DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed for V.P.O., Inc., providing for the manufacture of a 20-gram-per-pound tylosin premix. The premix will subsequently by used to make finished feeds for swine, beef cattle, and chickens.

EFFECTIVE DATE: January 30, 1984.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Bureau of Veterinary Medicine (HFV–130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; 301–443–4913.

SUPPLEMENTARY INFORMATION: V.P.O., Inc., 4444 South 76th St., Omaha, NE 68127, is the sponsor of a supplement to NADA 98–431 submitted on its behalf by Elanco Products Co. This supplement provides for the manufacture of a 20-gram-per-pound tylosin premix subsequently to make complete feeds for swine, beef cattle, and chickens for use as in 21 CFR 558.625(f)(1) (i) through (vi). The supplement is approved and the regulations are amended to reflect the approval.

The firm presently holds an approval for the manufacture of a 40-gram-per-pound tylosin premix for such use. The basis for approval of the 20-gram-per-pound premix is the same as for the approval of the 40-gram-per-pound premix. The supplement to NADA 98–431 providing for the 40-gram-per-pound premix was approved by a final rule published in the **Federal Register** of July 26, 1983 (48 FR 33865). The freedom of information summary made available under the provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), which consisted of a summary of safety and effectiveness data and information submitted to support approval of the 40-gram-per-pound premix, applies also to this application and may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Bureau of Veterinary Medicine has determined pursuant to 21 CFR 25.24(d)(1)(i) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 558.625 is amended by revising paragraph (b)(25) to read as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

§ 558.625 Tylosin.

* * * * *

(b) * * *

(25) To 043743: 4, 8, and 10 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 20 and 40 grams per pound, paragraph (f)(1) (i) through (vi) of this section.

* * * * *

Effective date. January 30, 1984.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: January 23, 1984.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 84–2415 Filed 1–27–84; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 808

[Docket No. 83N–0335]

Exemption From Federal Preemption of State and Local Medical Device Requirements; Number of Copies of Application

AGENCY: Food and Drug Administration.

ACTION: Final rule and request for comments.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule reducing the number of copies required to be submitted in an application for an exemption from Federal preemption of State and local requirements applicable to medical devices. The procedure is being changed to conform to Office of Management and Budget guidelines.

DATES: Effective March 30, 1984. Comments by February 29, 1984.

ADDRESS: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Les Weinstein, National Center for Devices and Radiological Health (HFK–140), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4874.

SUPPLEMENTARY INFORMATION: Section 521(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k(a)) (the act) contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

Section 521(b) of the act provides that, upon application by a State or political subdivision, the Commissioner of Food and Drugs may allow imposition of a requirement that is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation exempting the State or local requirement from preemption.

Part 808 of FDA's regulations (21 CFR Part 808) prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of any State or local requirement applicable to medical devices. Section 808.20(b) requires that the application be in the form of a letter to the Commissioner of Food and Drugs and be signed by an individual who is authorized to request the exemption on behalf of the State or political subdivision (Office of Management and Budget (OMB) approval number 0910–0129). Section 808.20(b) also requires that the State or political subdivision applying for the exemption submit to FDA four copies of the application and all accompanying material, as well as any subsequent reports or correspondence concerning the application.

In the **Federal Register** of March 31, 1983 (48 FR 13666), OMB published a final rule (5 CFR Part 1320)

implementing the provisions of the Paperwork Reduction Act of 1980 (Pub. L. 96–511), which establishes policies and procedures for controlling paperwork burdens imposed by Federal agencies on the public. Section 1320.6(c) of OMB's general information collection guidelines, which are codified as part of its final rule, provides that an agency should not require persons to submit to the agency more than one original and two copies of any document unless the agency demonstrates that the requirement is necessary to satisfy a statutory requirement or some other substantial need.

Therefore, FDA is changing its procedure to conform to OMB's guideline by requiring an applicant to submit only an original and two copies of an application for exemption from preemption, accompanying materials, and any subsequent reports or correspondence concerning the application.

In accordance with 5 U.S.C. 553 (b) and (d) and 21 CFR 10.40, FDA has determined that there is good cause not to follow the usual requirements of prior notice and comment and delayed effective date. The reasons for this determination are that reducing the number of copies of applications for exemption required to be submitted to the agency will not affect the public health and will be less burdensome on, and less costly for, the applicant. Also, FDA has learned from experience that two copies are adequate for the agency to review and make a decision on an application. The agency, nevertheless, is providing a 30-day period during which it will accept comments on its change to the rule. If FDA decides on the basis of comments received that the changes should be modified or revoked, it will provide further notice in the Federal Register.

List of Subjects in 21 CFR Part 808

Exemption of specific State requirement, Medical devices.

PART 808—[AMENDED]

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 521, 701, 52 Stat. 1055–1056 as amended, 90 Stat. 574 (21 U.S.C. 360k, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 808 is amended in § 808.20 by revising paragraph (b) to read as follows:

§ 808.20 Application.

* * * * *

(b) An application for exemption shall be in the form of a letter to the Commissioner of Food and Drugs and shall be signed by an individual who is authorized to request the exemption on behalf of the State or political subdivision. An original and two copies of the letter and any accompanying material, as well as any subsequent reports or correspondence concerning an application, shall be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. The outside wrapper of any application, report, or correspondence should indicate that it concerns an application for exemption from preemption of device requirements.

* * * * *

Interested persons may, on or before February 29, 1984, submit to the Dockets Management Branch (address above), written comments about the changes to this final rule. Such comments will be considered in determining whether further amendments, modifications, or revisions to the final rule are warranted. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. to 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective March 30, 1984.

(Secs. 521, 701, 52 Stat. 1055–1056, as amended, 90 Stat. 574 (21 U.S.C. 360k, 371))

Dated: January 12, 1984.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 84–2417 Filed 1–27–84; 8:45 am]

BILLING CODE 4160–01–M

VETERANS ADMINISTRATION

38 CFR Part 17

Grants to States for Construction of State Home Facilities

AGENCY: Veterans Administration.

ACTION: Final regulation amendment.

SUMMARY: This revision to the appendix of a medical regulation updates the estimates of veteran population for each State to reflect 1980 census data. As a result of these changes, the revision also adjusts the maximum number of beds required to provide adequate nursing home care to veterans residing in each State to reflect the 4 bed per thousand veteran population limit. The Administrator is required to prescribe the maximum number of such beds by 38 U.S.C. 5034(1). A State home construction grant application may not be approved if it will result in more than the maximum number of beds prescribed in Appendix A (see 38 U.S.C. 5035(b)(4)). Although Appendix A to 38 CFR 17.171, prescribes the maximum number of such beds, when the beds to be constructed in a State will result in more than 2.5 beds per thousand veterans, the State shall provide sufficient justification for the Administrator to determine that the additional beds are required in that State.

EFFECTIVE DATE: This revision is effective January 13, 1984.

FOR FURTHER INFORMATION CONTACT: Rita Frampton, State Home Program Coordinator, Department of Medicine and Surgery (182), Veterans Administration, 810 Vermont Avenue, NW., Washington, D.C. 20420, 202–389–3679.

SUPPLEMENTARY INFORMATION: This proposed regulation revision was published at 48 FR 38253 to 38254 of the Federal Register of August 23, 1983. Interested persons were given 30 days to submit comments, however no comments were received, and the proposed revision is hereby being adopted as final.

The Administrator hereby certifies that this revision to the regulation is nonmajor in accordance with the requirements of Executive Order 12291, Federal Regulation. It will not have an annual effect on the economy of $100 million or more, will not cause a major increase in cost or prices and will not have other significant adverse effects on the economy.

The Administrator hereby certifies that this revision will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Pursuant to 5 U.S.C. 605(b), this revision is therefore exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604. The reason for this certification is that this rule will regulate only States planning construction of nursing home care beds at State Veterans Homes. States do not come within the RFA definition of "small entities" according to 5 U.S.C. 601(5). It will therefore have no significant economic impact on small entities (i.e., small businesses, small private and nonprofit organizations, and small governmental jurisdictions).

The Catalog of Federal Domistic Assistance Number is 64.005.

List of Subjects in 38 CFR Part 17

Government contracts, grants programs—health, health care, health facilities, nursing homes, veterans.

Approved: January 13, 1984.

By direction of the Administrator.

Everett Alvarez, Jr.,

Deputy Administrator.

PART 38—[AMENDED]

38 CFR Part 17, *Medical,* is amended by revising APPENDIX A to § 17.171 to read as follows:

Appendix A—(See Sec. 17.171) State Home Facilities for Furnishing Nursing Home Care

The maximum number of beds, as required by 38 U.S.C. 5034(1), to provide adequate nursing home care to veterans residing in each State not to exceed four beds per 1,000 veteran population is established as follows:

State	Veteran population[1]	Number of beds
Alabama	436,000	1,744
Alaska	50,000	200
Arizona	383,000	1,532
Arkansas	270,000	1,080
California	3,003,000	12,012
Colorado	401,000	1,604
Connecticut	413,000	1,652
Delaware	77,000	308
District of Columbia	65,000	260
Florida	1,392,000	5,568
Georgia	632,000	2,528
Hawaii	99,000	396
Idaho	121,000	484
Illinois	1,348,000	5,392
Indiana	680,000	2,720
Iowa	354,000	1,416
Kansas	300,000	1,200
Kentucky	405,000	1,620
Louisiana	453,000	1,812
Maine	154,000	616
Maryland	544,000	2,176
Massachusetts	720,000	2,880
Michigan	1,117,000	4,468
Minnesota	525,000	2,100
Mississippi	245,000	980
Missouri	647,000	2,588
Montana	108,000	432
Nebraska	191,000	764
Nevada	137,000	548
New Hampshire	138,000	552
New Jersey	925,000	3,700
New Mexico	162,000	648
New York	1,951,000	7,804
North Carolina	660,000	2,640
North Dakota	69,000	276
Ohio	1,385,000	5,540
Oklahoma	397,000	1,588
Oregon	400,000	1,600
Pennsylvania	1,593,000	6,372
Rhode Island	126,000	504
South Carolina	351,000	1,404
South Dakota	80,000	320
Tennessee	543,000	2,172
Texas	1,732,000	6,928
Utah	155,000	620
Vermont	64,000	256
Virginia	664,000	2,656
Washington	628,000	2,512
West Virginia	243,000	972
Wisconsin	574,000	2,296
Wyoming	67,000	268

[1] Estimate as of March 31, 1983.

