program will apply to the placement of excess spoil on abandoned mine lands as referenced in proposed COMAR 25.20.26.05 (A)(3) and (B)(4). Maryland responded that since existing conditions on abandoned mine lands differ at each site, it would be extremely difficult to clarify exactly which requirements of Maryland's approved program would apply in every case for the placement of excess spoil. A field review during the application review process would verify conditions at the AML site and will determine which requirements are necessary to ensure that the excess spoil is placed in an environmentally sound manner.

c. Maryland was asked to clarify how placement of excess spoil on abandoned mine lands would achieve compliance with its AML program. Maryland responded that it considers the environmental reviews, public notice requirements and inspection requirements of its federally approved regulatory program to be comparable to those required by the AML program. Each abandoned mine lands site proposed for placement of excess spoil will be reviewed in conjunction with the application for a surface mining permit and subjected to the same requirements.

2. COMAR 25.20.14.09, Procedures for Release of Bonds

a. COMAR 25.20.14.09B(2)(e) is further modified by changing the word ''approximate'' to ''appropriate''.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. Specifically, OSM is seeking comments on the clarifications to the State's regulations that were submitted on December 8, 1997 (Administrative Record No. MD–576–07). Comments should address whether the proposed amendment with these clarifications satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate. it will become part of the Maryland program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Appalachian Regional Coordinating Center will not necessarily be considered in the final rulemaking or included in the Administrative Record.

IV. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

Unfunded Mandates

This rule will not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 920

Intergovernmental relations, Surface mining, Underground mining.

Dated: January 9, 1998.

Allen D. Klein,

Regional Director, Appalachian Regional Coordinating Center.

[FR Doc. 98–1215 Filed 1–16–98; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Chapter IV

[HCFA–1014–NC]

RIN 0938–AI45

Medicare Program: Request for Public Comments on Implementation of the Medicare+Choice Program, and Notice of Timeframes for Submission of Applications for Contracts

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

ACTION: Notice of intent to regulate; solicitation of comments.

SUMMARY: The Balanced Budget Act of 1997 (BBA) establishes a new Medicare+Choice program. Under this program, eligible individuals may elect to receive Medicare benefits through enrollment in one of an array of private health plans that contract with us.

The BBA directs the Secretary to publish by June 1, 1998, regulations establishing standards for the Medicare+Choice program. We have already received comments and inquiries from the public on a number of issues associated with the Medicare+Choice program. This document solicits further public comments on issues related to implementation of the Medicare+Choice program. We intend to consider these comments as we develop an interim

final rule to implement the Medicare+Choice program.

This document also includes preliminary information regarding application procedures for organizations that intend to contract with us to participate in the Medicare+Choice program.

This document also informs the public of a meeting to discuss the Medicare+Choice program.

DATES: We request that comments be submitted on or before February 19, 1998.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1014–NC, 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 C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850

Comments may also be submitted electronically to the following e-mail address: hcfa1014nc.hcfa.gov. E-mail comments must include the full name and address of the sender and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1014–NC. 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).

FOR FURTHER INFORMATION CONTACT: Medicare+Choice Regulation Team, (410) 786–7660.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

Medicare historically has consisted of two primary parts: Hospital insurance, also known as ''Part A,'' and supplementary medical insurance, also known as ''Part B.'' Part A is generally provided automatically to persons age 65 and over who are entitled to social security or railroad retirement board benefits. Similarly, individuals who have received either of these benefits based on their disability, for a period of at least 24 months, are also entitled to Part A benefits. Health care services covered under Part A include: inpatient hospital care, skilled nursing facility care, home health agency care, and hospice care.

Part B benefits are available to almost all resident citizens age 65 and over; certain aliens age 65 or over; and disabled beneficiaries who are entitled to Part A. Part B coverage is optional and requires payment of a monthly premium. Part B covers physician services (in both hospital and nonhospital settings) and services furnished by certain nonphysician practitioners. It also covers certain other services, including: clinical laboratory tests, durable medical equipment, most supplies, diagnostic tests, ambulance services, prescription drugs that cannot be self-administered, certain self-administered anticancer drugs, some other therapy services, certain other health services, and blood not supplied by Part A.

