health care services directly from, or through arrangements made by, the HMO or CMP, as specified in this section and §§ 417.442 and 417.444.

(2) A Medicare enrollee is also entitled to receive timely and reasonable payment directly (or have payment made on his or her behalf) for services he or she obtained from a provider or supplier outside the HMO or CMP if those services meet either of the following conditions:

(i) They are emergency services or urgently needed unforeseen services as defined in § 417.401.

(ii) They are services denied by the HMO or CMP and found (upon appeal under subpart Q of this part) to be services the enrollee was entitled to have furnished by the HMO or CMP.

(b) *Scope of services.* (1) *Part A and Part B services.* Except as specified in paragraphs (c) through (e) of this section, a Medicare enrollee is entitled to receive from the HMO or CMP all the Medicare-covered services that are available to individuals residing in the HMO's or CMP's geographic area, as follows:

(i) Medicare Part A and Part B services if the enrollee is entitled to benefits under both programs.

(ii) Medicare Part B services if the enrollee is entitled only under that program.

* * * * *

6. In § 417.452, paragraph (a) is revised to read as follows:

§ 417.452 Liability of Medicare enrollees.

(a) *Deductibles and coinsurance*—(1) *General rules.*

(i) A Medicare enrollee of an HMO or CMP is responsible for HMO or CMP charges that represent applicable Medicare deductible and coinsurance amounts.

(ii) The amounts that the HMO or CMP charges its Medicare enrollees under paragraph (a)(1)(i) of this section may not exceed, on the average, the actuarial value of the deductibles and coinsurance for which the Medicare enrollees would be responsible if they were not enrolled in an HMO or CMP.

(2) *Special rules: Medicare enrollees of risk HMOs and CMPs.* (i) If a risk HMO or CMP reduces the deductible and coinsurance charges in accordance with the "additional benefits" option provided in § 417.440(b)(4)(i), the enrollee pays less than would otherwise be required under paragraph (a)(1) of this section.

(ii) A Medicare enrollee of a risk HMO or CMP is not responsible for deductibles applicable to national coverage decision (NCD) services that the HMO or CMP is not required to furnish because they are excepted under § 417.414(b)(4). The exemption applies regardless of whether the HMO or CMP furnishes the services or the enrollee obtains them from other sources.

(3) *Type of charge and source of payment.* (i) The deductible and coinsurance charges imposed by an HMO or CMP may be in the form of premiums, membership fees, or per-unit or similar charges.

(ii) The deductible and coinsurance charges may be paid by the enrollee or on his or her behalf by another individual, organization, or entity.

* * * * *

7. Section 417.586 is revised to read as follows:

§ 417.586 Special rules: Payment for significant cost national coverage decision (NCD) services.

(a) *Applicability.* This section applies to NCD services that a risk HMO or CMP is not required to furnish because they are excepted under § 417.414(b)(4).

(b) *Method of payment.* If a Medicare enrollee of a risk HMO or CMP receives an NCD service specified in paragraph (a) of this section, payment for that service—

(1) Is in addition to the per capita payments to the HMO or CMP; and

(2) Is made by the fiscal intermediary or carrier under the usual Medicare rules and methods set forth in part 405; part 410, subpart E; part 412, 413, or 415, as appropriate; and subject to the requirements of part 424 of this chapter.

(c) *Exceptions.* HCFA does not make additional payments under paragraph (b) of this section if the HMO or CMP—

(1) Is obligated to furnish the NCD service as an "additional benefit" under § 417.592; or

(2) Furnishes the NCD service as an optional or required supplemental service paid for by the Medicare enrollee under § 417.440 (b)(2) or (b)(3).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 28, 1993.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: November 3, 1993.

Donna E. Shalala,

Secretary.

[FR Doc. 94–3609 Filed 2–18–94; 8:45 am]

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42 CFR Part 417

[OCC–018–P]

RIN 0938–AF16

Medicare Program; Limits on Payment to Health Maintenance Organizations (HMOs), Competitive Medical Plans (CMPs), and Health Care Prepayment Plans (HCPPs)

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would remove the provision (never implemented) that would have made the adjusted average per capita cost (AAPCC) the absolute limit on payment for services furnished to Medicare enrollees by an HMO or CMP with a cost contract.

This change is necessary to conform our rules to the interpretation of the statute as set forth in court decisions relating to payment of reasonable costs.

This rule would also provide for using the AAPCC as a presumptive limit, subject to exceptions, for HMOs and CMPs with cost contracts, and for health care prepayment plans (HCPPs) that furnish inpatient hospital care as well as part B services;

Eliminate the effective incentives exception that is currently available to HCPPs;

Require HCPPs that do not furnish inpatient hospital services to document that their costs do not exceed what Medicare's cost would have been if the Medicare beneficiaries who received the services had not enrolled in the HCPP; and revise the rules for reporting costs.

DATES: Comment date: We will consider comments received no later than 5 p.m. on April 25, 1994.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address:

Health Care Financing Administration, Department of Health and Human Services, Attention: OCC–018–P, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, MD 21207.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code

OCC–18–F. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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FOR FURTHER INFORMATION CONTACT: Jennifer Messersmith, (202) 401–2325; Alfred D'Alberto, (410) 966–7610 (For full reporting of costs).

SUPPLEMENTARY INFORMATION:

I. Introduction

Under the Medicare program (title XVIII of the Social Security Act (the Act)), HCFA helps pay for health services furnished to eligible beneficiaries. Under "part A" (Hospital Insurance), HCFA pays hospitals and other providers of services for inpatient hospital services, and some skilled nursing facility services, home health care, and hospice care. Under "part B" (Supplementary Medical Insurance), HCFA helps pay for physicians' services, as well as hospital outpatient and certain other medical services.

In general, HCFA pays for Medicare part A and part B services under a fee-for-service system that includes a variety of payment methods such as—

- Fee schedules for physician and laboratory services and durable medical equipment;
- Diagnosis-related groups for most hospital services under the prospective payment system (PPS);
- Reasonable costs for skilled nursing care, home health services and the services of certain hospitals not subject to the PPS; and
- Reasonable charges for some supplier services.

For part A services, HCFA usually pays the provider and, for part B services, the supplier who has accepted assignment or, if assignment has not been made, the beneficiary. Payment is on the basis of claims submitted by the provider, supplier, or beneficiary after the service has been furnished.

Title XVIII of the Act also permits beneficiaries to enroll in, and receive their Medicare benefits through, prepaid health care organizations. These include health maintenance organizations (HMOs), and competitive medical plans (CMPs), with contracts under section 1876 of the Act, and health care prepayment plans (HCPPs) with agreements under section 1833 of the Act. HMOs and CMPs are required to furnish the full range of Medicare benefits, and do not bill on a fee-for-service basis for covered services furnished to their Medicare enrollees. Rather, HCFA pays the organization in advance a monthly amount for each enrolled beneficiary. If the HMO or CMP contracts to be paid on a reasonable cost basis, there is a cost reconciliation at the end of the year. HCFA also pays HCPPs on a reasonable cost basis, following procedures similar to those used for HMOs and CMPs, but only for part B services. If an HCPP arranges for part A services for its enrollees, the Medicare intermediary pays the provider for these services on a fee-for-service basis.

As of March 1993, about 2.4 million of the 33 million Medicare beneficiaries had chosen to enroll in an HMO, CMP, or HCPP.

This proposed rule would impose presumptive limits on reasonable costs—

- For HMOs and CMPs that choose to contract with HCFA on a reasonable cost basis; and
- For HCPPs that furnish (to Medicare enrollees) services in general acute-care hospitals.

These presumptive limits replace absolute limits that were promulgated in 1985 but were never put into effect for reasons given in HCFA Ruling No. 89–2, and explained below under section II.B.2. This rule would establish bases for exceptions to the presumptive limit and would also establish limits on reasonable costs for HCPPs that do not furnish inpatient hospital services.

II. Background

A. HMOs, CMPs, and HCPPs

1. HMOs and CMPs

Under section 1876 of the Act we are authorized to contract with HMOs and CMPs to pay them either on a risk basis or on a cost basis for services they furnish to Medicare enrollees. HMOs and CMPs must provide all part A and part B services to Medicare enrollees entitled to both part A and part B, but HCPPs may limit the services they provide. Risk HMOs and CMPs receive monthly capitation payments equivalent to 95 percent of the adjusted average per capita cost (AAPCC).

The AAPCC is an estimate of the average per capita cost, under the fee-for-service system, for Medicare-covered services furnished to Medicare beneficiaries who are not enrolled in HMOs, CMPs, or HCPPs. HCFA's Office of the Actuary prepares an AAPCC for both aged and disabled beneficiaries for each county in the United States and adjusts the AAPCC rates demographically by age, sex, Medicaid status, and institutional status. For example, a 65–69 year old female, who is not eligible for Medicaid and not in an institution, might have a monthly AAPCC rate of $300 in a given county. An 80–84 year old female, institutionalized in the same county, might have an AAPCC rate of $680. These rate differences reflect the lower average Medicare costs for the younger, non-institutionalized beneficiary. There are 30 demographic groups for the aged Medicare population and 30 for the disabled Medicare population.

Cost HMOs and CMPs receive monthly interim payments based on the annual operating budget they submit before the beginning of their contract year. At the end of the contract year, they must submit a cost report to document their actual costs, as a basis for a final settlement.

As of March 1993, there were 93 risk HMOs and CMPs with 1,603,178 Medicare enrollees and 22 cost HMOs and CMPs with 140,415 enrollees.

2. HCPPs

HCPPs are prepaid health care organizations that have agreements with HCFA to be paid in accordance with section 1833(a)(1)(A) of the Act. Under such an agreement, HCFA pays the HCPP only for part B services. Payment is based on "reasonable costs" and those costs are generally determined following the methods used for cost HMOs and CMPs, as described under section II.A.1. of this preamble. Some HCPPs provide the full range of part B services, while others offer a much more limited scope.

HCPPs are not required to provide part A services and cannot be paid for those services under the HCPP agreement. Some HCPPs are organized to furnish comprehensive health care services to their Medicare enrollees and to their commercial enrollees. Those HCPPs, which could elect to contract as HMOs or CMPs, furnish or arrange for

all or most part A services. The providers of those part A services submit their claims to, and are paid by, Medicare intermediaries.

In March 1993, there were 57 HCPPs with 640,633 Medicare enrollees.

B. History of Cost Limits

1. Statutory basis for setting cost limits

Section 1861(v)(1)(A) of the Act authorizes us to establish limits on reasonable costs for entities that are paid on a reasonable cost basis. The limits must be based on estimates of the costs necessary in the efficient delivery of health care services. Our basic goal in establishing limits on costs for HMOs, CMPs, and HCPPs is to ensure that the Medicare program pays no more for care furnished to beneficiaries enrolled in these organizations than it would pay for services for beneficiaries not enrolled in an HMO, CMP, or HCPP. We consider that to pay more than we would have paid under the fee-for-service system would be inefficient and, thus, an inappropriate use of Medicare funds.

