more stringent than the CLIA requirements.

Subpart M—Personnel for Moderate and High Complexity Testing

We have found the COLA personnel requirements to be equal to the CLIA personnel requirements.

Subpart P—Quality Assurance for Moderate or High Complexity Testing or Both

We have determined that COLA's requirements are equal to the CLIA requirements of this subpart.

Subpart Q—Inspections

We have determined that COLA's inspection requirements are equal to the requirements of this subpart.

Subpart R—Enforcement Procedures for Laboratories

COLA meets the requirements of subpart R to the extent it applies to accreditation organizations. COLA policy stipulates the action it takes when laboratories it accredits do not comply with its requirements. COLA shall suspend, withdraw, revoke, or limit accreditation of a laboratory as appropriate and report the action to HCFA within 30 days. COLA also provides an appeals process for laboratories that have had accreditation denied.

We have determined that COLA's laboratory enforcement and appeal policies are essentially equivalent to the requirements of this subpart as they apply to accreditation organizations.

IV. Federal Validation Inspections and Continuing Oversight

The Federal validation inspections of COLA accredited laboratories may be conducted on a representative sample basis or in response to substantial allegations of noncompliance (complaint inspections). The outcome of those validation inspections, performed by HCFA or our agent, or the State survey agency, will be HCFA's principal means for verifying that the laboratories accredited by COLA remain in compliance with CLIA requirements. This Federal monitoring is an ongoing process.

V. Removal of Approval as an Accrediting Organization

Our regulations provide that we may remove the approval of an accreditation organization, such as that of COLA, for cause, before the end of the effective date of approval. If validation inspection outcomes and the comparability or validation review produce findings as described in § 493.573 (Continuing Federal oversight of private nonprofit accreditation organizations and approved State licensure program), HCFA will conduct a review of an approved accreditation organization's program. We also conduct a review when the validation review findings, irrespective of the rate of disparity (as defined in § 493.2), indicate systemic problems in the organization's processes that provide evidence that the organization's requirements, taken as a whole, are no longer equivalent to the CLIA requirements, taken as a whole.

If HCFA determines that COLA has failed to adopt or maintain requirements that are equal to or more stringent than the CLIA requirements, or systemic problems exist in its inspection process, a probationary period, not to exceed 1 year, may be given to COLA to adopt equal or more stringent requirements. HCFA will make a determination as to whether or not COLA retains its approved status as an accreditation organization under CLIA. If approved status is withdrawn, an accreditation organization such as COLA may resubmit its application if it revises its program to address the rationale for the denial, demonstrates that it can reasonably assure that its accredited laboratories meet CLIA condition level requirements, and resubmits its application for approval as an accreditation organization in its entirety. If, however, an approved accreditation organization requests reconsideration of an adverse determination in accordance with subpart D (Reconsideration of Adverse Determinations—Deeming Authority for Accreditation Organizations and CLIA Exemption of Laboratories Under State Programs) of part 488 (Survey, Certification, and Enforcement Procedures) of our regulations, it may not submit a new application until HCFA issues a final reconsideration determination.

Should circumstances result in COLA having its approval withdrawn, HCFA will publish a notice in the **Federal Register** explaining the basis for removing its approval.

Authority: Section 353 of the Public Health Service Act (42 U.S.C. 263a).

Dated: September 18, 2000.

Nancy-Ann Min-DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00–27956 Filed 10–30–00; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–4010–GNC]

RIN 0938–AK26

Medicare Program; Criteria and Standards for Evaluating Intermediary and Carrier Performance During Fiscal Year 2001

AGENCY: Health Care Financing Administration (HCFA), 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 and carriers in the administration of the Medicare program beginning October 1, 2000. The results of these evaluations are considered whenever we enter into, renew, or terminate an intermediary agreement or 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.

EFFECTIVE DATE: The criteria and standards are effective October 1, 2000.

COMMENTS: Comments will be considered if we receive them at the appropriate address as provided below no later than 5 p.m. (EDT) on November 30, 2000.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing, Administration, Department of Health and Human Services, Attention: HCFA–4010–GNC, P.O. Box 8016, Baltimore, MD 21244–8016.