B. The Balanced Budget Act of 1997

Subsequent to its initial enactment in 1965, the Medicare program has been subject to numerous legislative and administrative changes. However, one of the most significant changes results from the August 5, 1997 enactment of the Balanced Budget Act of 1997 (BBA), Public Law 105–33. Section 4001 of the BBA adds a new Part C to the Medicare program, by establishing sections 1851 through 1859 of the Social Security Act. The new Part C is known as ''Medicare+Choice.'' Section 4002 of the BBA establishes transitional rules for the current Medicare health maintenance organization (HMO) program; and section 4006 establishes special rules for Medicare+Choice medical savings accounts. Prior to the BBA, Medicare beneficiaries could choose between receiving their Medicare benefits on a fee-for service basis or enrolling in an HMO with a Medicare contract. In the latter case, the beneficiary selects a specific HMO or competitive medical plan (CMP) within a service area for Medicare-covered health care services. This selected plan coordinates all of the Medicare-covered health care services for the beneficiary and receives a per-person payment from Medicare that is predetermined. Under the new Medicare+Choice program, the beneficiaries' options have been expanded to include provider-sponsored organizations (PSOs), preferred provider organizations (PPOs), private fee-for-service plans, and, for those who qualify, religious fraternal benefit society plans. In addition, up to 390,000 beneficiaries nationwide (and prior to the year 2003) may elect a new Medical Savings Account (MSA) option. A Medicare+Choice MSA is a tax-exempt trust created to pay the qualified medical expenses of the account holder. A beneficiary who elects the MSA option will receive a catastrophic health care policy paid by Medicare. Any difference between the MSA plan insurance premium and the amount that Medicare would have paid if the beneficiary had elected Medicare+Choice coverage under any of the other options will be deposited into the beneficiary's MSA.

Under Medicare+Choice, plans with which we contract must have quality programs that stress outcomes, create utilization protocols, assess consumer satisfaction, and monitor high-risk and high-volume services. In addition, all plans, other than non-network MSAs and certain private fee-for-service plans, must provide for external review. Each Medicare+Choice plan must provide Medicare members all benefits (other than hospice care) that are available under Parts A and B. In the case of an MSA plan, however, these benefits are not provided until after a catastrophic deductible amount has been satisfied.

The law sets forth provisions relating to the following topics:

- Eligibility, election, and enrollment.
- Benefits and beneficiary protections.
- Organizational relationships with participating providers.
- Payments to Medicare+Choice organizations.
- Premiums.
- Organizational and financial requirements for Medicare+Choice organizations.
- Establishment of standards.
- Contract requirements.

Additional information about the Medicare+Choice program is available on our Internet site (http://www.hcfa.gov).

C. Issues and Questions To Be Resolved

As stated earlier, we are required to publish regulations implementing the Medicare+Choice program by June 1, 1998. The statute provides that these regulations may be issued as an interim final rule. We intend to use this mechanism and will formally request comments on our policies at that time.

We have already received comments and inquiries from the public on a number of issues associated with the

Medicare+Choice program. However, to ensure that we receive the full range of public opinion, we are using this notice as a vehicle to request public suggestions on specific policy issues that are detailed in the following sections. In addition, at this time, we encourage the public to comment on any other relevant Medicare+Choice program policy areas, with the exception of comments on Federal solvency standards for PSOs. (A discussion of PSO solvency standard policy decisions and implementation issues and a request for public comment were contained in a notice published on September 23, 1997 (62 FR 49649).) We will consider public comments that are received timely as we develop the interim final rule, but we will not otherwise issue a separate set of responses to those comments. We request that commenters provide a brief summary of any detailed comments. Also, commenters should, whenever possible, identify the relevant section or subsection of the BBA or of the Social Security Act. Note that in the following sections, citations to the law are to sections of the Social Security Act as established by the BBA.

