Louisiana, to be used as a park, are designated as follows: Richard J. Putnam Park, on the grounds of the John M. Shaw United States Courthouse, 800 Lafayette Street, Lafayette, LA 70501.

Dated: December 19, 2001.

Stephen A. Perry,

Administrator of General Services.

[FR Doc. 01–31883 Filed 12–27–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–4021–GNC]

RIN 0938–ZA22

Medicare Program; Criteria and Standards for Evaluating Intermediary, Carrier, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Regional Carrier Performance During Fiscal Year 2002

AGENCY: Centers for Medicare & 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, carriers, and DMEPOS regional carriers in the administration of the Medicare program beginning the first day of the month following publication 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. The criteria and standards for DMEPOS regional carriers (also referred to as Durable Medical Equipment Regional Carriers (DMERCs)) were previously published under a separate **Federal Register** notice, but with this release will now be incorporated in the notice of criteria and standards for the intermediaries and carriers. We are requesting public comment on these criteria and standards.

EFFECTIVE DATE: The criteria and standards are effective January 2, 2002.

COMMENTS: Comments will be considered if we receive them at the appropriate address as provided below no later than 5 p.m. (EDT) on January 28, 2002.

ADDRESSES: In commenting, please refer to file code CMS–4021–GNC. Because of staff and resource limitations, we cannot accept comments by facsimile (fax) transmission. Mail written comments (one original and three copies) to the following address: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4021–GNC, P.O. Box 8016, Baltimore, MD 21244–8016.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC, 20201 or

Room C5–16–03, 7500 Security Boulevard, Baltimore, Maryland 21244–8016.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

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

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

SUPPLEMENTARY INFORMATION

Inspection of Public Comments: 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) 786–7197.

I. Background

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 fiscal intermediaries, 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), community mental health centers, etc.) 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. Evaluations of Medicare fee-for-service performance need not be limited to the current fiscal year (FY), other fixed term basis, or agreement term. We may evaluate performance using a time frame that does not mirror the FY or other fixed term. The evaluation of intermediary performance is part of our contract management process.

B. Part B 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 performance need not be limited to the current FY, other fixed term basis, or contract term. We may evaluate performance using a timeframe that does not mirror the FY. 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, CMS has 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. The criteria and standards to be used for evaluating the performance of DMEPOS regional carriers were first published on June 18, 1992 at 57 FR 27302. 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 and 421.122 provide for publication of a **Federal Register** notice to announce criteria and standards for intermediaries prior to implementation. Section 421.201 provides for publication of a **Federal Register** notice to announce criteria and standards for carriers prior to implementation. The current criteria and standards for intermediaries and carriers were published in the **Federal Register** on October 31, 2000 at 65 FR 64968 and for DMEPOS regional carriers on January 26, 1996 at 61 FR 2516.

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 on the first day of the first month following publication. Any revised criteria and standards will measure performance prospectively; that is, we will not apply new measurements to assess performance on a retroactive basis.

It is not our intention to revise the criteria and standards that will be used during the evaluation period once this information has been published in a **Federal Register** notice. However, on occasion, either because of administrative action or congressional 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 a **Federal Register** notice prior to 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.

II. Analysis of and Response to Public Comments Received on FY 2001 Criteria and Standards

In response to the October 31, 2000 **Federal Register** general notice with comments, we received comments from 12 entities or individuals. We acknowledge and thank each respondent for submitting comments. All comments were reviewed, but none necessitated our reissuance of the FY 2001 Criteria and Standards. Not all comments submitted pertained specifically to the FY 2001 Criteria and Standards. Medicare program components were advised of the concerns as appropriate. When warranted, revisions have been incorporated in this **Federal Register** notice. We are responding to the following performance evaluation issues:

Comment: We were asked to clarify the time frames of 45 days for Standard 4 and 120 days for Standard 5 under the Customer Service criterion for carriers.

Response: Sections 1842(b)(2)(B)(i) and (ii) of the Act specifies time frames for carriers to complete review determinations and to make hearing decisions. A review determination is to be completed within 45 days after the date of a request. A hearing decision is to be made within 120 days after the date of receipt of a request. The date of receipt is the date the request is received and date stamped in the contractor's mailroom.

Comment: A commenter advised us of their concern about what they feel is the inconsistent manner in which the DMERCs conduct medical review. We were asked to instruct the DMERCs on what constitutes appropriate medical record review regarding suppliers, facilities, and physicians, and to instruct the DMERC to take into account that suppliers are not the appropriate conduits for medical record review. Further, we were asked to develop standards to ensure that DMERCs comply with these instructions.