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

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

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

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. When commenting, please refer to file code HCFA–4010–GNC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's office at 200 Independence Avenue,

SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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

SUPPLEMENTARY INFORMATION:

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 payable amount 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. 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 were published in the **Federal Register** on December 3, 1999 at 64 FR 67920.

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 choose to publish a notice in this manner, the evaluation period for any such criteria and standards that are the subject of the notice will be revised to 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 direct impact upon 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 2000 Criteria and Standards

We received a total of 19 comments in response to the **Federal Register** notice published on December 3, 1999. All comments were reviewed, but none necessitated our reissuance of the FY 2000 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 advised that the Blue Cross and Blue Shield Medicare contractors have a different scope of work for fraud and abuse (F&A) activities than the commercial contractors. As a result, Blue Cross and Blue Shield Plans' performance would need to be evaluated against the negotiated scope of work, not our manuals, since not all of our manual requirements are addressed in the contract amendment.

Response: While it is true that there are some differences between performance expectations for Blue Cross and Blue Shield Plans as opposed to commercial contractors, the protocols used for evaluation of F&A activities in FY 2000 did not contain performance expectations that were not already contained in the Blue Cross and Blue Shield Medicare contract.

Comment: We were advised that references under the Fiscal Responsibility Criterion relating to the evaluation of a contractor's adherence to the Chief Financial Officers' Act (CFO), 31 USC 503, *et seq.* are incorrect. The expectation to comply with this law is applicable to us, not the contractors. The expectation should be reworded to reflect that contractors assist the Secretary with being compliant with the CFO Act.

Response: We agree that the requirement referenced in the above comment is applicable to us and not to the contractors. The FY 2001 **Federal Register** notice has been revised to correctly reflect language as contained in the contract. Language in the **Federal Register** notice now specifically references the Federal Managers' Financial Integrity Act (FMFIA), 31 U.S.C. 1105, et seq; rather than the CFO Act and also states that contractors must cooperate with us in complying with the FMFIA.

Comment: We were advised that the Agency issued a moratorium on the review of all demand bills because of the SNF prospective payment system

(PPS). It was suggested that we acknowledge that the standard would not be evaluated until the Agency issued instructions and intermediaries had a chance to train staff on such.

Response: The moratorium on the review of all demand bills was lifted, and we issued appropriate instructions in March 2000.

Comment: HCFA was advised that the carrier Customer Service criterion states that carriers are to achieve a monthly All Trunks Busy (ATB) Rate of not more than 5 percent. For callers choosing to speak with a customer service representative, 97.5 percent or more of the calls are to be answered within 120 seconds; no less than 85 percent are to be answered within the first 60 seconds. A question was raised as to whether this requirement applies only to call centers servicing beneficiaries (and providers, if the call centers are not separate).

Response: The telephone service requirement referenced in the above comment is applicable to call centers servicing beneficiaries (and providers if the centers are not separate). The requirement is not applicable to call centers that specifically service providers.

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 management program for FY 2001 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 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 2001, we may conduct follow-up evaluations in areas when contractor performance was out of compliance with laws, regulations, and our performance expectations during FY 2000, thus having required the contractor to submit a Performance Improvement Plan (PIP).

We have structured the FY 2001 Contractor Performance Evaluation into five criteria designed to meet those objectives. The first criterion is ''Claims Processing,'' which measures contractual performance against claims processing accuracy and timeliness requirements. Within the Claims Processing criterion, we have identified those performance standards that are mandated by either legislation, regulation, or judicial decision. These standards include claims processing timeliness, the accuracy of Explanations of Medicare Benefits (EOMBs) or Medicare Summary Notices (MSNs), the rate of cases reversed by the Administrative Law Judge (ALJ), the timeliness of intermediary reconsideration cases and the timeliness of carrier reviews and hearings. Further evaluation in the Claims Processing criterion may include, but is not limited to, the accuracy of bill and claims processing, the level of electronic claims payment, the percent of bills and claims paid with interest, and the accuracy of reconsiderations, reviews, and hearings.

