economic, environmental, public health and safety effects; distributive impacts; and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final notice recognizes AAAASF as a national accreditation organization for ASCs that request participation in the Medicare and Medicaid programs. There are neither significant costs nor savings for the program and administrative budgets of Medicare. Therefore, this notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and Government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. For purposes of the RFA, States and individuals are not considered small entities. We are not preparing an analysis for the RFA because we have determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a 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 604 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 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

In an effort to better assure the health, safety, and services of beneficiaries in ASCs already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we deem ASCs accredited by AAAASF as meeting its Medicare requirements. Thus, we continue our focus on assuring the health and safety of services by providers and suppliers already certified for participation in a cost-effective manner.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This notice will have no consequential effect on the governments mentioned or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this notice does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplemental Medical Insurance Program)

Dated: October 22, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–25830 Filed 11–19–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1374–GNC]

RIN: 0938–ZA50

Medicare Program; Criteria and Standards For Evaluating Intermediary, Carrier, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carrier Performance During Fiscal Year 2005

AGENCY: Centers for Medicare and Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: General notice with comment period.

SUMMARY: This notice describes the criteria and standards to be used for evaluating the performance of fiscal intermediaries (FIs), carriers, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) regional carriers in the administration of the Medicare program beginning on the first day of the first month following publication of this notice in the **Federal Register**. The results of these evaluations are considered whenever we enter into, renew, or terminate an intermediary agreement, carrier contract, or DMEPOS regional carrier contract or take other contract actions, for example, assigning or reassigning providers or services to an intermediary or designating regional or national intermediaries. We are requesting public comment on these criteria and standards.

DATES: *Effective Date:* The criteria and standards are effective December 27, 2004.

Comment Date: Comments will be considered if we receive them at the appropriate address as provided below no later than 5 p.m. on December 27, 2004.

ADDRESSES: In commenting, please refer to file code CMS–1374–GNC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments to *http://www.cms.hhs.gov/regulations/ecomments* or to *http://www.regulations.gov* (attachments must be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1374–GNC, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government

identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Sue Lathroum, (410) 786–7409.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this notice to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–1374–GNC and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. After the close of the comment period, CMS posts all electronic comments received before the close of the comment period on its public Web site. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–7195.

I. Background

[If you choose to comment on issues in this section, please include the caption ''BACKGROUND'' at the beginning of your comments.]

A. Part A—Hospital Insurance

Under section 1816 of the Social Security Act (the Act), public or private organizations and agencies participate in the administration of Part A (Hospital Insurance) of the Medicare program under agreements with us. These agencies or organizations, known as FIs, determine whether medical services are covered under Medicare, determine correct payment amounts and then make payments to the health care providers (for example, hospitals, skilled nursing facilities (SNFs), and community mental health centers) on behalf of the beneficiaries. Section 1816(f) of the Act requires us to develop criteria, standards, and procedures to evaluate an intermediary's performance of its functions under its agreement.

Section 1816(e)(4) of the Act requires us to designate regional agencies or organizations, which are already Medicare intermediaries under section 1816 of the Act, to perform claim processing functions for freestanding Home Health Agency (HHA) claims. We refer to these organizations as Regional Home Health Intermediaries (RHHIs). *See* 42 CFR 421.117 and the final rule published on May 19, 1988 in the **Federal Register** (53 FR 17936) for more details about the RHHIs.

The evaluation of intermediary performance is part of our contract management process. These evaluations need not be limited to the current fiscal year (FY), other fixed term basis, or agreement term.

B. Part B—Supplementary Medical Insurance

Under section 1842 of the Act, we are authorized to enter into contracts with carriers to fulfill various functions in the administration of Part B, Supplementary Medical Insurance of the Medicare program. Beneficiaries, physicians, and suppliers of services submit claims to these carriers. The carriers determine whether the services are covered under Medicare and the amount payable for the services or supplies, and then make payment to the appropriate party.

Under section 1842(b)(2) of the Act, we are required to develop criteria, standards, and procedures to evaluate a carrier's performance of its functions under its contract. Evaluations of Medicare fee-for-service (FFS) contractor performance need not be limited to the current FY, other fixed term basis, or contract term. The evaluation of carrier performance is part of our contract management process.

C. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carriers

In accordance with section 1834(a)(12) of the Act, we have entered into contracts with four DMEPOS regional carriers to perform all of the duties associated with the processing of claims for DMEPOS, under Part B of the Medicare program. These DMEPOS regional carriers process claims based on a Medicare beneficiary's principal residence by State. Section 1842(a) of the Act authorizes contracts with carriers for the payment of Part B claims for Medicare covered services and items. Section 1842(b)(2) of the Act requires us to publish in the **Federal Register** criteria and standards for the efficient and effective performance of carrier contract obligations. Evaluation of Medicare FFS contractor performance need not be limited to the current FY, other fixed term basis, or contract term. The evaluation of DMEPOS regional carrier performance is part of our contract management process.

D. Development and Publication of Criteria and Standards

In addition to the statutory requirements, 42 CFR 421.120, 421.122 and 421.201 provide for publication of a **Federal Register** notice to announce criteria and standards for intermediaries and carriers before the beginning of each evaluation period. The current criteria and standards for intermediaries, carriers, and DMEPOS regional carriers were published in the December 24, 2003 notice (68 FR 74613).

To the extent possible, we make every effort to publish the criteria and standards before the beginning of the Federal FY, which is October 1. If we do not publish a **Federal Register** notice before the new FY begins, readers may presume that until and unless notified otherwise, the criteria and standards that were in effect for the previous FY remain in effect.

In those instances in which we are unable to meet our goal of publishing the subject **Federal Register** notice before the beginning of the FY, we may publish the criteria and standards notice at any subsequent time during the year. If we publish a notice in this manner, the evaluation period for the criteria and standards that are the subject of the notice will be effective 30 days after the date of the publication. Any revised criteria and standards will measure performance prospectively; that is, any new criteria and standards in the notice will be applied only to performance after the effective date listed on the notice.