Response: We must hold the entity receiving Medicare payments accountable for providing documentation that supports that services and equipment are covered by the Medicare program. The law requires physicians or practitioners ordering certain services and equipment to provide suppliers with this information to support claims payments.

Comment: Several commenters advised us that there seemed to be a discrepancy between the All Trunks Busy (ATB) internal rate, under the Customer Service criterion for carriers Standard 1, published in the October 31, 2000 **Federal Register** notice and the ATB internal rate in CMS' FY 2001 Budget and Performance Requirements (BPRs) for contractors. The October 31, 2000 **Federal Register** notice states, ''Carriers are to achieve a monthly ATB rate of not more than 10%.'' In contrast, the FY 2001 BPRs states the monthly ATB rate ''shall average 10%.''

Response: The BPRs changed during FY 2001. The commenter is correct in noting a difference between the BPRs ATB internal rate and the ATB internal rate published in the **Federal Register**. However, we want to assure the commenter that we conducted Contractor Performance Evaluation (CPE) reviews based on the BPRs. If any contractor was evaluated earlier in the fiscal year on the basis of a BPR requirement that was subsequently changed, CMS subsequently reevaluated its performance against the latest BPR requirements. When necessary, revised CPE reports were issued to reflect our evaluation changes.

Comment: Commenters asked several questions concerning issues under section VII, Action Based on Performance Evaluations of the FY 2001 notice. The questions are as follows: CMS refers to the possibility of contractors (manipulating data in order to receive a ''more favorable performance evaluation.)'' How does the intermediary or carrier obtain a more favorable evaluation? How will the affected public know whether a contractor ''meets the level of performance required?'' Will the contractor's annual performance reports, referred to in paragraph three, be made available to the affected public?

Response: Many standards established for contractors, including some mandated ones specified in each year's **Federal Register** notice, rely on data submitted to the CMS Contractor Reporting of Operational and Workload Data Database. If a contractor manipulates data to reflect quicker processing of appeals or changes a claim identified as clean to be one identified as other than clean, the contractor's actions could result in more favorable timeliness data for those workloads. Because we identified only those performance standards, which are mandated by law, regulations, or judicial decision and provide examples of some other possible standards, we believe we have minimized the situations in which contractors are certain of the precise methodology by which we evaluate them.

The public may request CPE review reports through the Freedom of

Information Act, but we do not normally publish information on the findings of our performance evaluations.

Comment: A commenter stated, ''We understand that the numerical CPEP requirements of past years, for example, an old requirement that intermediaries find $5.99 to $7.99 in disallowance for every dollar they received to perform medical review and utilization review, have been eliminated.'' ''Clearly something has been substituted for the old ''quotas''.'' ''We ask that CMS make this information available to the affected public.'' ''Many providers have the perception that CMS still requires its contractors to meet some sort of numerical ratios and/or that the contractors are free to set up their own quotas and reward system.''

Response: CMS does not require contractors to meet savings quotas or targets, nor have reward systems. Instead, CMS assesses contractor activities that support the accomplishment of core performance standards specified in the annual Budget and Performance Requirements for medical review. These activities include, for example, workload management and data analysis.

Comment: One commenter stated that Medicare intermediary workload data from some recent years showed that approximately 35–40 percent of intermediary denials of home health or hospice care were reversed by Administrative Law Judges (ALJs) after reconsideration determinations by intermediaries. The commenter believes that, in light of CMS' definition of an acceptable reversal rate, this past data on reversals is quite disturbing. Home health intermediaries should be held accountable to the standards and criteria established by CMS.

Response: Certain intermediaries have as an amendment to their contract the responsibility to serve as a Regional Home Health Intermediary (RHHI). This means that in addition to processing claims from hospitals and skilled nursing facilities they are also responsible for claims and appeals from home health agencies and hospices. The mandate for intermediaries to have an acceptable ALJ reversal rate of their determinations applies to the full range of claims determinations which may be appealed to the ALJ level. That is, the determination of acceptable is not based solely on ALJ decisions concerning home health claims for intermediaries designated as RHHI's. As a result, the data applicable to only reversals of home health and hospice claims is not reflective of the data CMS uses to evaluate this standard.

Comment: Commenters stated that the use of the verbiage, ''criterion may include, but is not limited to * * *'' specific items, appears to broaden the scope of CMS' contractor performance evaluation by indicating that the five criteria can be expanded. The commenter believes that in a year of tight contractor funding, CMS should be more focused in its directions to carriers and intermediaries and indicate standards for activities that must be performed regardless of budgeted levels. This will allow contractors to prioritize activities within funding constraints.