The second criterion is ''Customer Service,'' which assesses the completeness of the service provided to customers by the contractor in its administration of the Medicare program. Mandated standards in the Customer Service criterion include timeliness of carrier replies to beneficiary telephone inquiries and the accuracy and clarity of responses to written inquiries. In FY 2001, customer feedback may be used to collect comparable data on customer satisfaction and identify areas in need of improvement. Further evaluation of services under this criterion may include, but is not limited to, a review of beneficiary relations; provider education; appropriateness of telephone inquiry responses; and walk-in 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 medical review (MR), Medicare secondary payer (MSP), F&A (also referred to as benefits integrity (BI)), overpayments (OP) , provider enrollment (PE), and audit and reimbursement (A&R). Mandated performance standards in the Payment Safeguards criterion are 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. Further evaluation in this criterion may include, but is not limited to, review of the efficient and effective compilation and analysis of data to bring about continuous improvement in a contractor's efforts to safeguard Medicare program dollars. Intermediaries and carriers may also be evaluated on any Medicare Integrity Program (MIP) activities if performed under their Part A agreement or Part B 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 HCFA. Additional functions reviewed under this criterion may include, but are not limited to, adherence to approved budget, compliance with the BPRs, and 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 to ensure constant improvement in the way it does business. 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 FMFIA. Administrative Activities evaluations may also include reviews related to implementation of change management 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 bill processing functions with respect to freestanding home health agency (HHA) bills. 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 bills 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 and carriers. In several instances, we identify a Medicare manual as a source of more detailed requirements. Intermediaries and carriers have copies of 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.hcfa.gov/pubforms/progman.htm.* Some manuals may be obtained from the following web site: *www.hcfa.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 HCFA 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 percent of clean electronically submitted non-Periodic Interim Payment (PIP) bills paid within statutorily specified time frames. Clean bills are defined as bills that do not require Medicare intermediaries and/or carriers to investigate or develop external to their Medicare operations on a prepayment basis. Specifically, clean, non-PIP 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).

Standard 2: 95 percent of clean paper non-PIP bills paid within specified time frames. Specifically, clean, non-PIP 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).

Standard 3: Reversal rate by Administrative Law Judge (ALJ) is acceptable. We have defined an acceptable reversal rate by an ALJ as one that is at or below 5.0 percent.

Standard 4: 75 percent of reconsiderations are processed within 60 days and 90 percent are processed within 90 days.

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

- Bill processing accuracy;
- Establishment and maintenance of relationship with Common Working File (CWF) Host;
- Management of shared processing sub-contract;
- Analysis and validation of data; and
- Accuracy of processing reconsideration cases with clear responses and appropriate customer-friendly tone and clarity.

B. Customer Service Criterion

We may review the intermediary's efforts to enhance customer satisfaction through the use of customer feedback. Results of the feedback may be used to establish comparable data on customer satisfaction and to identify areas in need of improvement. The results may be summarized for publication in the Report of Contractor Performance (RCP) and shared with individual contractors.

Functions that may be evaluated under this criterion include, but are not limited to—

- Accuracy, timeliness and appropriateness of responses to telephone inquiries;
- Accuracy and timeliness of responses to written inquiries with appropriate customer-friendly tone and clarity;
- Establishment and maintenance of relationships with professional and beneficiary organizations;
- Use of focus groups; and
- Conduct of educational and outreach efforts.

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 Part A agreement. These functions and activities include, but are not limited to—

- Medical Review.
- Applying analytical skills and focusing resources on particular providers or claim types that represent unnecessary or inappropriate care.
- Developing local and national data that identify aberrancies and form the basis of corrective actions, such as educating the provider, or become the basis of medical review policies or review screens as directed by Medicare program manuals and BPR requirements.
- Making decisions that comply with current coverage guidelines.
- Developing means of addressing aberrancies identified during the analysis of all local and national data.
- Medicare Secondary Payer.
- Identifying and recovering mistaken Medicare payments in accordance with appropriate Medicare Intermediary Manual instructions and other pertinent HCFA general instructions.
- Accurately reporting savings and following claim development procedures.
- Prioritizing and processing recoveries in compliance with instructions.
- Fraud and Abuse (also known as BI).
- Identifying fraud cases that exist within the intermediary's service area and taking appropriate actions to dispose of these cases.
- Investigating allegations of fraud made by beneficiaries, providers, HCFA, Office of Inspector General (OIG), and other sources.
- Putting in place effective fraud detection and deterrence programs.
- Overpayments.
- Collecting Medicare debts timely.
- Accurately reporting overpayments to HCFA.