Source: Office of Reports and Statistics, Veterans Administration. (Based on last available Bureau of the Census data.) (June 1983.)

(38 USC 50 503(i); 38 U.S.C. 5035(b)(4))

[FR Doc. 84-2445 Filed 1-27-84; 8:45 am]

BILLING CODE 8320-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA Docket Nos. AW043/044VA; A-3-FRL 2513-4]

Approval of Revisions to the Virginia State Implementation Plan

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: On December 30, 1982, the Commonwealth of Virginia submitted an alternate compliance schedule for the Ford Motor Company's plant in Norfolk, Virginia as a revision to the State Implementation Plan (SIP). The schedule provides for compliance with the volatile organic compound (VOC) emission regulations through the installation of an electrophoretic deposition process (EDP) and the development of low solvent coating technology by November 30, 1984. EPA approves this alternative compliance schedule as a revision to the Virginia State Implementation Plan (SIP), as the schedule meets all of the necessary requirements of the Clean Air Act, and 40 CFR Part 51.

The Commonwealth submitted a variance for the Oyster Point Municipal Incinerator in Newport News, Virginia. However, EPA is withdrawing this SIP revision from further consideration, as Virginia has notified EPA that operation of the incinerator terminated on July 1, 1983.

EFFECTIVE DATE: February 29, 1984.

ADDRESSES: Copies of the revision and accompanying support material are available for public inspection during normal business hours at the following locations:

U.S. Environmental Protection Agency, Air Management Branch, Curtis Building, Sixth and Walnut Streets, Philadelphia, PA 19106; ATTN: Mr. Harold Frankford.

Public Information Reference Unit, Room 2922, EPA Library, U.S. Environmental Protection Agency, 401 "M" Street, SW. (Waterside Mall), Washington, D.C. 20460.

Virginia State Air Pollution Control Board, Room 801, Ninth Street Office Building, Richmond, Virginia 23219, ATTN: Mr. John M. Daniel, Jr.

Office of the Federal Register, 1100 L Street, NW., Room 8401, Washington, D.C. 20408.

FOR FURTHER INFORMATION CONTACT: Mr. Harold Frankford at the Region III address stated above or telephone 215/597-8392.

SUPPLEMENTARY INFORMATION: The Ford Motor Company, located in Norfolk, Virginia, is engaged in the assembly of light duty trucks. The coating operations at the Ford plant are subject to the provisions of Section 4.55(e) of the Virginia regulations which prescribe the emission standards for the prime coat, top coat and final repair. Specifically, Ford is requesting an extension of two years to comply with the prime coat emissions standard in Section 4.55(e)(1).

Originally, Ford had planned to use high solids coatings applied by the conventional spray method to achieve the desired reduction by the end of 1982. However, response to customer demands for better product quality in the automotive industry led Ford to abandon the spray method for a combination of the dip and spray method. Ford now plans to control emissions by use of the electrophoretic deposition process (EDP) followed by a spray (guide coat) primer system to smooth out the rough spots. This new method will use low solvent coatings. While the change is directed primarily at quality control, the new approach will also significantly reduce emissions over the original approach. Current regulations set a standard of 3.2 lbs. of VOC per gallon of coating and the use of EDP will meet a standard of 1.9 lbs. of VOC per gallon of coating.

However, Ford cannot complete installation of the new equipment by the end of 1982 and wishes an extension until the end of 1984. The delay did not affect the attainment of the ozone standard in Southeastern Virginia by the end of 1982. The Commonwealth has certified that, after adequate public notice, a public hearing was held with respect to the Ford Motor Company SIP revision on March 15, 1982 in Virginia Beach, as required by 40 CFR 51.4.

The Commonwealth's attainment strategy for the Ford Motor Company's alternate compliance schedule is based upon a maximum allowable emission rate of 3188 tons per year by the end of 1982. In 1977 the actual emissions for the plant were 2,396 tons. Since production levels are now much lower and unlikely to return to 1977 levels before the end of 1984, the delay in compliance did not affect the attainment date. In a separate action apart from this rulemaking, EPA will determine whether the line and

process modifications should be subject to New Source Performance Standards (NSPS) requirements. Agency policy on this matter discussed in the October 21, 1981 **Federal Register** notice, 46 FR 51386.

On June 28, 1983, 48 FR 29716, EPA proposed approval of the alternate compliance schedule for Ford Motor Company, Norfolk and requested public comment. During the public comment period, ending July 28, 1983, no comments were received.

The Commonwealth had also submitted to EPA a variance request for the Oyster Point Municipal Incinerator in Newport News. EPA had proposed approval of this variance request and requested public comment on June 28, 1983, 48 FR 19176. However, on October 27, 1983, Virginia informed EPA that the Oyster Point Municipal Incinerator closed down permanently on July 1, 1983, and requested that the variance request be withdrawn from further consideration as a revision to the Virginia SIP. Accordingly, EPA withdraws this variance request from further rulemaking action.

Conclusion

The Administrator is approving this SIP revision based on a determination that it meets the requirements of Section 110(a)(2) of the Clean Air Act and 40 CFR Part 51. Requirements for Preparation, Adoption, and Submittal of State Implementation Plans.

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291.

Under Section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 30, 1984. This action may not be challenged later in proceedings to enforce its requirements. (See 307(b)(2).)

List of Subjects in 40 CFR Part 52

Air pollution control, Ozone, Sulfur oxides, Nitrogen dioxide, Lead, Particulate matter, Carbon monoxide, Hydrocarbons, Intergovernmental relations, Incorporation by reference.

Dated: January 19, 1984.

William D. Ruckelshaus,

Administrator.

Note.—Incorporation by reference of the State Implementation Plan for the Commonwealth of Virginia was approved by the Director of the Federal Register on July 1, 1982.

PART 52—[AMENDED]

Title 40, Part 52, Subpart VV of the Code of Federal Regulations is amended as follows:

Subpart VV—Virginia

1. Section 52.2420 is revised by adding paragraph (c)(82) as follows:

§ 52.2420 Identification of plan.

* * * * *

(c) * * *

(82) Amendment for an alternate compliance schedule for the Ford Motor Company plant in Norfolk, Virginia submitted on December 30, 1982 by the Virginia State Air Pollution Control Board.

(Clean Air Act, Sec. 110 (42 U.S.C. 7401–7642))

[FR Doc. 84-2164 Filed 1-27-84; 8:45 am]

BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 400, 405 and 421

Medicare Program; Reduction in the Number of Providers Dealing Directly With HCFA

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

ACTION: Final rule.

SUMMARY: These regulations modify current Medicare rules concerning the option that allows Medicare providers to elect to receive payment directly from us, rather than through an intermediary, for covered services furnished to beneficiaries. The regulations also give us the authority to make other arrangements to service health care prepayment plans (health maintenance organizations (HMOs) and group practice prepayment plans (GPPPs)) that are presently dealing directly with us. The regulations clarify under what circumstances we may contract out for the purpose of making payments to providers. In addition, although this is a final rule, we are requesting public comment on the impact analysis.

EFFECTIVE DATE: These regulations are effective February 29, 1984.

FOR FURTHER INFORMATION, CONTACT: Norman Fairhurst, 301–594–9498.

SUPPLEMENTARY INFORMATION:

I. Background

In the Medicare program, the Secretary is responsible for making payment to providers of services and other entities for the covered services they furnish to Medicare beneficiaries.

Section 1816 of the Social Security Act (the Act) gives groups of providers the option of nominating an intermediary to determine the proper amount of reimbursement and to make such payments. Alternatively, if the provider declines to exercise the option of dealing with an intermediary, it submits its claims directly to the Secretary under section 1815. In such instances, section 1874 authorizes the Secretary to reimburse such providers either directly or by contract.

Section 1816 of the Act was amended in 1977 by the Medicare-Medicaid Anti-Fraud and Abuse Amendments (Pub. L. 95–142). The amendments authorize the Secretary to assign and reassign providers who had nominated intermediaries to other intermediaries. The amendments also authorize the Secretary to designate regional or national intermediaries with respect to a class or classes of providers.

Section 930(o) of the Omnibus Reconciliation Act of 1980 (Pub. L. 96–499) further amended section 1816(e) of the Act by adding a new paragraph (4), which requires the Secretary to designate regional agencies or organizations that have entered into an agreement under section 1816 of the Act to perform functions under that agreement for freestanding HHAs (that is, HHAs that are not a subdivision of a hospital) in the region. The statute further requires that if an HHA is hospital-affiliated (that is, the hospital and HHA are under common control), the Secretary shall assign that HHA to a regional intermediary only if the Secretary, after applying published criteria relating to administrative efficiency and effectiveness, determines that the assignment would result in the more effective and efficient administration of the Medicare program.

As of October 1, 1983, about 154 hospitals, 34 skilled nursing facilities (SNFs), 480 home health agencies (HHAs), 75 health maintenance organizations (HMOs), 42 group practice prepayment plans, (GPPPS), 361 Federal hospitals, 21 providers of outpatient physical therapy services and seven end-stage renal disease facilities, out of the approximately 12,800 providers and other entities that currently participate in the program, receive payment and "deal directly" with us.

On August 2, 1983 we published a proposed rule (48 FR 34979) that complied with certain court-imposed requirements that we carry out a full rulemaking process before contracting out the direct-deal freestanding HHA

workload. (For a full summary of legislative and legal actions, see 48 FR 34979.) The proposed rule also expanded on a previous NPRM (47 FR 7269) concerning contracting out our direct-dealing function for other types of providers such as hospitals, SNFs, providers of outpatient physical therapy services, end-stage renal disease facilities, and HMOs.

II. Provisions of the Proposed Rule

A. Reductions in the Number of Providers Dealing Directly With Us

Section 1874 of the Social Security Act gives the Secretary the authority to perform directly or by contract any of his or her functions under Medicare. Under that authority, we proposed to modify 42 CFR 421.103 to specify that we may contract out the functions of making payment determinations, disbursing payments, and related activities with respect to providers and other entities that we currently service directly. Thus, we would have required providers and other entities that currently deal directly with us to deal instead with fiscal intermediaries that already are under contract with us. However, we stated our intention to review carefully each type of provider or other entity now dealing directly with us to determine the least disruptive and most cost effective arrangement for the long term.

We also included in the preamble to that rule a detailed discussion of our tentative implementation plan. The implementation plan discussed: intermediary selection, transfer schedule, procedures during the change-over period, assurance of cash flow, and transition costs. The list of designated regional intermediaries to service freestanding HHAs published in a preamble to a final rule on September 1, 1982 (47 FR 38535) was repeated for information purposes.