2. Provisions of the Regulations

Before 1986, the regulations provided that, for HMOs and CMPs paying physicians on a salaried basis, costs were reasonable if they did not exceed the costs for comparable services in the HMO's or CMP's geographic area. Those costs, however, were not subject to the reasonable charge levels of the Medicare fee-for-service payment system, and HMOs and CMPs were not required to document the comparability of their costs to the costs allowed under that system.

Costs incurred for payment to groups of physicians (organized either on a group practice or an individual practice basis) and for payment for other part B services could not exceed the Medicare reasonable charge levels. However, with respect to physicians' services, most HMOs and CMPs were exempted from this limit, under the "effective incentives" policy. Under this policy, the exemption was available if the members of the group of physicians accepted effective incentives, such as risk-sharing, designed to discourage unnecessary or unduly costly utilization of health services. In connection with these rules, the AAPCC was used as a guideline, but not as a limit, in assessing the reasonableness of the total costs incurred by HMOs and CMPs.

The rules for HCPPs were similar and are still in effect. For HCPPs that pay physicians on a basis other than fee-for-service, such as capitation, costs are not measured against the reasonable charge or other fee-for-service rate. Rather, costs are measured against what a "prudent buyer" would pay for comparable services in the geographic area. Payments based on fee-for-service are generally subject to Medicare reasonable charge levels. However, if the payments are to a medical group whose members accept "effective incentives" to control utilization, the payments are subject to the "prudent buyer" standard rather than reasonable charge levels.

On January 10, 1985, at 50 FR 1314, we published a final rule that established a new part 417 containing the rules applicable to prepaid health care. Section 417.532 provided that, beginning in 1986, 100 percent of the weighted average of the AAPCCs of each class of a cost HMO's or CMP's Medicare enrollees would be applied as an absolute limit on the total amount payable to that HMO or CMP. There would be no exceptions and no possibility of payments in excess of that limit. The provisions relating to effective incentives were removed from the rules for HMOs and CMPs as no longer necessary, but retained for HCPPs, to which the new absolute limit would not apply. Although the new absolute limit never went into effect, the effective incentives policy was not restored for HMOs and CMPs, and the inoperative rule (§ 417.532(a)(3)) was not removed from the CFR.

In October 1989, HCFA issued HCFA Ruling (HCFAR) No. 89–2, which stated that: "Since the time that § 417.532 of the regulations was promulgated, the courts have construed the authority to set cost limits under section 1861(v)(1)(A) [of the Act] to support generalized cost limits applied on a presumptive basis, but not absolute cost limits applied on a final or conclusive basis * * *." The courts have interpreted section 1861(v)(1)(A) of the Act as requiring that a Medicare provider be afforded an opportunity under the regulations to show that in its particular case, costs in excess of the applicable cost limits were reasonable and therefore reimbursable. Thus, the court decisions support application of presumptive limits, that is, limits with an exception process that affords the cost-contracting entity the opportunity to qualify for additional payments if it can show that its excess costs are justified as "reasonable."

As a result of the policies discussed above, we have not accumulated data that would show whether the furnishing of health care services by cost HMOs and CMPs, and HCPPs is cost-effective as compared to the furnishing of those services under the Medicare fee-for-service system.

III. Provisions of the Proposed Rule

A. Provisions Applicable to HMOs and CMPs, and to HCPPs That Furnish Inpatient Hospital Services

1. Background

Since HCPP agreements pertain only to part B services, HCFA makes payment directly to the providers for part A services furnished to HCPP enrollees. However, some HCPPs "furnish inpatient services" in the sense that they make the arrangements for enrollees to receive those services, and pay applicable Medicare coinsurance and deductibles in return for a premium from the enrollee. Like HMOs, HCPPs that furnish both part A and part B services would generally have an incentive to use more cost-effective part B services when possible, rather than more expensive part A services.

However, if we imposed a cost limit only on the services we reimburse through the HCPP agreement (that is, part B services), it would create an incentive for the HCPP to shift costs by authorizing more expensive part A services (which will be reimbursed directly to the provider), rather than part B services that would be subject to the limit. Accordingly, to avoid potentially inappropriate increases in part A utilization, we propose to apply the aggregate part A and part B presumptive limit to all costs incurred for Medicare beneficiaries enrolled in HCPPs that furnish inpatient hospital services. If the aggregate costs exceed the limit, the HCPP would be considered to have an overclaim for its part B services. (The limit would apply to HCPPs that furnish inpatient care in hospitals commonly referred to as "general acute-care" or "short-stay" hospitals, as distinguished from psychiatric or rehabilitation hospitals or other chronic or long-term hospitals.)

2. Presumptive Limit

The presumptive limit on costs would be 100 percent of the weighted average of the AAPCCs of each class of Medicare enrollees. Since the AAPCC is based on the costs of all Medicare services received by beneficiaries, as a presumptive limit it must be applied to the total cost of all Medicare-covered services received by the Medicare enrollees, including all part A and part B services, whether furnished by the prepaid health care organization or obtained from other sources. In other words, all costs attributable to Medicare enrollees, whether paid by the organization or paid by Medicare's

intermediaries and carriers, would be totaled and compared to the presumptive limit.

We note that we plan to consider adjustment to, or a replacement for, the AAPCC as the basis for payment to risk HMOs and CMPs. If we make any such changes, we might also need to modify using the AAPCC as the basis for the presumptive limit. This would involve additional rulemaking activity.

3. Exception Process

If costs exceed the presumptive limit, there would be an exceptions process that would permit payments in excess of the limit, for either of the following reasons:

a. Special needs. The Medicare enrollees have special needs that require a volume and intensity of services that exceeds the average for Medicare beneficiaries of the same age and sex living in the same service area.

- For exceptions based on special needs, we are proposing the methodology discussed under section IV of this preamble.
- If, after application of that methodology, the organization wished further review, it could present additional documentation for HCFA's consideration. The organization could seek such further review if HCFA found that the organization did not meet HCFA's standards for special needs or the HMO or CMP believed that not enough money was being allowed for its special needs enrollees.

b. Extraordinary circumstances. There were extraordinary circumstances beyond the control of the organization. The circumstances include, but are not limited to, strikes, fire, earthquake, flood or similar unusual occurrences with substantial cost effects.

For exceptions based on extraordinary circumstances, the HMO or CMP would be required to submit to HCFA information documenting the particular extraordinary circumstances that it believes constitute justification for additional payments and the amount of additional payments justified by the extraordinary circumstances.

4. Decision Not to Restore the Effective Incentives Exception

We would not restore the effective incentives exception that was deleted from the regulations when we promulgated the absolute limitation on payment to cost HMOs and CMPs in 1985.

The existence of "effective incentives" was used by HCFA as a proxy for efficiency. We are now using the presumptive limit as a proxy for efficiency, and we believe this is a more appropriate standard.

5. Exemption Based on Number of Medicare Enrollees

Under the proposed rule, HCFA could exempt organizations with fewer than 500 Medicare enrollees from the cost limits for up to 2 consecutive years. HCFA could specify additional criteria that these organizations must meet in order to qualify for this exemption.

6. Effect of Having a Final Overclaim for 2 Consecutive Years

HCFA could terminate contracts with organizations that have a final overclaim for at least 2 consecutive years. Final overclaim means that, after application of the exception process, the organization still has excess claims that it cannot justify as "reasonable." The rationale for termination is that organizations with final overclaims are inefficient as compared to the fee-for-service system, and it is not prudent for HCFA to continue to contract with inefficient organizations.

B. Provisions Applicable to HCPPs That do not Furnish Inpatient Hospital Services

1. Criteria for Reasonableness

The costs incurred by the HCPP for physicians' services and other part B supplier services would be considered reasonable if they did not exceed, in the aggregate, the amount that HCFA would pay, in the aggregate, for those services if they were furnished to beneficiaries not enrolled in the HCPP or any other prepaid health care plan. HCPP costs would be compared to costs under the usual fee-for-service payment methods, based on fee schedules, reasonable charge limits, or reasonable cost limits, whichever is appropriate for the particular services. The aggregate amount would include an amount equivalent to the costs of claims processing.

2. Documentation of Services

- Participating HCPPs would be required to include in their cost reports documentation of each service furnished to their Medicare enrollees, using the Medicare billing codes.
- Organizations seeking an agreement for participation as an HCPP would be required to demonstrate that they have in place a system that enables them to comply with the documentation requirement.
- Failure to comply with the documentation requirement would be a basis for termination or nonrenewal of the agreement.

We would amend § 417.800(b), to include the documentation requirement.

3. Removal of "Effective Incentives" Provision

We would remove the effective incentives provisions that appear in § 417.802(2)(ii)(B) and (b)(3)(ii) of the current HCFA rules. We believe that all HCPPs should be subject to the requirement that payment for services furnished to their Medicare enrollees not exceed the estimate of what HCFA would have paid for those services under the fee-for-service system. We believe that a more effective way to ensure that outcome is to use the presumptive limit for HCPPs that furnish inpatient hospital services, and to use reasonable charges to define reasonable costs for other HCPPs.

IV. Methodology for Calculating Payments in Excess of the Presumptive Limit (Additional Payments)

Note: We believe that HMOs, CMPs, and HCPPs will be particularly interested in this methodology, and we are receptive to suggestions for alternative methodologies. Any proposed alternatives must specifically address how that methodology would ensure that HCFA pays no more for care to beneficiaries enrolled in these organizations than it would pay for their care if the beneficiaries were not so enrolled.

The methodology discussed below applies only to HMOs and CMPs, and to HCPPs that furnish inpatient hospital services. It pertains only to determining whether we can make additional payments based on special needs of Medicare enrollees. We use the term "sicker than average enrollment" to mean enrollees who require a volume and intensity of services that exceeds the average for Medicare beneficiaries of the same age and sex, living in the same geographic area.

A. Background

1. The Act

Section 1861(v)(1)(A) of the Act authorizes us to establish limits on costs for entities paid on a reasonable cost basis so that the Medicare payment does not exceed the "estimates of the costs necessary in the efficient delivery of needed health services". Section 1861(v)(1)(A) also gives us flexibility for setting those limits.

2. The Courts

The courts have indicated that absolute limits on costs are not acceptable, but, to date, appear to approve of presumptive limits. A presumptive limit means that the organization may obtain additional payments, that is, payments above that limit, if it can document that such payments are justified, using reasonable

criteria to estimate payable amounts in excess of the limits.

3. Proposal

We are proposing to establish 100 percent of the weighted average of the AAPCC as the presumptive limit for HMOs and CMPs, and for HCPPs that furnish inpatient hospital services. We consider the presumptive limit to be a proxy for whether or not the HMO, CMP, or HCPP is delivering needed health services efficiently. In other words, we consider an organization with total costs below the presumptive limit to be operating more efficiently than Medicare operates under the fee-for-service system. Conversely, we consider organization with costs above the presumptive limit to be operating less efficiently.

B. Methodology

The methodology discussed below is based on the fact that, generally in health care financing, a small number of high-cost cases, called "outliers," account for a large percentage of outlays. For example, in 1989, in the Medicare program, about 90 percent of persons served accounted for only 37 percent of the outlays, while the remaining 10 percent of persons served required 63 percent of the outlays.