- 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.
- Audit and Reimbursement.
- Performing the activities specified in our general instructions for conducting audit and settlement of Medicare cost reports.
- Settling Medicare cost reports timely and accurately in establishing interim provider payments.

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 matters to be reviewed under the Fiscal Responsibility criterion may include, but are not limited to—

- Adherence to approved program management and MIP budgets;
- Compliance with the BPRs;
- Compliance with financial reporting requirements and;
- 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 to ensure constant improvement in the way it does business. 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 its—

- Systems security;
- ADP maintenance (configuration management, testing, change management, security, etc.);
- Disaster recovery plan;
- Change management plan implementation;
- Data and reporting requirements implementation; and
- 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 Carriers

A. Claims Processing Criterion

The Claims Processing criterion contains five mandated standards.

Standard 1: 95 percent of clean electronically submitted claims processed within statutorily specified time frames. 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).

Standard 2: 95 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).

Standard 3: 98 percent of EOMBs and MSNs are properly generated.

Standard 4: 95 percent of review determinations are accurate and clear with appropriate customer-friendly tone and clarity, and are completed within 45 days.

Standard 5: 90 percent of carrier hearing decisions are accurate and clear with appropriate customer-friendly tone and clarity, and are completed within 120 days.

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

- Claims Processing accuracy;
- Management of shared processing sub-contract;
- Establishment and maintenance of relationship with the CWF Host; and
- Analysis and validation of data.

B. Customer Service Criterion

The Customer Service criterion contains two mandated standards.

Standard 1—Telephone inquiries are answered timely.

Carriers are to achieve a monthly ATB Rate of not more than 10%. For callers choosing to speak with a customer service representative, 97.5% or more of telephone calls are to be answered within 120 seconds; no less than 85% are to be answered within the first 60 seconds.

Standard 2—Accuracy and timeliness of responses to written inquiries with appropriate customer-friendly tone and clarity. Responses to beneficiary written inquiries are written at an appropriate reading level.

We may review the carrier's efforts to enhance customer satisfaction through the use of customer feedback. Results of the feedback may be used to establish comparable data on customer satisfaction and to identify areas in need of improvement. The results may be summarized for publication in the RCP and shared with individual contractors.

Additional functions may be evaluated under this criterion. These functions include, but are not limited to, the carrier's—

- Accuracy and appropriateness of responses to telephone inquiries;
- Establishment and maintenance of relationships with professional and beneficiary organizations;
- Use of focus groups;
- Conduct of educational and outreach efforts; and
- Walk-in services.

C. Payment Safeguards Criterion

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

- Medical Review.
- Applying their analytical skills and focusing resources on particular providers or claim types that represent unnecessary or inappropriate care.
- Developing effective means of addressing aberrancies identified through analyzing data to target prepay and postpay review.
- Using medical coverage guidelines to determine if each medical review screen is supported by sufficient documentation.
- Developing means of addressing aberrancies identified during the analysis of all local and national data.
- Medicare Secondary Payer.
- Identifying and recovering mistaken Medicare payments in accordance with the appropriate Medicare Carriers Manual instructions, and other pertinent HCFA general instructions.
- Accurately reporting savings and following claim development procedures.
- Prioritizing and processing recoveries in compliance with instructions.
- Fraud and Abuse (also known as BI).
- Identifying fraud and abuse cases that exist within the carrier's service area and taking appropriate actions to dispose of these cases.
- Investigating allegations of fraud and/or abuse made by beneficiaries, providers, HCFA, OIG, and other sources.

- Putting in place effective fraud and abuse detection and deterrence programs.
- Overpayments.
- Collecting Medicare debts timely.
- Accurately reporting overpayments to HCFA.
- 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 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 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 agreements with us.