1. Information for Informed Choice

One of the objectives of the Medicare+Choice program is to expand Medicare beneficiaries' options for health care. In order to ensure that beneficiaries have the appropriate information necessary to choose from the various Medicare+Choice options, section 1851(d) of the Act requires that we collect and disseminate information on the coverage options available. For example, the statute requires that, prior to each open season, we provide a notice to Medicare-eligible individuals that includes a list of the Medicare+Choice plans, a comparison of plan options that includes information on benefits and premiums, a general description of the benefits under the original Medicare fee-for-service program, and other general information. The statute also requires, at 1851(e)(3)(D), that, during November 1998, we provide for an educational and publicity campaign to inform Medicare+Choice eligible individuals about the availability of Medicare+Choice plans and the Medicare fee-for-service option. The statute further requires that we maintain a toll-free number for inquiries regarding Medicare+Choice options and an Internet site providing information on Medicare+Choice options. As we begin the information collection process, and analyze how best to provide information to beneficiaries, we ask that interested parties respond to the following questions:

- What are the most effective ways to communicate Medicare+Choice information to beneficiaries, individuals, advocates, ombudsmen, providers, and other groups that have need of and will use this information?
- How can we reduce confusion for beneficiaries who also receive health care information from other sources, for example, from employers who offer retiree coverage or Federal purchasers such as the Federal Employees Health Benefit Plan, the Department of Defense, and sellers of health care insurance products?
- How can the information programs best recognize the special needs of certain populations, such as beneficiaries with disabilities?

2. Enrollment/Disenrollment Process

Under section 1851(e) of the Act, we are charged with establishing a process, including the format and procedures, through which Medicare+Choice elections are made. According to section 1851(e), a beneficiary's enrollment in a Medicare+Choice option is initially made at the time the individual becomes entitled to Part A and enrolled in Part B. Beneficiaries may change their Medicare+Choice plan election during continuous open enrollment periods through the year 2001. After 2001, beneficiaries are locked in to their Medicare+Choice election for defined time periods, except for special election periods under certain circumstances. The process must permit a beneficiary to make enrollment and disenrollment elections by filing a form with the Medicare+Choice organization. The statute also permits, at section 1851(g), that a Medicare+Choice organization may terminate an individual's election with respect to a Medicare+Choice plan that it offers if (1) required premiums are not paid on a timely basis, (2) the individual has engaged in disruptive behavior, or (3) the plan is terminated with respect to all individuals residing in the area in which the individual resides. We request comments related to the election and enrollment procedures in general, and the Medicare+Choice organization's ability to disenroll a beneficiary. For example—

- Should our standards be specific with regard to each of the factors; for example, timeframes for timely payment of premiums or a definition for ''disruptive''? Should we require a mechanism for appealing termination of a beneficiary's enrollment ''for cause''?

3. Medicare+Choice Enrollment Demonstrations

Section 4018 of the BBA requires that we conduct a 3-year demonstration project to evaluate the use of a third-party contractor to conduct the Medicare+Choice plan enrollment and disenrollment functions. We are soliciting comments on how this demonstration could be designed. For example—

- What constitutes an enrollment or disenrollment ''function''? Is it distributing applications, collecting applications, processing applications, providing benefits counseling, ascertaining reasons for disenrollment, or other activities?
- What functions should the contractor perform?
- What exactly are the tasks involved in enrollment/disenrollment?
- What would be the most desirable/efficacious processes for enrollment/disenrollment from the perspective of the beneficiaries and plans?
- What is a demonstration ''area''?
- Should all Medicare+Choice plans in the demonstration area be involved in the demonstration? If not, which ones should be exempt?
- What requirements under Medicare Part C, if any, is the Secretary likely to have to waive in order for the demonstration to work?
- Should a single, standard form be used for enrollment?
- What standards should be used to monitor the performance of the contractor, given that enrollment in Medicare+Choice plans is voluntary and that disenrollment may be due to various causes? Should any of these standards be tied to contractor payment?
- What would constitute ''substantial compliance'' with the performance standards?
- What criteria should we use to select the third-party contractor?