Response: In the general criteria and standards we state the goal of the contractor performance evaluation is to ensure that contractors meet their contractual obligations. To ensure that contractors are meeting their contractual obligations we have established criteria and standards that are mandated or authorized by law, regulation, judicial decision, contract, or administration directives. We take into consideration the BPRs, any changes to them, and any abatements. It is not our intention to evaluate performance for which a contractor is not budgeted.

Comment: A commenter noted that in the Actions Based on Performance Evaluations section we state, ''In addition, if the cost incurred by the intermediary or 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.'' The commenter states CMS should identify and ensure that contractors report costs accurately within each activity and ensure that there is consistent performance activities across the contractor community. This will allow effective contractor comparisons.

Response: CMS budget staff, who review contractor cost reporting and budget expenditures, review the overall spending associated with contractors' work. Additionally, CMS' functional components may include in their protocols an evaluation of the appropriateness of spending for the work performed.

Comment: A commenter recommended that until Administrative Law Judges (ALJs) are required to follow CMS manuals, the standard for intermediaries to not have more than 5.0 percent of appeals determinations reversed by ALJs should be removed.

Response: Section 1816 (f)(2)(A)(ii) of the Act requires that CMS evaluate ''the extent to which such agency's or organization's determinations are reversed on appeal.'' In response to this requirement, CMS has defined an acceptable reversal rate by ALJs as one that is at or below 5.0 percent. We recognize that ALJs act independently. As we evaluate this standard we take into consideration whether the ALJ followed Medicare laws, regulations, and/or CMS program manuals.

Comment: Commenters stated that while the preamble mentions provider education as an element for evaluation under the Customer Service criterion it is unclear in the standards whether intermediaries are being evaluated on responsiveness to providers or just to beneficiaries.

Response: We agree that clarification is needed. With this notice we have specified that intermediaries may be evaluated on their responsiveness to providers as well as to beneficiaries.

Comment: One commenter expressed disappointment that the details of the FY 2001 process, while containing a number of objectively measured standards, depended heavily upon the subjective judgements of the individuals who would perform the reviews.

Response: We acknowledge that there were criteria and standards that permitted reviewers to make more subjective determinations concerning acceptableness of performance. We are working to decrease the number of these standards.

Comment: A commenter noted that the background portion of Section I indicated CMS may evaluate contractors' performance using a time frame that does not mirror the fiscal year or other fixed term. This means that the criteria and standards do not necessarily pertain to work performed during FY 2001, but rather to evaluations performed during that time. The concern is that a lack of a uniform time frame for the work being evaluated adds further to the subjectivity, imprecision, and variability that characterize the ''rules'' by which individual contractors' performance will be judged.

Response: Reviewers use evaluation protocols developed by CMS business function components. The use of standard protocols by all CPE reviewers helps to add greater overall consistency to the evaluation process. Our general focus, is on reviewing the work performed during the current FY, however, there could be situations where review of work conducted in previous years may be appropriate. The criteria and standards that were in effect at the time the work was performed will be used to evaluate work performed in previous years.

Comment: Commenters stated that contractor workloads, overall funding, and funding for specific activities, as well as CMS priorities and instructions to contractors, all fluctuate from year to year. In addition, in any fiscal year contractors often spend several months operating under restricted continuation budgets that do not reflect the full level of funding for the year that CMS eventually authorizes sometimes too late to be spent efficiently. We were told it is important that reviews of contractor performance take these time-related variances into account.

Response: In conducting CPE reviews we take into consideration budgetary restraints and situations experienced by each contractor. Authorizing the full level of funding to contractors is dependent upon the timing of Congressional appropriations.

Comment: A commenter requested that we provide a description of the types of analysis by intermediaries and carriers that we intend to address under the Claims Processing Criterion.

Response: In the October 31, 2000 **Federal Register** notice of criteria and standards we identified analysis and validation of data as additional functions that may be evaluated under the Claims Processing Criterion. However, rather than being functions we may evaluate, they are methods by which we can evaluate the accuracy of data submitted to CMS by intermediaries and carriers. We erred in listing this as a contractor function that could be reviewed. Thus, there was no analysis in this area that we had planned to evaluate.

