L. 98-369. The statutory change provides that Medicare payment may be made for certain services furnished up to 30 days after the date of termination from the Medicare program.

4. Section 420.126(e)

- This paragraph has also been revised to reflect the recent statutory change contained in section 2348 of Pub. L. 98-369. The statutory change provides that Medicare payment may be made for certain services furnished up to 30 days after the date of termination from the Medicare program.

5. Section 474.0(a)

- The reference to Statewide Councils has been deleted from paragraph (a)(2).

6. Section 474.0(b)

- The definition of *economically* has been revised to clarify that the appropriate level of care is a level of care that is actually available.

- A definition for *gross and flagrant violation* has been added.

- A definition for *substantial violation* has been added.

- The definition for *Statewide Council* has been deleted.

- The definitions for *PRO* and *PSRO* have been deleted because the terms are already defined in Part 400, § 400.200 General definitions.

7. Section 474.36(b)

• The term *substantial failure to comply* has been changed to read a *substantial violation in a substantial number of cases*.

• We have clarified that the PRO's notice to the practitioner or other person must be in writing.

8. Sections 474.36(b)(6), 474.38(b)(5), and 474.39(b)(2)

• These sections have been revised to specify that the practitioner's or other person's time to respond to the PRO notice begins on the date the PRO notice is received. Further, the date of the receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

9. Section 474.40(c)(4)

• The word *finding* has been changed to *recommendation* to clarify that the PRO makes a recommendation and not a determination concerning the practitioner's or other person's ability to comply with an obligation that was violated.

10. Section 474.41

• The typographical error in paragraph (c) of the proposed rule has been corrected by adding the statement originally intended.

• A new paragraph (e) has been added to recognize that a PRO must consider the availability of alternative sources of service in the community when deciding whether to recommend a sanction.

• Paragraph (e) of the proposed rule has been redesignated as paragraph (f) in this final rule.

11. Section 474.42

• To correct a typographical error in the proposed rule, paragraphs (d), (e), and (f) have been redesignated as paragraphs (c), (d), and (e), respectively.

• Paragraph (e) has been revised to clarify the provisions concerning an automatic exclusion sanction.

• A new paragraph (f) has been added to clarify the provisions concerning a monetary penalty.

12. Section 474.52

• Paragraph (e)(5) has been revised to clarify that a notice of sanction will be provided to the hospital where the sanctioned individual has privileges and to the hospital where the case originated, if known.

• Paragraph (f) of the proposed rule has been revised to clarify the notification procedures when an automatic exclusion sanction is involved.

• A new paragraph (g) has been added to clarify that the determination and notice of sanction constitute an initial determination and a notice of initial determination for purposes of administrative appeals procedures.

13. Section 474.54(b)

• This paragraph has been revised as required by section 2348 of Pub. L. 98-369. The statute provides that Medicare payment may be made for certain services furnished up to 30 days after the date of termination from the Medicare program.

14. Section 474.56(a)

• This paragraph has been revised to clarify that the OIG must comply with §§ 420.130 through 420.136 when deciding whether an exclusion sanction should be terminated.

15. Section 474.58(a)

• This paragraph was revised to clarify the practitioner's or other person's appeal rights.

16. Section 489.55

• This section was also revised to reflect a change contained in section 2348 of Pub. L. 98-369. The statutory change provides that Medicare payment may be made for certain services furnished up to 30 days after the date of termination from the Medicare program.

17. Miscellaneous changes

• We have made numerous minor editorial and technical revisions to clarify and correct the language in the regulations and to provide easier reading. All regulations sections contain one or more of these types of revisions.

18. Conforming changes

• Sections 405.1504, 405.1530, and 405.1531 have been revised to include a cross-reference to new § 405.1502(f).

V. Waiver of Notice of Proposed Rulemaking for Certain Sections

The revisions in §§ 420.115(c), 420.126(e), 474.54(b), and 489.55 are conforming changes made necessary by section 2348 of Pub. L. 98-369. This statutory provision became effective on July 18, 1984, the date of enactment of Pub. L. 98-369. Our conforming changes are being issued as part of this final rule because the effective date of the provision was statutorily mandated and because the provision itself is self-implementing.