It is not our intention to revise the criteria and standards that will be used during the evaluation period once this information is published in a **Federal Register** notice. However, on occasion, either because of administrative action or statutory mandate, there may be a need for changes that have a direct impact on the criteria and standards previously published, or that require the addition of new criteria or standards, or that cause the deletion of previously published criteria and standards. If we must make these changes, we will

publish an amended **Federal Register** notice before implementation of the changes. In all instances, necessary manual issuances will be published to ensure that the criteria and standards are applied uniformly and accurately. Also, as in previous years, this **Federal Register** notice will be republished and the effective date revised if changes are warranted as a result of the public comments received on the criteria and standards.

On December 8, 2003, President Bush signed into law the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Section 911 of the MMA establishes the Medicare FFS Contracting Reform (MCR) initiative that will be implemented over the next several years. This provision requires that we use competitive procedures to replace our current FIs and carriers with Medicare Administrative Contractors (MACs). The MMA requires that we compete and transition all work to MACs by October 1, 2011.

FIs and or carriers will continue administering Medicare FFS work until the final competitively selected MAC is up and operating. We will continue to develop and publish standards and criteria for use in evaluating the performance of FIs, carriers, and DMERCs as long as these types of contractors exist.

II. Analysis of and Response to Public Comments Received on FY 2004 Criteria and Standards

We received no comments in response to the December 24, 2003 **Federal Register** general notice with comment.

III. Criteria and Standards—General

[If you choose to comment on issues in this section, please include the caption ''CRITERIA AND STANDARDS—GENERAL'' at the beginning of your comments.]

Basic principles of the Medicare program are to pay claims promptly and accurately and to foster good beneficiary and provider relations. Contractors must administer the Medicare program efficiently and economically. The goal of performance evaluation is to ensure that contractors meet their contractual obligations. We measure contractor performance to ensure that contractors do what is required of them by statute, regulation, contract, and our directives.

We have developed a contractor oversight program for FY 2004 that: outlines expectations of the contractor, measures the performance of the contractor; evaluates the performance against the expectations; and provides for appropriate contract action based upon the evaluation of the contractor's performance.

As a means to monitor the accuracy of Medicare FFS payments, we have established the Comprehensive Error Rate Testing (CERT) program that produces error rates for claims payment decisions made by carriers, DMERCs, and FIs. Beginning in November 2003, the CERT program produced claims payment error rates for each individual carrier and DMERC. FI-specific rates will be available in November 2004. These rates measure not only how well contractors are doing at implementing automated review edits and identifying which claims to subject to manual medical review but they also measure the impact of the contractor's provider outreach/education, as well as the effectiveness of the contractor's provider call center(s). We will use these contractor-specific error rates as a means to evaluate a contractor's performance.

Several times throughout this notice, we refer to the appropriate reading level of letters, decisions, or correspondence that are going to Medicare beneficiaries from intermediaries or carriers. In those instances, appropriate reading level is defined as whether the communication is below the 8th grade reading level unless it is obvious that an incoming request from the beneficiary contains language written at a higher level. In these cases, the appropriate reading level is tailored to the capacities and circumstances of the intended recipient.

In addition to evaluating performance based upon expectations for FY 2005, we may also conduct follow-up evaluations throughout FY 2005 of areas in which contractor performance was out of compliance with statute, regulations, and our performance expectations during prior review years where contractors were required to submit a Performance Improvement Plan (PIP).

We may also utilize Statement of Auditing Standards–70 (SAS–70) reviews as a means to evaluate contractors in some or all business functions.

In FY 2001, we established the Contractor Rebuttal Process as a commitment to continual improvement of contractor performance evaluation (CPE). We will continue the use of this process in FY 2005. The Contractor Rebuttal Process provides the contractors an opportunity to submit a written rebuttal of CPE findings of fact. Whenever we conduct an evaluation of contractor operations, contractors have 7 calendar days from the date of the CPE review exit conference to submit a written rebuttal. The CPE review team or, if appropriate, the individual reviewer will consider the contents of the rebuttal before the issuance of the final CPE report to the contractor.

The FY 2005 CPE for intermediaries and carriers is structured into five criteria designed to meet the stated objectives. The first criterion, claims processing, measures contractual performance against claims processing accuracy and timeliness requirements, as well as activities in handling appeals. Within the claims processing criterion, we have identified those performance standards that are mandated by legislation, regulation, or judicial decision. These standards include claims processing timeliness, the accuracy of Medicare Summary Notices (MSNs), the appropriateness of determinations reversed by an administrative law judge (ALJ), the timeliness of intermediary redeterminations, reconsiderations, reviews and hearings and the timeliness of carrier redeterminations, reviews and hearings, and the appropriateness of the reading level of carrier review determination letters. Further evaluation in the Claims Processing Criterion may include, but is not limited to, the accuracy of claims processing, the percent of claims paid with interest, and the accuracy of reconsiderations, reviews, and hearings.

The second criterion, customer service, assesses the adequacy of the service provided to customers by the contractor in its administration of the Medicare program. The mandated standard in the customer service criterion is the need to provide beneficiaries with written replies that are responsive, that is, they provide in detail the reasons for a determination when a beneficiary requests this information, they have a customer-friendly tone and clarity, and they are at the appropriate reading level. Further evaluation of services under this criterion may include, but will not be limited to, the following: timeliness and accuracy of all correspondence both to beneficiaries and providers; monitoring of the quality of replies provided by the contractor's telephone customer service representatives (quality call monitoring); beneficiary and provider education, training, and outreach activities; and service by the contractor's customer service representatives to beneficiaries and providers who come to the contractor's facility (walk-in inquiry service).

The third criterion, payment safeguards, evaluates whether the Medicare Trust Fund is safeguarded against inappropriate program expenditures. Intermediary and carrier

performance may be evaluated in the areas of Medical Review (MR), Medicare Secondary Payer (MSP), Overpayments (OP), and Provider Enrollment (PE). In addition, intermediary performance may be evaluated in the area of Audit and Reimbursement (A&R).