Comment: A commenter noted that the FY 2001 Payment Safeguards Criterion specifies identifying fraud cases, investigating allegations of fraud, and putting in place effective fraud detection and deterrence programs. In contrast, the same criterion for carriers specifies identifying fraud and abuse cases, investigating fraud and/or abuse cases, and putting into place effective fraud and abuse detection and deterrence programs. We were asked if the failure to mention ''abuse'' in the criteria and standards for intermediaries meant to imply a distinction between CMS'' evaluations of intermediaries and those of carriers, or was this a drafting oversight?

Response: Failing to mention ''abuse'' under the Payment Safeguards Criterion for intermediaries was indeed a drafting oversight. We have corrected the oversight with this notice.

Comment: We were advised that in section VII, Action Based on Performance Evaluations for the FY 2001 notice, we provided a definition for deficiency and vulnerability but not for ''weakness.'' We have been requested to provide a definition of what constitutes a ''weakness.''

Response: A weakness may be an observed decline in contractor performance or a shortcoming in an operational process.

III. Criteria and Standards—General

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 law, regulation, contract, and our directives. We have developed a contractor oversight program for FY 2002 that outlines expectations of the contractor; measures the performance of the contractor; evaluates the performance against the expectations; and, takes appropriate contract action based upon the evaluation of the contractor's performance. We will work to develop and refine measurable performance standards in key areas in order to better evaluate contractor performance. In addition to evaluating performance based upon expectations for FY 2002, we may conduct follow-up evaluations of areas in which contractor performance was out of compliance with laws, regulations, and our performance expectations during FY 2001, thus having required the contractor to submit a Performance Improvement Plan (PIP).

In FY 2001, CMS introduced the Contractor Rebuttal Process as a commitment to continual improvement of CPE. This mechanism provides an opportunity for contractors to submit a written rebuttal of CPE findings of fact. Contractors have 7 calendar days from the CPE exit conference to submit a written rebuttal. The contents of the rebuttal will be considered by the review team prior to the issuance of the final CPE report to the contractor. We will assess the implementation and effectiveness of this new process during the FY 2001 CPE review cycle and, in consultation with the Medicare contractors, will determine if the rebuttal process adequately meets our respective needs.

Throughout this notice, we frequently refer to mandated standards. Mandated standards are those required by law, regulation, or judicial decision. We have reviewed the language of the laws, regulations, and court decisions in which the mandates were presented comparing them to those standards we identified as mandated in the more recent notices that have been published. In so doing, we determined that in some cases we had included requirements that in fact were not mandated, for example, accuracy of review decisions. In this FY 2002 notice of criteria and standards we have corrected those erroneously indicated performance mandates. Those requirements were standards in the Claims Processing Criterion and Customer Service Criterion.

The FY 2002 Contractor Performance Evaluation for intermediaries and carriers is structured into five criteria designed to meet the stated objectives. The first criterion is ''Claims Processing,'' which 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 Explanations of Medicare Benefits (EMOBs) and Medicare Summary Notices (MSNs), the appropriateness of determinations reversed by Administrative Law Judges (ALJs), the timeliness of intermediary reconsideration cases, the timeliness of carrier reviews and hearings, and the readability of carrier reviews. 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 is ''Customer Service'' which assesses the adequacy of the service provided to customers by the contractor in its administration of the Medicare program. The mandated standards in the Customer Service Criterion include achieving and maintaining the monthly All Trunks Busy rate for beneficiary telephone inquiries; responding timely to beneficiary telephone inquiries; and providing beneficiaries with written replies that are responsive, written with appropriate customer-friendly tone and clarity, and are at the appropriate reading level. Further evaluation of services under this criterion may include, but is not limited to, the timeliness and accuracy of all correspondence both to beneficiaries and providers; monitoring of the quality of responses provided by the contractor's customer service representatives (quality call

monitoring); beneficiary and provider education and outreach; and service by contractor's customer service representatives to beneficiaries who come to the contractor's facility (walk-in inquiry service).

The third criterion is ''Payment Safeguards,'' which evaluates whether the Medicare Trust Fund is safeguarded against inappropriate program expenditures. Intermediary and carrier performance may be evaluated in the areas of Benefit Integrity (BI) (referred to in prior **Federal Register** notices as Fraud and Abuse), 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). Mandated performance standards for intermediaries in the Payment Safeguards criterion are the accuracy of decisions on Skilled Nursing Facility (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 is ''Fiscal Responsibility,'' which 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 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 is ''Administrative Activities,'' which 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, which are essential in all aspects of a contractor's operation and 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 implementation of general CMS instructions and data and reporting requirements.