The conforming changes do not expand upon the statutory provision, but merely paraphrase it. Accordingly, we find that a notice of proposed rulemaking for the conforming changes

would be impractical and unnecessary, and find good cause to waive it.

VI. Impact Analyses

A. Executive Order 12291

Executive Order 12291 requires that a regulatory impact analysis be performed for any "major" regulation; that is, a regulation that will result in an economic impact of \$100 million or more, or a regulation that meets other criteria specified in section 1(b) of the Order.

Under these final regulations, a PRO can recommend certain sanctions to the OIG when a practitioner or other person fails to meet obligations specified at section 1156(a) of the Act.

The PRO can recommend exclusion or, in lieu of exclusion, the assessment of a monetary penalty. An exclusion will become effective automatically 120 days after a PRO submits a recommendation for exclusion to the OIG, if a decision is not made within the 120-day period. This does not represent a major change from our current sanction activities. Although these regulations will expedite the review and completion of sanction cases, the incremental impact of these regulations will be negligible.

In this final rule, we are also clarifying and revising certain provisions of the proposed rule to accommodate questions and issues raised by numerous commenters. Taken as a whole, these changes are not significant departures from our current policies and procedures. Therefore, we have determined that a regulatory impact analysis is not required because these regulations do not meet the criteria for a "major" regulation.

B. Regulatory Flexibility Act

We do not expect these regulations to cause a significant incremental increase in our sanction activity. Historically, we have imposed administrative sanctions only in particularly abusive situations. Therefore, we believe that these sanction regulations will affect relatively few practitioners or other persons. Accordingly, we have determined that these regulations will not result in a significant impact on a substantial number of providers and practitioners.

Therefore, the Secretary certifies under 5 U.S.C. 605(b), as enacted by the Regulatory Flexibility Act of 1980 (Pub. L. 96-354), that these regulations will not result in a significant impact on a substantial number of small entities.

C. Reporting and Recordkeeping Requirements

Sections 474.36(b), 474.38(b), 474.38(c), 474.39(b), 474.40(b), and 474.40(c) contain information collection requirements to which PROs must adhere. We are submitting the requirements in these regulations to the Office of Management and Budget (OMB) for review under the requirements of the Paperwork Reduction Act of 1980 (Pub. L. 96-511). PROs are not required to comply with these information collection requirements until OMB approves them. Comments on these requirements should be sent directly to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Washington, D.C., Attention: Fay Iudicello. A notice will be published in the *Federal Register* when approval is obtained.

VII. LIST OF SUBJECTS**42 CFR Part 405**

Administrative practice and procedure, Certification of compliance, Clinics, Cost-based reimbursement, Contracts (Agreements), End-Stage Renal Disease (ESRD), Health care, Health facilities, Health maintenance organizations (HMO), Health professions, Health suppliers, Home health agencies, Hospitals, Inpatients, Kidney diseases, Laboratories, Medicare, Nursing homes, Onsite surveys, Outpatient providers, Reasonable charges, Reporting and recordkeeping requirements, Rural areas, Prospective payment system, X-rays.

42 CFR Part 420

Abuse, Administrative practice and procedure, Contracts (Agreements), Conviction, Convicted, Courts, Exclusion, Fraud, Health care, Health facilities, Health maintenance organizations (HMO), Health professions, Health suppliers, Information (Disclosure), Lawyers, Medicaid, Medicare, Penalties, Professional Standards Review Organizations (PSRO), Reporting and recordkeeping requirements, Supervision.

42 CFR Part 474

Health care, Health professions, Penalties, Professional Standards Review Organization (PSRO), Reporting and recordkeeping requirements, Sanctions, and Utilization and Quality Control Peer Review Organization (PRO).

42 CFR Part 489

Clinics, Health care, Health facilities, Medicare, Provider Agreements, Rural health clinics, Termination procedures. 42 CFR Chapter IV is amended as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED**A. Part 405 is amended as follows:**

1. The authority citation for Subpart O is revised to read as follows:

Authority: Secs. 1102, 1866, 1869, 1871, and 1872 of the Social Security Act; 42 U.S.C. 1302, 1395cc, 1395ff, 1395hh, and 1395il, unless otherwise noted.