4. Post-Stabilization Coverage

Section 1852(d)(2) of the Act authorizes us to develop policies to ensure coordination of care and appropriate payment between Medicare+Choice organizations and out-of-plan providers after the beneficiary's medical condition is determined to be stable. We are particularly interested in comments about the following issues:

- Should we specify which provider is responsible for developing a plan of care to appropriately maintain the beneficiary's health, or should this be negotiated between the emergency providers and the plan providers?
- Should we establish a requirement that the Medicare+Choice plan respond

to an emergency service provider's request for approval/authorization within a certain period of time? If so, what should that time period be?

- Should we require that Medicare+Choice plans make available a central contact for emergency providers to call for authorization and medical history data?
- Finally, with regard to post-stabilization benefits and coverage, our primary objective is to ensure that Medicare enrollees are held harmless in payment disputes between the Medicare+Choice plans and the non-network service provider. What are the most appropriate standards to accomplish this goal?

5. Grievances, Organization Determinations and Reconsiderations

Appropriate and meaningful appeals and grievance procedures for the resolution of individual enrollee complaints about their health care are among the most important beneficiary protections in the Medicare+Choice program. Section 1852(g) requires that all Medicare+Choice organizations have procedures for making determinations regarding whether an enrollee is entitled to receive specific health services. The organization must provide for reconsideration of adverse coverage determinations at the request of the enrollee within a time period specified by us, but not later than 60 days after the date of the receipt of the request for reconsideration. However, the Medicare+Choice organization must have in place procedures for expedited reconsiderations under certain circumstances.

We are soliciting comments with regard to these protections. For example—

- Should guidelines for a grievance process be established?
- What is an appropriate timeframe for a reconsideration of a nonexpedited determination?
- Should plans be able to subcontract organization determinations and reconsiderations to subcontractors?
- Should Medicare+Choice plans be required to continue coverage during the reconsideration process?
- Should reductions in care be subject to the reconsideration process?

6. Provider Rights in Medicare+Choice Plans

Section 1852(b)(2) provides that a Medicare+Choice organization may not discriminate with respect to participation, reimbursement, or indemnification as to any provider that is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of the license or certification. The statute provides, however, that this prohibition is not to be construed to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's enrollees or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan.

In addition, provider rights set forth in section 1852(j) include the right of health care professionals to advise Medicare beneficiaries of possible medical procedures, treatments, or care, regardless of whether benefits for the treatment or care are provided under the plan. Section 1852(j) also establishes certain provider protections, including the physician's right to written notice of a Medicare+Choice plan's decision to exclude him or her from participation in the plan and provides that a process for appealing such a decision be established. We would like to obtain general comments about the scope of the various provider protection requirements. In addition, we would like comments regarding the following:

- What procedures should Medicare+Choice plans be required to put in place to ensure that providers are notified of adverse participation decisions?
- In a case where multiple types of providers or practitioners can provide a specific service, how should we interpret the anti-discrimination provision at section 1852(b)?

7. Encounter Data Collection

The payment standards and methodology contained in the new Part C anticipate an eventual transition from a payment based on Medicare fee-for-service utilization and cost, to a payment adjusted for the individual medical conditions of the enrolled population—a process known as risk adjustment. In response to the requirement that inpatient hospital encounter data be collected from health plans for services on or after July 1, 1997, we have developed instructions concerning collection of inpatient hospital encounter data for hospitals, plans, and contractors. Many questions, however, remain about non-inpatient encounter data. For example—

- What information systems issues do organizations face when asked to submit non-inpatient hospital encounter data?
- What are appropriate transmission mechanisms for collection of non-inpatient hospital encounter data? Should they vary by type of plan, by size of plan, or by type of data collected?
- What issues do organizations face relating to the transmission of non-inpatient hospital encounter data, especially regarding the frequency and the methodology of transmission? Under what circumstances and for what purposes are such data currently being generated? How could we coordinate our data collection efforts with ongoing activities?