In FY 1996 the Congress enacted the Health Insurance Portability and Accountability Act (HIPAA), Medicare Integrity Program, giving us the authority to contract with entities other than, but not excluding, Medicare carriers and intermediaries to perform certain program safeguard functions. In situations where one or more program safeguard functions are contracted to another entity, we may evaluate the flow of communication and information between a Medicare FFS contractor and the payment safeguard contractor. All benefit integrity functions have been transitioned from intermediaries, carriers, and one DMERC to the program safeguard contractors. Because the other three DMERC contractors will continue to conduct benefit integrity activities in FY 2005, we may evaluate their performance of that function.

Mandated performance standards for intermediaries in the payment safeguards criterion include the accuracy of decisions on SNF demand bills and the timeliness of processing Tax Equity and Fiscal Responsibility Act (TEFRA) target rate adjustments, exceptions, and exemptions. There are no mandated performance standards for carriers in the payment safeguards criterion. Intermediaries and carriers may also be evaluated on any Medicare Integrity Program (MIP) activities if performed under their agreement or contract.

The fourth criterion, fiscal responsibility, evaluates the contractor's efforts to protect the Medicare program and the public interest. Contractors must effectively manage Federal funds for both the payment of benefits and the costs of administration under the Medicare program. Proper financial and budgetary controls, including internal controls, must be in place to ensure contractor compliance with its agreement with HHS and CMS.

Additional functions reviewed under this criterion may include, but are not limited to, adherence to approved budget, compliance with the Budget and Performance Requirements (BPRs), and compliance with financial reporting requirements.

The fifth and final criterion, administrative activities, measures a contractor's administrative management of the Medicare program. A contractor must efficiently and effectively manage its operations. Proper systems security (general and application controls), Automated Data Processing (ADP) maintenance, and disaster recovery plans must be in place. A contractor's evaluation under the administrative activities criterion may include, but is not limited to, establishment, application, documentation, and effectiveness of internal controls that are essential in all aspects of a contractor's operation, as well as the degree to which the contractor cooperates with us in complying with the Federal Managers' Financial Integrity Act of 1982 (FMFIA). Administrative activities evaluations may also include reviews related to contractor implementation of our general instructions and data and reporting requirements.

We have developed separate measures for RHHIs in order to evaluate the distinct RHHI functions. These functions include the processing of claims from freestanding HHAs, hospital-affiliated HHAs, and hospices. Through an evaluation using these criteria and standards, we may determine whether the RHHI is effectively and efficiently administering the program benefit or whether the functions should be moved from one intermediary to another in order to gain that assurance.

In section IV through VII of this notice, we list the criteria and standards to be used for evaluating the performance of intermediaries, RHHIs, carriers, and DMEPOS regional carriers.

IV. Criteria and Standards for Intermediaries

[If you choose to comment on issues in this section, please include the caption ''CRITERIA AND STANDARDS FOR INTERMEDIARIES'' at the beginning of your comments.]

A. Claims Processing Criterion

The claims processing criterion contains the following seven mandated standards:

Standard 1. Not less than 95.0 percent of clean electronically submitted non-Periodic Interim Payment claims are paid within statutorily specified time frames. Clean claims are defined as claims that do not require Medicare intermediaries to investigate or develop them outside of their Medicare operations on a prepayment basis. Specifically, the statute specifies that clean non-Periodic Interim Payment electronic claims be paid no earlier than the 14th day after the date of receipt, and that interest is payable for any clean claims if payment is not issued by the 31st day after the date of receipt. The HIPAA Administrative Simplification provisions and the implementing regulations established standards for electronic transmission of claims. CMS issued instructions that effective July 1, 2004, electronic claims that do not comply with the appropriate HIPAA claim standard will no longer qualify for payment as early as the 14th day after the date of receipt. These ''non-HIPAA'' claims will not be paid earlier than the 27th day after the date of receipt. These ''non-HIPAA'' claims will continue to have interest payable if payment is not issued by the 31st day after the date of receipt. Our expectation is that contractors will pay 95 percent of these clean claims by the 31st day (30 days after date of receipt) on a monthly basis.

Standard 2. Not less than 95.0 percent of clean paper non-Periodic Interim Payment claims are paid within specified time frames. Specifically, clean non-Periodic Interim Payment paper claims can be paid as early as the 27th day (26 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 3. The percentage of reconsideration determinations reversed by ALJs is acceptable. We have defined an acceptable reversal rate by ALJs as one that is at or below 5.0 percent.

Standard 4. 75.0 percent of reconsiderations are processed within 60 days, and 90.0 percent are processed within 90 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 5. 95.0 percent of Part B review determinations are completed within 45 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 6. 90.0 percent of Part B hearing decisions are completed within 120 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 7. 100 percent of redeterminations must be concluded and mailed within 60 days of receipt of the request. We have determined that the 60-day timeframe will begin with redetermination requests received on or after October 1, 2004.

Because intermediaries process many claims for benefits under the Part B portion of the Medicare Program, we also may evaluate how well an intermediary follows the procedures for processing appeals of any claims for Part B benefits.

Additional functions that may be evaluated under this criterion include, but are not limited to, the following:

- Accuracy of claims processing.
- Remittance advice transactions.

• Establishment and maintenance of a relationship with Common Working File (CWF) Host.
• Accuracy of processing reconsideration cases.
• Accuracy of reviews and hearings, as well as the appropriateness of the reading level of any review determination letters.
• Accuracy and timeliness of processing appeals under section 521 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) and sections 933 and 940 of the MMA.