We have also developed separate measures for evaluating unique activities of Regional Home Health Intermediaries (RHHIs). Section 1816(e)(4) of the Act requires us to designate regional agencies or organizations, which are already Medicare intermediaries under section 1816, to perform claim processing functions with respect to freestanding Home Health Agency (HHA) claims. The law requires that we limit the number of these regional intermediaries (RHHIs) to not more than 10; see 42 CFR 421.117 and the final rule published in the **Federal Register** on May 19, 1988 at 53 FR 17936 for more details about the RHHIs.

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 functions should be moved from one intermediary to another in order to ensure effective and efficient administration of the program benefit.

Below, we list the criteria and standards to be used for evaluating the performance of intermediaries, RHHIs, carriers, and DMEPOS regional carriers. In several instances, we identify a Medicare manual as a source of more detailed requirements. Medicare fee-for-service contractors have copies of the various Medicare manuals referenced in this notice. Members of the public also have access to our manualized instructions. Medicare manuals are available for review at local Federal Depository Libraries (FDLs). Under the FDL Program, government publications are sent to approximately 1,400 designated public libraries throughout the United States. Interested parties may examine the documents at any one of the FDLs. Some may have arrangements to transfer material to a local library not designated as a FDL. To locate the nearest FDL, individuals should contact any public library.

In addition, individuals may contact regional depository libraries, which receive and retain at least one copy of nearly every Federal government publication, either in printed or microfilm form, for use by the general public. These libraries provide reference services and interlibrary loans; however, they are not sales outlets. Individuals may obtain information about the location of the nearest regional depository library from any library. Information may also be obtained from the following web site: *www.cms.hhs.gov/pubforms/program.htm.* Some manuals may be obtained from the following web site: *www.cms.gov/pubforms/p2192toc.htm.*

Finally, all of our Regional Offices (RO) maintain all Medicare manuals for public inspection. To find the location of the nearest available CMS RO, you may call the individual listed at the beginning of this notice. That individual can also provide information about purchasing or subscribing to the various Medicare manuals.

IV. Criteria and Standards for Intermediaries

A. Claims Processing Criterion

The Claims Processing criterion contains 4 mandated standards.

Standard 1. 95.0 percent of clean electronically submitted non-Periodic Interim Payment claims 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, clean, non-Periodic Interim Payment electronic claims can be paid as early as the 14th day (13 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). CMS' expectation is that contractors will meet this percentage on a monthly basis.

Standard 2. 95.0 percent of clean paper non-Periodic Interim Payment claims 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). CMS' expectation is that contractors will meet this percentage on a monthly basis.

Standard 3. 5.0 percent reversal rate 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. CMS' expectation is that contractors will meet this percentage on a monthly basis.

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

- Claims processing accuracy.
- Establishment and maintenance of relationship with Common Working File (CWF) Host.
- Accuracy of processing reconsideration cases with determination letters that are clear and have appropriate customer-friendly tone.

B. Customer Service Criterion

There are no mandated standards for this criterion for intermediaries.

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

- Ensuring that the monthly All Trunks Busy rate for beneficiary and provider inquiries is achieved and maintained.
- Responding timely and accurately to beneficiary and provider telephone inquiries.
- Quality Call Monitoring.
- 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 responses to beneficiaries and providers that are responsive and written with appropriate customer-friendly tone and clarity and those written to beneficiaries are at the appropriate reading level.
- Conducting beneficiary and provider education and outreach.
- Walk-in inquiry service.

C. Payment Safeguards Criterion

The Payment Safeguard criterion contains 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 agreement or contract. 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

- Identifying potential fraud cases that exist within the intermediary's service area and taking appropriate actions to resolve these cases.
- Investigating allegations of potential fraud that are made by beneficiaries, providers, CMS, Office of Inspector General (OIG), and other sources.
- Putting in place effective detection and deterrence programs for potential fraud.

Medical Review

- Applying analytical skills and focusing resources on particular providers or claim types that represent unnecessary or inappropriate care.
- Making accurate and defensible decisions on medical reviews.
- Developing means of addressing any aberrance identified during the analysis of all local and national data.
- Effectively educating and communicating with the provider community.

Medicare Secondary Payer

- Identifying, recovering, and referring mistaken Medicare payments in accordance with appropriate Medicare Intermediary Manual instructions and other pertinent CMS general instructions.
- Accurately reporting savings and following claim development procedures.
- Prioritizing and processing recoveries in compliance with instructions.
- Financial reporting activities.