In addition to a January 28, 1998 general meeting (discussed in section II. of this notice), we are considering holding a public meeting specifically regarding the collection of hospital encounter data that will be used for the implementation of risk adjustment for payment of health plans. Individuals and organizations interested in attending such a meeting should write to Cynthia Tudor, HCFA Center for Health Plans and Providers, Room C3–15–06, 7500 Security Blvd., Baltimore, MD 21244, or by Internet at ''Ctudor@hcfa.gov'' (please specify ''Encounter Data Meeting'' in the Subject line).

8. Private Fee-for-Service Plans

One of the new Medicare+Choice health care options for beneficiaries is the ''private fee-for-service (PFFS)'' plan. These plans are defined at 1859(b)(2). Private fee-for-service plans must meet most of the same requirements as other Medicare+Choice plans and will be capitated on a full risk basis in exchange for providing enrollees with the full package of Medicare benefits. Unlike coordinated care Medicare+Choice plan options however, PFFS plans are expressly prohibited from placing the provider at financial risk or from varying payment based on utilization experience. PFFS plans must pay all service providers (regardless of contracting status) on a fee-for-service basis. We request public comments expressing opinions on the most effective implementation of the unique PFFS plan program requirements, including, but not limited to the following topics:

Section 1852(j) states that a provider furnishing covered services to PFFS plan enrollees must be treated as if the provider had a direct contract with the PFFS if, before furnishing the services, the provider is informed of or given a reasonable opportunity to obtain information about the terms and conditions of payment for these services. We are soliciting comments on appropriate standards to determine when a provider has an implied contract under section 1852(j). For example—

- What notification requirements, if any, must be met by the PFFS plan or

the provider in order to establish a de facto contracting arrangement?

With regard to ''fee-for-service payment'' as specified in the statute—

- Could the definition of these payments include bundled provider fees, or global fees?
- What should be the enrollee's responsibility for payment of claims?
- As with other Medicare+Choice options, should providers in PFFS plans be *prohibited* from billing beneficiaries in most cases?

PFFS plans must meet substantially different requirements than other Medicare+Choice plans with regard to utilization review requirements and enrollee premiums. We are interested in the public's perception of the most effective ways to implement statutory requirements that apply certain utilization review standards to these entities. For example—

- How should utilization protocols based on standards of medical practice be defined?
- Should PFFS plans that use utilization review to determine medical necessity be required to include limitation on liability as a mechanism to protect PFFS plan enrollees against liability for full payment when they did not know or have reason to know that the PFFS would deny the services as being not medically necessary?
- How can these entities be able to comply with the access standards in section 1852? That is, to what extent are Medicare+Choice program access requirements met by establishment of a health service delivery network?

9. Medical Savings Accounts

As part of the Medicare+Choice program implementation, we are establishing procedures for a maximum of 390,000 beneficiaries to enroll under an MSA option in accordance with section 1851. Under the MSA option, a beneficiary's Medicare capitated payment rate will be used to purchase a MSA high deductible health insurance plan meeting certain standards. An MSA plan must pay for at least all Medicare-covered items and services after the enrollee meets the annual deductible, which for 1999 cannot exceed $6,000. The difference between the individual's capitated payment rate and the insurance premium will be placed in an MSA designated by the enrollee. These funds can then be used by the individual to meet medical expenses under the insurance deductible, they can be allowed to accrue from year to year, or they can be withdrawn for nonmedical expenses subject to applicable tax and penalty rules.

We are requesting input from the public regarding the appropriate standards for MSA insurers and account managers. For example—

- What types of information should potential MSA insurers be required to submit to us as part of the application process?
- What other standards and requirements should approved MSA entities meet for monitoring and evaluation purposes?

10. Other Issues

We are also interested in receiving responses to the following questions:

- A Medicare+Choice contract may include more than one plan. We view this as permitting an entity to offer more than one Medicare+Choice product (for example, an HMO and an PPO) as well as allowing a national contract. How can these contracts be structured to facilitate the application and approval process, including the need for multiple State licenses?
- What standards for out-of-area dialysis should apply?
- How should accrediting bodies be treated for purposes of deeming that a plan meets standards for internal quality review, external quality review, and confidentiality of records?
- Under what circumstances should we waive independent external review for plans with an excellent record of quality and other performance?
- How should State agreements to monitor and enforce Medicare+Choice requirements be structured?
- What procedures or requirements for a hearing for the organization prior to termination of its contract should we establish?
- How should Medicaid-only plans be treated for Medicare+Choice purposes? For example, how should we define ''licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in [a] State'' (section 1855(a)(1))?