Finally, we announced that the contracting out of certain functions that we presently perform for HMOs is currently under study. HMOs, while they are not providers with an election right, are presently serviced by us. The proposed rule announced our intention to establish our authority to modify this practice should we, in the future, choose to contract out some or all of that workload.

B. Contracting Out the Workload of Hospitals, Skilled Nursing Facilities, Outpatient Physical Therapy Providers and End-Stage Renal Disease Facilities

We stated that the proposed rule would be applicable to all direct-dealing providers, including hospitals, skilled nursing facilities, outpatient physical therapy providers, and end-stage renal disease facilities. The regional ombudsman (see section III. below) would have been available to address any concerns providers may have other than those that are the province of the Provider Reimbursement Review Board.

C. Contracting Out the Workload of Freestanding HHAs to Regional Intermediaries

Currently, we designate regional intermediaries under section 1816(e)(4) of the Act to serve those freestanding HHAs that have elected to nominate an intermediary. We proposed to modify 42 CFR 421.117 by requiring that freestanding HHAs that had been receiving payment directly from us would instead receive payments from the same regional intermediaries designated under section 1816(e)(4) of the Act; thus, each statewide regional intermediary would service all freestanding HHAs within its State.

We service approximately 12 percent of the HHAs participating in the Medicare program. We stated that approximately 425 freestanding HHAs were to be serviced under contract with designated intermediaries as a result of implementation of these regulations. This decision was reached after considering the following:

1. *Consolidating the workload*—In each State an intermediary under contract had already been designated to service freestanding HHAs that had elected to be reimbursed by a nominated intermediary (47 FR 38535).

We stated that we believe that contracting out the workload of those freestanding HHAs that had previously elected to be reimbursed directly by us would improve the administration of the home health benefit under the Medicare program, as discussed below.

We stated that we believe the use of statewide intermediaries would facilitate onsite review of HHAs by the intermediaries. This review has proven to be a significant tool for assuring improved reimbursement determinations and controlling overutilization of services and overpayments that have been of concern to us and the Congress for some time.

Finally, we stated that the use of one intermediary for each State would result in consistent application of Medicare policies with respect to HHAs within each State and would enhance delivery of necessary services by providing a consistent approach to medical policy interpretation and reimbursement for providers, beneficiaries and the home health community.

2. *Impact on Multi-State (Chain) Organizations*—We stated our preference that chain organizations choose to deal with designated regional intermediaries. We recognized that there may be cases in which the degree of centralization of the chain would make it more efficient for a lead intermediary to handle the home office audit and desk review of the chain's provider cost reports, determine the scope of provider audits, and perform final settlement of individual HHA cost reports. We included in the preamble to the NPRM our intention to consider that the designated regional intermediaries would have responsibility for provider reimbursement for the reporting period based on necessary input from the lead intermediary, would provide input to the lead intermediary in terms of provider audit and cost report settlement, and would perform the actual field audit work required.

We announced that any chain wishing to avail itself of this alternative would have to present its request in writing to the HCFA regional office serving the home office. The request would have to provide information concerning the chain's degree of centralization, such as is now required for a single intermediary to service an entire chain of any type. The regional office would evaluate each request and notify the chain in writing of our determination.

We also stated that we would consider allowing HHA chains to be serviced by a single intermediary and, to the extent appropriate, we would make provisions for audit and coverage determinations.

When evaluating the potential of single intermediaries to accommodate home health chains, we stated that we would consider: the capacity of the intermediary as it is affected by changes in data processing technology; the cost and/or savings to providers to transfer and operate; economy and timeliness in the delivery of services; conflict of interest between an intermediary and provider; and any additional pertinent factors.

D. Technical Clarifications

1. We proposed to modify 42 CFR 421.104 to clarify that a provider that does not belong to a provider association, or a provider that does not concur with its association's nomination for intermediary, may elect to receive payments from an intermediary with which we already have an agreement if both the intermediary and we agree to it. Current regulations at § 421.104(b) do not specifically state that a single provider may elect to receive payment

from an intermediary but rather imply that it may only form a group of two more providers to nominate an intermediary or receive payment directly from us.

2. We proposed a technical revision to § 421.104(b) that would change the title of § 421.104(b) from "Nomination by members or nonconcurring members" to "Action by nonmembers or nonconcurring members" to reflect that a single provider may elect to deal with an intermediary or with HCFA. The use of the word "action" instead of "nomination" is consistent with the language in § 421.103, which concerns provider options to elect to deal through an intermediary or directly with HCFA. "Nomination" is a more restrictive term in these regulations and concerns only provider associations' choice of intermediary.

3. We proposed to add language to § 421.1, Basis and Scope, to clarify that Section 1874 of the Act is one of the bases of Part 421 and that the statute and regulations permit us to perform certain functions directly or by contract.

4. We proposed to delete the definition of "the Administrator" from the definitions section (§ 421.3) and to revise all references to "the Administrator" to "HCFA". For consistency, we were going to change all references to "he or she" and "his or her" to "it" and "its", respectively.

III. Analysis and Response to Comments

We received 31 comments, primarily from freestanding HHAs or associations that represent freestanding HHAs. The commenters consisted of: 19 HHAs (18 freestanding and one hospital-based), six associations representing the HHAs, three intermediaries, two HMOs and one union (representing HCFA employees).

Most comments furnished the providers' views of the effects of using designated intermediaries and making greater use of contracting out. Two commenters endorsed the proposed rule. A number of providers that submit bills and claims to our Office of Direct Reimbursement (ODR) wrote in to express satisfaction with the present arrangement, especially with HHA electronic bill processing aspects, and to raise questions about how the proposed changes would be implemented.

Many HHAs, both those served by ODR and those served by intermediaries, have been opposed to the designated regional intermediary concept because the freestanding HHAs have no alternative to the designated intermediary. After discussions with provider associations and after evaluating the comments received, we have determined that freestanding HHAs should be allowed an opportunity to request an alternate intermediary. Consequently, we have designated (under section 1816(e)(4)) three intermediaries already serving as designated regional intermediaries to be additionally available as a group on a national basis to serve as alternative designated regional intermediaries.

All freestanding HHAs are being advised by this notice of the existence of the alternative designated intermediaries.

We will send the HHAs now served by ODR a separate notification and give them an opportunity to select the alternate intermediary in their area. Those ODR HHAs not wishing to receive payment from the designated regional intermediary may request to receive payment from the alternative designated regional intermediary. This request must be made within 30 days from the date of receipt of our notification.

Freestanding HHAs now served by designated regional intermediaries will also be allowed an opportunity to request a change from the designated regional intermediary to the alternative designated regional intermediary. Such requests will not be granted automatically; rather, an HHA will be required to demonstrate that the change to the alternative designated regional intermediary would be consistent with the effective and efficient administration of the Medicare program. (This policy is consistent with existing regulations at § 421.106(b) where HCFA is currently empowered to permit a provider to change to another intermediary or to direct payment if HCFA concludes that such change is in the best interest of the Medicare program.) Requests for such change must be made in accordance with the existing change-of-intermediary timeframe (§ 421.106(a)); i.e., at least 120 days before the end of the provider's current fiscal year.

In summary, the policy regarding which intermediary serves HHAs is that HHAs will deal with the designated regional intermediary except that:

- Chains may deal with a single intermediary where they meet the criteria stated elsewhere in this notice.
- HHAs currently serviced by ODR may request, within 30 days of receipt of our notification, to be serviced by the alternative designated regional intermediary.
- All other freestanding HHAs may request the opportunity to switch to the alternative designated regional intermediary. These requests must be made within the timeframe set forth at § 421.106 and will be evaluated consistent with the criteria set forth in that section.

All future HHA requests to transfer from the designated regional intermediary to an alternative designated regional intermediary or vice versa must be filed, and will be evaluated, in accordance with § 421.106.

A summary of the comments and our responses follow:

Comment: Several commenters expressed the view that assigning HHAs currently serviced by ODR to designated intermediaries was contrary to the intent of the Omnibus reconciliation Act of 1980. These commenters alleged that the 1980 amendments required the designation of intermediaries to serve HHAs but did not remove a provider's option to deal directly with the Federal government. The commenters placed great reliance on the following statement from the Conference Committee Report which accompanied Pub. L. 96–499: ". . . In requiring the designation of regional intermediaries for home health agencies, it is not the intent of the conferees that home health agencies would be precluded from contracting directly with the Health Care Financing Administration." (H.R. Rep. No. 1479, 96th Cong., 2nd Sess. 129 (1980).)

Response: As noted in the preamble to the NPRM, on September 14, 1982 the United States Court of Appeals for the District of Columbia Circuit held that, under Section 1874 of the Social Security Act, the Secretary has the authority to contract out reimbursement responsibilities and could thereby require direct-dealing freestanding home health agencies to seek reimbursement from designated regional intermediaries. The Court of Appeals' ruling indicated that the aforementioned statement in the Conference Committee Report did not mean that the Congress intended to give HHAs an unlimited right to deal directly with the Secretary. Rather, the Court found that this language merely indicated that the 1980 amendments did not mandate that the Secretary was absolutely required to designate regional intermediaries for direct-dealing HHAs. The Court found that the statement in the Conference Report did not limit, and in fact preserved, the Secretary's discretion to continue to perform his reimbursement function for the direct deal HHAs, either directly or by contract.

Comment: A number of commenters questioned that the transfer of providers currently serviced by ODR would result in efficiency or economy and asked that we further explain this change in light of anticipated costs that surely would have

to accompany transferring providers and in light of increased costs to intermediaries. A few commenters stated that the absence of a detailed cost comparison study is contrary to requirements of OMB Circular No. A-76.

Response: Currently, contractor intermediaries process 95 percent of the Part A bill volume. Our decision to contract out the ODR workload is based upon the general policy of the Federal Government to rely on commercial sources to supply the products and services the Government needs. Many of the ODR personnel have a good understanding and knowledge of the Medicare program and the impact of HCFA decisons on beneficiaries, providers and contractors. We believe that this knowlege would be better used in the overall administration of the Medicare and Medicaid programs.

Based on the consolidations and resulting transitions completed in the past, we have estimated that these transfers will not increase overall costs. There will be some one-time costs, of approximately $1 million, because of the need of some intermediaries to change their automated systems to accept bills using ODR's format. Costs to providers will be very minimal and such provider costs are reimbursable.