2. The introductory paragraph for § 405.1502 is reprinted unchanged and the section is amended by adding a new paragraph (f) to read as follows:

§ 405.1502 Initial determinations.

The Secretary will make findings setting forth the pertinent facts and conclusions, and an initial determination with respect to:

(f) The determination and notice of sanction provided for in §§ 474.52(a) and 474.52(g) of this chapter.

3. Section 405.1503 is revised to read as follows:

§ 405.1503 Notice of initial determinations.

A written notice of an initial determination as specified in paragraphs (a) through (f) of § 405.1502 will—

(a) Be mailed to the concerned provider, supplier, or practitioner; and
(b) Include the basis or reasons for the determination, and information concerning appeal rights. (See § 405.1510 concerning the right to a reconsideration, if applicable, and § 405.1530 concerning the right to a hearing.)

4. Section 405.1504 is revised by adding a cross-reference to § 405.1502(f) to read as follows:

§ 405.1504 Effect of initial determination.

The initial determination shall be final and binding upon the parties to the determination unless: (a) It is revised (see § 405.1519); (b) in the case of a determination described in § 405.1502 (a), (b)(1), or (d)(1), it is reconsidered in accordance with § 405.1514; or (c) in the case of a determination described in § 405.1502 (b)(2), (c), (d)(2), (e), or (f), a request for a hearing is filed and the initial determination is reversed.

5. Section 405.1530 is revised by adding a cross-reference to § 405.1502(f) to read as follows:

§ 405.1530 Hearing: Right to hearing.

After an initial and reconsidered determination described in §§ 405.1502 (a), (b)(1), (d)(1), and 405.1514; or after an initial determination described in § 405.1502 (b)(2), (c), (d)(2), (e), or (f); or after a revised determination described in § 405.1519, an institution, agency, clinic, laboratory, portable X-ray supplier, ambulatory surgical center, end-stage renal disease treatment facility, or person shall be entitled to a hearing with respect to such determination, if such person or the representative of the institution, agency, clinic, laboratory, portable X-ray supplier, ambulatory surgical center, end-stage renal disease treatment facility, or person files a written request for hearing as provided in § 405.1531.

6. Section 405.1531(a) is revised by adding a cross-reference to § 405.1502(f) to read as follows:

§ 405.1531 Filing a request for a hearing: time and manner of filing.

(a) The request for a hearing shall be made in writing, signed by the person, or a proper official of the institution, agency, clinic, laboratory, portable X-ray supplier, ambulatory surgical center, or end-stage renal disease treatment facility concerned and filed at an office of the Department of Health and Human Services, or with a presiding officer of the Appeals Council of the Office of Hearings and Appeals. The request must be filed within 60 days after the date notice of an initial determination provided for in § 405.1502 (b)(2), (c), (d)(2), (e), or (f); or a reconsidered or revised determination, is received by the institution, agency, clinic, laboratory, portable X-ray supplier, ambulatory surgical center, end-stage renal disease treatment facility, or person (see §§ 405.1503, 405.1516, and 405.1520), except where the time is extended for "good cause" (see § 405.1569). For purposes of this section, the date of receipt of notice of the initial, reconsidered or revised determination shall be presumed to be 5 days after the date of such notice, unless there is a reasonable showing to the contrary.

PART 420—PROGRAM INTEGRITY**B. Part 420 is amended as follows:**

1. The authority citation for Part 420 continues to read as follows:

Authority: Secs. 1102, 1862(d) (1), (2), (3), and (4), 1862(e), 1866(b) (2)(D), (E), and (F), 1871, 1902(a)(39), and 1903(i)(2) of the Social Security Act (42 U.S.C. 1302, 1395y(d), 1395cc, 1395hh, 1396a, and 1396b, unless otherwise noted).

2. Section 420.115(c) is revised to read as follows:

§ 420.115 Effect of exclusion.