Overpayments

- Collecting and referring Medicare debts timely.
- Accurately reporting overpayments to CMS.
- 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

While there are no mandated standards in this 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 matters 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

While there are no mandated standards in this 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, security, etc).
- Disaster recovery plan.
- Implementation of general CMS 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)

The following standards are mandated for the RHHI criterion:

Standard 1. 95.0 percent of clean electronically submitted non-Periodic Interim Payment HHA/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, clean, non-Periodic Interim Payment electronic claims can be paid

as early as the 14th day (13 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). CMS' expectation is that contractors will meet this percentage on a monthly basis.

Standard 2. 95.0 percent of clean paper non-Periodic Interim Payment HHA/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). CMS' expectation is that contractors will meet this percentage on a monthly basis.

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

We may use this criterion to review a RHHI's performance with respect to handling the HHA/hospice workload. This includes processing HHA/hospice claims timely and accurately; properly paying and settling HHA cost reports; and timely and accurately processing reconsiderations from beneficiaries, HHAs, and hospices, interim rate setting, and accuracy of MR coverage decisions.

VI. Criteria and Standards for Carriers

A. Claims Processing Criterion

The Claims Processing criterion contains six mandated standards.

Standard 1. 95.0 percent of clean electronically submitted claims 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, clean electronic claims can be paid as early as the 14th day (13 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). CMS' expectation is that contractors will meet this percentage on a monthly basis.

Standard 2. 95.0 percent of clean paper claims 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). CMS' expectation is that contractors will meet this percentage on a monthly basis.

Standard 3. 98.0 percent of EOMBs and MSNs are properly generated.

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

Standard 6. Responses to beneficiary reviews are written at an appropriate reading level.

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

- Claims Processing accuracy.
- Establishment and maintenance of relationship with the CWF Host.
- Accuracy of processing review cases.
- Accuracy of processing hearing cases with determination letters that are clear and have appropriate customer-friendly tone.

B. Customer Service Criterion

The Customer Service criterion contains three mandated standards.

CMS' obligation to evaluate performance of these activities was mandated by the court decisions of *Gray Panther* v. *Heckler*, 1985 WL 81770 (D.D.C.) for Standards 1 and 2 and in *David* v. *Heckler*, 591, F. Supp. 1033, (U.S. Dist. Ct. 1984) for Standard 3. Contractors are expected to comply with performance expectations set forth in the court renderings, unless expectations established by CMS are more stringent. In these instances, contractors must meet CMS' performance expectations.

Standard 1. Achieve and maintain the monthly All Trunks Busy rate for beneficiary telephone inquiries.

Standard 2. Respond timely to beneficiary telephone inquiries.

Standard 3. Responses to beneficiary correspondence are responsive, written with appropriate customer-friendly tone and clarity, and are at the appropriate reading level.

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

- Ensuring that the monthly All Trunks Busy rate for provider inquiries is achieved and maintained.
- Responding timely to provider telephone inquiries.
- Quality Call Monitoring.
- 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 responses to beneficiaries and providers that are responsive and written with appropriate customer-friendly tone and clarity.
- Conducting beneficiary and provider education and outreach.
- Walk-in inquiry service.

C. Payment Safeguards Criterion

While there are no mandated standards in this 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

- Identifying potential fraud cases that exist within the carrier's service area and taking appropriate actions to resolve these cases.
- Investigating allegations of potential fraud that are made by beneficiaries, providers, CMS, OIG, and other sources.
- Putting in place effective detection and deterrence programs for potential fraud.

Medical Review

- Applying analytical skills and focusing resources on particular providers or claim types that represent unnecessary or inappropriate care.
- Developing effective means of addressing any aberrance identified through analyzing data to target prepay and post-pay review.
- Making accurate and defensible decisions on medical reviews.
- Effectively educating and communicating with physician and/or supplier communities.

Medicare Secondary Payer

- Identifying, recovering, and referring mistaken Medicare payments in accordance with the appropriate Medicare Carriers Manual instructions, and other pertinent CMS general instructions.
- Accurately reporting savings and following claim development procedures.
- Prioritizing and processing recoveries in compliance with instructions.
- Financial reporting activities.

Overpayments

- Collecting and referring Medicare debts timely.
- Accurately reporting overpayments to CMS.
- Compliance with CMS 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 providers.

D. Fiscal Responsibility Criterion

While there are no mandated standards in this 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 matters 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

While there are no mandated standards in this 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), Automatic Data Processing (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, security, etc.).
• Disaster recovery plan.
• Implementation of general CMS 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.

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

The complete list of criteria and standards for evaluating the performance of DMEPOS regional carriers is contained in detail in the DMEPOS' regional carrier statement of work (SOW), which is subject to change due to modifications to the contractor BPRs, as well as legal and administrative changes that have a direct impact on the contractors.