In order to estimate what percentage, if any, of an organization's costs is attributable to inefficiency, we would compare the average annual per capita cost for the organization's non-outliers with the average annual per capita cost for non-outliers under the fee-for-service system. If the organization's average for non-outliers were less than the fee-for-service average, we would consider the organization to be operating more efficiently than Medicare operates under the fee-for-service system. We would make the assumption that, since the organization operates efficiently for its non-outliers (who constitute the majority of its enrollment) its costs in excess of the presumptive limit are attributable to a sicker than average enrollment. We would pay any excess costs that are otherwise allowable.

However, if the organization's average for non-outliers exceeded the fee-for-service average, we would consider it to be operating less efficiently than Medicare operates under the fee-for-service system. If, for example, the organization's average exceeded the fee-for-service average by 3 percent, we would consider that the organization's services cost 3 percent more than Medicare would have paid for those services under the fee-for-service system. We would assess a presumptive overpayment of 3 percent on the organization's total costs for services to Medicare enrollees, that is, costs for both outliers and non-outliers.

C. Application and Example

The methodology consists of 3 stages:

Stage 1. Determine whether the organization's total costs exceed the presumptive limit.

Example of Stage 1: (a) Determine the presumptive limit on the organization's costs for Medicare enrollees, which is 100 percent of the weighted average of the AAPCC's of each class of Medicare beneficiaries.

Presumptive limit: $4,230,000.

b. Determine the organization's total costs for its Medicare enrollees, that is, part A and part B costs, both in-plan and out-of-plan, and administrative costs.

Audited Cost Report Costs[1] ...	$1,500,000
In-plan hospital & SNF costs ..	2,700,000
Out-of-plan costs, parts A & B	800,000
Total Costs	5,000,000

[1] Costs on the cost report currently include costs for in-plan part B services (except hospital outpatient department services), costs for part A services other than hospital and SNF, and administrative costs.

c. Determine whether the organization's total costs exceed the presumptive limit.

Total costs	$5,000,000
Presumptive limit	(4,230,000)
Presumptive overpayment ...	770,000

- If the costs were equal to, or less than, the presumptive limit, HCFA would pay the total allowable costs for the organization's Medicare enrollees.
- Since there is a presumptive overpayment, the process would continue to Stage 2. (HCFA would give the organization written notice and opportunity to respond in accordance with § 417.532(a)(6) of the proposed rules.)

To carry out Stage 2, we need the annual outlier cost threshold, which HCFA establishes on a national or regional basis, to distinguish "outlier costs" from "non-outlier costs." For example, if the threshold is $39,000, the costs for all beneficiaries whose costs exceed $39,000 would be outlier costs, and the costs for all beneficiaries whose annual costs are equal to, or less than, $39,000 would be considered "non-outlier costs." HCFA's determination of the outlier threshold is discussed under section VI of this preamble. The organization would determine its costs for outliers using HCFA's payment methods such as fee schedules, reasonable charge limits, and reasonable cost limits, as appropriate.

Stage 2. Determine whether the average annual per capita non-outlier cost for the organization's Medicare enrollees exceeds the average non-outlier costs for the fee-for-service beneficiaries in the organization's service area.

a. If the average for the organization's enrollees is equal to, or less than, the average for the fee-for-service beneficiaries, there is no final overpayment. As noted above, the presumption is that the organization is also efficient in furnishing services to outlier enrollees.

b. If the average cost for the organization's non-outlier enrollees exceeds the average cost for the fee-for-service beneficiaries, the process continues to stage 3.

Stage 3. Determine how much of the organization's presumptive overpayment is attributable to sicker than average enrollment, and how much to inefficiency.

Examples of stages 2 and 3.

Stage 2:

	Fee-for-service beneficiaries	Plan enrollees
Total costs	$100,000,000	$5,000,000
Outlier costs	(25,000,000)	(1,500,000)
Non-outlier costs	75,000,000	3,500,000
Number of non-outliers	30,000	1,375
Average annual cost for non-outliers, weighted by the AAPCC factors: age, sex, institutional status, Medicaid status, and geographic area.	2,500	2,545

The average non-outlier cost for the organization's Medicare enrollees exceeds the average non-outlier costs for fee-for-service beneficiaries by $45.

Stage 3: Divide the excess average cost by the average claimed costs to determine the inefficiency factor:

$$\frac{\$45}{\$2545} = 1.77 \text{ percent inefficiency factor}$$

The inefficiency factor represents HCFA's estimate of the percentage by which the organization's costs exceeded HCFA's estimate of the costs for all the organization's Medicare enrollees if HCFA had paid for their care under the fee-for-service system. Determine the final overclaim amount by applying the 1.77 percent "inefficiency factor" to the total costs attributable to the organization's Medicare enrollees, as follows:

Total Costs	$5,000,000
Inefficiency Factor	× .0177
Final Overclaim	$88,500

If the organization chooses to submit additional documentation in support of higher additional payments after application of this methodology, the final overclaim amount may be adjusted.

In this example of a presumptive overpayment of $770,000, the final overclaim or disallowance is $88,500. The organization would receive $681,500 ($770,000 minus $88,500) in additional payments because of the exceptions process. In other words, HCFA would estimate that $681,500 of the presumptive overpayment is attributable to a sicker than average enrollment and $88,500 is attributable to inefficiency. HCFA would pay the amount attributable to a sicker than average enrollment.

V. Options Considered

A. Options Considered for the Presumptive Limit

Our primary goal in setting limits for coordinated care organizations is to ensure that we do not pay more for Medicare beneficiaries enrolled in these organizations than we would pay if the beneficiaries were not so enrolled. The AAPCC is an estimate of the average per capita cost for Medicare beneficiaries who receive their Medicare-covered services in the fee-for-service sector, that is, Medicare beneficiaries who are not enrolled in HMOs, CMPs, or HCPPs. Because it is a per capita estimate based on 100% of the costs for these beneficiaries in a geographic area, we consider it to be an excellent basis for estimating the aggregate amount that HCFA would have paid for HMO, CMP, and HCPP enrollees if they had not been so enrolled.

HCFA has used the AAPCC in connection with cost limits or other controls for prepaid health care organizations as follows:

1. Before 1985, under a demonstration, as the basis for payment to risk HMOs.
2. Beginning in 1985, as the basis for payment to risk HMOs and CMPs.
3. As the basis for calculating payments for an earlier model of risk HMO that was repealed when the current HMO and CMP risk program was enacted.
4. Before 1986, as a guideline for cost HMOs.
5. As the basis for a proposed absolute cost limit for cost HMOs and CMPs promulgated to be effective in 1986, but never implemented.

In HCFA Ruling 89–2, we indicated that the courts "have construed the authority to set cost limits under section 1861(v)(1)(A) [of the Act] to support generalized cost limits applied on a presumptive basis."

We considered two options. First, we considered using 100 percent of the AAPCC as a guideline, as we had done before promulgation of the 1985 regulation establishing the AAPCC as an absolute limit. Second, we considered using 100% of the AAPCC as a presumptive limit.

Application of a guideline simply triggers a closer scrutiny of the claimed costs. Use of a presumptive limit with an exceptions process provides a clearer standard for determining the amount of payment. We expect that a presumptive limit will provide incentives for more efficient operation, because overpayments will be determined unless the organization can document that additional payments are appropriate either (1) because of a sicker than average enrollment or (2) because of extraordinary circumstances. For this reason, we believe the use of a presumptive limit better serves the intent, articulated in section 1861(v)(1)(A) of the Act, of using Medicare monies only to pay for the efficient delivery of needed health services.

B. Options Considered for Methodology for Calculating Exceptions for a Sicker Than Average Enrollment

We considered four options for a methodology to use in estimating what portion, if any, of an organization's presumptive overpayment was attributable to inefficiency. Two of the options addressed only part B costs, and administrative costs. The other two approaches addressed the full range of costs for Medicare enrollees.

First, we considered setting absolute limits for the organization's administrative and part B costs based on fee-for-service payments. The final overpayment or disallowance would have been the amount by which (1) the organization's aggregate payments for part B services exceeded Medicare's aggregate payments for the same services and (2) the organization's relative administrative costs exceeded Medicare's relative administrative costs. This approach did not address our concerns about the inappropriate utilization of part A services and would not have recognized the efficiencies that can be achieved by using outpatient services rather than inpatient services, as most prepaid health care organizations do.

Second, we considered calculating averages of volume and price for part B services, comparing the organization's average price and volume with the Medicare fee-for-service average. The final overpayment or disallowance would have been based on whether the organization exceeded Medicare averages for price, or volume, or both. The disallowance for overpayments on the price side would have been the amount by which the organization's average price exceeded Medicare's fee-for-service average. The disallowance for overpayments on the volume side would have been in the form of reductions to allowable administrative costs, using the rationale that we should not pay 100% of administrative costs to an organization that is not managing care, as evidenced by its higher volume.

Both of these options would have required organizations to document all services on an individual basis. However, they focused only on part B and administrative costs. They did not take into consideration the entire range of services. We believe that HMOs and CMPs and HCPPs that furnish inpatient hospital services should be held accountable for all of the Medicare-covered services received by their Medicare enrollees, whether furnished by the plan or obtained from other sources. For this reason, we considered the two following options, both of which use an outlier-based approach. The first option looked only at the organization's outlier costs in relation to outlier costs in the comparable fee-for-service area. We realized that we could not limit our review to outlier costs because outliers are, by definition, not representative of the relevant costs by which HCFA may judge whether a prepaid health care organization is efficient or inefficient in comparison with the fee-for-service sector overall.

The second option was the one described in this preamble. We concluded it was the best approach for three reasons.

- When compared to the other outlier approach, it was more in consonance with the statutory directive to make estimates of the costs for the efficient provision of needed health services.
- A calculation based on outliers imposes manageable administrative requirements on the organization because outliers comprise a small percentage of enrollees and because most coordinated care organizations must track costs for outliers in order to receive payments from their reinsurers.
- Unlike the first two options, this approach examines all of the Medicare services and costs and thus holds the

organization accountable for all the Medicare-covered services received by its enrollees.

C. Options Considered for HCPPs That do not Furnish Inpatient Hospital Services

Our primary goal in setting limits for prepaid health care organizations is to ensure that we do not pay more for Medicare beneficiaries enrolled in these organizations than we would pay if the beneficiaries were not so enrolled. We consider Medicare fee-for-service payment amounts for individual services to be the most appropriate proxy for the amount that Medicare would have paid for a group of HCPP enrollees if those beneficiaries were not so enrolled. As discussed above, we also consider the AAPCC, which is derived from Medicare fee-for-service payment amounts, to be an appropriate estimate of total Medicare fee-for-service costs for a group of Medicare beneficiaries. In addressing changes to the regulations governing allowable payments to these HCPPs, we considered three options.

First, we considered making only technical changes to the current regulations by updating them to reflect the movement in fee-for-service Medicare away from reasonable charge-based payment to fee schedules for physician and lab services and durable medical equipment. Under this option, we would have retained the effective incentives provisions. This approach was not consistent with our primary goal.