Note: Section 521 of BIPA and sections 933 and 940 of MMA amend section 1869 of the Act by requiring major revisions to the Medicare appeals process. ''Redeterminations'' replace the current ''reconsideration'' for Part A appeals and the current ''review'' for Part B appeals. Under section 940 of the MMA, amending section 1869 of the Act, intermediaries will be required to conclude all requests for redeterminations within 60 days of receipt of the request. We have determined that implementation of the new redetermination timeframes will begin with redetermination requests received on or after October 1, 2004. Consequently, there will be a period of time in which intermediaries will not only be concluding redeterminations, but will continue to process the reconsiderations, reviews, and hearing workloads with receipt dates prior to October 1, 2004. Because timeliness remains crucial to due process rights for cases with the receipt dates prior to October 1, 2004, we will continue to monitor and evaluate the contractor's ability to meet statutorily mandated timeframes for any reconsideration and review cases with receipt dates prior to October 1, 2004.

We may evaluate other provisions of section 521 of BIPA and sections 933 and 940 of MMA as they are implemented.

B. Customer Service Criterion

Functions that may be evaluated under this criterion include, but are not limited to, the following:

• Providing timely and accurate written replies to beneficiary or provider inquiries, responsiveness to the concerns raised, and writing the replies with an appropriate customer-friendly tone and clarity.
• Ensuring replies to beneficiary written inquiries are written at the appropriate reading levels.
• Maintaining a properly programmed interactive voice response system to assist callers.
• Performing quality call monitoring.
• Training of customer service representatives.
• Ensuring the validity of the call center performance data that are being reported in the customer service assessment and management system.
• Providing timely and accurate written replies to beneficiaries and providers that address the concerns raised and are written with an appropriate customer-friendly tone and clarity and that those written to beneficiaries are at the appropriate reading level.
• Maintaining walk-in inquiry service for beneficiaries and providers.
• Conducting beneficiary and provider education, training, and outreach activities.
• Effectively maintaining an Internet Web site dedicated to furnishing providers and physicians timely, accurate, and useful Medicare program information.

C. Payment Safeguards Criterion

The Payment Safeguard criterion contains the following two mandated standards:

Standard 1. Decisions on SNF demand bills are accurate.

Standard 2. TEFRA target rate adjustments, exceptions, and exemptions are processed within mandated time frames. Specifically, applications must be processed to completion within 75 days after receipt by the contractor or returned to the hospitals as incomplete within 60 days of receipt.

Intermediaries may also be evaluated on any MIP activities if performed under their Part A contractual agreement. These functions and activities include, but are not limited to, the following:

• Audit and Reimbursement
+ Performing the activities specified in our general instructions for conducting audit and settlement of Medicare cost reports.
+ Establishing accurate interim payments.
• Benefit Integrity
+ Referring allegations of potential fraud that are made by beneficiaries, providers, CMS, Office of Inspector General (OIG), and other sources to the Payment Safeguard Contractor.
+ Putting in place effective detection and deterrence programs for potential fraud.
• Medical Review
+ Increasing the effectiveness of medical review activities.
+ Exercising accurate and defensible decision making on medical reviews.
+ Effectively educating and communicating with the provider community.
+ Collaborating with other internal components and external entities to ensure the effectiveness of medical review activities.
• Medicare Secondary Payer
+ Accurately reporting MSP savings.
+ Accurately following MSP claim development and edit procedures.
+ Auditing hospital files and claims to determine that claims are being filed to Medicare appropriately.
+ Supporting the Coordination of Benefits Contractors' efforts to identify responsible payers primary to Medicare.
+ Identifying, recovering, and referring mistaken/conditional Medicare payments in accordance with appropriate Medicare Manual instructions and any other pertinent general instructions, in the specified order of priority.
• Overpayments
+ Collecting and referring Medicare debts timely.
+ Accurately reporting and collecting overpayments.
+ Adhering to our instructions for management of Medicare Trust Fund debts.
• Provider Enrollment
+ Complying with assignment of staff to the provider enrollment function and training the staff in procedures and verification techniques.
+ Complying with the operational standards relevant to the process for enrolling providers.

D. Fiscal Responsibility Criterion

We may review the intermediary's efforts to establish and maintain appropriate financial and budgetary internal controls over benefit payments and administrative costs. Proper internal controls must be in place to ensure that contractors comply with their agreements with us.

Additional functions that may be reviewed under the fiscal responsibility criterion include, but are not limited to, the following:

• Adherence to approved program management and MIP budgets.
• Compliance with the BPRs.
• Compliance with financial reporting requirements.
• Control of administrative cost and benefit payments.

E. Administrative Activities Criterion

We may measure an intermediary's administrative ability to manage the Medicare program. We may evaluate the efficiency and effectiveness of its operations, its system of internal controls, and its compliance with our directives and initiatives.

We may measure an intermediary's efficiency and effectiveness in managing its operations. Proper systems security (general and application controls), ADP maintenance, and disaster recovery plans must be in place. An intermediary must also test system changes to ensure

the accurate implementation of our instructions.

Our evaluation of an intermediary under the administrative activities criterion may include, but is not limited to, reviews of the following:

- Systems security.
- ADP maintenance (configuration management, testing, change management, and security).
- Implementation of the Electronic Data Interchange (EDI) standards adopted for use under HIPAA.
- Disaster recovery plan/systems contingency plan.
- Implementation of our general instructions.
- Data and reporting requirements implementation.
- Internal controls establishment and use, including the degree to which the contractor cooperates with the Secretary in complying with the FMFIA.

V. Criteria and Standards for Regional Home Health Intermediaries (RHHIs)

[If you choose to comment on issues in this section, please include the caption ''CRITERIA AND STANDARDS FOR RHHIs'' at the beginning of your comments.]