(c) *Exceptions.* Payment is available for up to 30 days after the effective date of exclusion for—

(1) Inpatient hospital services or posthospital skilled nursing facility care services furnished to a beneficiary who was admitted to a hospital or a SNF before the effective date of exclusion; and

(2) Home health services furnished under a plan established before the effective date of exclusion.

3. Section 420.126(e) is revised to read as follows:

§ 420.126 Effect of suspension.

(e) *Exceptions.* Payment is available for up to 30 days after the effective date of the suspension for—

(1) Inpatient hospital services or posthospital skilled nursing facility care furnished to a beneficiary who was admitted to a hospital or a SNF before the effective date of the suspension; and

(2) Home health services furnished under a plan established before the effective date of the suspension.

PART 474—IMPOSITION OF SANCTIONS ON HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES

C. Part 474 is amended as follows:

1. The table of contents and the authority statement are revised to read as follows:

Subpart A—General Provisions

Sec.

474.0 Scope and definitions.

Subpart B—Sanctions Under the PSRO Program

474.1 Statutory obligations of practitioners and providers.

474.2 Sanctions.

474.3 PSRO responsibilities.

474.4 Action on potential violation.

474.5 Factors in PSRO determination of a violation.

474.6 Basis for recommended sanction.

474.7 Notice and review of PSRO determination of violation.

474.8 PSRO report to the Statewide Council or to HCFA.

474.9 Role and functions of the Statewide Council.

474.10 Action by HCFA on receipt of the report.

474.14 Effective dates of exclusion.

474.15 Reinstatement after exclusion.

474.17 Right to judicial review.

Subpart C—Sanctions under the PRO Program: General Provisions

474.30 Statutory obligations of practitioners and other persons.

474.32 Sanctions.

Subpart D—PRO Responsibilities

474.34 Basic responsibilities.

474.36 Action on identification of a violation.

474.38 Action on determination of a violation.

474.39 Final PRO determination of a violation.

474.40 PRO report to OIG.

474.41 Basis for recommended sanction.

Subpart E—OIG Responsibilities

474.42 Acknowledgment and review of report.

474.52 Notice of sanction.

Subpart F—Effect and Duration of Exclusion

474.54 Effect of an exclusion on Medicare payments and services.

474.56 Reinstatement after exclusion.

Subpart G—Appeals

474.58 Appeal rights.

Authority: Section 1102 of the Social Security Act, 42 U.S.C. 1302. Subpart B is also issued under sec. 150 of Pub. L. 97-248, 42 U.S.C. 1320c note. Subparts C through G are also issued under sec. 1156 of the Social Security Act, 42 U.S.C. 1320c-5.

2. A new Subpart A entitled "General Provisions" is established to include the current § 474.0.

3. Section 474.0 is revised to read as follows:

§ 474.0 Scope and definitions.

(a) *Scope.*

This part implements section 150 of Pub. L. 97-248 (PSROs) and section 1156 of the Act (PROs) by—

(1) Setting forth certain obligations imposed on practitioners and providers of services under Medicare;

(2) Establishing criteria and procedures for the reports required from PSROs and PROs when there is failure to meet those obligations;

(3) Specifying the policies and procedures for making determinations on violations and imposing sanctions; and

(4) Defining the procedures for appeals by the affected party and the procedures for reinstatements.

(b) *Definitions.* As used in this part, unless the context indicates otherwise:

"Economically" means that services are provided at the least expensive, medically appropriate type of setting or level of care available.

"Exclusion" means that items or services furnished or ordered by a specified health care practitioner, provider, or other person during a

specified period are not reimbursed under Medicare.

"Gross and flagrant violation" means a violation of an obligation has occurred in one or more instances which presents an imminent danger to the health, safety or well-being of a Medicare beneficiary or places the beneficiary unnecessarily in high-risk situations.

"Health care services" or "Services" means services or items for which payment may be made (in whole or in part) under the Medicare program.

"Obligation" means any of the obligations specified at section 1156(a) of the Act.