The requirements of OMB Circular A-76 are not applicable to this decision. Section 8 of the Revised Circular states that a decision for *in-house* performance is authorized only if a comparative cost analysis demonstrates that the Government is operating or can operate the activity at a lower cost. There is no comparable requirement for analysis concerning contracting out work performed in-house to the private sector.

Several of the commenters that questioned our conclusion raised specific issues involving implementation of a transfer, especially involving automated billing procedures. We do not intend to place automated providers in a position where they must forego efficiencies acquired via automation. For automated providers, the designated regional intermediary or alternative designated regional intermediary will be able to accommodate the automated functions currently provided by ODR. There should be no, or extremely minor, adjustments for paper-billing providers who constitute the majority of ODR providers. Any costs these providers incur will, at most be negligible.

We recognized that a major item of concern to providers would be the impact of a transfer on individual providers' automated data systems (i.e., billing, admission notices, discharge data, plans of treatment and denial notices). Of the 480 HHAs dealing with ODR, only 185 submit or receive automated data. Ninety-three of the 185 providers represent two multi-State chains that have each chosen to be served by a single intermediary for their entire chain. The remaining 92 HHAs scattered in 14 States may elect to be serviced by the designated regional intermediary or the alternative designated regional intermediary for that area. Most of the designated regional intermediaries and all of the alternative designated regional intermediaries are currently capable of accepting automated data. They will be required to write an interface program to accept data in the ODR format and modify their EDP systems to accept and respond to admission notices, starts of care, and billing formats used by ODR.

As we stated before, no provider will be asked to abandon its automated procedures to conform to the operations of a nonautomated intermediary in its area. Currently, all but eight intermediaries are capable of receiving and sending provider data via electronic media. An automated provider whose regional intermediary cannot process automated billing may deal with the alternative designated regional intermediary that can.

Comment: Nearly one-half of the commenters stated that we are not following the recommendations of the President's Private Sector Task Force (Grace Commission). The Grace Commission Report indicated three concerns—the basis for the decision to contract out, the value of ODR as an in-house laboratory and the value of ODR as a competitor.

Several other commenters requested, in a related comment, that we reconsider our plans to contract out our intermediary function, noting that ODR is reported to be efficient in its claim processing operations. These commenters stated numerous benefits to us of retaining an intermediary function. For example:

(a) ODR could be used as a testing ground for us to try innovative intermediary activities;

(b) ODR could be used as the intermediary for a host of demonstrations or experimental projects, such as hospice care;

(c) The ongoing availability of ODR creates a competitive environment for other intermediaries, since providers dissatisfied with their intermediary's performance could transfer to ODR; and

(d) ODR experience could be used to establish benchmarks to measure all intermediary performance.

Response: Our decision to contract out the intermediary functions for servicing providers now dealing directly with us is based upon a determination of our proper role. We do not believe the agency should perform operations which the private sector has demonstrated it can perform as well as we can.

On the basis of a wide range of measures, such as costs, timeliness, and accuracy, we concluded that the performance of private sector intermediaries usually ranks as well as or better than ODR. Hence, the providers being transferred to contractor intermediaries can be assured that they will continue to receive good service.

Our ongoing intermediary performance evaluation plans, the Contractor Performance Evaluation Program and the Annual Contractor Evaluation Report, help us to monitor intermediary performance and take action to assure that providers receive good service.

Concerning the issue of our having an in-house laboratory, we believe that our plans and ongoing operations are compatible with the tone of the Grace Commission. We recognize the need for a laboratory to test new methodologies. We will retain, within our Office of Research and Demonstrations, a claims processing capacity for multi-State demonstration projects and a limited capacity for new methodology testing.

ODR has never been our sole source for special analyses and testing; moreover, many of our contractors are engaged, on their own initiative or with our direct support, in billing initiatives and other productivity investments. We will also continue to experiment, demonstrate and improve operations through our private sector contractors.

The practicality of ODR's role as a competitor and alternative to intermediaries in a given area is at best marginal. ODR currently works at full capacity and would have little capability under any conditions to serve as a competitor and/or alternative for any substantial block of providers. Such alternatives can be better provided through the capacities of our private sector contractors than through any available HCFA resources.

Contrary to the opinion expressed by some providers, the claims workload of ODR does not lend itself to be used as a benchmark to evaluate other intermediaries. ODR processed only about 5 percent of the total Medicare intermediary volume in fiscal year 1982 and half of that volume was generated in one State. Benchmarks derived from this workload would not fairly and accurately assess other intermediaries.

Comment: Several HHAs reported that they had previously used other intermediaries and were pleased with

ODR's processing of their claims. They expressed dissatisfaction with a change and felt that their nomination rights were restricted with the assignment of the ODR providers to other intermediaries. The providers believe that phasing out ODR gives the Blue Cross Plans a monopoly in administering the Medicare program.

Response: After evaluating the comments received, we have determined that ODR's freestanding HHAs should be allowed an alternative to the designated regional intermediary. Before transferring the freestanding HHAs away from ODR, we are giving them the opportunity to choose either the designated intermediary for their region or the alternative regional intermediary designated by HCFA. Other freestanding HHAs now assigned to designated regional intermediaries may also request a transfer to the alternative designated regional intermediary. In addition, individual HHA chain organizations will have the opportunity to request lead and local intermediaries, or a single intermediary, to process their entire workload.

We are developing policy for use by the various regional designated, single, and lead and local intermediaries. The policy will address postpayment coverage compliance reviews, adequate onsite reviews of HHAs and consistent decisions pertaining to medical utilization and reimbursement.

The view that the phasing our of ODR will leave the Blue Cross Plans with a monopoly in the program is erroneous. We also have contracts with Aetna Life and Casualty Company, Hawaii Medical Service Association, Mutual of Omaha, The Prudential Insurance Company of America and the Travelers Insurance Company. With the exception of the Travelers Insurance Company, all of these intermediaries have also been designated to service freestanding HHAs. The performance of all intermediaries is monitored to assure adequacy of performance, and we are committed to assuring that the ODR providers receive the same as or a better level of service than is being provided by ODR. Furthermore, we are taking a number of steps to assure and measure good performance as discussed in Section V, Implementation.

Comment: Several commenters questioned our conclusions that using regional (usually statewide) intermediaries would permit a consistent application of coverage and reimbursement rules by auditors in those cases where all providers in an area have the same intermediary or intermediaries. In their view, use of statewide intermediaries would undermine Medicare as a national program.

Response: The commenters assume a rigidity in interpreting the application of coverage rules that is not borne out by the experience. They also disregard the benefits of centralization of bill processing expected to result from combining many small scale operations.

Some degree of latitude in judgment is allowed on how intermediaries are to implement coverage policy in the light of local medical practice. When individual judgment is applied, it can lead to differences among intermediaries in a small percentage of decisions. As we review this situation and meet regularly with providers, their associations and intermediaries, we will further reduce the instances, if any remain, of inconsistencies occurring in an area.

Comment: A few freestanding HHAs commented that HHA chain organizations are being granted preferential treatment by having opportunities in selecting an intermediary. Chains are to be granted an appeal mechanism through the lead intermediary alternative and the single intermediary concept gives chains the opportunity to select the most desirable intermediary.

Response: We define a chain as a group of providers under common ownership or control. The chain has effective central management controls such as:

(a) The parent company owns the controlling financial interest in each component facility;

(b) The home office controls the hiring, training, and discharging of individual facility administrators;

(c) The chain has an effective program of utilization controls ensuring proper utilization of services; and

(d) The chain management effectively oversees the individual facilities to assure compliance with company policies and procedures (e.g., periodic home office visits to facilities).

Our proposed plans for transferring freestanding HHAs announced in the preamble to the NPRM and our alternatives for chains were not developed to provide better service to one group or the other. Rather, the plans are based on our determination of the most cost effective and least disruptive approach for all concerned. In some instances it is logical that chains, because of their fiscal or operational makeup and degree of centralization, be allowed to deal with lead and local intermediaries, or with a single intermediary, to service the entire chain. These alternatives are not guaranteed. The chain must establish the need for an alternative.

We are giving HHAs an opportunity to request an alternative designated regional intermediary to assure that HHAs not belonging to a chain also have an alternative.

Comment: Several commenters expressed concern over the use of a contractor to carry out activities we presently perform for HMOs. They cite possible loss of competitive proprietary information if they are audited by intermediaries or carriers. Others suggested that we defer contracting out this function until a number of operational issues are addressed, such as whether risk-basis HMOs and cost-basis HMOs should be treated differently.

Response: As we stated in the preamble to the NPRM, we are announcing our option to perform our functions for HMOs and, by implication, other prepayment plans such as GPPPs, directly or by contract. We will continue to consult with health care prepayment plans to discuss concerns such as maintaining the confidentiality of proprietary information. No firm decision to contract out the health care prepayment plan workload has been made at this time.

Comment: Two commenters were concerned with our statement in the NPRM that we intend to contract with existing or newly established Medicare fiscal intermediaries or "other organizations" whose accountants are specialists in Medicare principles of reimbursement. They believed that the proposal to contract with organizations other than fiscal intermediaries does not follow the intent of Congress in sections 1816(e) and 1874 of the Act or the opinion of the Court of Appeals for the District of Columbia Circuit in *National Association of Home Health Agencies v. Schweiker.*

Response: We do not agree with this comment. Section 1816 of the Act merely authorizes (subject to restrictions) the Secretary to enter into an agreement with any organization or agency that is nominated as intermediary by a group of providers.

Section 1874 of the Act, on the other hand, concerns the Secretary's ability to perform Medicare functions either directly or by contract; there are no restrictions on the type of organization that we may choose to perform a given function by contract. The Court of Appeals found that we have the statutory authority to contract out the direct dealing providers; the Court did not limit us to contracting out with existing intermediaries.

Nevertheless, while we assert that we have the legal ability and right to

contract out with *any* entity under the authority of section 1874, our present intent, as we have announced previously, is to limit the contracting out of the direct-deal provider workload to current fiscal intermediaries (i.e., organizations who have entered into an agreement with the Secretary under section 1816).

Comment: Three commenters were concerned about our policy regarding appointment of an ombudsman for each HCFA regional office. One was concerned that the ombudsman would be biased because he or she would be a HCFA employee. Another commenter believed the ombudsman should not be another step in the appeals process. The third commenter stated that the provision for an ombudsman should be in the regulations.

Response: The concept of regional ombudsman was developed as a result of meetings with various provider groups and their association representatives who believed their views and concerns were seldom considered. They believed the elimination of ODR would deprive them of the one source receptive to their concerns.