The following four standards are mandated for the RHHI criterion:

Standard 1. Not less than 95.0 percent of clean electronically submitted non-Periodic Interim Payment home health and hospice claims are paid within statutorily specified time frames. Clean claims are defined as claims that do not require Medicare intermediaries to investigate or develop them outside of their Medicare operations on a prepayment basis. Specifically, the statute specifies that clean non-Periodic Interim Payment electronic claims be paid no earlier than the 14th day after the date of receipt, and that interest is payable for any clean claims if payment is not issued by the 31st day after the date of receipt. The HIPAA Administrative Simplification provisions and the implementing regulations established standards for electronic transmission of claims. We issued instructions that are effective July 1, 2004, electronic claims that do not comply with the appropriate HIPAA claim standard will no longer qualify for payment as early as the 14th day after the date of receipt. These ''non-HIPAA'' claims will not be paid earlier than the 27th day after the date of receipt. These ''non-HIPAA'' claims will continue to have interest payable if payment is not issued by the 31st day after the date of receipt. Our expectation is that contractors will pay 95 percent of these clean claims by the 31st day (30 days after date of receipt) on a monthly basis.

Standard 2. Not less than 95.0 percent of clean paper non-periodic interim payment home health and hospice claims are paid within specified time frames. Specifically, clean, non-periodic interim payment paper claims can be paid as early as the 27th day (26 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 3. 75.0 percent of HHA and hospice reconsiderations are processed within 60 days and 90.0 percent are processed within 90 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 4: 100 percent of redeterminations must be concluded and mailed within 60 days of receipt of the request. We have determined that the 60-day timeframe will begin with redetermination requests received on or after October 1, 2004.

We may use this criterion to review an RHHI's performance for handling the HHA and hospice workload. This includes processing HHA and hospice claims timely and accurately, properly paying and settling HHA cost reports, and timely and accurately processing reconsiderations and BIPA section 521 redeterminations from beneficiaries, HHAs, and hospices.

Note: Section 521 of BIPA and sections 933 and 940 of MMA amend section 1869 of the Act by requiring major revisions to the Medicare appeals process. ''Redeterminations'' replace the current ''reconsideration'' for Part A appeals and the current ''review'' for Part B appeals. Under section 940 of the MMA, RHHIs will be required to conclude all requests for redeterminations within 60 days of receipt of the request. We have determined that implementation of the new redetermination timeframes will begin with redetermination requests received on or after October 1, 2004. Consequently, there will be a period of time in which RHHIs will not only be concluding redeterminations, but will also continue to process the reconsideration, review, and hearing workloads receipt dates prior to October 1, 2004. Because timeliness remains crucial to due process rights for cases with receipt dates prior to October 1, 2004, we will continue to monitor and evaluate the contractor's ability to meet statutorily mandated timeframes for any reconsideration and review cases with receipt dates prior to October 1, 2004. We may evaluate compliance with our instructions concerning other provisions of section 521 of BIPA and sections 933 and 940 of MMA as they are implemented.

VI. Criteria and Standards for Carriers

[If you choose to comment on issues in this section, please include the caption ''CRITERIA AND STANDARDS FOR CARRIERS'' at the beginning of your comments.]

A. Claims Processing Criterion

The Claims Processing criterion contains the following seven mandated standards:

Standard 1. Not less than 95.0 percent of clean electronically submitted claims are processed within statutorily specified time frames. Clean claims are defined as claims that do not require Medicare carriers to investigate or develop them outside of their Medicare operations on a prepayment basis. Specifically, the statute specifies that clean non-Periodic Interim payment electronic claims be paid no earlier than the 14th day after the date of receipt, and that interest is payable for any clean claims if payment is not issued by the 31st day after the date of receipt. The HIPAA Administrative Simplification provisions and the implementing regulations established standards for electronic transmission of claims. CMS issued instructions that effective July 1, 2004, electronic claims that do not comply with the appropriate HIPAA claim standard will no longer qualify for payment as early as the 14th day after the date of receipt. These ''non-HIPAA'' claims will not be paid earlier than the 27th day after the date of receipt. These ''non-HIPAA'' claims will continue to have interest payable if payment is not issued by the 31st day after the date of receipt. Our expectation is that contractors will pay 95 percent of these clean claims by the 31st day (30 days after date of receipt) on a monthly basis.

Standard 2. Not less than 95.0 percent of clean paper claims are processed within specified time frames. Specifically, clean paper claims can be paid as early as the 27th day (26 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 3. 98.0 percent of MSNs are properly generated. Our expectation is that MSN messages are accurately reflecting the services provided.

Standard 4. 95.0 percent of review determinations are completed within 45 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 5. 90.0 percent of carrier hearing decisions are completed within 120 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 6. Review determination letters prepared in response to beneficiary initiated appeal requests are written at an appropriate reading level.

Standard 7. 100 percent of redeterminations must be concluded and mailed within 60 days of receipt of the request. We have determined that the 60-day timeframe will begin with redetermination requests received on or after October 1, 2004.

Additional functions that may be evaluated under this criterion include, but are not limited to, the following:

- Claims processing accuracy.
- Establishment and maintenance of relationship with the CWF Host.
- Accuracy of processing review determination cases.
- Accuracy of processing hearing cases with decision letters that are clear and have an appropriate customer-friendly tone.
- Accuracy and timeliness of processing appeals under BIPA and MMA.

Note: Section 521 of BIPA and sections 933 and 940 of MMA amend section 1869 of the Act by requiring major revisions to the Medicare appeals process. ''Redeterminations'' replace the current ''review'' for Part B appeals. Under section 940 of the MMA, amending section 1869 of the Act, carriers will be required to conclude all requests for redeterminations within 60 days of receipt of the request. We have determined that implementation of the new redetermination timeframes will begin with redetermination requests received on or after October 1, 2004. Consequently, there will be a period of time in which carriers will not only be concluding redeterminations, but will also be continuing to process the review and hearing workloads with receipt dates prior to October 1, 2004. Because timeliness remains crucial to due process rights for any cases receipt dates prior to October 1, 2004, we will continue to monitor and evaluate the contractor's ability to meet statutorily mandated timeframes for any review cases with receipt dates prior to October 1, 2004. We may evaluate other provisions of section 521 of BIPA and sections 933 and 940 of MMA as they are implemented.