II. Timelines and Procedures for Participation in the Medicare+Choice Program

The following discussion applies to Medicare+Choice applications and to Medicare risk contract applications submitted in calendar year 1998 for contracts with an effective date of on or before January 1, 1999. We will discuss application requirements for subsequent contracting periods in subsequent HCFA policy notices.

It should also be noted that we will submit, as required, the three applications and related information collection requirements, that is, the adjusted community rate (ACR) proposal and the Medicare+Choice and PSO applications, referenced in this notice to the Office of Management and Budget (OMB) for emergency Paperwork Reduction Act (PRA) approval, prior to implementation. A **Federal Register** notice will be published soliciting public comment on each of the proposed information collections submitted for emergency PRA approval. Although the notices will allow the public only an abbreviated public comment period, the maximum approval period of an emergency approval is 6 months. Once, we have obtained the required OMB approval, we will resubmit the approved information collections to OMB for reapproval under the routine PRA approval process. As part of the routine process, we will publish two consecutive **Federal Register** notices, soliciting public comment for a total of 90 days, on the reapproval of the collections.

We plan to apply the following procedures to organizations that submit applications for new risk contracts under section 1876. In accordance with the BBA, we may not enter into any new risk contracts under section 1876 after publication of the interim final rule. Therefore, all applications for risk contracts under section 1876 that are not approved prior to the publication of the interim final rule (regardless of when submitted) will automatically be reviewed under the Medicare+Choice contracting standards, and organizations will need to submit a supplemental application as discussed below.

Adjusted Community Rate Proposals

Section 1854(a) requires that Medicare+Choice organizations submit ACR proposals for Medicare+Choice plans by May 1st of the calendar year prior to the benefit year in question. This statutory requirement does not apply, however, to entities that have not yet been certified as Medicare+Choice organizations under the interim final rule to be published by June 1. The June 1 regulation will establish ACR deadlines that apply when the statutory May 1 deadline does not apply. In 1999 and thereafter, organizations that apply for new contracts will be required to submit their ACR proposals by May 1st. Risk contractors that have contracts in effect prior to May 1, 1998 should submit ACRs by May 1, 1998 in order to ensure timely processing.

Applicants for risk contracts whose applications are not approved before the publication of the interim final rule will be reviewed as applicants for Medicare+Choice contracts. Because we

will publish payment rates for 1999 on March 1, 1998, these applicants must resubmit their ACR proposals to cover the proposed contract period. The contract period must cover all of calendar year 1999 and may include a period of time involving 1998. However, persons are not required to comply with the information collection requirements associated with the ACR proposal until OMB, PRA emergency approval has been obtained.

Application Process for Medicare+Choice Plans

We encourage organizations that wish to participate in the Medicare+Choice program to submit their applications as soon as possible and no later than August 1, 1998. Although our goal is to process applications in a timely manner, we cannot guarantee that complete applications submitted by August 1, 1998 will be approved for an effective date of January 1, 1999; let alone for those applications submitted after August 1. We may experience delays in processing applications, as current resources are reassigned to respond to the requirements of the Medicare+Choice program.

This section applies to State-licensed organizations. The procedures for PSOs that seek Federal waiver of the State licensure requirement are discussed in a subsequent section. Upon receipt of a State-licensed candidate's application for a Medicare+Choice contract, we will immediately review the application to determine whether the responses and documentation are complete. If we identify incomplete responses, we will allow only 60 days for the applicant to submit the necessary information. We will consider an application that, for any reason, is not complete after the 60-day period to be nonresponsive, and we will return it to the applicant. Once we determine that an application is complete, we will initiate an extensive review of the data, including a site visit for most plans. We will provide applicants a 15-day time period in which to provide any information required as a result of the site visit.