We have appointed individuals and alternates to ombudsman-type positions. These individuals will have the authority to investigate and facilitate the resolution of issues that have not been settled by discussion between the provider and intermediary. They will continue to be available after the transition process to assure provider views are heard and considered in HCFA's management process. They will address all issues *except* Provider Reimbursement Review Board appeals. These individuals are knowledgeable with respect to program, operational and administrative concerns affecting HCFA, as well as the providers and intermediaries. As such, we expect them to make responsible decisions. The selection or appointment of individuals to various functions or positions, such as the ombudsman functions, are a part of HCFA's ongoing administrative processes; therefore, we see no need to include the appointment of individuals to this position in regulations.

Comment: One commenter requested that we define "chain organization" to (a) include two or more agencies under common ownership or control or (b) be subject to common operating manuals or procedures, and/or to common support services such as data processing, cost report preparation and tax return preparation.

Response: We do not agree with all of this comment. We have defined a chain elsewhere in the preamble. Example (a) of the comment falls under that definition but example (b) does not. The commenter's definition under (b) could include franchise providers. By definition a franchise is run independently of the franchisor and may have separate accounting and billing procedures in this instance. While the chain may provide general guidelines and support, the acutal decisionmaking and responsibility for adhering to program requirements lie with the franchisee.

We have agreed to the lead intermediary and single intermediary concepts to accommodate a chain's highly centralized accounting or common billing systems. While we wish to facilitate administrative simplicity for providers, we must also be concerned about program safeguards and, consequently, we do not feel it would serve any program purpose to broaden the definition of chain to encompass franchise providers.

Comment: One commenter wanted the fiscal impact of transfers to be minimized by guaranteeing reimbursement of "pass through" costs when HCFA requires a transfer to an organization not of the provider's choosing and that there be a transition plan to which the old and new intermediaries, HCFA and the provider all agree. Another commenter wanted us to state in our regulations that we will reimburse costs incurred because of the transfer.

Response: Provider costs incurred due to the transfer will be allowable and reimbursable under established Medicare reimbursement principles. If an HHA's costs exceed cost limits as a result of the intermediary transfer from ODR to an intermediary, an exception may be granted under § 405.460(f)(2). As § 405.460(f)(2) deals with excess costs, there is no need to include a statement in Part 421 indicating these costs may be allowable.

We anticipate few, if any, costs to be incurred by a provider because of the transition and these costs will be reimbursable under the usual rules.

We normally follows a transition procedure whenever providers are transferred from one intermediary to another. The procedure is followed whether one provider or a large group of providers is involved. From January 1982 through July 1983 we transferred almost 500 home health agencies to designated intermediaries. These transitions were completed successfully with no interruption to cash flow.

Comment: One commenter requested assurance that HAA chain providers' choices of a single intermediary would not be subjected to arbitrary rejection.

Response: Our decision will not be arbitrary; instead, it will be based upon whether a change improves the effective and efficient administration of the program.

Comment: One commenter suggested we reorganize the regulations to more closely follow the actual process we will follow. He gave specific suggestions for recodifying the regulation sections.

Response: We are not accepting this comment as we believe the order and format of the provisions are adequate for our purposes. However, we will consider the commenter's suggestions when contemplating further revisions or recodification of Part 421 in the future.

Comment: One commenter thought that providers should have at least 120 days lead time to transfer to an intermediary. Another commenter believed that it should not have to transfer until 1985.

Response: We do not believe that providers need 120 days, or more, to transfer. Previous transfers have been made in as little as two weeks without major disruption. For the impending transfers, providers will have at least 60 days notice, and we believe this is adequate to facilitate smooth transfers.

Comment: One commenter wanted us to add a performance measure to the Contractor Performance Evaluation Plan (CPEP) now instead of to the 1984 CPEP.

Response: The CPEP is a performance evaluation program designed to assess the effectiveness and efficiency with which Medicare contractors administer the Medicare program. The CPEP is comprised of criteria containing measures for evaluating levels of performance demonstrated by contractors in carrying out essential operations such as bill processing, provider reimbursement, and beneficiary services. It also contains statistical standards against which performance is measured in terms of cost, timeliness and quality.

The CPEP evaluation periods are based on the Federal government's fiscal year (i.e., October 1 through September 30). Thus, the performance elements that will measure an intermediary's responsiveness to provider concerns were effective October 1, 1983.

Comment: One commenter wanted us to guarantee cash flow by arranging a fixed regular monthly payment during the transition period.

Response: We believe existing payment procedures under ongoing operations and special circumstances are adequate to meet provider cash flow requirements.

IV. Provisions of the Final Regulations

A. We Are Adopting the NPRM as Final With the Changes as Summarized Below

As proposed, we are amending 42 CFR Part 421 to clarify the application of Section 1874 of the Act to providers that choose not to nominate or elect fiscal intermediaries. The amendments clarify our authority to contract with intermediaries or other organizations to make payments to those providers that have not elected to exercise the option to deal with an intermediary.

As proposed, we are redesignating § 421.103 (a) and (b) as § 421.103(a) (1) and (2). We are adding a clause to the contents of § 421.103(a)(1) to indicate that a provider's election to receive payment directly from HCFA is subject to a new § 421.103(b) (which states that we may contract out our direct payment functions). We are making a technical revision to § 421.105(b) as well, to show that a provider's option to receive payment directly from us as provided in § 421.103(a)(1) is subject to § 421.103(b). In addition to these proposed revisions, we are changing the word "shall" to "must" to be consistent with other such changes in Title 42, Chapter IV.

As proposed, we are adding a paragraph (b) to § 421.103 to state that FCFA may, as it determines to be appropriate, contract with any organization (including an intermediary with which we have previously entered into an agreement under 42 CFR 421.105 or designated as a regional or alternative designated intermediary under § 421.117) to make payments to any provider or group of provider. The amendments preserve the option now available to most providers to choose to receive payment through nominated intermediaries, but would modify the providers' option to deal directly with us.

As proposed, we are revising the contents of the current 42 CFR 421.104(b)(2) and redesignating the paragraph as § 421.104(b)(3). Current § 421.104(b)(2) states that providers may exercise their right to receive payment from the Administrator. As we stated earlier, we have the right under section 1874 of the Act to contract out the functions required to service providers; thus, providers do not have the absolute right to receive payment directly from us. Instead, they may elect to receive payment from us directly, and we may then either make those payments or contract out the responsibility. Section 421.104(b)(3) is revised to show that providers may elect to receive payment directly from HCFA as provided in § 421.103, which states that we may contract out our direct-payment function.

Again, as proposed, we are also making a technical revision to 42 CFR 421.104(b), by changing the title of § 421.104(b) from *Nomination by members or nonconcurring members* to *Action by nonmembers or nonconcurring members* to reflect that a single provider, as opposed to a group, may elect to deal with an intermediary or with us. We are also adding a new paragraph (b)(2) to clarify that a provider that does not belong to a provider association, or a provider that does not concur with its association's nomination for intermediary, may elect to receive payments from an intermediary with which we already have an agreement if both we and the intermediary agree to it.

In the proposed rule, we proposed two revisions to § 421.117, which concerns designation of intermediaries for freestanding home health agencies, to give section 1874 of the Act as a basis for the section and to require all freestanding HHAs to receive payment through HCFA-designated regional intermediaries. In this final rule, we are making four revisions to 42 CFR 421.117. First, as proposed, as stated in § 421.117(a), we are changing the basis for the section to include section 1874 of the Act; that is, intermediaries (both regional and alternative designated regional intermediaries) are designated under both section 1816(e)(4) and section 1874 of the Act.

The second revision to 42 CFR 421.117 revises paragraph (b) to require all freestanding HHAs to receive payment through regional intermediaries designated by us, except as permitted by new paragraphs (d), (e), and (f).

We are adding a paragraph (d) to § 421.117 to give each HHA chain the opportunity to deal with a lead and local intermediary, or a single intermediary, of its choice, subject to our approval.

Next, we are adding a new paragraph (e) to § 421.117 that offers freestanding HHAs an opportunity to request an alternative designated regional intermediary.

We are adding a new paragraph (f) to show that we will evaluate an HHA's request to change from its designated regional intermediary to the alternative designated regional intermediary in accordance with § 421.106(a) and that the request must be filed within the time frames set forth in § 421.106(a). We also state that there is an exception to the rules set forth in the new paragraph (f); the exception follows in a new paragraph (g).

The new paragraph (g) will give each of ODR's HHAs 30 days from the date it is notified that it will be transferred to the designated intermediary to request to be serviced by the alternative designated regional intermediary for its area.

As conforming changes, we are adding the concept of "alternative designated regional intermediary" to the definition of "intermediary" in § 421.3, and to § 421.103(b), and we are adding a necessary clarification to show that we do not designate alternative regional intermediaries for hospices, which were added to the definition on December 16, 1983 (48 FR 56008). We are also revising the latter section's title to show that the section discusses options available to both providers and to us.

In addition, we are revising § 421.128(f) to show clearly that intermediary rights to an appeals process do not include the right to appeal our designation of an alternative regional intermediary. We are revising § 421.1, Basis and Scope, as well, to show that in the regulations we state under what circumstances an intermediary or carrier may appeal an adverse action. This change is necessary to conform this section with § 421.128(f), which does not give an intermediary the right to appeal our designation of intermediaries as regional or alternative regional intermediaries for freestanding HHAs or as intermediary for hospices.

(In the regulations concerning hospices, the word "regional" was deleted in §§ 421.3, 421.103, and 421.128(f). We have revised these three sections to more clearly delineate the procedural differences between hospices and freestanding HHAs.)

We are amending 42 CFR Part 405, Subpart T, as proposed, to show that HCFA may, at its option, use a contractor to carry out the activities it presently performs for HMOs.

We are also adopting as proposed some technical changes to 42 CFR Part 421:

1. We are adding language to 42 CFR 421.1, *Basis and Scope*, to clarify that Section 1874 of the Act is one of the bases of Part 421 and that the statute and regulations permit us to perform certain functions, directly or by contract.

2. We are deleting the definition of "the Administrator" from the definitions section (§ 421.3) and revising all references to "the Administrator" to "HCFA." For consistency, we are changing all references to "he or she" and "his or her" to "it" and "its," respectively.