B. Customer Service Criterion

The customer service criterion contains the following mandated standard: Replies to beneficiary written correspondence are responsive to the beneficiary's concerns, are written with an appropriate customer-friendly tone and clarity, and are written at the appropriate reading level.

Contractors must meet our performance expectations that beneficiaries and providers are served by prompt and accurate administration of the program in accordance with all applicable laws, regulations, and our general instructions.

Additional functions that may be evaluated under this criterion include, but are not limited to, the following:

- Providing timely and accurate written replies to beneficiary or provider inquiries.
- Ensuring replies to beneficiary written inquires are written at the appropriate reading levels.
- Maintaining a properly programmed interactive voice response system to assist callers.
- Performing call monitoring.
- Training of customer service representatives.
- Providing timely and accurate written replies to beneficiary and provider inquiries.
- Ensuring the validity of the call center performance data that are being reported in the customer service assessment and management system.
- Maintaining walk-in inquiry service for beneficiaries and providers.
- Conducting beneficiary and provider education, training, and outreach activities.
- Effectively maintaining an internet Web site dedicated to furnishing providers timely, accurate, and useful Medicare program information.

C. Payment Safeguards Criterion

Carriers may be evaluated on any MIP activities if performed under their contracts. In addition, other carrier functions and activities that may be reviewed under this criterion include, but are not limited to the following:

- Benefit Integrity

+ Referring allegations of potential fraud that are made by beneficiaries, providers, CMS, OIG, and other sources to the payment safeguard contractor.

+ Putting in place effective detection and deterrence programs for potential fraud.

- Medical Review

+ Increasing the effectiveness of medical review activities.

+ Exercising accurate and defensible decision making on medical reviews.

+ Effectively educating and communicating with the provider community.

+ Collaborating with other internal components and external entities to ensure the effectiveness of medical review activities.

- Medicare Secondary Payer

+ Accurately reporting MSP savings.

+ Accurately following MSP claim development/edit procedures.

+ Supporting the Coordination of Benefits Contractor's efforts to identify responsible payers primary to Medicare.

+ Identifying, recovering, and referring mistaken/conditional Medicare payments in accordance with the appropriate *Medicare Manual* instructions, and our other pertinent general instructions.

- Overpayments

+ Collecting and referring Medicare debts timely.

+ Accurately reporting and collecting overpayments.

+ Compliance with our instructions for management of Medicare Trust Fund debts.

- Provider Enrollment

+ Complying with assignment of staff to the provider enrollment function and training staff in procedures and verification techniques.

+ Complying with the operational standards relevant to the process for enrolling suppliers.

D. Fiscal Responsibility Criterion

We may review the carrier's efforts to establish and maintain appropriate financial and budgetary internal controls over benefit payments and administrative costs. Proper internal controls must be in place to ensure that contractors comply with their contracts.

Additional functions that may be reviewed under the Fiscal Responsibility criterion include, but are not limited to, the following:

- Adherence to approved program management and MIP budgets.
- Compliance with the BPRs.
- Compliance with financial reporting requirements.
- Control of administrative cost and benefit payments.

E. Administrative Activities Criterion

We may measure a carrier's administrative ability to manage the Medicare program. We may evaluate the efficiency and effectiveness of its operations, its system of internal controls, and its compliance with our directives and initiatives.

We may measure a carrier's efficiency and effectiveness in managing its operations. Proper systems security (general and application controls), ADP maintenance, and disaster recovery plans must be in place. Also, a carrier must test system changes to ensure accurate implementation of our instructions.

Our evaluation of a carrier under this criterion may include, but is not limited to, reviews of the following:

- Systems security.
- ADP maintenance (configuration management, testing, change management, and security).
- Disaster recovery plan/systems contingency plan.
- Implementation of our general instructions.
- Data and reporting requirements implementation.
- Internal controls establishment and use, including the degree to which the

contractor cooperates with the Secretary in complying with the FMFIA.

- Implementation of the Electronic Data Interchange (EDI) Standards adopted for use under the Health Insurance Portability and Accountability Act (HIPAA).

VII. Criteria and Standards for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carriers

[If you choose to comment on issues in this section, please include the caption ''CRITERIA AND STANDARDS FOR DMEPOS'' at the beginning of your comments.]

The five criteria for DMEPOS regional carriers contain a total of eight mandated standards against which all DMEPOS regional carriers must be evaluated.

There also are examples of other activities for which the DMEPOS regional carriers may be evaluated. The mandated standards are in the claims processing and customer service criteria. In addition to being described in these criteria, the mandated standards are also described in the DMEPOS regional carrier statement of work (SOW).

A. Claims Processing Criterion

The claims processing criterion contains the following seven mandated standards:

Standard 1. Not less than 95.0 percent of clean electronically submitted claims are processed within statutorily specified time frames. Clean claims are defined as claims that do not require Medicare DMEPOS regional carriers to investigate or develop them outside of their Medicare operations on a prepayment basis. Specifically, the statute specifies that clean non-Periodic Interim Payment electronic claims be paid no earlier than the 14th day after the date of receipt, and that interest is payable for any clean claims if payment is not issued by the 31st day after the date of receipt. The HIPAA Administrative Simplification provisions and the implementing regulations established standards for electronic transmission of claims. CMS issued instructions that effective July 1, 2004, electronic claims that do not comply with the appropriate HIPAA claim standard will no longer qualify for payment as early as the 14th day after the date of receipt. These ''non-HIPAA'' claims will not be paid earlier than the 27th day after the date of receipt. These ''non-HIPAA'' claims will continue to have interest payable if payment is not issued by the 31st day after the date of receipt. Our expectation is that contractors will pay 95 percent of these clean claims by the 31st day (30 days after date of receipt) on a monthly basis.

Standard 2. Not less than 95.0 percent of clean paper claims are processed within specified timeframes. Specifically, clean paper claims can be paid as early as day 27 (26 days after the date of receipt) and must be paid by day 31 (30 days after the date of receipt). Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 3. 98.0 percent of MSNs are properly generated. Our expectation is that MSN messages are accurately reflecting the services provided.