Note that an approved organization must be ready to enroll and serve beneficiaries on the first day that the contract becomes effective. To ensure that new applicants are approved in time for the contract to be implemented by January 1, 1999, we plan to establish a two-step process whereby new contractors may submit a core application at any time prior to publication of the final interim rule and then submit a supplemental application after the interim final rule is published. The core application will be similar to the current application for a risk contract. At present, we expect that it will contain the following information:

- Medicare+Choice option (HMO, State-licensed PSO, MSA, etc.).
- General information: description of plan, brief history, banking information, board of directors, management staff, geographic region, and other pertinent data for the Medicare product.
- Organization and contract information: type of legal entity, State authority to operate, organizational charts, and management contracts.
- Health services delivery network: detailed description of delivery system, Medicare subscriber agreements, evidence of coverage, membership information, and quality assurance systems.
- Financial information: certified audits, financial projections, and all information necessary to demonstrate a fiscally-sound operation.
- Marketing information: marketing plans, projections, and enrollment assumptions.
- Any additional information to support the Medicare+Choice application.

The core application package will be available on our Internet web site (http://www.hcfa.gov) on or about February 1, 1998. Additional information regarding the core application process can be obtained by writing to us at—HPPAG, Field Liaison Staff, Health Care Financing Administration, Center for Health Plans and Providers, Health Plan Purchasing and Administration Group, 7500 Security Blvd., 03–18–13 South Building, Baltimore, MD 21244–1850. Alternatively, you may call the Health Plan Purchasing and Administration Group (HPPAG) at 410–786–7623.

ACR instructions will also be available beginning February 1, 1998 on the Internet or from the above address. However, persons are not required to comply with the information collection requirements associated with the core Medicare+Choice application and ACR proposal until OMB, PRA emergency approval has been obtained.

Supplemental Medicare+Choice Application Process

Our plans are that Medicare+Choice applicants that submit a core application must complete the application process by submitting a supplemental application. The supplemental application will cover provisions that are specific to the Medicare+Choice program as specified by the interim final rule, including the fiscal solvency standards for PSOs, which are scheduled to be published on April 1, 1998. The supplemental application will also solicit plan specific information relevant to each of the different types of Medicare+Choice program options (for example, PSO, PFFS, MSA). The supplemental applications will be available beginning June 1, 1998, when the interim final rule is published. The application will be available from our Internet web site or from HPPAG at the above address. Persons are not required to comply with the information collection requirements associated with the Medicare+Choice supplemental application until OMB, PRA emergency approval has been obtained.

Federal Waiver of State Licensure Requirement for PSOs

Consistent with current policy, only applications that have obtained State licenses will be approved for Medicare+Choice contracts. The only exception to this requirement are PSOs, which are allowed to request waivers of the State licensure requirement as specified by BBA. In accordance with section 1855(a)(2), PSO applicants may request waivers of the State licensure requirement under any of the following circumstances:

- The State failed to act on a timely basis, that is, within 90 days of its receipt of a substantially complete application.
- The denial of the application was based on discriminatory treatment. The ground for approval of such a waiver on the basis of discriminatory treatment is that the State has denied a licensing application and (1) the standards or review process imposed by the State as a condition of approval of the license imposes any material requirements, procedures, or standards (other than solvency requirements) to such organizations that are not generally applicable to other entities engaged in a substantially similar business, or (2) the State requires the organization, as a condition of licensure, to offer any product or plan other than a Medicare+Choice plan.
- The denial was based on application of solvency requirements. With respect to waiver applications filed on or after the date of publication of solvency standards under section 1856(a), the ground for approval of the waiver application on this basis is that the State denied the licensing application based (in whole or in part) on the organization's failure to meet applicable solvency requirements and (1) the requirements are not the same as the solvency standards established under section 1856(a), or (2) the State has imposed a condition of approval of the license documentation or

information requirements relating to solvency or other material requirements, procedures, or standards relating to solvency that are different from the requirements, procedures, and standards applied by us under section 1856(d)(2).