Second, we considered using the part B AAPCC plus an appropriate amount for administrative costs. We discarded this option because it might constitute an incentive for these HCPPs to allow or encourage their Medicare enrollees to seek part A services for medical conditions for which part B services would be equally or even more appropriate, but might bring the HCPPs' incurred costs above the part B AAPCC.

Third, we considered using aggregate Medicare payment levels for individual part B services to define "reasonable cost" for these HCPPs. We selected this approach because we believe it is consistent with our primary goal. We also considered whether it would be feasible to specify an appropriate volume of services. We concluded that, at this time, we do not have sufficient data to determine appropriate volume for part B services for HCPP enrollees, so a volume formula is not included in this proposed rule.

VI. Outlier Threshold

In setting the amount of the outlier threshold, we are concerned that it include an adequate number of high cost beneficiaries, without including such a substantial proportion of costs that its utility as a measure of efficient behavior is limited. Because in general in health care financing a small number of individuals account for a large percentage of outlays, finding an appropriate balance between the percentage of total costs represented by the outlier threshold and the percentage of beneficiaries represented is difficult. There is a range of reasonable choices.

Using 1989 data summarized in the table below, we examined the relationship between the cumulative percentage of persons served and the cumulative percentage of program payments to determine a reasonable outlier threshold. At the low end for a potential outlier threshold, we believe a figure that accounts for about 2 percent of beneficiaries and about 25 percent of outlays is reasonable. At the high end, we believe a figure that accounts for about 0.3 percent of beneficiaries and about 7 percent of total outlays is reasonable. The approximate mid-point between these two ends is the 1 percent of beneficiaries who account for about 16 percent of total payments.

We are proposing to set the outlier threshold at the lowest annual per capita amount that we project to account for the 1 percent of Medicare beneficiaries with the highest annual per capita outlays. In 1989, that amount was about $39,000.

For 1993, the annual per capita amount that we project to account for the 1 percent of Medicare beneficiaries with the highest annual per capita outlays is $55,000. Outlays on behalf of this group of Medicare beneficiaries would account for about 16 percent of total outlays.

1989 DATA

Part A and Part B payments per person served	Cumulative percent person served	Cumulative percent program payments
$5,000	82.4	21.6
10,000	90.4	37.9
20,000	96.2	61.7
30,000	98.2	76.2
39,000	99.0	84.0
40,000	99.1	84.9
50,000	99.5	90.0
60,000	99.7	93.0
70,000	99.8	94.7
100,000	99.9	97.6

Using a set percentage of beneficiaries, for example, 1 percent as we are proposing here, instead of a set dollar figure eliminates the need to determine an inflation factor. The amount of the outlier threshold would increase by the change in the annual per capita amount that we project to account for the 1 percent of Medicare beneficiaries with the highest annual per capita outlays.

VII. Other Proposed Changes

A. Full Reporting

1. Background

Most HMOs and CMPs paid on a cost basis have elected under section 1876(h)(2) of the Act (as implemented by § 417.532(c) of the regulations) to allow HCFA to process all bills for hospital and skilled nursing facility services furnished to their Medicare enrollees. Under this election, HCFA simply performs a service (bill processing and payment) for the HMO or CMP. The HMO or CMP authorizes the services and retains responsibility for coordination of those services with other services it furnishes to its Medicare enrollees.

Section 417.576(b)(2)(i) implements the requirement of section 1876(h)(4)(A) of the Act that the HMO or CMP report its "per capita incurred cost". However, cost HMOs and CMPs have not been reporting the part A costs paid by the Medicare intermediaries. For those services, they currently report only the deductibles and coinsurance. When the regulations that would have imposed an absolute limit were developed, the cost report was revised to include the part A costs paid by Medicare intermediaries. However, because the absolute limit policy was never implemented, the revised cost report instructions were not implemented either.

We propose to amend § 417.576 to make clear that the incurred per capita costs in the cost report must include the costs of hospital and skilled nursing facility services paid by Medicare intermediaries at the election of the HMO or CMP.

B. Technical Amendments

1. In § 417.1, we would add a definition of "furnished", to make clear that in part 417, the term means made available by the HMO, CMP, or HCPP either directly or under arrangements it makes with other entities.

2. In § 417.800, we would revise paragraph (c)(2)(ii) to conform to the statutory provision and long-standing practice, under which the following are deducted from the reasonable cost incurred by the HCPP:

- An amount equal to 20 percent of that cost, representing the Medicare coinsurance.
- The actuarial equivalent of the Medicare part B deductible.

3. We also propose to remove, as outdated, the following sections and

paragraphs that were applicable to contract periods that began before January 1, 1986, and to realign the designation schemes as necessary:

- (b) Paragraph (b) of § 417.546 (Physicians' services and other part B supplier services furnished under arrangements) and the Editorial note at the end of the section.
- Paragraph (d)(2) of § 417.560 (Apportionment: part B physician and supplier services).
- All of § 417.562 (Weighing of direct services furnished by physicians and other practitioners).

VIII. Other Required Information

A. Paperwork Reduction Act

Section 417.532(b) (with respect to HMOs and CMPs) and § 417.800(c) (with respect to HCPPs) require those organizations to submit the information necessary for HCFA to determine whether payment in excess of the presumptive limit is appropriate, because of the health condition of the organization's Medicare enrollees, or because of extraordinary occurrences. The time needed to prepare the information would depend on the particular circumstances but would not, we believe, exceed 8 hours per organization. Section 417.576 requires HMOs and CMPs to submit certified cost reports as a basis for final settlement. We estimate that preparation of the full cost report will require 100 hours.

If you comment on the information collection requirements, please send a copy of those comments directly to:

Office of Information and Regulatory Affairs, Office of Management and Budget, room 3002, New Executive Office Bldg., Washington, DC 20503, Attention: Allison Herron Eydt, Desk Officer for HCFA.

B. Response to Comments

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

IX. Regulatory Impact Statement and Flexibility Analysis

This proposed rule would establish a presumptive limit on payment to HMOs, CMPs, and HCPPs. We anticipate the following savings in Medicare expenditures for the next 5 fiscal years as a result of this proposed policy:

Medicare Program Savings

[In millions of dollars]

Fiscal year:	
1994	14
1995	15
1996	17
1997	19
1998	21

This rule would also require HMOs and CMPs to include in their cost reports the costs of inpatient hospital services and SNF care furnished to their Medicare enrollees, for which payment is made by Medicare intermediaries directly to the providers.

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all HMOs, CMPs, and HCPPs are considered to be small entities. Individuals are not considered small entities under the RFA.

Since this proposed rule represents a significant change in the application of cost limits for cost of HMOs, CMPs, and HCPPs, and would also require HMOs and CMPs to make minor changes in the reporting of their per capita costs, we are providing the following voluntary regulatory flexibility analysis.

1. Effect of the Presumptive Limit on Cost HMOs and CMPs and on HCPPs That Provide Inpatient Hospital Services

We believe that the costs of services furnished by these prepaid health care organizations should not exceed the costs for services furnished to an actuarially similar group of Medicare beneficiaries whose services are paid for under the Medicare fee-for-service payment systems. Excess cost can often be avoided by reducing unnecessary utilization and by electing effective but less expensive treatment modalities.

There are approximately 55 plans (22 HMOs and CMPs, and an estimated 33 HCPPs) that would be subject to the proposed presumptive limit. Program data from 1989, the most recent year for which we have audited cost report data, indicate that, in 1989, 38 percent of these organizations would have exceeded a presumptive limit of 100 percent of the AAPCC, half of them by 0 to 10 percent. These organizations had, at that time, little incentive to monitor costs. This proposed rule makes two changes that should encourage them to pay more attention to costs incurred on behalf of Medicare enrollees:

- The imposition of the presumptive limit on all these organizations; and
- The elimination of the effective incentives policy that had remained in effect for HCPPs.

We believe that many of these organizations would respond promptly to these incentives and reduce expenditures. Consequently, we anticipate that, in the first year of implementation of these proposed rules, only 25 percent of the HMOs, CMPs, and HCPPs would exceed the presumptive limit, that is, for only 25 percent would all the costs incurred on behalf of their Medicare enrollees exceed 100 percent of the AAPCC. In subsequent years, we expect that this percentage would decline, as more of these organizations modify their practices in response to the incentives.

There are two basic methods for reducing costs. First, the organizations can implement utilization controls, particularly for inpatient hospital care. Currently these organizations are not reporting inpatient hospital and SNF costs and hence have no reason to opt for lower-cost alternatives. However, the proposed full reporting requirement would change this. HMOs and CMPs would be required to report all services furnished to Medicare beneficiaries. (See section B.3. of this voluntary regulatory flexibility analysis.)

Second, the organizations can review claims more aggressively to identify and remove duplicate claims that result in payment both from the organizations and the Medicare carrier to a physician or other supplier for the same service. Although organizations are currently required to identify duplicate claims, they have no incentive to do a thorough job. Although we do not have data on what percentage of total costs is represented by duplicate payments, we believe that the elimination of those payments could, in many cases, bring costs below the presumptive limit.

The proposed presumptive limit rules would provide exceptions of two kinds. In the first place, HCFA could exempt small organizations (those with fewer than 500 Medicare enrollees) from the presumptive cost limit for up to two consecutive years. The rationale is that a small enrollment is less likely (than a large enrollment) to be representative of the general Medicare population in the area served by the organization. The small enrollment could be more healthy or less healthy, and if less healthy, could lead to costs in excess of the limit.

In the second place, organizations that exceed the presumptive limit have the opportunity to document that their Medicare enrollees have health care needs that exceed those of the average mix of Medicare beneficiaries who reside in their service areas but, since

they are not enrollees, have their services paid for under the Medicare fee-for-service payment systems. An HMO, CMP, or HCPP that exceeded the presumptive limit would have the option of providing to HCFA data to document that its costs in excess of the limit are justified because of the greater health care needs of its Medicare enrollees. The full reporting requirement would assist HMOs and CMPs in this endeavor.

The organizations could also document unusual circumstances beyond their control (such as fire, flood, earthquake, strike) that had significant impact on their costs.

Upon documentation and verification by HCFA, the organization would receive payment for costs in excess of the limit if it could show that the excess costs were "reasonable."

Some organizations may feel disadvantaged because they are located in areas where there is a relatively low AAPCC. However, in all geographic areas, the basis for the AAPCC is precise data on Medicare costs for Medicare beneficiaries who are not enrolled in HMOs, CMPs, or HCPPs. In areas where the AAPCC is relatively low because the delivery of services under the fee-for-services systems is very efficient, prepaid health care organizations are still expected to be at least as efficient as the fee-for-service payment system. Only if the group of Medicare enrollees is less healthy than the Medicare average in the area could costs in excess of the presumptive limit be justified. In other words, a managed care system, as represented by prepaid health care organizations, is expected to be at least as efficient as the fee-for-service system.