Standard 4. 95.0 percent of DMEPOS regional carrier review determinations are completed within 45 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 5. 90.0 percent of DMEPOS regional carrier hearing decisions are completed within 120 days. Our expectation is that contractors will meet this percentage on a monthly basis.

Standard 6. Review determination letters prepared in response to beneficiary initiated appeal requests are written at an appropriate reading level.

Standard 7. 100 percent of redeterminations must be concluded and mailed within 60 days of receipt of the request. We have determined that the 60-day timeframe will begin with redetermination requests received on or after October 1, 2004.

Additional functions that may be evaluated under this criterion include, but are not limited to, the following:

- Claims processing accuracy.
- Review determinations and hearing decisions are written accurately, clearly, and in a customer friendly tone.
- Telephone reviews are appropriately documented and adjudicated timely.
- Requests for ALJ hearings are forwarded timely.
- Accuracy and timeliness of processing appeals under BIPA and MMA.

Note: Section 521 of BIPA and sections 933 and 940 of MMA amend section 1869 of the Act by requiring major revisions to the Medicare appeals process. ''Redeterminations'' replace the current ''review'' for Part B appeals. Under section 940 of the MMA, amending section 1869 of the Act, DMEPOS regional carriers will be required to conclude all requests for redeterminations within 60 days of receipt of the request. We have determined that implementation of the new redetermination timeframes will begin with redetermination requests received on or after October 1, 2004. Consequently, there will be a period of time in which DMEPOS regional carriers will not only be concluding redeterminations, but will also be continuing to process the review and hearing workloads with receipt dates prior to October 1, 2004. Because timeliness remains crucial to due process rights for any cases with receipt dates prior to October 1, 2004, we will continue to monitor and evaluate the contractor's ability to meet statutorily mandated timeframes for any review cases with receipt dates prior to October 1, 2004. We may evaluate other provisions of section 521 of BIPA and sections 933 and 940 of MMA as they are implemented.

B. Customer Service Criterion

The customer service criterion contains the following mandated standard: Replies to beneficiary written correspondence address the beneficiary's concerns, are written with an appropriate customer-friendly tone and clarity, and are written at the appropriate reading level.

Contractors must meet our performance expectations that beneficiaries and suppliers are served by prompt and accurate administration of the program in accordance with all applicable laws, regulations, the DMEPOS regional carrier SOW, and our general instructions.

Additional functions that may be evaluated under this criterion include, but are not limited to, the following:

- Providing timely and accurate replies to beneficiary and supplier telephone inquiries.
- Maintaining a properly programmed interactive voice response system to assist callers.
- Monitoring calls for quality.
- Training of Customer Service Representatives.
- Ensuring the validity of the call center performance data that are being reported in the customer service assessment and management system.
- Providing timely and accurate replies to beneficiaries, providers, and suppliers.
- Maintaining walk-in inquiry service for beneficiaries and providers.
- Conducting beneficiary and supplier education, training, and outreach activities.
- Effectively maintaining an internet Web site dedicated to furnishing suppliers timely, accurate, and useful Medicare program information.
- Ensuring that communications are made to interested supplier organizations for the purpose of developing and maintaining collaborative supplier education and training activities and programs.

C. Payment Safeguards Criterion

DMEPOS regional carriers may be evaluated on any MIP activities if performed under their contracts. The DMEPOS regional carriers must

undertake actions to promote an effective program administration for DMEPOS regional carrier claims. These functions and activities include, but are not limited to the following:

• Benefit Integrity

+ Identifying potential fraud cases that exist within the DMEPOS regional carrier's service area and taking appropriate actions to resolve these cases.

+ Investigating allegations of potential fraud made by beneficiaries, suppliers, CMS, OIG, and other sources.

+ Putting in place effective detection and deterrence programs for potential fraud.

• Medical Review

+ Increasing the effectiveness of medical review activities.

+ Exercising accurate and defensible decision making on medical reviews.

+ Effectively educating and communicating with the supplier community.

+ Collaborating with other internal components and external entities to ensure the effectiveness of medical review activities.

• Medicare Secondary Payer

+ Accurately reporting MSP savings.

+ Accurately following MSP claim development/edit procedures.

+ Supporting the coordination of benefits contractors' efforts to identify responsible payers primary to Medicare.

+ Identifying, recovering, and referring mistaken/conditional Medicare payments in accordance with the appropriate program instructions in the specified order of priority.

• Overpayments

+ Collecting and referring Medicare debts timely.

+ Accurately reporting and collecting overpayments.

+ Compliance with our instructions for management of Medicare Trust Fund debts.

D. Fiscal Responsibility Criterion

We may review the DMEPOS regional carrier's efforts to establish and maintain appropriate financial and budgetary internal controls over benefit payments and administrative costs. Proper internal controls must be in place to ensure that contractors comply with their contracts. Additional matters that may be reviewed under this criterion include, but are not limited to, the following:

• Compliance with financial reporting requirements.

• Adherence to approved program management and MIP budgets.

• Control of administrative cost and benefit payments.

E. Administrative Activities

We may measure a DMEPOS regional carrier's administrative ability to manage the Medicare program. We may evaluate the efficiency and effectiveness of its operations, its system of internal controls, and its compliance with our directives and initiatives. Our evaluation of a DMEPOS regional carrier under this criterion may include, but is not limited to, review of the following:

• Systems security.

• Disaster recovery plan/systems contingency plan.

• Internal controls establishment and use, including the degree to which the contractor cooperates with the Secretary in complying with the FMFIA.

• Implementation of the EDI standards adopted for use under HIPAA.

VIII. Action Based on Performance Evaluations

[If you choose to comment on issues in this section, please include the caption ''ACTION BASED ON PERFORMANCE EVALUATIONS'' at the beginning of your comments.]