B. Other Technical Changes

1. In the proposed rule as published on August 2, 1983, there were numerous

typographical errors, most of which are obvious. However, we wish to point out the more technical and less obvious errors at this time:

A. Page 34980, column 2, last line: The letters "EB" in the parenthetical reference should be "FR".

B. Page 34981, column 2, line 8 of paragraph 2: The section number of the Omnibus Reconciliation Act of 1980 should read "930", not "940".

C. Page 34982, column 3: Under "III. Public Comments," the year in line 2 should read "1982", not "1981".

2. On March 25, 1983, we published definitions applicable to all regulations in 42 CFR Chapter IV, unless otherwise noted in particular rules (48 FR 12526). Although we deleted the definition in 42 CFR 421.3 of "Administrator", we did not delete or conform the other definitions to those in § 400.202.

We are deleting from § 421.3 the definitions of "Act", "carrier", "provider" and "Secretary" since they are now defined in Part 400. We are retaining the definition of "intermediary" since it has a broader meaning in § 421.3 than in § 400.202, but we are also revising it so that its wording conforms to that in Part 400 where the meanings of the two definitions are the same. We are changing "Blue Cross Association", in § 421.3 to the more accurate title of Blue Cross and Blue Shield Association. We are also revising 42 CFR 400.202 to eliminate references to ODR as part of the definitions of intermediaries and carriers.

V. Implementation

A. Notification to Providers

HCFA will send a notice to each affected provider (other than freestanding HHAs) serviced by ODR, requesting a preference of intermediary, where applicable.

Each freestanding HHA will be transferred to the appropriate designated regional intermediary. The notice to the HHAs will include the name of the alternative designated regional intermediary. Those ODR HHAs not wishing to receive payment from the designated regional intermediary may choose to receive payment from the alternative designated regional intermediary.

In addition, each HHA chain may choose, subject to our approval, to use local intermediaries from member HHAs and a lead intermediary for the chain as a whole. Alternatively, each HHA chain may also select a single intermediary to service the entire chain, subject to our approval. All single intermediaries and lead and local intermediaries must be designated regional intermediaries.

B. Classification of Intermediaries

The classifications of intermediaries to service HHAs are as follows:

1. Designated regional intermediary: The intermediary we designate to service freestanding HHAs under section 1816(e)(4) and 1874 of the Act.

2. Alternative designated regional intermediary: The designated regional intermediary we select as being available in an area to service a freestanding HHA in its area, as an alternative to the designated regional intermediary.

3. Lead and local intermediaries: An option available to a chain whose degree of centralization makes it more efficient for a lead intermediary to conduct the home office audit and final settlement of individual cost reports. The lead and local intermediaries are selected from the designated regional intermediaries. In cooperation with the lead intermediary, the designated regional intermediaries (the local intermediaries) are responsible for provider reimbursement throughout the year in the individual States.

4. Single intermediary: A designated regional intermediary we approve to service an HHA chain.

C. Ombudsman

As we indicated earlier in the Analysis and Response to Comments section, we have arranged for ombudsmen-type positions in each HCFA region. These individuals will assist providers in resolving any problems encountered during the transition or thereafter.

D. Transfer Schedule

In the proposed rule we announced that we planned to begin the transfer process on October 1, 1983 and, when possible, to transfer providers at the beginning of their fiscal year. The transfer schedule is primarily affected by the necessity to complete the transfer process in FY 1984 and by our commitment to a smooth orderly transition with adequate notice to providers.

1. All providers will receive at least 60 days notice of the date of transfer.

2. A preliminary transfer schedule has been prepared and will be made available upon request.

3. Providers may request an accelerated transfer date and approval will be granted unless the movement would create a burden on either ODR or the receiving intermediary.

4. Providers having a choice of intermediary will be notified shortly after this final rule is published and given 30 days to indicate their intermediary preference.

E. Procedures During the Change-Over Period

Each provider serviced by ODR will be notified by mail of procedures to follow during the change-over process. We will arrange for an orderly transition of service. As providers are transferred to intermediaries, the entire workload for that provider will be transferred, including pending claims, unsettled cost reports, outstanding appeals, etc.

F. Assurance of Cash Flow

We will make every effort to assure that there will be no interruption of cash flow to providers. We will work closely with the intermediaries and providers to identify and try to resolve problems that might interrupt the cash flow.

G. Transition Cost

Provider costs incurred due to the transfer will be allowable and reimbursable under established Medicare reimbursement principles.

We will be responsible for only those costs directly attributable to Medicare. As provided in 42 CFR 405.460(f)(2), administrative cost limits may be adjusted upward for a provider that shows that the additional costs are due to the transition. Where providers' costs exceed the limits as the result of the transfers to an intermediary, we will grant an exception, provided that the costs are reasonable, attributable to the circumstances specified, separately identified by the provider, and verified by its intermediary.

H. List of Designated Regional Intermediaries to Service Freestanding Home Health Agencies

Below is the list of intermediaries we have previously designated as the regional intermediaries to service freestanding HHAs. These designations were published in the preamble to a final rule on September 1, 1982 (47 FR 38535). The notifications sent to the individual HHAs will include the name of the designated regional intermediary as well as the alternative designated regional intermediary listed in section I below.

Alabama—Blue Cross and Blue Shield of Alabama
Alaska—Blue Cross and Blue Shield of Washington and Alaska
Arizona—Aetna Life and Casualty
Arkansas—Arkansas Blue Cross and Blue Shield, Inc.
California—Blue Cross of California
Colorado—Blue Cross of Colorado

Connecticut—Blue Cross and Blue Shield of Connecticut, Inc.
Delaware—Blue Cross of Delaware
District of Columbia—Group Hospitalization, Inc. (Washington, D.C.)
Florida—Aetna Life and Casualty (Clearwater, Florida)
Georgia—Blue Cross of Georgia/ Columbus, Inc.
Hawaii—Hawaii Medical Service Association
Idaho—Blue Cross of Idaho Health Service
Illinois—Health Care Service Corporation, a Mutual Legal Reserve Company (Chicago, Illinois)
Indiana—Mutual Hospital Insurance, Inc. (Indianapolis, Ind.)
Iowa—Blue Cross of Iowa, Inc.
Kansas—Blue Cross of Kansas, Inc.
Kentucky—Blue Cross and Blue Shield of Kentucky, Inc.
Louisiana—Blue Cross of Louisiana
Maine—Associated Hospital Service of Maine
Maryland—Blue Cross of Maryland, Inc.
Massachusetts—Blue Cross of Massachusetts, Inc.
Michigan—Blue Cross and Blue Shield of Michigan
Minnesota—Blue Cross and Blue Shield of Minnesota
Mississippi—Blue Cross and Blue Shield of Mississippi, Inc.
Missouri—Blue Cross Hospital Service, Inc. of Missouri (St. Louis, Missouri)
Montana—Blue Cross of Montana
Nebraska—Mutual of Omaha Insurance Company
Nevada—Aetna Life and Casualty (Reno, Nevada)
New Hampshire—New Hampshire-Vermont Health Services, Inc.
New Jersey—The Prudential Insurance Company of America
New Mexico—New Mexico Blue Cross and Blue Shield, Inc.
New York—Blue Cross and Blue Shield of Greater New York
North Carolina—Blue Cross and Blue Shield of North Carolina
North Dakota—Blue Cross of North Dakota
Ohio—Hosiptal Care Corporation (Cincinnati, Ohio)
Oklahoma—Blue Cross and Blue Shield of Oklahoma
Oregon—Blue Cross of Oregon
Puerto Rico —Cooperative De Seguros De Vida De Puerto Rico
Pennsylvania—Blue Cross of Greater Philadelphia
Rhode Island—Hospital Service Corporation of Rhode Island
South Carolina—Blue Cross and Blue Shield of South Carolina
South Dakota—Blue Cross of Western Iowa and South Dakota
Tennessee—Blue Cross and Blue Shield of Tennessee (Chattanooga, Tennessee)
Texas—Group Hospital Service, Inc. (Dallas, Texas)
Utah—Blue Cross of Utah
Vermont—New Hamsphire-Vermont Health Services, Inc.
Virginia—Blue Cross of Southeastern Virginia (Roanoke, Virginia)
Washington—Blue Cross of Washington and Alaska
West Virginia—Blue Cross Hospital Service, Inc. (Charleston, West Virginia)
Wisconsin—Blue Cross/Blue Shield United of Wisconsin
Wyoming—Blue Cross of Wymong

Certain designated intermediaries service HHAs across State lines in keeping with their longstanding service areas in the following cases:

- Group Hospitalization, Inc., which services the District of Columbia; Prince Georges and Montgomery Counties in Maryland; Arlington County, Fairfax County, and the cities of Alexandria, Falls Church and Fairfax in Virginia;
- Blue Cross of Western Iowa and South Dakota, which services all of South Dakota and 26 counties in Iowa;
- Oregon Blue Cross, which services Oregon and Clark County in Washington, a suburb of Portland;
- St. Louis Blue Cross, which services Missouri, and Johnson and Wyandotte Counties in Kansas; and
- Chattanooga Blue Cross, which services Walker, Dade and Catoosa Counties in Georgia.

These service areas do not overlap with those of other designated intermediaries and thus meet the intent of the legislative mandate in Pub. L. 96-499.

I. Alternative Designated Regional Intermediaries

The alternate intermediaries and the States in which they will serve as alterntes are as follows:

The Prudential Insurance Company of America—Alabama, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Iowa, Kentucky, Maine, Maryland, Massachusetts, Mississippi, New Hampshire, New York, North Carolina, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, and West Virginia.
Blue Cross of Iowa—Arkansas, California, Illinois, Indiana, Kansas, Louisiana, Michigan, Minnesota, Missouri, Nebraska, New Jersey, New Mexico, Ohio, Oklahoma, Texas, and Wisconsin.
Blue Cross of California—Alaska, Arizona, Colorado, Hawaii, Idaho, Montana, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, and Wyoming.

J. Other Entities Dealing Directly with HCFA

The contracting out of certain functions presently performed by HCFA for health care prepayment plans (HMOs and GPPPs) is currently under study. Health care prepayment plans, while they are not providers with a nomination right, are presently serviced by HCFA. This regulation establishes our authority to modify this practice should we, in the future, choose to contract out some or all of the work.

VI. Impact Analyses

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 meet other threshold criteria that are specified in that order. In addition, the Regulatory Flexibility Act of 1980 (Pub. L. 96-354) requires us to prepare and publish a regulatory flexibility analyses for regulations unless the Secretary certifies that the regulations will not have a significant economic impact on a substantial number of small entities. (For purposes of the Regulatory Flexibility Act, small entities include all nonprofit and most for-profit providers.) Under both the Executive Order and the Regulatory Flexibility Act, such analysis must, when prepared, show that the agency issuing the regulations has examined alternatives that might minimize unnecessary burden or otherwise ensure the regulations to be cost-effective.