This proposed rule could have a positive effect on the revenues of organizations that meet the criteria for payments in excess of the presumptive limit; organizations that do not meet those criteria may face reduced revenues. We estimate that the loss of revenue for HMOs, CMPs, and HCPPs that exceed the presumptive limit would be approximately 5 percent on the average. However, we believe that many of these organizations will change their practices in ways that will reduce their costs to correspond to the reduction in revenues. This would achieve the purpose of the proposed rule, which is to protect the Medicare program against excessive payments by giving the affected organizations an incentive to hold their costs to reasonable levels.

HCPPs that furnish hospital services are subject to the presumptive limit, which applies to all services, part B as well as part A. For these HCPPs, therefore, the removal of the "effective incentives" exception (under which these HCPPs were exempt from reasonable charge limits for physicians' services) does not have any additional impact.

2. Effect of Cost-Reporting Changes on HMOs, CMPs, and HCPPs

The change in reporting per capita costs (referred to as full reporting) would affect all 26 cost HMOs and CMPs. HCPPs that furnish inpatient hospital care would also have to monitor part A costs. As explained earlier in this regulatory flexibility analysis, inpatient hospital and SNF costs are not being reported. This may constitute an incentive to use more costly inpatient (part A) services, when outpatient (part B) services may be as, or even more appropriate. Under this proposed rule, HMOs and CMPs and the specified HCPPs would be required to report or monitor these costs. Although full reporting may cause a slight decrease in Medicare payments to HMOs and CMPs, accounting for these costs should be the first step in establishing utilization controls and determining the most appropriate use of resources for the least cost.

The time needed for compliance with this requirement would depend on what systems the plan already has in place, how much modification, if any, they require, and, for an HCPP, the number of particular part B services the HCPP furnishes to its Medicare enrollees.

3. Effect of Increased Reporting Requirements on HCPPs that do not Furnish Inpatient Hospital Services

For HCPPs that do not furnish inpatient hospital services, the elimination of the effective incentives policy requires major changes. As noted above, under this policy, HCPPs were in some cases exempt from reasonable charge limits and therefore were not required to document what they paid for individual services. Under the proposed rule, these HCPPs would be required to document what they paid for services using the Medicare coding systems and to determine the Medicare payment level for all services. This would require changed procedures for these HCPPs, most of which are currently exempt from such documentation either because they provide services on other than a fee-for-service basis, or because they contract with physician groups that use effective incentives and thus are subject to the prudent buyer standard of current § 417.802(b) of the rules. Since the information is readily available from the Medicare contractor, we estimate that not more than 40 hours would be required to include it in the annual cost report. However, for a staff or group plan that does not pay its physicians on a fee-for-service basis, the conversion may be more time-consuming.

4. Effect on Physicians

Physicians would be affected by the presumptive limit, if an HMO, CMP, or HCPP—

- Terminates its contract with HCFA; or
- In order to keep costs within the presumptive limit—
- Reduces its payments to physicians;
- Controls utilization so that the fewer services are furnished; or
- Reduces the number of physicians on staff or under contract.

5. Effect on Medicare Enrollees

Medicare enrollees could be affected if the organization in which they are enrolled decides, because its costs exceed the presumptive limit, not to contract with Medicare. However, many HMOs and CMPs entered into contracts or retained contracts when the AAPCC was to be applied as an absolute limit, so it does not seem likely this proposed regulation alone would lead them to drop their cost contracts.

6. Effect on Medicare Intermediaries and Carriers

If an organization exceeds the presumptive limit and seeks payment under the special circumstances exception, intermediaries and carriers might be required to provide information necessary to verify a plan's documentation of special circumstances. However, this would not significantly affect intermediary or carrier workload and would not require renegotiation of their contracts. If organizations terminate their cost contracts, carriers (and intermediaries for home health claims) would have to process claims for those Medicare enrollees who do not enroll in another prepaid health care organization.

7. Conclusion

The chief objective of the presumptive limit is to ensure that HMOs, CMPs, and HCPPs are paid no more for services than would have been paid under the Medicare fee-for-service payment systems. We believe that this proposed rule would move the Medicare program toward this objective by encouraging HMOs, CMPs, and HCPPs to operate more efficiently without impeding reasonable and necessary service to Medicare enrollees.

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any rule that may have a significant impact on the operations of

a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

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

In accordance with the provisions of Executive Order 12866 this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 417

Administrative practice and procedure, Health maintenance organizations (HMOs), Medicare, and Reporting and record keeping requirements.

42 CFR part 417 would be amended as set forth below:

1. The authority citation for part 417 continues to read as follows:

Authority: Secs. 1102, 1833(a)(1)(A), 1861(s)(2)(H), 1866(a), 1871, 1874, and 1876 of the Social Security Act (42 U.S.C. 1302, 1395l(a)(1)(A), 1395x(s)(2)(H), 1395cc(a), 1395hh, 1395kk, and 1395mm); sec. 114(c) of Pub. L. 97–248 (42 U.S.C. 1395mm note); 31 U.S.C. 9701; and secs. 215 and 1301 through 1318 of the Public Health Service Act (42 U.S.C. 216 and 300e through 300e–17), unless otherwise noted.

2. In § 417.1, the following definition is added in alphabetical order:

§ 417.1 Definitions.

* * * * *

Furnished, when used in connection with prepaid health care services, means services that are made available to an enrollee either directly by, or under arrangements made by, the HMO, CMP, or HCPP.

* * * * *

3. In § 417.494, revise paragraph (b)(1) introductory text, revise paragraph (b)(1)(iv), and add a new paragraph (b)(1)(v), to read as follows:

§ 417.494 Modification or termination of contract.

* * * * *

(b) *Termination by HCFA.* (1) HCFA may terminate a Medicare contract with an HMO or CMP for any of the following reasons: * * *

(iv) HCFA determines that the HMO or CMP no longer meets the requirements of section 1876 of the Act for entering into a Medicare contract.

(v) The HMO or CMP has had, for two consecutive years, a final overclaim as determined under § 417.532.

* * * * *

4. Throughout subpart O, except in § 417.532(a)(2), all forms of the verb "reimburse" are changed to the corresponding forms of the verb "pay", "reimbursement" is changed to "payment", and "reimbursable" is changed to "payable".

5. In § 417.532, paragraphs (a) through (d) and paragraph (e) introductory text are revised to read as follows:

§ 417.532 General considerations.

(a) *Conditions and criteria for payment*—(1) *Basic criteria.* The costs incurred by an HMO or CMP to furnish services covered by Medicare are payable if they are—

(i) Proper and necessary;

(ii) Reasonable in amount; and

(iii) Except as provided in § 417.550, appropriately apportioned among the Medicare enrollees, other enrollees, and nonenrolled patients of the HMO or CMP.

(2) *Cost reimbursement principles.* In determining fair and equitable payment to the HMO or CMP, HCFA generally applies the cost reimbursement principles set forth in § 413.5 of this chapter.

(b) *Presumptive limit*—(1) *Applicability.* The provisions of this paragraph apply to cost HMOs and CMPs and to HCPPs that furnish any inpatient services in general, acute care, short stay hospitals (as distinguished from psychiatric, chronic, or rehabilitation hospitals that are long-stay hospitals). In this paragraph, references to HMOs and CMPs must be read as applicable also to HCPPs that furnish inpatient services in acute care hospitals.

(2) *Criteria for reasonableness.* In judging whether costs are reasonable, HCFA applies, as a presumptive limit on the total amount payable on behalf of Medicare enrollees, the weighted average of the AAPCCs for those enrollees.

(3) *Terminology.* As used in this paragraph—(i) *Overclaim* means a claim for costs in excess of the presumptive limit; and

(ii) *Final overclaim* means that portion of an overclaim that the HMO or CMP cannot document as "reasonable" under paragraph (b)(4) of this section.

(4) *Exceptions to presumptive limit.* HCFA may accept and pay claims for costs that exceed the presumptive limit if the HMO or CMP documents that those excess costs are reasonable because of either of the following circumstances:

(i) The Medicare enrollees of the HMO or CMP have special needs and require a volume and intensity of services that exceed the average for Medicare beneficiaries of the same age and sex living in the same geographical area.

(ii) There were extraordinary occurrences beyond the control of the HMO or CMP including, but not limited to, strikes, fire, earthquake, flood, or similar unusual happenings that had substantial cost effects.

(5) *Conditions for additional payments.* If an HMO or CMP seeks additional payments as an exception to the presumptive limit, it must comply with HCFA instructions for the exception process described in paragraphs (a)(6) through (a)(10) of this section.

(6) *Response to first notice*—(i) *Timing of response.* Within 60 days after receipt of a first notice indicating that its costs exceed the presumptive limit, the HMO or CMP must submit the required information to HCFA.

(ii) *Required information.* The required information is any information that HCFA identifies as necessary for it to evaluate whether the HMO or CMP qualifies for an exception to the presumptive limit. It may include, but is not limited to, data on costs of services furnished to individual enrollees, documenting the volume and intensity of services required by the Medicare enrollees.

(iii) *Consequences of failure to provide required information.* If the HMO or CMP fails to submit the information requested by HCFA, the HMO or CMP forgoes the option of seeking additional payments, and is subject to the final adjustment procedures of § 417.576(c).

(7) *Determination and notice of determination.* If the HMO or CMP submits the information requested by HCFA, HCFA considers that information, determines whether the HMO or CMP meets the conditions for additional payments, and gives the HMO or CMP notice of that determination.

(8) *Response to notice of adverse determination.* (i) If HCFA's determination under paragraph (a)(7) of this section does not provide for additional payments, or provides for them in amounts that the HMO or CMP considers to be less than the special needs of its Medicare enrollees justify, the HMO or CMP may submit additional materials to support its position that its costs in excess of the presumptive limit are the result of one of the circumstances specified in paragraph (b)(4) of this section, or that the special

needs specified in that paragraph justify larger additional payments.

(ii) The HMO or CMP must submit the additional materials within 60 days of receipt of the notice of adverse determination.

(9) *Verification.* All information submitted by HMOs and CMPs seeking additional payments is subject to verification by HCFA or its authorized representatives. HCFA may seek verification from sources such as Medicare intermediaries or carriers and State and local agencies. For example, the local chapter of the American Red Cross might be able to confirm the impact of a natural disaster.

(10) *Determination and notice of final overclaim.* HCFA determines whether there is a final overclaim and gives the HMO or CMP written notice of that determination as follows:

(i) After the notice of presumptive overclaim, if the HMO or CMP does not timely submit required information under paragraph (b)(6) of this section.

(ii) After a notice of adverse determination under paragraph (b)(7) of this section, if the HMO or CMP does not submit additional justification under paragraph (b)(8) of this section.

(iii) After consideration of any additional material submitted by the HMO or CMP under paragraph (b)(8) of this section.

(11) *Adjustment for final overclaim.* (i) If the HMO or CMP has a contract with HCFA under subpart L of this part, the rules of § 417.576(c) apply.

(ii) If the HMO or CMP no longer has any contract under subpart L of this part, it must, unless other arrangements are mutually agreed upon, reimburse within 30 days after receipt of the notice, any amounts due HCFA under the final overclaim determination.