"OIG" stands for the Office of the Inspector General, Department of Health and Human Services.

"Other person" means a hospital or other health care facility, an organization, or an agency that furnishes health care services for which payment may be made under the Medicare program.

"Physician" means a doctor of medicine or osteopathy or another individual who is authorized under State or Federal law to practice medicine and surgery or osteopathy.

"Practitioner" means a physician or other health care professional licensed under State law to practice his or her profession.

"PRO area" means the geographic area subject to review by a particular PRO.

"Provider" means a hospital or other health care facility, agency, or organization.

"PSRO area" means the geographic area subject to review by a particular PSRO.

"Sanction" means an exclusion or monetary penalty that the Secretary may impose on a practitioner or other person as a result of a recommendation from a PRO.

"Substantial violation in a substantial number of cases" means a pattern of care has been provided that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care as required by the PRO.

4. A new Subpart B entitled "Sanctions Under the PSRO Program" is established to include current §§ 474.1-474.17.

5. New Subparts C through G are added to read as follows:

Subpart C—Sanctions Under the PRO Program: General Provisions**§ 474.30 Statutory obligations of practitioners and other persons.**

It is the obligation of any health care practitioner or other person who furnishes or orders health care services that may be reimbursed under Medicare, to ensure, to the extent of his or her authority, that those services are—

(a) Furnished economically and only when and to the extent medically necessary;

(b) Of a quality that meets professionally recognized standards of health care; and

(c) Supported by evidence of the medical necessity and quality of the services in the form and fashion that the reviewing PRO may reasonably require (including copies of the necessary documentation and evidence of compliance with pre-admission or pre-procedure review requirements to ensure that the practitioner or other person is meeting the obligations imposed by section 1156(a) of the Act.

§ 474.32 Sanctions.

In addition to any other sanction provided under law, a practitioner or other person may be—

(a) Excluded from Medicare; or

(b) In lieu of exclusion and as a condition for continued participation in Medicare, if the violation involved the provision or ordering of health care services that were medically improper or unnecessary, required to pay an amount not in excess of the cost of the improper or unnecessary services that were furnished or ordered. The practitioner or other person will be required either to pay the monetary assessment within 6 months of the date of notice or have it deducted from any sums the Federal Government owes the practitioner or other person.

Subpart D—PRO Responsibilities**§ 474.34 Basic responsibilities.**

(a) The PRO must use its authority or influence to enlist the support of other professional or government agencies to ensure that each practitioner or other person complies with the obligations specified in § 474.30.

(b) The PRO must identify situations where the obligations specified in § 474.30 are violated and afford the practitioner or other person reasonable notice and opportunity for discussion in accordance with §§ 474.36 and 474.38.

(c) The PRO must submit a report to the OIG after the notice and opportunity provided under paragraph (b) of this

section, if the PRO determines that the practitioner or other person has—

(1) Failed substantially to comply with any obligation in a substantial number of cases; or

(2) Grossly and flagrantly violated any obligation in one or more instances.

(d) The PRO report to the OIG must comply with the provisions of § 474.40.

(e) The PRO must deny services or items ordered by an excluded practitioner or other person when the PRO identifies the services or items and reports the findings to HCFA.

§ 474.36 Action on identification of a violation.

When a PRO identifies a violation, it must determine the nature of the violation.

(a) If the PRO determines the violation as one that is gross and flagrant, it must proceed in accordance with § 474.38.

(b) If the PRO determines the violation as a substantial violation in a substantial number of cases it must send the practitioner or other person a written initial notice of the identification of a violation containing the following information:

(1) The obligation involved.

(2) The situation, circumstances, or activity that resulted in a violation.

(3) The authority and responsibility of the PRO to report violations of obligations.

(4) At the discretion of the PRO, a suggested method for correcting the situation and a time period for corrective action.

(5) The sanction that the PRO could recommend to the OIG if the violation continues.

(6) An invitation to submit additional information to or discuss the problem with representatives of the PRO within 20 days of receipt of the notice. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(7) A summary of the information used by the PRO in arriving at its determination of a violation of an obligation.

§ 474.38 Action on determination of a violation.