In this final rule, we are responding to public comments concerning the Impact Analysis published in the August 2, 1983 NPRM and are making several changes and technical clarifications to provisions of the NPRM. Because of the concerns expressed by many commenters about this transfer, we are also providing the following analysis, that when combined with the rest of the preamble, constitutes a voluntary regulatory flexibility analysis.

A. Executive Order 12291

Executive Order 12291 requires us to prepare and make available to the public a regulatory impact analysis for any regulations likely to have an annual effect on the economy of $100 million or more, cause a major increase in costs or prices, or meet other threshold criteria specified in section 1(b) of the Order. We had determined that the proposed

rules did not meet the criteria for a "major rule" in section 1(b). Therefore, a regulatory impact analysis was not required.

In the proposed rule we also stated that these rules would increase our ability to improve administration and program effectiveness. We expected relatively minor one-time implementation costs substantially smaller than $100 million per year. Changes made in this final rule to the NPRM also do not meet the threshold criteria.

Under these final regulations, provision is made for all 185 automated HHAs to transfer to those regional intermediaries with capability to process their claims. We estimate that the one-time cost for intermediary assumption of these automated HHAs and the estimated transfer cost for the remaining providers will be approximately $1 million. This estimate incorporates costs for bill processing operations, audits, reimbursement for hearings and medical and utilization review functions. We are controlling contractor costs to assure operations in the private sector are no more costly than in ODR. Our discussions with other designated and alternative designated regional intermediaries and those intermediaries assuming the workload of the ODR hospitals and SNFs indicate that, in most cases, we can transfer the ODR workload at reasonable marginal rates.

We believe that extending to all freestanding HHAs the option of selecting one of the alternatives designated regional intermediaries, rather than the designated regional intermediary, will probably also result, at most, in a negligible economic impact. Each of the alternative designated regional intermediaries is properly equipped for automated billing procedures, thus mitigating any increase in operational costs. Also, the annual cost to process the bill volume generated by the freestanding HHAs will not increase overall but will simply shift among the intermediaries.

Therefore, we believe that the budgetary impact of this transfer will not be significant and we have determined that these final regulations will not meet the threshold criteria noted in section 1(b) of the Executive Order.

B. Regulatory Flexibility Act

In the proposed rule we stated that the Regulatory Flexibility Act requires us to prepare and make available to the public an initial regulatory flexibility analysis, under 5 U.S.C. 603(b), unless the Secretary certifies that an analysis is not required. The purpose of the analysis would be to explain the expected impact of the proposed regulations and to analyze alternatives that might reduce negative effects of regulations on small entities. (A small entity is a small business, a nonprofit enterprise, or a governmental jurisdiction with a population of less than 50,000.)

For purposes of regulatory flexibility analysis, we consider all providers and other entities participating in Medicare to be small entities. In the NPRM it was clear that a substantial number of small entities would be affected. However, we also determined that the impact on affected entities would not be significant. In the proposed rule we stated that we would minimize the impact of the rule change by making every effort to assure continued cash flow, basing reassignment on established cost reporting periods, and providing exceptions for providers that have costs exceeding their cost limits as a result of reassignment. Furthermore, changes made in these final rules result in additional efforts to minimize the impact of our decision to contract out the bill processing functions of ODR.

We continue to believe, as was discussed in the NPRM, that the impact of these regulations will not be significant and that an analysis is not required under 5 U.S.C. 603. Nevertheless, a number of commenters, including several members of Congress, expressed concern that no analysis of the impact on small businesses was completed prior to publication of the proposed rule. Therefore, we are providing a voluntary analysis to clarify our choice and to respond to concerns expressed. We are providing the public an opportunity to comment on the analysis.

(a) *Number of providers (Hospitals, SHFs, HHAs).* As of October 1, 1983, there were 1,057 providers remaining in ODR that would be affected by this transfer: 154 hospitals, 34 skilled nursing facilities, 480 home health agencies, 361 Federal hospitals and emergency hospitals, 21 providers of outpatient physical therapy services and 7 end-stage renal disease services facilities. (We are not contracting out the functions HCFA performs for health care prepayment plans at this time. These functions are performed by a component different from ODR.)

(b) *Efforts to minimize impact.* We believe these providers could be significantly affected by this rule if: (1) providers were not granted adequate time to prepare for a transfer; (2) a disruption in cash flow occurs; (3) chain organizations were forced to deal with multiple intermediaries; or, (4) automated providers were transferred to nonautomated intermediaries.

In their comments, providers also stated that they could be significantly affected by less tangible factors, such as perceived poor communications with certain intermediaries, previous differences of opinions (which may have led to their switching from an intermediary to ODR) or a general perference for a commercial intermediary over a Blue Cross Plan or *vice versa*.

To address all concerns, we developed three options: a single national alternative intermediary to the designated regional intermediaries; a small number of alternative designated intermediaries that providers could select, regardless of the providers' location; or a small number of alternative designated regional intermediaries that service designated areas.

The single national alternative intermediary would seem to preserve for providers a choice most similar to their present choice to select ODR. We did not select this option for several reasons. Unrestricted access to a designated national alternative intermediary could result in inefficient and expensive claims processing, audit and communications due to the distance and need for travel. (This is one of the problems that led Congress to require us to designate regional intermediaries for freestanding HHAs.) The potential for lack of timely response to provider concerns is high. Furthermore, this approach would be least compatible with our efforts to encourage consistent medical review and coverage decisions since the intermediary may be at a great distance from the provider. Finally, the choice of a single national intermediary runs counter to our future plans to regionalize our intermediary configuration.

The second option, a small number of alternative designated regional imtermediaries from which all providers could freely choose would be most responsive to those providers that felt it important to select a commercial intermediary instead of a Blue Cross Plan or vice verse. We rejected this option for many of the reasons stated above, since it is very likely that selections resulting in a great distance between the provider and intermediary could occur. In fact, if all selected the same intermediary, the result could be identical to the first option.

We selected the opton of three alternative designated regional intermediaries to service designated

areas and also developed operational provisions to minimize impact.

Included within the selected alternative are the following provisions that seek to minimize the affect of this rule change. First, all providers will receive at least 60 days' notice prior to transfer. This will give the provider and intermediary adequate time to conduct meetings, address concerns and complete any training the provider may require.

Second, we will work with the various intermediaries to assure that there is no disruption to providers' cash flow. We have experience in transferring large numbers of providers from one intermediary to another (HHA intermediary reconfiguration of 1982–July 1983; consolidation of Mutual of Omaha workload; consolidation of Blue Cross Plans and consolidation of The Travelers workload). In none of these instances did providers suffer a disruption in cash flow.

Third, with regard to chain organizations, each organization may request to use a single intermediary for its entire workload or to use local and lead intermediaries. Because of the fiscal or operational organizations of some chains and because of their degree of centralization, certain chains may find service by a single intermediary, or lead and local intermediaries, to be preferable to being serviced by the designated regional intermediary or the alternative designated regional intermediary.

Finally, we are responding to the needs of the 250 automated providers in several ways. We have begun transition activities with some hospitals and home health agencies. The intermediaries elected by these provider are automated. Where necessary the intermediaries are making adjustments to their system to accommodate billing procedures.

Automated HHAs will not have to transfer to an intermediary that cannot accept their automated billing. All three alternative designated regional intermediaries have the same systems capacity as ODR and may be chosen instead of a nonautomated regional intermediary. Automated billers represent only 185 of the 480 HHAs dealing with ODR; 93 of the 185 are members of two multi-State chains that have each chosen to be serviced by a single intermediary for the entire chain. The remaining 92 will each be transferred to one of 14 intermediaries or an alternative designated regional intermediary if selected by the HHA.

The remaining providers affected by the ODR transfer all submit paper bills to their intermediaries. These providers will experience few, if any, transition costs as the procedures for completing and submitting bills will remain the same. The primary changes will be learning the new intermediary contacts and the intermediary's address for mailing purposes.

A few providers commented that the Medicare regulations on cost apportionment may result in an impact on them, as they may not be totally reimbursed for administrative costs associated with the transfer. We agree that the lack of significant impact on a substantial number of providers does not preclude the fact that some individual providers could be affected, especially HHAs as noted by several commenters. However, the increased costs incurred by these providers because of the transition are allowable for Medicare reimbursement purposes under the usual rules. An appropriate portion will be reimbursed by Medicare. If increased costs subject the provider to the cost limits, the provider may request an exception to its cost limits for that fiscal year. By keeping overall transfer costs to a minimum, we also minimize the share of administrative costs not reimbursed using the cost apportionment rules. Further, we believe that expected intermediary improvements and increases in efficiency will diminish the impact of this transfer on individual providers.

Therefore, the Secretary certifies under 5 U.S.C. 605(b), as enacted by Pub. L. 96–354 (the Regulatory Flexibility Act of 1980), that these final regulations will not have a significant impact on a substantial number of small providers.

Although these regulations are final, we are providing interested parties an opportunity to comment on the Impact Analyses. If additional information results in changes to announced policies the comments and our responses will be published in a subsequent **Federal Register.** To assure consideration, comments on this impact analysis should be received by February 29, 1984.

Address comments in writing to: Health Care Financing Administration, Department of Health and Human Services, Attention: BPO–28–F, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your comments to Room 309–G, Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, D.C., or to Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

In commenting, please refer to file code BPO–28–F.

Comments will be availabe for public inspection as they are received, beginning approximately three weeks after publication, in Room 309–G of the Department's offices at 200 Independence Ave., SW., Washington, D.C. 20201, on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (202–245–7890).

List of Subjects

42 CFR Part 400

Medicare, Medicaid.

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 requirements, Rural Areas, X-rays.

42 CFR Part 421

Administrative practices and procedure, Contracts (Agreements), Courts, Health care, Health facilities, Health maintenance organizations (HMO), Health professions, Information (Disclosure), Lawyer, Medicare, Professional Standards Review Organizations (PSRO), Reporting requirements.

A. 42 CFR Part 400 is amended as set forth below:

PART 400—INTRODUCTION: DEFINITIONS

Part 400, Subpart B is amended as follows:

Subpart B—Definitions

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

Section 400.202 is amended by revising the definitions "Carrier and "Intermediary" as follows:

§ 400.202 Definitions specific to Medicare.