(12) *Exemptions based on size.* HCFA may exempt an HMO or CMP from the presumptive limit requirements for up to 2 consecutive years if the HMO or CMP has 500 or fewer Medicare enrollees at the beginning of its contract period. HCFA may establish additional criteria that these HMOs or CMPs must meet in order to qualify for this exception.

(13) *Termination of contact.* As provided in § 417.494(b)(1)(v), HCFA may terminate its Medicare contact with an HMO or CMP that has a final overclaim for 2 consecutive years, on the grounds that the HMO or CMP is inefficient and that it is not prudent for HCFA to contract with inefficient entities.

(c) *Method and amount of payment to the HMO or CMP.* (1) HCFA makes interim per capita payments each month for each Medicare enrollee, equivalent to the interim per capita cost rate determined in accordance with § 417.570.

(2) HCFA adjusts the interim per capita rate as necessary during the contract period and makes final adjustments at the end of the contract period.

(3) In determining the amount due the HMO or CMP, HCFA deducts from the reasonable cost that the HMO or CMP actually incurs for covered services furnished to its Medicare enrollees, an amount equal to the actuarial value of the applicable Medicare part A and part B deductible and coinsurance amounts that would have applied to the covered services for which payment is being made if these enrollees had not enrolled in this or another HMO or CMP.

(d) *Payment for hospital and SNF services*—(1) *Election by the HMO or CMP.* An HMO or CMP must elect, for each provider that furnishes hospital or SNF services to the HMO's or CMP's Medicare enrollees, either direct payment or payment by HCFA.

(2) *Timing, notice, and effect of election.* (i) The HMO or CMP must make the election and notify HCFA in writing before the beginning of its contract period.

(ii) The election is binding for the full contract period.

(e) *Reimbursement by organization.* If the HMO or CMP elects to pay providers directly, as provided in paragraph (d) of this section, it must—

* * * * *

6. In § 417.576, paragraph (b)(2)(i) is revised to read as follows:

§ 417.576 Final settlement.

* * * * *

(b) * * *

(2) * * *

(i) The per capita costs incurred in furnishing covered services to its Medicare enrollees, determined in accordance with § 417.532 through 417.568, and including—

(A) The costs incurred by entities related to the HMO or CMP by common ownership or control; and

(B) The costs of hospital and skilled nursing facility services paid by HCFA's intermediaries under the option provided in § 417.532(d).

* * * * *

7. In § 417.800, the section heading is revised, the definition of *reporting period* is added, and paragraphs (b), (c), and (d) are revised to read as follows:

§ 417.800 Payment to HCPPs: Definitions and basic rules.

(a) *Definitions.*

* * * * *

Reporting period means a period specified by HCFA, for which the HCPP must report its cost and utilization data.

(b) *Qualifying conditions.* An organization wishing to participate as an HCPP must—

(1) Enter into a written agreement with HCFA as specified in § 417.801;

(2) Furnish physicians' services through its employees or under a formal arrangement with a medical group, individual practice association, or individual physicians;

(3) Furnish covered part B services to its Medicare enrollees through institutions, entities, and persons that have qualified under the applicable requirements of title XVIII of the Social Security Act; and

(4) If it does not furnish inpatient hospital services as specified in paragraph (c)(1) of this section, demonstrate to HCFA's satisfaction that it has in place systems that will enable it to use the Medicare billing codes to document on its cost reports the cost of each part B service furnished to its Medicare enrollees.

(c) *Payment of reasonable costs*—(1) *Applicability.* This paragraph applies to HCPPs that do not furnish inpatient services in general acute-care, short-term hospitals. For HCPPs that furnish inpatient services in those hospitals, the rules of § 417.532(b) apply.

(2) *Payment for part B services: Basic rules*—(i) *Cost basis payment.* Except as provided in paragraph (d) of this section, HCFA pays an HCPP on the basis of the reasonable cost it incurs, as specified in subpart O of this part, for the covered part B services furnished to its Medicare enrollees.

(ii) *Deductions.* In determining the amount due an HCPP for covered part B services furnished to its Medicare enrollees, HCFA deducts, from the reasonable cost actually incurred by the HCPP—

(A) An amount equal to 20 percent of the incurred cost, representing the Medicare coinsurance; and

(B) The actuarial value of the part B deductible.

(3) *Criteria for reasonableness.* The costs incurred by the HCPP in furnishing physicians' services and other part B supplier services may be considered reasonable if they—

(i) Are comparable to costs incurred for similar services furnished by similar physicians and other suppliers in the same or a similar location; and

(ii) Do not exceed what HCFA would pay, in the aggregate (as determined under subpart E of part 405 or part 415 of this chapter, as appropriate), for the same services under the fee-for service system.

(4) An HCPP must use the Medicare billing codes to document, on its cost reports, the cost of each part B service furnished to its Medicare enrollees.

(5) *Verification by HCFA.* All information furnished by the HCPP is subject to verification by HCFA or its authorized representatives. Methods of verification may include but are not limited to on-site visits and audits.

(d) *Payment for services furnished by providers.* For part A or part B services furnished to the HCPP's Medicare enrollees by a provider, HCFA pays the provider through the provider's Medicare intermediary.

* * * * *

8. In § 417.801, paragraphs (a), (b)(4) and (b)(5) are revised and paragraph (b)(7) is added; and revise paragraphs (d)(1)(ii) and (d)(1)(iii) and add a paragraph (d)(1)(iv), to read as follows:

§ 417.801 Agreements between HCFA and health care prepayment plans.

(a) *Basic requirement.* In order to participate and receive payment under the Medicare program as an HCPP, an organization must enter into a written agreement with HCFA.

(b) * * *

(4) Not impose any limitations on the acceptance of Medicare enrollees or beneficiaries for care and treatment that it does not impose on all other individuals;

(5) Consider any additional requirements that HCFA finds necessary or desirable for efficient and effective program administration; and

* * * * *

(7) Document the cost of part B services as required by § 417.800(c)(4).

* * * * * *

(d) * * *

(1) * * *

(ii) The HCPP is not in substantial compliance with the provisions of the agreement, applicable HCFA regulations, or applicable provisions of the Medicare law;

(iii) The HCPP undergoes a change of ownership as specified in subpart M of this part; or

(iv) An HCPP that furnishes inpatient hospital care has had a final overclaim, as determined under § 417.532(b), for 2 consecutive years.

* * * * *

9. Section 417.802 is revised to read as follows:

§ 417.802 Other applicable regulations.

(a) *General rule.* The payment rules set forth in §§ 417.530 through 417.550 for cost HMOs and CMPs also apply to HCPPs except as specified in paragraph (b) of this section.

(b) *Exceptions*—(1) § 417.532(d). HCPPs do not have the option of paying providers that furnish inpatient hospital services, SNF services, or part B services to the HCPP's Medicare enrollees. HCFA pays the providers, as indicated in § 417.800(d).

(2) *§ 417.536(1).* Return on equity capital of proprietary providers owned by the HCPP is not an allowable cost.

(3) *§ 417.536(m).* These limitations on payment do not apply to HCPPs. The limitations that do apply are set forth in this subpart.

(4) *§ 417.548.* The rules governing payment for provider services furnished through arrangements do not apply because HCPPs do not pay providers.

(5) *§ 417.550(b)(2).* Payment of reasonable cost for independent certification of cost reports does not apply because HCPPs are not required to have their cost reports independently certified.

§ 417.546 [Amended]

10. In § 417.546, the following changes are made:

a. Paragraph (b) and the Editorial Note are removed.

b. In paragraph (a), the "(a)" designation is removed, and the "(1)" and "(2)" designations are changed to "(a)" and "(b)", respectively.

§ 417.560 [Amended]

11. In § 417.560, the following changes are made:

a. Paragraph (d)(2) is removed.

b. In paragraph (d)(1), the designation "(1)" and the clause "Except as provided in paragraph (d)(2) of this section" are removed, and the word "the", preceding "Medicare share" is revised to "The".

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 28, 1993.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: November 3, 1993.

Donna E. Shalala,

Secretary.

[FR Doc. 94–3610 Filed 2–18–94; 8:45 am]

BILLING CODE 4120–01–P

42 CFR Part 421

[BPO–111–P]

RIN 0938–AG06

Medicare Program; Intermediary and Carrier Functions

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

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would bring certain sections of the regulations concerning Medicare fiscal intermediaries and carriers into conformity with the appropriate sections of Title XVIII of the Social Security Act. The rule would distinguish between those functions which applicable statutory authorities require to be included in agreements with fiscal intermediaries and those functions that, while not required to be performed by organizations that have entered into intermediary agreements with the Secretary pursuant to section 1816 of the Social Security Act, may be included in such agreements at our discretion.

We would require that the intermediary agreements include, as functions, requirements that intermediaries determine proper payment amounts and pay bills. All other functions would be optional. We propose that all functions for carriers are optional. These changes would provide us with the flexibility to transfer functions from one intermediary or carrier to another or to otherwise limit the functions an intermediary or carrier performs when we determine to do so would result in more effective and efficient program administration.

In addition, we propose a number of technical or clarifying revisions concerning carrier payment on a fee schedule basis and the distinction between nonrenewal and termination of intermediary agreements and carrier contracts.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 25, 1994.

ADDRESSES: Mail written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPO–111–P, P.O. Box 26676, Baltimore, MD 21207.

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

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Due to staffing and resource limitations, we cannot accept facsimile (FAX) transmissions. In commenting, please refer to file code BPO–111–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (410) 966–7411).

FOR FURTHER INFORMATION CONTACT: Alan Bromberg, (410) 966–7441

SUPPLEMENTARY INFORMATION:

I. Background

Intermediary Agreements and Carrier Contracts—Under sections 1816(a) and 1842(a) of the Social Security Act (the Act), public or private organizations and agencies may participate in the administration of the Medicare program under agreements or contracts entered into with us (on the Secretary's behalf). These Medicare contractors are known as fiscal intermediaries (section 1816(a) of the Act) and carriers (section 1842(a) of the Act). With certain exceptions, intermediaries perform bill processing and benefit payment functions for part A of the program (Hospital Insurance) and carriers perform claims processing and benefit payment functions for part B of the program (Supplementary Medical Insurance).

Our regulations at 42 CFR 421.100, Intermediary functions, require that the agreement between us and a fiscal intermediary specify the functions the intermediary is to perform. In addition to any items specified by us unique to that intermediary, the regulations require that all intermediaries perform activities relating to Medicare coverage, fiscal management, provider audits, utilization patterns, resolution of cost report disputes, and reconsideration of determinations. In addition, the regulations require that all intermediaries furnish information and reports, undertake dual intermediary responsibilities for service to provider-based Home Health Agencies (HHAs) and provider-based hospices, and comply with all applicable laws and regulations and with any other terms and conditions included in their agreements.

Similarly, our regulations at 42 CFR 421.200, Carrier functions, require that the contract between HCFA and a part B carrier specify the functions the carrier is to perform. In addition to any items specified by us unique to that carrier, the regulations require that all part B carriers perform activities relating to Medicare coverage, payment on a cost basis, payment on a charge basis, fiscal management, provider audits, utilization patterns and hearings to part B beneficiaries. In addition, the regulations require that all carriers furnish information and reports, maintain and make available records, and comply with any other terms and conditions included in their contracts.