We will use the same six criteria contained in the DMEPOS regional carrier SOW to evaluate the overall performance of DMEPOS regional carriers. They are (1) Quality, (2) Efficiency, (3) Service, (4) Benefit Integrity, (5) National Supplier Clearinghouse, and (6) Statistical Analysis DMEPOS regional carrier.

These six criteria contain a total of nine mandated standards against which all DMEPOS regional carriers must be evaluated as well as examples of other activities for which the DMEPOS regional carriers may also be evaluated. The mandated standards are in the Quality, Efficiency, and Service Criteria.

In addition to being described in these criteria, the mandated standards are also described in Attachment J–37 to the DMEPOS regional carrier SOW.

A. Quality Criterion

The Quality criterion contains one mandated standard.

A DMEPOS regional carrier must pay claims accurately and in accordance with program instructions. The DMEPOS regional carrier is required to:

Standard 1. Properly generate 98.0 percent of MSN's.

The DMEPOS regional carriers must undertake actions to promote effective program administration with respect to DMEPOS regional carrier claims. These activities include, but are not limited to: processing claims accurately, overpayment recovery and offsetting of claims payment; assuring the proper submission of certificates of medical necessity; review of the implementation of fee schedules and reasonable charge updates; medical review activities; implementation of coverage policy; and, analysis of workload to detect patterns of outcomes. We may evaluate the DMEPOS regional carriers in performing these kinds of activities.

B. Efficiency Criterion

The Efficiency criterion contains five mandated standards.

Standard 1. 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, clean claims can be paid as early as the 14th day (13 days after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt). CMS' expectation is that contractors will meet this percentage on a monthly basis.

Standard 2. 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). CMS' expectation is that contractors will meet this percentage on a monthly basis.

Standard 3. 95.0 percent of review determinations are completed within 45 days. CMS' expectation is that contractors will meet this percentage on a monthly basis.

Standard 4. 90.0 percent of DMEPOS regional carrier hearing decisions are completed within 120 days. CMS' expectation is that contractors will meet this percentage on a monthly basis.

Standard 5. Letters prepared to respond to beneficiary requests for reviews are written at an appropriate reading level.

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

• Determinations on review and hearing requests are written accurately and clearly.
• Documentation of telephone reviews is accurate and timely.
• Requests for ALJ hearings are processed timely, to include preparation and forwarding to the ALJ of the case files.
• Completed ALJ decisions are reviewed for accuracy.
• Agency referral and case files are submitted timely to the designated CMS Regional Office.
• ALJ decisions are effectuated correctly and within specified timeframes.
• Documentation of completed ALJ decisions is maintained.
• Requests from the Departmental Appeals Board for ALJ case files are processed.

C. Service Criterion

The Service criterion contains three mandated standards.

CMS' obligation to evaluate performance of these activities was mandated by the court decisions of Gray Panther v. Heckler, 1985 WL 81770 (D.D.C.) for Standards 1 and 2 and in David v. Heckler, 597, F. Supp. 1033, (U.S. Dist. Ct. 1984) for Standard 3. Contractors are expected to comply with performance expectations set forth in the court renderings, unless expectations established by CMS are

more stringent. In such instances, contractors must meet CMS' 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 statement of work (SOW), and CMS' general instructions.

Standard 1. Achieve and maintain a monthly All Trunks Busy rate for beneficiary telephone inquiries.

Standard 2. Respond timely to beneficiary telephone inquiries.

Standard 3. Responses to beneficiary correspondence are responsive and are written with appropriate customer-friendly tone and clarity, and are at the appropriate reading level. Additional functions which may be evaluated under this criterion include, but are not limited to the following:

- Ensuring that the monthly All Trunks Busy rate for provider inquiries is achieved and maintained.
- Responding timely to provider telephone inquiries.
- Quality Call Monitoring.
- 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 responses to beneficiaries, providers, and suppliers that are responsive and written with appropriate customer-friendly tone and clarity.

- Conducting beneficiary and provider education and outreach.
- Responding to beneficiary and supplier education and training needs.

D. Benefit Integrity Criterion (referred to in prior ***Federal Register*** *notices as Fraud and Abuse)*

While there are no mandated standards in this criterion, other DMEPOS regional carrier functions and activities that may be reviewed under this criterion include, but are not limited to the following:

- 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, providers, CMS, OIG, and other sources.
- Putting in place effective detection and deterrence programs for potential fraud.