As used in connection with the Medicare program, unless the context indicates otherwise—

"Carrier" means an entity that has a contract with HCFA to determine and make Medicare payments for Part B benefits payable on a charge basis and to perform other related functions.

* * * * *

Intermediary" means an entity that has a contract with HCFA to determine and make Medicare payments for Part A or Part B benefits payable on a cost

basis and to perform other related functions.

* * * * *

B. 42 CFR Part 405 is amended as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

Part 405, Subpart T is amended as follows:

Subpart T—Health Maintenance Organizations

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

Authority: Sec. 1102, 1833(a)(1)(A), 1871, 1874, and 1876 (42 U.S.C. 1302, 1395l(a)(1)(A), 1395hh, 1395kk and 1395mm).

2. Section 405.2001 is amended by revising paragraph (a) as follows:

§ 405.2001 Health maintenance organizations; general.

(a) *Introduction.* The regulations in this Subpart T set forth the requirements which an organization must meet in order to be eligible to enter into a contract with the Secretary as a health maintenance organization (HMO) under the health insurance program for the aged and disabled (title XVIII of the Social Security Act) and to be reimbursed through capitation payments for covered items or services the organization furnishes title XVIII beneficiaries who have enrolled with it. Any references in this subpart to functions being performed by HCFA may at HCFA's option be performed directly by HCFA or by contract.

C. 42 CFR Part 421 is amended as set forth below:

PART 421—INTERMEDIARIES AND CARRIERS

1. The Table of Contents is amended as follows:

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Subpart B—Intermediaries

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Sec.

421.103 Options available to providers and HCFA.

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421.114 Assignment and reassignment of providers by HCFA.

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421.117 Designation of Regional and Alternative Designated Regional Intermediaries for Freestanding Home Health Agencies and for Hospices.

* * * * *

2. The authority citation is revised as follows:

Authority: Sec. 1102, 1815, 1816, 1833, 1842, 1861(u), 1871, 1874, and 1875 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395h, 1395, 1395u, 1395x(u), 1395hh, 1395kk, and 1395ll), and 42 U.S.C. 1395b–1.

3. In addition to revisions noted below, all references to "the Administrator" in Part 421 are revised to read "HCFA."

4. Part 421, Subpart A is amended as follows:

Subpart A—Scope, Definitions, and General Provisions

a. Section 421.1 is revised to read as follows:

§ 421.1 Basis and scope.

(a) This part is based on sections 1815, 1816, 1842, and 1874 of the Social Security Act and 42 U.S.C. 1395b–1 (experimental authority).

(b) The provisions of this part apply to agreements with Part A (Hospital Insurance) intermediaries and contracts with Part B (Supplementary Medical Insurance) carriers. They also state that HCFA may perform certain functions directly or by contract. They specify criteria and standards to be used in selecting intermediaries and evaluating their performance; in assigning or reassigning a provider or providers to particular intermediaries, and in designating regional or national intermediaries for certain classes of providers. The provisions set forth the instances where there is the opportunity for a hearing for intermediaries and carriers affected by certain adverse actions. In some circumstances, the adversely affected intermediaries may request a judicial review of hearings decisions on (1) assignment or reassignment of a provider or providers or (2) designation of an intermediary or intermediaries to serve a class of providers.

b. Section 421.3 is amended by removing the definitions of Act, Administrator, Carrier, Provider and Secretary and revising the definition of Intermediary as follows:

§ 421.3 Definitions.

"Intermediary" means an entity that has a contract with HCFA to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions. For purposes of designating regional or alternative regional intermediaries for freestanding home health agencies and of designating intermediaries for hospices under § 421.117 as well as for applying the performance criteria in § 421.120 and the statistical standards in § 421.122 and any adverse action resulting from such application, the term intermediary also means a Blue Cross Plan which has entered into a subcontract approved by HCFA with the Blue Cross and Blue Shield Association to perform intermediary functions.

5. Part 421, Subpart B is amended as follows:

Subpart B—Intermediaries

a. Section 421.100 is amended by revising paragraph (g) as follows:

§ 421.100 Intermediary functions.

* * * * *

(g) *Information and reports.* The intermediary must furnish to HCFA any information and reports that HCFA requests in order to carry out its responsibilities in the administration of the Medicare program.

* * * * *

b. Section 421.103 is revised as follows:

§ 421.103 Option available to providers and HCFA.

(a) Except for hospices (which are covered under § 421.117), a provider may elect to receive payment for covered services furnished to Medicare beneficiaries:

(1) Directly from HCFA (subject to the provisions of paragraph (b) of this section); or

(2) Through an intermediary, when both HCFA and the intermediary consent.

(b) Whenever HCFA determines it appropriate, it may contract with any organization (including an intermediary with which HCFA has previously entered into an agreement under § 421.105 and § 421.110 or designated as a regional or alternative regional intermediary under § 421.117) for the purposes of making payments to any provider that does not elect to receive payment from an intermediary.

c. Section 421.104 is amended by revising the heading of paragraph (b), by revising paragraph (b)(2), and by adding a new paragraph (b)(3) as follows:

§ 421.104 Nominations for intermediary.

* * * * *

(b) *Action by nonmembers or nonconcurring members.* Providers that nonconcur in their association's nomination, or are not members of an association, may:

* * * * *

(2) Elect to receive payments from a fiscal intermediary with which HCFA already has an agreement, if HCFA and the intermediary agree to it (see § 421.106); or

(3) Elect to receive payment from HCFA as provided in § 421.103.

d. Section 421.105 is amended by revising paragraph (b) as follows:

§ 421.105 Notification of action on nomination.

* * * * *

(b) Any member of a group or association having more than one nominated intermediary approved by HCFA to act on its behalf must withdraw its nomination from all but one or exercise the option provided in § 421.103(a), subject to § 421.103(b), to receive payment directly from HCFA.

e. Section 421.106 is amended by revising paragraph (b) as follows:

§ 421.106 Change to another intermediary or to direct payment.

* * * * *

(b) If HCFA finds the change is consistent with effective and efficient administration of the program and approves the request under paragraph (a) of this section, it will notify the provider, the outgoing intermediary and the newly elected intermediary (if any) that the change will be effective on the first day following the close of the fiscal year in which the request was filed.

f. Section 421.114 is amended by revising the title and introductory paragraph as follows:

§ 421.114 Assignment and reassignment of providers by HCFA.

HCFA may assign or reassign any provider to any intermediary if it determines that the assignment or reassignment will result in more effective and efficient administration of the Medicare program. Before making this determination HCFA will consider—

* * * * *

g. Section 421.116 is amended by revising paragraph (a) as follows:

§ 421.116 Designation of national or regional intermediaries.

(a) After considering intermediary performance measured against the criteria and standards specified in §§ 421.120 and 421.122, HCFA may designate a particular intermediary to serve a class of providers nationwide or in any geographic area it defines. HCFA may make this designation if it determines that the designation will result in a greater degree of effectiveness and efficiency in the administration of the Medicare program than could be achieved by an assignment of providers to an intermediary preferred by the providers.

* * * * *

h. Section 421.117 is revised by revising the title and paragraphs (a) and (b), and by adding paragraphs (d), (e), (f), and (g) as follows:

§ 421.117 Designation of Regional and Alternative Designated Regional Intermediaries for Freestanding Home Health Agencies and for Hospices.

(a) This section is based on section 1816(e)(4) of the Social Security Act, which requires the Secretary to designate regional intermediaries for freestanding home health agencies (HHAs), on section 1816(e)(5) of the Social Security Act, which requires the Secretary to designate intermediaries for hospices, and on Section 1874 of the Act, which permits HCFA to contract with any organization for the purpose of making payments to any provider that elects to receive payment directly from HCFA.

(b) Except as provided in paragraphs (d), (e), and (f) of this section, freestanding HHAs that elect to receive payment for covered services furnished to Medicare beneficiaries through an intermediary under § 421.103(a)(2) of this subpart and HHAs that elect to receive payment directly from HCFA under § 421.103(a)(1) of this subpart must receive payment through a regional intermediary designated by HCFA.

* * * * *

(d) An HHA chain not desiring to receive payment from designated regional intermediaries may request service by one lead intermediary with the assistance of a local designated regional intermediary. Alternatively, the chain may request to be serviced by a single intermediary. A lead, local, or a single intermediary must be an organization that is a designated regional intermediary. Any request made under this paragraph is evaluated by HCFA in accordance with the critiera contained at § 421.106 of the subpart.

(e) An HHA not wishing to receive payment from a regional intermediary designated under paragraph (b) of this section may submit a request to the HCFA Regional Office to receive payment through an alternative regional intermediary designated by HCFA.

(f) Except as provided in paragraph (g) of this section, any request that an HHA may make to change from a designated regional intermediary to an alternative designated regional intermediary, in accordance with paragraph (e) of this section, is evaluated by HCFA in accordance with the criteria set forth at § 421.106(b) of this subpart and must be filed within the timeframe established at § 421.106(a) of this subpart.

(g) Exception: An HHA that is receiving payment directly from HCFA under § 421.103(a)(1) of this subpart as of January 30, 1984 is eligible to request that it receive payments from an alternative designated regional intermediary without regard to the limitations contained in § 421.106 of this subpart. However, each such HHA will have only 30 days after the date of receipt of HCFA's notification that the HHA will be transferred to a designated regional intermediary to request the alternative designated regional intermediary.

i. Section 421.128(f) is revised to read as follows:

§ 421.128 Intermediary's opportunity for a hearing and right to judicial review.

* * * * *

(f) Exception. An intermediary adversely affected by the designation of a regional intermediary or an alternative regional intermediary for freestanding HHAs, or an intermediary for freestanding hospices, under § 421.117 of this subpart is not entitled to a hearing or judicial review concerning adverse effects caused by the designation of an intermediary.

6. Part 421, Subpart C is amended as follows:

Subpart C—Carriers

Section 421.200 is amended by revising paragraph (g) as follows:

§ 421.200 Carrier functions.

* * * * *

(g) *Information and reports.* The carrier must furnish to the Administrator any information and reports that HCFA requests in order to carry out its responsibilities in the administration of the Medicare program. The carrier must be responsive to requests for information from the public.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 13.773, Medicare-Hospital Insurance)

Dated: November 26, 1983.

Carolyne K. Davis,

Administrator, Health Care Financing Administration.

Approved: December 27, 1983.

Margaret M. Heckler,

Secretary.

[FR Doc. 84-2424 Filed 1-27-84; 8:45 am]

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