Once a prospective Medicare+Choice contractor submits documentation that one or more of the above conditions has been met, we have 60 days to grant or deny the waiver application. A separate application for PSOs seeking a waiver from State licensure will be available on or about February 15, 1998, on our Internet web site or from HPPAG at the address given above. This application will include the waiver forms as well as the contract application and all definitions. In addition, solvency standards for PSOs seeking a waiver will be available on April 1, 1998. PSOs requesting a waiver that submitted an application prior to April 1 will be required to submit a supplemental application showing how they meet the solvency standards. However, persons are not required to comply with the information collection requirements associated with the PSO application until OMB, PRA emergency approval has been obtained.

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

Information Campaign

To assist Medicare beneficiaries' decision-making process relative to new Medicare+Choice health care options, we will incorporate information on newly-approved plans into our plan comparison database. This database will contain information on all existing and new plans, except for MSAs. Plan comparison information will be posted on the Internet and will be updated at least quarterly. Thus, newly-approved plans will be entered into the plan comparison database at the next update cycle.

February 4, 1998 Public Meeting

In addition to seeking written comments from the public, we will hold a public meeting on Wednesday, February 4, 1998 from 9 a.m. to 3 p.m. in our auditorium at 7500 Security Boulevard, Baltimore, Maryland. The purpose of this meeting will be to discuss issues and concerns from plans, providers, beneficiaries, and other interested parties on the requirements and implementation of the Medicare+Choice program. The agenda for this meeting will be posted on our Internet web site. Further information can be obtained from Rondalyn Kane at (202) 690–7874.

(Secs. 1851 through 1857, 1859, 1876, and 1877 of the Social Security Act (Secs. 4001, 4002, and 4006 of Pub.L. 105–33, 42 U.S.C. 1395*l* and 1395mm))

Dated: December 23, 1997.

Nancy-Ann Min DeParle,

Adminstrator, Health Care Financing Administration.

[FR Doc. 98–1381 Filed 1–16–98; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 424

[HCFA–1864–P]

RIN 0938–AH19

Medicare Program; Additional Supplier Standards

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish additional standards for an entity to qualify as a Medicare supplier for purposes of submitting claims for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). This proposed rule would establish additional standards that must be satisfied before a DMEPOS supplier could receive payment from the Medicare program. The Social Security Act Amendments of 1994 require that a DMEPOS supplier meet standards related to compliance with State and Federal licensure requirements, maintaining a physical facility on an appropriate site, proof of appropriate liability insurance, and other standards the Secretary may specify.

DATES: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 23, 1998.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1864–P, P.O. Box 26676, 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 C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1864–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: (202) 690–7890). Electronically submitted comments will also be available for public inspection at the Independence Avenue address.

FOR FURTHER INFORMATION CONTACT: Larry Bonander, (410) 786–4479.

SUPPLEMENTARY INFORMATION:

I. Background

Medicare services are furnished by two types of entities, that is, providers and suppliers. The term ''provider'', as defined in our regulations at § 400.202, means a hospital, a rural primary care hospital, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare. A clinic, a rehabilitation agency, or a public health agency that has a similar agreement to furnish outpatient physical therapy or speech pathology services, or a community mental health center with a similar agreement to furnish partial hospitalization services, is also considered a provider (see sections 1861(u) and 1866(e) of the Social Security Act (the Act)).

In general, a supplier is an individual or entity that furnishes certain types of medical and other health services under Medicare Part B. There are different definitions of the term ''supplier'' and specific regulations governing different types of suppliers. A supplier that furnishes durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) is one category of supplier. Other categories of suppliers could include, for example, physicians, nurse practitioners, and physical therapists. The term ''DMEPOS'' encompasses the types of items included in the definition of medical equipment and supplies found at section 1834(j)(5) of the Act.

For purposes of DMEPOS supplier standards, the term ''supplier'' is currently defined in § 424.57(a) of our regulations as an entity or individual, including a physician or Part A provider, that sells or rents Part B covered DMEPOS items to Medicare beneficiaries, and that meets certain standards. We are retaining this