(a) *Written notice.* The PRO must give written notice to the practitioner or other person if it determines that—

(1) A substantial violation has occurred in a substantial number of cases; or

(2) A violation is gross and flagrant in one or more cases.

(b) *Contents.* The notice must contain the following information:

(1) The determination of a violation.

(2) The obligation violated.

(3) The basis for the determination.

(4) The sanction the PRO will recommend to the OIG.

(5) The right of the practitioner or other person to submit to the PRO within 30 days of receipt of the notice, additional information or a written request for a meeting with the PRO to review and discuss the determination, or both. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(6) A copy of the material used by the PRO in arriving at its determination.

(c) *Review of PRO determination.*

(1) The PRO may, on the basis of additional information received, affirm, modify, or reverse its determination.

(2) The PRO must give written notice to the practitioner or other person, of any action it takes as a result of the additional information received, as specified in § 474.39.

§ 474.39 Final PRO determination of a violation.

If the issue is not resolved to the PRO's satisfaction as specified in § 474.38(c), the PRO must—

(a) Submit its report and recommendation to the OIG; and

(b) Send the affected practitioner or other person a concurrent final notice, with a copy of the PRO report that is being forwarded to the OIG, advising that—

(1) The PRO recommendation has been submitted to the OIG;

(2) The practitioner or other person has 30 days from receipt of this final notice to submit any additional material to the OIG at its central office location. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary; and

(3) Due to the 120-day statutory requirement specified at § 474.42(e), the period for submitting additional information will not be extended and any material received by the OIG after the 30-day period will not be considered.

§ 474.40 PRO report to OIG.

(a) *Manner of reporting.* If the PRO determines that a substantial violation has occurred in a substantial number of cases or that a gross and flagrant violation has occurred, it must submit a report and recommendation to the OIG at the regional office with jurisdiction.

(b) *Content of report.* The PRO report must include the following information—

(1) Identification of the practitioner or other persons and when applicable, the

name of the director, administrator, or owner of the entity involved;

(2) The type of health care services involved;

(3) A description of each failure to comply with an obligation, including specific dates, places, circumstances, and any other relevant facts;

(4) Pertinent documentary evidence;

(5) Copies of written correspondence and written summaries of oral exchanges with the practitioner or other person regarding the violation;

(6) The PRO's determination that an obligation under section 1156(a) of the Act has been violated and that the violation is substantial and has occurred in a substantial number of cases or is gross and flagrant;

(7) The professional qualifications of the PRO's reviewers; and

(8) The PRO's sanction recommendation.

(c) *PRO Recommendation.* The PRO must specify in its report—

(1) The sanction recommended;

(2) The amount of the monetary penalty recommended, if applicable;

(3) The period of exclusion recommended, if applicable; and

(4) A recommendation as to whether the practitioner or other person is unable or unwilling substantially to comply with the obligation that was violated.

§ 474.41 Basis for recommended sanction.

The PRO's specific recommendation must be based on a consideration of—

(a) The type of offense involved;

(b) The severity of the offense;

(c) The deterrent value;

(d) The practitioners' or other person's previous sanction record;

(e) The availability of alternative sources of services in the community; and

(f) Any other factors that the PRO considers relevant (for example, the duration of the problem).

Subpart E—OIG Responsibilities

§ 474.42 Acknowledgement and review of report.

(a) *Acknowledgement.* The OIG will inform the PRO of the date it received the PRO's report and recommendation.

(b) *Review.* The OIG will review the PRO report and recommendation to determine whether—

(1) The PRO is following its procedures;

(2) A violation has occurred; and

(3) The practitioner or other person has demonstrated an unwillingness or lack of ability substantially to comply with an obligation.

(c) *Rejection of the PRO recommendation.* If the OIG decides

that a sanction is not warranted, it will notify the PRO that recommended the sanction and the affected practitioner or other person that the recommendation is rejected.