We evaluate a contractor's performance against applicable program requirements for each criterion. Each contractor must certify that all information submitted to us relating to the contract management process, including, without limitation, all files, records, documents and data, whether in written, electronic, or other form, is accurate and complete to the best of the contractor's knowledge and belief. A contractor is required to certify that its files, records, documents, and data have not been manipulated or falsified in an effort to receive a more favorable performance evaluation. A contractor must further certify that, to the best of its knowledge and belief, the contractor has submitted, without withholding any relevant information, all information required to be submitted for the contract management process under the authority of applicable law(s), regulation(s), contract(s), or our manual provision(s). Any contractor that makes a false, fictitious, or fraudulent certification may be subject to criminal or civil prosecution, as well as appropriate administrative action. This administrative action may include debarment or suspension of the contractor, as well as the termination or nonrenewal of a contract.

If a contractor meets the level of performance required by operational instructions, it meets the requirements of that criterion. When we determine a contractor is not meeting performance requirements, we will use the terms ''major nonconformance'' or ''minor nonconformance'' to classify our findings. A major nonconformance is a nonconformance that is likely to result in failure of the supplies or services, or to materially reduce the usability of the supplies or services for their intended purpose. A minor nonconformance is a nonconformance that is not likely to materially reduce the usability of the supplies or services for their intended purpose, or is a departure from established standards having little bearing on the effective use or operation of the supplies or services. The contractor will be required to develop and implement PIPs for findings determined to be either a major or minor nonconformance. The contractor will be monitored to ensure effective and efficient compliance with the PIP, and to ensure improved performance when requirements are not met.

The results of performance evaluations and assessments under all criteria applying to intermediaries, carriers, RHHIs, and DMEPOS regional carriers will be used for contract management activities and will be published in the contractor's annual Report of Contractor Performance (RCP). We may initiate administrative actions as a result of the evaluation of contractor performance based on these performance criteria. Under sections 1816 and 1842 of the Act, we consider the results of the evaluation in our determinations when—

• Entering into, renewing, or terminating agreements or contracts with contractors, and

• Deciding other contract actions for intermediaries and carriers (such as deletion of an automatic renewal clause). These decisions are made on a case-by-case basis and depend primarily on the nature and degree of performance. More specifically, these decisions depend on the following:

+ Relative overall performance compared to other contractors.

+ Number of criteria in which nonconformance occurs.

+ Extent of each nonconformance.

+ Relative significance of the requirement for which nonconformance occurs within the overall evaluation program.

+ Efforts to improve program quality, service, and efficiency.

+ Deciding the assignment or reassignment of providers and designation of regional or national intermediaries for classes of providers.

We make individual contract action decisions after considering these factors in terms of their relative significance and impact on the effective and efficient administration of the Medicare program.

In addition, if the cost incurred by the intermediary, RHHI, carrier, or DMEPOS regional carrier to meet its contractual requirements exceeds the amount that we find to be reasonable and adequate to meet the cost that must be incurred by an efficiently and economically operated intermediary or carrier, these high costs may also be grounds for adverse action.

IX. Collection of Information Requirements

This document does not impose information collection and record keeping requirements. Consequently the Office of Management and Budget need not review it under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

X. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are unable to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **Comment Period** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble of that document.

XI. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million in any one year). Since this notice only describes criteria and standards for evaluating FIs (including RHHIs), carriers, and DMEPOS regional carriers and has no significant economic impact on the program, its beneficiaries, providers or suppliers, this is not a major notice.

The RFA requires agencies to analyze options for regulatory relief of small businesses, but intermediaries, RHHIs, carriers and DMEPOS regional carriers are not small businesses.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This notice does not affect small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. In accordance with section 202, we have determined that the notice does not impose any unfunded mandates on States, local or tribal governments, or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a notice that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. We have determined that the notice does not significantly affect the rights, roles, and responsibilities of States.

We have not prepared a Regulatory Impact Analysis for this notice, in accordance with Executive Order 12866, because it will not have a significant economic impact, nor does it impose any unfunded mandates on State, local, or tribal governments or the private sector. Furthermore, we certify that the notice will not have a significant impact on a substantial number of small entities or small rural hospitals.

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

Authority: Sections 1816(f), 1834(a)(12), and 1842(b) of the Social Security Act (42 U.S.C. 1395h(f), 1395m(a)(12), and 1395u(b))

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

Dated: May 27, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Editorial Note: This document was recieved at the Office of the Federal Register on November 23, 2004.

[FR Doc. 04–26278 Filed 11–24–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3149–N]

Medicare Program; Meeting of the Medicare Coverage Advisory Committee—January 25, 2005

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a public meeting of the Medicare Coverage Advisory Committee (MCAC). The Committee provides advice and recommendations about whether scientific evidence is adequate to determine whether certain medical items and services are reasonable and necessary under the Medicare statute. This meeting concerns the data from and the quality of clinical evidence pertaining to the effects of lifestyle modification such as diet, exercise, stress reduction and group counseling as it relates to reversal or resolution of diseases such as coronary heart disease and diabetes. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES: The public meeting will be held on Tuesday, January 25, 2005, from 7:30 a.m. until 4:30 p.m. e.s.t.

Deadline for Presentations and Comments: Written comments and presentations must be received by December 27, 2005, 5 p.m., e.s.t.

ADDRESSES: The meeting will be held in the auditorium at the Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244.

Presentations and Comments: Interested persons may present data, information, or views orally or in writing on issues pending before the Committee. Please submit written comments to Michelle Atkinson, by e-mail at *Matkinson@cms.hhs.gov* or by mail to the Executive Secretary for MCAC, Coverage and Analysis Group, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C1–09–06, Baltimore, MD 21244.

Web site: You may access up-to-date information on this meeting at *http://www.cms.hhs.gov/mcac/default.asp#meetings.*

Hotline: You may access up-to-date information on this meeting on the CMS Advisory Committee Information Hotline, 1–877–449–5659 (toll free) or in the Baltimore area (410) 786–9379.