E. National Supplier Clearinghouse Criterion

(The National Supplier Clearinghouse (NSC) DMEPOS regional carrier function is assigned to one of the DMEPOS regional carriers. It performs the functions measured under this criterion.)

While there are no mandated standards in this criterion, the NSC DMEPOS regional carrier is required to properly administer the NSC.

We review the NSC activities to ensure the NSC DMEPOS regional carrier meets various requirements, such as—processing new and renewal applications for billing numbers, maintaining supplier files, matching OIG sanctioned suppliers, and enforcing supplier standards.

F. Statistical Analysis DMEPOS Regional Carrier Criterion

(The Statistical Analysis DMEPOS regional carrier function is assigned to one of the DMEPOS regional carriers. It performs the functions measured under this criterion.)

While there are no mandated standards in this criterion, the Statistical Analysis DMEPOS regional carrier is required to properly administer the Statistical Analysis DMEPOS regional carrier program.

We review the activities of the Statistical Analysis DMEPOS regional carrier to ensure it meets various requirements such as: analyzing national reports to identify trends, aberrancies, and utilization patterns; generating reports according to our specifications; serving as the Healthcare Common Procedure Coding System (HCPCS) definition resource center; and developing national parental and enteral nutrition pricing as well as oral anti-cancer drugs pricing.

In addition, we evaluate the Statistical Analysis DMEPOS regional carrier's performance in conducting statistical analysis of data to identify potential areas of over utilization, fraudulent or abusive claims practices, and other areas of concern.

VIII. Action Based on Performance Evaluations

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 will also be 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 with respect to the contract management process under the authority of applicable law(s), regulation(s), contracts, or CMS' manual provision(s). Any contractor that makes a false, fictitious, or fraudulent certification may be subject to criminal and/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 non-renewal 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 a PIP 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.
- 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, they depend on the following:

- Relative overall performance compared to other contractors.
- Number of criteria in which nonconformance occurs.
- Extent of each major nonconformance.
- Relative significance of the requirement for which major 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. Response to Public 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 **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble of that document.

X. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980 Public Law 96–354). 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 or more annually). Since this notice only describes criteria and standards for evaluating FI's, Carriers and DMEPOS carriers and has no economic or social impact on the program, its beneficiaries or providers or suppliers, this is not a major notice.

The RFA requires agencies to analyze options for regulatory relief of small businesses. This notice does not affect small businesses, individuals and States are not included in the definition of a small business 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 notice does not affect small rural hospitals.

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. This notice does not require an impact analysis because it does not have an economic impact on small entities, small rural hospitals, or State, local, or tribal governments.

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

XI. Federalism

We have reviewed this notice under the threshold criteria of Executive Order 13132, Federalism. We have determined that the notice does not significantly affect the rights, roles, and responsibilities of States.

XII. Collection of Information Requirements

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

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

Dated: September 13, 2001.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 01–31720 Filed 12–27–01; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2135–N]

RIN: 0938–AL34

Medicare Program; Deductible Amount for Medigap High Deductible Options for Calendar Year 2002

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

ACTION: Notice.

SUMMARY: This notice announces the annual deductible amount of $1,620 for the Medicare supplemental health insurance (Medigap) high deductible options for 2002. High deductible policy options are those with benefit packages classified as ''F'' or ''J'' that have a high deductible feature. The deductible amount represents the annual out-of-pocket expenses (excluding premiums) that a beneficiary who chooses one of these options must pay before the policy begins paying benefits.

EFFECTIVE DATE: January 1, 2002.

FOR FURTHER INFORMATION CONTACT: Kathryn McCann, (410) 786–7623.

SUPPLEMENTARY INFORMATION:

I. Background

A. Medicare Supplemental Insurance

A Medicare supplemental, or Medigap, policy is the principal type of private health insurance that a beneficiary may purchase to cover certain costs that Medicare does not cover. The beneficiary is responsible for deductibles and coinsurance amounts for both Part A (hospital insurance) and Part B (supplementary medical insurance) of the Medicare program. In addition, Medicare generally does not cover custodial nursing home care, eyeglasses, dental care, and most outpatient prescription drugs. A beneficiary must either pay the full cost of these services, or he or she may purchase additional private health insurance to help pay these costs. Medigap policies offer coverage for some or all of the deductibles and coinsurance amounts required by Medicare. Additionally, Medigap policies may provide coverage for some services that are not covered under the Medicare program.

Section 1882 of the Social Security Act (the Act) establishes, among other things, minimum standards for Medigap policies. No Medigap policy may be issued in a State unless the policy complies with State laws that conform to section 1882(b)(1) of the Act.