(d) *Decision of sanction.* If the OIG decides that a violation of obligations has occurred, it will determine the appropriate sanction by considering—

(1) The recommendation of the PRO;

(2) The type of offense;

(3) The severity of the offense;

(4) The previous sanction record of the practitioner or other person;

(5) The availability of alternative sources of services in the community;

(6) Any prior problems the Medicare carrier or intermediary has had with the practitioner or other person;

(7) Whether the practitioner or other person is unable or unwilling to comply substantially with the obligations; and

(8) Any other matters relevant to the particular case.

(e) *Exclusion sanction.* If the PRO submits a recommendation for exclusion to the OIG, and a determination is not made by the 120th day after actual receipt by the OIG, the exclusion sanction recommended will become effective and the OIG will provide notice in accordance with § 474.52(f).

(f) *Monetary penalty.* If the PRO recommendation is to assess a monetary penalty, the 120-day provision does not apply and the OIG will provide notice in accordance with § 474.52 (a) through (e).

§ 474.52 Notice of sanction.

(a) The OIG notifies the practitioner or other person of the adverse determination and of the sanction to be imposed.

(b) The sanction is effective 15 days from the date of receipt of the notice. The date of receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

(c) The notice specifies—

(1) The legal and factual basis for the determination;

(2) The sanction to be imposed;

(3) The effective date and, if appropriate, the duration of the exclusion;

(4) The appeal rights of the practitioner or other person; and

(5) In the case of exclusion, the earliest date on which the OIG will accept a request for reinstatement.

(d) The OIG notifies the public by publishing in a newspaper of general circulation in the PRO area a notice that identifies the sanctioned practitioner or other person, the obligation that has been violated, the sanction imposed and, if the sanction is exclusion, the effective date and duration.

(e) Notice of the sanction is also provided to the following entities as appropriate:

(1) The PRO that originated the sanction report.

(2) PROs in adjacent areas.

(3) State Medicaid fraud control units and State licensing bodies.

(4) Appropriate Medicare contractors and State agencies.

(5) Hospitals, including the hospital where the sanctioned individual's case originated and where the individual currently has privileges, if known; skilled nursing facilities, home health agencies, and health maintenance organizations (HMOs).

(6) Medical societies and other professional organizations.

(7) Medicare carriers and intermediaries, health care prepayment plans, and other affected agencies and organizations.

(f) If an exclusion sanction is effected because a decision was not made within 120 days after receipt of the PRO recommendation, notification is as follows:

(1) The OIG notifies the practitioner or other person that the exclusion from the Medicare program is effective 15 days from the date the notice is received by the practitioner or other person. The date of receipt is presumed to be five days after the date on the notice, unless there is a reasonable showing to the contrary.

(2) Notice of the sanction is also provided as specified in paragraph (e) of this section.

(3) As soon as possible after the 120th day, the OIG will issue a notice to the practitioner or other person affirming the PRO recommendation or modifying the recommendation based on the OIG's review of the case.

(g) The determination and notice of sanction provided for in this section constitute an "initial determination" and a "notice of initial determination" for purposes of the administrative appeals procedures specified in Part 405, Subpart O of this chapter concerning determinations and appeals procedures for providers and suppliers.

Subpart F—Effect and Duration of Exclusion

§ 474.54 Effect of an exclusion on Medicare payments and services.

(a) *General provisions.* Except as provided under paragraphs (b) and (c) of this section—

(1) Payment will not be made under Medicare to an excluded practitioner or other person for services or items furnished or ordered during the period of exclusion;

(2) Payment will not be made under Medicare to any provider for services or items ordered by an excluded practitioner or other person when the order was a necessary precondition for payment under Medicare; and

(3) Assignment of a beneficiary's claim for services or items furnished or ordered by an excluded practitioner or other person on or after the effective date of exclusion will not be valid.

(b) *Exceptions.* Payment is available for services or items provided up to 30 days after the effective date of an exclusion for—

(1) Inpatient hospital or skilled nursing services or items furnished to a beneficiary who was admitted before the effective date of the exclusion; and

(2) Home health services or items furnished under a plan established before the effective date of the exclusion.