For both intermediaries and carriers, our regulations at 42 CFR 421.5, General provisions, state that HCFA has the authority not to renew a part A agreement or a part B Contract when it expires. Our regulations at 42 CFR 421.126, Termination of agreements, provide the Secretary with the authority to terminate fiscal intermediary agreements in certain circumstances, while the regulations at 42 CFR 421.205, Termination by the Secretary, give the Secretary similar authority to terminate carrier contracts.

II. Proposed Changes to the Regulations

As noted earlier, our regulations at § 421.100 for intermediaries and § 421.200 for carriers specify a list of functions that must, at a minimum, be included in all intermediary agreements and carrier contracts. These requirements far exceed those of the statute. Section 1816(a) of the Social Security Act requires only that an intermediary agreement provide for determination of the amount of payments to be made to providers and for the making of such payments. Section 1816(a) permits, but does not require, an intermediary agreement to include provisions for the intermediary to provide consultative services to providers to enable them to establish and maintain fiscal records or to otherwise qualify as providers and, for those providers to which it makes payments, to serve as a channel of communications between us and the providers, to make audits of the records of the providers, and to perform such other functions as are necessary.

We believe that section 1816(a) mandates only that an intermediary agreement include the functions currently required by § 421.100 paragraph (a) (Coverage) and paragraph (b) (Fiscal management) of the regulations. We believe that the other functions (§ 421.100 paragraphs (c) through (i)) that the regulations currently require to be included in all intermediary agreements are not required by statute and the mandatory inclusion of them in all agreements limits our ability to efficiently and effectively administer the Medicare program.

Paragraph (a) of section 1842 of the Act, which pertains to carrier contracts, requires that the contracts must provide for some or all of the functions listed in that paragraph, but does not specify any functions which must be included in a carrier contract. As in the case of intermediary agreements, our experience has been that mandatory inclusion of a long list of functions in all contracts restricts our ability to administer the carrier contracts with optimum efficiency and effectiveness. We believe that the requirements of the regulations for both intermediaries and carriers should be brought into conformity with the statutory requirements. Moreover, we believe that such action would substantially enhance the efficient and effective administration of the Medicare program by giving both HCFA and the contractor community more flexibility in their approaches to the performance of intermediary and carrier functions.

We further believe that intermediaries and carriers would benefit from the ability to enter voluntarily into regional arrangements for the performance of some functions. Intermediaries and carriers have shown interest in entering into agreements with other contractors in their regions to shift the performance of a given function to a single intermediary or carrier that is able to perform the function with the greatest efficiency or at the least cost, while another function might in turn be shifted to a second contractor. For example, one intermediary in a region might perform medical review for the entire region, while another would assume the audit function. Under the existing requirement that all intermediaries and carriers perform all functions, such arrangements are not permitted, except through subcontracts, which must be awarded through the competitive procurement process and which leave the final responsibility for the performance of the function with the original contractor. The proposed change in the regulations would provide the intermediaries and carriers with the ability to enter into arrangements to transfer formally the entire responsibility for performance of a function to other intermediaries and carriers, subject to our approval.

The change would also simplify the process of our paying the intermediary or carrier actually performing the function. Under a subcontracting arrangement, we pay the contractor that subcontracts out the function and that entity, in turn, pays the subcontractor

which is actually doing the work. Under the proposed change, we would make direct payment to the intermediary or carrier performing the function.

Our conclusion is that the existing regulations, which state that intermediary agreements and carrier contracts must include all of the functions cited, are not only inconsistent with applicable statutory authority, but also are too restrictive. They deny us the flexibility to improve the administration of the Medicare program by removing some of the functions from an intermediary's agreement or a carrier's contract and transferring them to another intermediary or carrier where either we or the contractors themselves determine that such action would be more efficient than having every intermediary and carrier perform all functions specified in the regulations.

We are proposing to redesignate § 421.100, Intermediary functions, as § 421.101, Optional intermediary functions. In a new § 421.100, Required intermediary functions, we would specify that all agreements must include the functions of coverage (current content of § 421.100(a)) and fiscal management (current § 421.100(b)). We believe these functions are required to be included in all agreements by section 1816(a) of the Act. In the redesignated § 421.101, Optional intermediary functions, we would indicate that the intermediary agreement may include the functions currently contained in § 421.100(c) through 421.100(i). That is, the cumulative effect of the change would be to separate the two required functions that must be in all intermediary agreements from the remaining functions that may or may not be included.

In § 421.200, Carrier functions, we would change the word "must" to "may" in the first sentence, making all the functions listed for inclusion in carrier contracts optional. This change would reflect section 1842(a) of the Act, which does not list specific functions that must be included.

Our use of the term "optional" does not mean that some functions might not be performed in some jurisdictions. All functions will continue to be performed in all intermediary and carrier jurisdictions. "Optional" in this case means only that HCFA will have the option of determining whether a given function should be performed in a specific jurisdiction by the intermediary or carrier which normally serves that jurisdiction and therefore included in that intermediary's agreement or carrier's contract, or should be performed by some other intermediary or carrier.

In § 421.200, we propose to add payment on a fee schedule basis as a new function which may be performed by carriers. While the original carrier functions included payment on a cost basis and on a charge basis, recent statutory changes and corresponding changes in the regulations have shifted some classes of physician and Medicare suppliers to payment according to fee schedules. However, § 421.200 has never been updated to recognize these changes. Accordingly, the addition of payment on a fee schedule basis as a function which may be included in carrier contracts will bring this section of the regulations into conformity with current statutory provisions for Medicare part B payment.

In addition, 42 CFR 421.5(d) states that, notwithstanding any of the provisions of part 421, HCFA has the authority not to renew an agreement or contract when its term expires. Section 421.126(b) allows the Secretary to terminate intermediary agreements under certain circumstances, while § 421.205 gives the Secretary the authority to terminate carrier contracts at any time for cause. The distinction between the termination and nonrenewal of an agreement or contract is important because the right of an intermediary or carrier to a hearing applicable to terminations does not apply to nonrenewals. Consequently, we are proposing to revise §§ 421.5, 421.126, and 421.205 to make certain that the distinction between nonrenewals and terminations is clear. The proposed changes are not substantive. They are meant to reflect existing statutory and regulatory requirements, as well as HCFA's longstanding policy and practice, as expressed in the standard intermediary agreements and carrier contracts.

The objective of these proposed changes is to make the regulations fully consistent with the relevant statutory authority and to provide, as necessary, clarification of the distinction between contract nonrenewals and terminations. In addition, the change to the regulations concerning mandatory and optional functions will provide us with the flexibility to shift non-mandatory functions among intermediaries and carriers so that the Medicare program may be administered in the most efficient and effective manner possible. We anticipate using the authority granted us by this change sparingly. Any transfer or consolidation of functions will be determined on a case-by-case basis, and, prior to taking action in any specific case, we will closely study the situation to determine whether the benefits to the effective administration of the Medicare program warrant the action. It is not our intent at this time to shift functions from intermediaries and carriers to any entities except other intermediaries and carriers.

III. Response to Comments

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

IV. Collection of Information Requirement

This rule contains no information collection requirements. Consequently, this rule need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

V. Regulatory Impact Statement

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a proposed rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, intermediaries and carriers are not considered to be small entities that will be affected as a result of these regulations. Individuals and States are not included in the definition of a small entity.

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

This proposed rule would potentially affect the 47 Medicare part A intermediaries and 33 part B carriers with agreements or contracts with HCFA to make payments to Medicare providers and beneficiaries for covered services and to perform certain other functions currently described in § 421.100 for intermediaries and § 421.200 for carriers. Under this

proposed rule, we would have authority to redefine intermediary agreement and carrier contract requirements and remove functions from some contractors and transfer them to other contractors. We would also be able to consolidate some tasks under one contractor in regions where several contractors are all performing the same functions simultaneously.

The proposed rule would also add payment on a fee schedule basis as a function which may be included in carrier contracts and distinguishes between contract nonrenewals and terminations. This proposed rule would make the regulations more consistent with the relevant statutory authority and promote the more effective and efficient administration of the Medicare program. Service to beneficiaries and Medicare providers would not be disrupted in the affected regions.

Implementing this proposed rule would not create any additional expenses but should enable the Medicare program to realize savings in administrative costs. At present, we are unable to estimate the potential dollar amount of these savings.

We evaluated the potential impact of these regulations changes on intermediaries and carriers for purposes of determining whether a regulatory flexibility analysis is required. We believe that the effects or the changes will be minimal. Almost all of the present contractors have been performing the functions for a number of years and have developed efficiencies that would argue against our needlessly altering their functions. Therefore, it is not our intention to use the flexibility of this regulation to make wholesale changes.

Consequently, we have determined, and the Secretary certifies, that this proposed rule would not result in a significant impact on a substantial number of small entities. Similarly, the Secretary certifies that it would not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

In accordance with the provisions of Executive Order 12866 this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 421

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR part 421 would be amended as set forth below.

PART 421—INTERMEDIARIES AND CARRIERS

1. The authority citation for part 421 continues to read as follows:

Authority: Secs. 1102, 1815, 1816, 1833, 1834 (a) and (h), 1842, 1861(u), 1871, 1874, and 1875 of the Social Security Act (42 U.S.C. 1302, 1395g, 1395h, 1395l, 1395m (a) and (h), 1395u, 1395x(u), 1395hh, 1395kk, and 1395ll), and 42 U.S.C. 1395b–1.

2. Section 421.5(d) is revised to read as follows:

§ 421.5 General provisions.

* * * * *

(d) *Nonrenewal of agreement or contract.* Notwithstanding any of the provisions of this part, HCFA has the authority to nonrenew an agreement or contract when its term expires. An intermediary or carrier has the authority to nonrenew an agreement or contract when its term expires. The notice and hearing requirements for the termination of an agreement or contract set forth in §§ 421.126, 421.128, and 421.205 do not apply to such nonrenewal of an agreement or contract. An intermediary or carrier also has the authority to nonrenew an agreement or contract when its term expires.

* * * * *

3. Section 421.100 is redesignated as § 421.101 and revised to read as follows:

§ 421.101 Optional intermediary functions.

An agreement between HCFA and an intermediary may specify the optional functions to be performed by the intermediary, which may include, but are not necessarily limited to, the following:

(a) *Provider audits.* The intermediary must audit the records of providers of services as necessary to assure proper payments.

(b) *Utilization patterns.* The intermediary must assist providers to—

(1) Develop procedures relating to utilization practices;

(2) Make studies of the effectiveness of those procedures and recommend methods to improve them;

(3) Evaluate the results of utilization review activity; and

(4) Assist in the application of safeguards against unnecessary utilization of services.

(c) *Resolution of cost report disputes.* The intermediary must establish and maintain procedures approved by HCFA to consider and resolve any disputes that may result from provider dissatisfaction with an intermediary's determinations concerning provider cost reports.

(d) *Reconsideration of determinations.* The intermediary must establish and maintain procedures approved by HCFA for the reconsideration of its determinations to deny payments to an individual or to the provider that furnished services to the individual. The PRO performs reconsideration of cases in which it made a determination subject to reconsideration.

(e) *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.

(f) *Other terms and conditions.* The intermediary must comply with all applicable laws and regulations and with any other terms and conditions included in its agreement.

(g) *Dual intermediary responsibilities.* With respect to the responsibility for service to provider-based HHAs and provider-based hospices, where the HHA or hospice and its parent provider will be served by different intermediaries under § 421.117 of this part, the designated regional intermediary will process bills, make coverage determinations and make payments to the HHAs and hospices. The intermediary serving the parent provider will perform all fiscal functions, including audits and settlement of the Medicare cost reports and the HHA and hospice supplement worksheets.

4. A new § 421.100 is added to subpart B to read as follows:

§ 421.100 Required intermediary functions.

An agreement between HCFA and an intermediary specifies the functions to be performed by the intermediary, which must include the following required functions and may include optional functions listed in § 421.101 of this part and any others agreed to by HCFA. The required functions are:

(a) Coverage. (1) The intermediary ensures that it makes payments only for services that are:

(i) Furnished to Medicare beneficiaries;

(ii) Covered under Medicare; and

(iii) In accordance with PRO determinations when they are services for which the PRO has assumed review responsibility under its contract with HCFA.

(2) The intermediary takes appropriate action to reject or adjust the claim if—

(i) The intermediary or the PRO determines that the services furnished were not reasonable, not medically necessary, or not furnished in the most appropriate setting; or

(ii) The intermediary determines that the claim does not properly reflect the kind and amount of services furnished.

(b) Fiscal management.

The intermediary must receive, disburse, and account for funds in making Medicare payments.

5. Section 421.126 is amended by revising the heading and by adding a new paragraph (c) to read as follows:

§ 421.126 Termination or nonrenewal or agreements.

* * * * *

(c) *Nonrenewal by the intermediary or Secretary.* (1) An intermediary may nonrenew an agreement with the Secretary by giving the Secretary written notice of the intermediary's intention to nonrenew the agreement at least 90 days before the end of the current period of the agreement.

(2) The Secretary may nonrenew an agreement with an intermediary by giving the intermediary written notice of the Secretary's intention to nonrenew the agreement at least 90 days before the end of the current period of the agreement.

(3) In the event that either the Secretary or intermediary gives notice of intention to nonrenew an agreement, the Secretary may extend the agreement for such time and under such conditions as may be specified in the agreement.

(4) The providers served by an intermediary whose contract is not being renewed have the opportunity to nominate another intermediary, in accordance with § 421.104.

(5) The provisions for notice and the opportunity for a hearing in connection with the termination of an intermediary agreement, set forth in paragraph (b)(2) of this section and § 421.128, do not apply to any nonrenewal of an intermediary agreement.

6. Section 421.200 is amended by redesignating paragraphs (d) through (j) as (e) through (k), respectively. The introductory text is revised and a new paragraph (d) is added to read as follows:

§ 421.200 Carrier functions.

A contract between HCFA and a carrier, other than a regional DMEPOS carrier, specifies the functions to be performed by the carrier, which may include, but are not necessarily limited to the following:

* * * * *

(d) *Payment on a fee schedule basis.* If payment is on a fee schedule basis, the carrier must assure that payments are made in accordance with the applicable provisions of parts 414 and 415 of this chapter.

* * * * *

7. Section 421.205 is revised to read as follows:

§ 421.205 Termination or nonrenewal of contracts.

(a) *Termination by the carrier.* A carrier may terminate its contract at any time upon written notice to the Secretary of its intention to terminate. Upon notice to terminate, the contract continues for 180 days after such notice unless the Secretary decides to terminate at an earlier date.

(b) *Termination by the Secretary.* (1) The Secretary may terminate a contract with a carrier at any time if he or she determines that the carrier has failed substantially to carry out any material terms of the contract or has performed its functions in a manner inconsistent with the effective and efficient administration of the Medicare Part B program.

(2) Upon notification of the Secretary's intent to terminate the contract, the carrier may request a hearing within 20 days after the date of the notice of intent to terminate.

(3) The hearing procedures will be those specified in § 421.128(c).

(c) *Nonrenewal by the Secretary or carrier.* (1) A carrier may nonrenew a contract with the Secretary by giving the Secretary written notice of its intention to nonrenew the contract at least 90 days before the end of the current period of the contract.

(2) The Secretary may nonrenew a contract with a carrier by giving the carrier written notice of the Secretary's intention to nonrenew the contract at least 90 days before the end of the current period of the contract.

(3) In the event that either the Secretary or the carrier gives notice of intention to nonrenew a contract for an additional period, the Secretary may extend the contract for such time and under such conditions as may be specified in the contract.

(4) The provisions for notice and the opportunity for a hearing in connection with the termination of a carrier contract, set forth in paragraph (b) of this section and § 421.128, do not apply to the nonrenewal of a carrier contract.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicare Assistance Program; 13.773, Medicare—Hospital Insurance Program; No. 93.774, Medicare-Supplemental Medical Insurance)

Dated: August 5, 1993.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: December 10, 1993.

Donna E. Shalala,

Secretary.

[FR Doc. 94–3608 Filed 02–18–94; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AC10

Endangered and Threatened Wildlife and Plants; Notice of Public Hearing and Reopening of Public Comment Period on Proposed Threatened Status for the Flat-Tailed Horned Lizard

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of public hearing and reopening of public comment period.

SUMMARY: The Fish and Wildlife Service (Service), under the Endangered Species Act of 1973, as amended, gives notice that a public hearing will be held on the proposed threatened status for the flat-tailed horned lizard (*Phrynosoma mcallii*). At the hearing, the Service will allow all interested parties to submit oral or written comments on the proposal. The public comment period is extended to provide the public with more time to comment.

DATES: A public hearing will be held from 6 to 8 p.m. on Tuesday, March 22, 1994, in Imperial, California. The public comment period, which closed on January 28, 1994, will be reopened from February 22, 1994 until April 22, 1994. Any comments received after the closing date may not be considered in the final decision on this proposal.

ADDRESSES: The hearing will be held on Tuesday, March 22, 1994, at Imperial Valley College, 380 Ira Aten Road, Health Sciences Building Assembly Room 2131, Imperial, California.

Written comments and materials may be submitted at the hearing or sent directly to the Field Supervisor, U.S. Fish and Wildlife Service, 2730 Loker Avenue West, Carlsbad, California 92008. Comments and materials received will be available for public inspection during business hours by appointment, at the above address.

FOR FURTHER INFORMATION CONTACT: Gail Kobetich, Field Supervisor, at the address listed above (telephone 619/431–9440).

SUPPLEMENTARY INFORMATION:

Background

The flat-tailed horned lizard (*Phrynosoma mcallii*) is a small iguanid lizard restricted to flats and valleys of the western Sonoran desert. Its maximum length, excluding the tail, is about 8 centimeters (3 inches) (Stebbins 1985). The range of the flat-tailed horned lizard includes portions of Riverside, Imperial and extreme eastern San Diego Counties, California; northeastern Baja California, Mexico; Yuma County, Arizona; and northwestern Sonora, Mexico. An estimated 34 percent of historically occupied flat-tailed horned lizard habitat has been lost. About 95 percent of remaining optimal habitat in California is threatened by one or more factors. Various human activities threaten 36 percent of the remaining habitat in Arizona. The flat-tailed horned lizard and its habitat are also being adversely affected in Mexico, but to a lesser degree. The Service published the proposed rule detailing these factors in the **Federal Register** on November 29, 1993 (58 FR 62629).

The Service has scheduled a public hearing on Tuesday, March 22, 1994, in response to formal requests from the public. Those parties wishing to make a statement for the record should bring a copy of their statement to present to the Service at the start of the hearing. Oral statements may be limited in length, if the number of parties present at the hearing necessitates such a limitation. However, the length of written comments or materials presented at the hearing or mailed to the Service are not limited. Written comments will be given the same weight as oral comments. Written comments may be submitted at the hearing or mailed to the address given in the ADDRESSES section of this notice. The comment period closes on April 22, 1994.

Author

The primary author of this notice is Larry Salata, U.S. Fish and Wildlife Service, Carlsbad Field, Office, 2730 Loker Avenue West, Carlsbad, California, 92008.

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, and Transportation.

Dated: February 14, 1994.

Marvin L. Plenert,

Regional Director, Region 1, U.S. Fish and Wildlife Service.

[FR Doc. 94–3837 Filed 2–18–94; 8:45 am]

BILLING CODE 4310–55–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 649

[I.D. 021494E]

American Lobster Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability of an amendment to a fishery management plan and request for comments.

SUMMARY: NMFS issues this notice that the New England Fishery Management Council has submitted Amendment 5 to the Fishery Management Plan for American Lobster (FMP) for Secretarial review and is requesting comments from the public.

DATES: Written comments will be accepted through April 15, 1994.

ADDRESSES: Send comments to Richard B. Roe, Regional Director, National Marine Fisheries Service, 1 Blackburn Dr., Gloucester, Massachusetts 01930. Clearly mark the outside of the envelope "Comments on Lobster FMP." Copies of the Amendment and Draft Supplemental Environmental Impact Statement are available upon request from Douglas G. Marshall, Executive Director, New England Fishery Management Council, Suntaug Office Park, 5 Broadway, Saugus, Massachusetts 01906.

FOR FURTHER INFORMATION CONTACT: Paul H. Jones, Fishery Policy Analyst, 508–281–9273.

SUPPLEMENTARY INFORMATION: The Magnuson Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*) (Magnuson Act) requires that each regional fishery management council submit any fishery management plan or plan amendment it prepares to the Secretary for review and approval, disapproval, or partial disapproval. The Magnuson Act also requires that the Secretary, upon receiving the plan or amendment, must immediately publish a notice that it is available for public review and comment. The Secretary will consider the public comments in determining whether to approve, disapprove, or partially disapprove the FMP amendment.

Amendment 5 would implement: (1) A freeze of the minimum size limit for lobsters at the current carapace size of 3¼ inches; (2) a five year moratorium on new Federal vessel permits; (3) new permit requirements for vessel operators and dealers; (4) several categories of Federal vessel permits and limits on lobster landings according to a vessel's permit category; (5) the development a stock rebuilding program for all segments of the lobster fishery; (6) mandatory reporting for permitted vessels and dealers; (7) changes to the width of the escape vent size from 6 inches to 5¾ inches; and (8) framework measures to adjust the effort control and other measures in the proposed amendment and provisions in the plan. This amendment also includes a revised definition of overfishing for lobster and a determination, based on this definition, that the resource is overfished. The intent of this amendment is to reduce the fishing mortality rate and rebuild the American lobster resource.

This proposed amendment also included a provision that would allow moratorium qualification for vessels with state endorsed permits in states that did not notify vessel owners of the control date for lobster. This provision has been disapproved based on National Standard 4 and the determination that it would discriminate against individuals from different states.

A notice of proposed rulemaking will be published within 15 days after the submission of the amendment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 15, 1994.

David S. Crestin,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 94–3811 Filed 2–15–94; 4:46 pm]

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