(c) *Denial of payments to beneficiaries.* If a beneficiary submits claims for services or items furnished or ordered by an excluded practitioner or other person on or after the effective date of exclusion—

(1) HCFA pays the first claim submitted and immediately gives the beneficiary notice of the exclusion; and

(2) The beneficiary's right to payment extends to services or items furnished or ordered up to 15 days after the date on the notice.

(d) *Effective date of termination of provider agreement.* The effective date of termination of a Medicare provider agreement is determined in accordance with §§ 489.53 and 489.55 of this chapter.

§ 474.56 Reinstatement after exclusion.

Exclusion will remain in effect until—

(a) The OIG determines, in accordance with §§ 420.130 through 420.136 of this chapter, that the basis for the exclusion no longer exists and there is reasonable assurance that the problems will not recur; or

(b) The OIG's determination to exclude is reversed by a hearing decision.

Subpart G—Appeals

§ 474.58 Appeal rights.

(a) *Right to administrative review.*

(1) A practitioner or other person dissatisfied with an OIG determination or an exclusion that results from a determination not being made within 120 days is entitled to a hearing before

an Administrative Law Judge and may also request a review of that decision by the Appeals Council in accordance with §§ 405.1530 through 405.1595 of this chapter.

(2) Due to the 120-day statutory requirement specified at § 474.42(e) of this part, the following limitations apply:

(i) The period for submitting additional information will be not be extended.

(ii) Any material received by the OIG after the 30-day period allowed, will not be considered and will not be subject to review by the Administrative Law Judge and the Appeals Council.

(3) OIG's determination continues in effect unless reversed by a hearing decision.

(b) *Right to judicial review.* Any practitioner or other person dissatisfied with a decision of the Appeals Council or an administrative law judge (if a request for Appeals Council review is denied), may file a civil action in accordance with the provisions of section 205(g) of the Act.

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

D. Part 489 is amended as follows:

1. The authority citation for Part 489 continues to read as follows:

Authority: Secs. 1102, 1861, 1864, 1866, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa, 1395cc, and 1395hh).

2. Section 489.55 is revised to read as follows:

§ 489.55 Exceptions to effective date of termination.

Payment is available for up to 30 days after the effective date of termination for—

(a) Inpatient hospital services (including inpatient psychiatric hospital services) and posthospital extended care services furnished to a beneficiary who was admitted before the effective date of termination; and

(b) Home health services furnished under a plan established before the effective date of termination.¹

(Catalog of Federal Domestic Assistance Programs, No. 13.773, Medicare—Hospital Insurance and No. 13.774, Medicare—Supplementary Medical Insurance)

¹For terminations before July 18, 1984, payment was available through the calendar year in which the termination was effective.

Dated: December 11, 1984.

Carolyn K. Davis,

Administrator, Health Care Financing Administration.

R.P. Kusserow,

Inspector General, Department of Health and Human Services.

Approved: January 28, 1985.

Margaret M. Heckler,

Secretary.

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42 CFR Parts 400 and 476

[HSQ-110-F]

Medicare Program; Acquisition, Protection, and Disclosure of Utilization and Quality Control Peer Review Organization (PRO) Information

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

ACTION: Final rule.

SUMMARY: These regulations govern the acquisition, protection, and disclosure of information obtained or generated by Utilization and Quality Control Peer Review Organization (PROs). The Peer Review Improvement Act of 1982 authorizes PROs to acquire information necessary to fulfill their duties and functions, places limits on disclosure of PRO information, and establishes penalties for unauthorized disclosure. These regulations implement the PROs' statutory right of access to necessary information and set forth their responsibilities to assure that information once acquired is adequately safeguarded and disclosed only for proper purposes.

EFFECTIVE DATE: The regulations are effective May 17, 1985.

Sections 476.105, 476.116, and 476.134 of this rule contain information collection requirements with which the public is not required to comply until the Executive Office of Management and Budget (EOMB) approves these requirements. (See section VI. of the preamble for a discussion of information collection.)

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Legislative History

The Peer Review Improvement Act of 1982 (Title I, Subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97-248)) amended Part B of Title XI of the Social Security Act (Act) to establish the Utilization and Quality