Additional matters to be reviewed under the Fiscal Responsibility criterion may include, but are not limited to—

- Adherence to approved program management and MIP budgets;
- Compliance with the BPRs;
- Compliance with financial reporting requirements; and
- 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.

A carrier must efficiently and effectively manage its operations to assure constant improvement in the way it does business. 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 its—

- Systems security;
- ADP maintenance (configuration management, testing, change management, security, etc.);
- Disaster recovery plan;
- Change management plan implementation;
- Data and reporting requirements implementation; and
- Internal controls establishment and use including the degree to which the contractor cooperates with the Secretary in complying with the FMFIA.

VI. Criterion and Standards for RHHIs

The following standards are mandated for the RHHI criterion:

Standard 1: 95 percent of clean electronically submitted non-PIP HHA/hospice bills are paid within statutorily specified time frames. Specifically, clean, non-PIP electronic claims can be paid as early as the 14th day (13 pays after the date of receipt) and must be paid by the 31st day (30 days after the date of receipt).

Standard 2: 95 percent of clean paper non-PIP HHA/hospice bills are paid within specified time frames. Specifically, clean, non-PIP 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).

Standard 3: 75 percent of HHA/hospice reconsiderations are processed within 60 days and 90 percent are processed within 90 days.

We may use this criterion to review a RHHI's performance with respect to handling the HHA/hospice workload. This includes processing HHA/hospice bills 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.

VII. 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 HCFA 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 nonrenewal of a contract.

If a contractor meets the level of performance required by operational instructions, it meets the requirements of that criterion. Any performance measured below basic operational requirements constitutes a program deficiency. The contractor will be required to develop and implement a PIP for each program deficiency identified. 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 contractor will also be monitored when a program vulnerability in any performance area is identified. A program vulnerability exists when a contractor's performance complies with basic program requirements, but one or more weaknesses are present that could result in deficient performance if left ignored.

The results of performance evaluations and assessments under all five criteria will be used for contract management activities and will be published in the contractor's annual performance report. 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—
- Relative overall performance compared to other contractors;
- Number of criteria in which deficient performance occurs;
- Extent of each deficiency;
- Relative significance of the requirement for which deficient performance occurs within the overall evaluation program; and
- 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 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.

VIII. 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.

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

IX. 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.

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

Dated: September 8, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care, Financing Administration.

[FR Doc. 00–27955 Filed 10–30–00; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development.

ADDRESSES: Licensing information and a copy of the U.S. patent application referenced below may be obtained by contacting J. R. Dixon, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804 (telephone 301/496–7056 ext 206; fax 301/402–0220; e-mail jd212g@NIH.GOV). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

Entitled: ''USE OF 14–3–3σ AS A DIAGNOSTIC MARKER AND THERAPEUTIC TARGET''—A Method to Diagnosis and Determine the Prognosis of Breast and/or Ovarian Cancers.

Inventors: Drs. Olga Aprelikova (NCI) and Edison T. Liu (NCI) DHHS Ref. No. E–307–00/0, Filed with the USPTO on September 7, 2000.

Breast cancer is one of the most significant cancerous diseases that affects women. At the current rate, American women have a 1 in 8 risk of developing breast cancer by age 95 (American Cancer Society, 1992). Treatment of breast cancer at later stages is often futile and disfiguring, making early detection a high priority in medical management of the disease. Ovarian cancer, although less frequent than breast cancer is often rapidly fatal and is the fourth most common cause of cancer mortality in American women. Genetic factors contribute to an ill-defined proportion of breast cancer incidence, estimated to be about 5% of all cases but approximately 25% of cases diagnosed before age 40. Breast cancer has been subdivided into two types, early-age onset and late-age onset, based on an inflection in the age-specific incidence curve around age 50. Mutation of one gene, BRCA1, is thought to account for approximately 45% of familial breast cancer, but at least 80% of families with both breast and ovarian cancer.

The 14–3–3σ checkpoint control gene is significantly downregulated in BRCA1 -/-cells. The cell cycle profile of these cells treated with ionizing radiation showed an inability to sustain G2/M growth arrest typical for 14–3–3σ deprived cells. In addition, 14–3–3σ has been identified as a p53 inducible gene after DNA damage. Thus, BRCA1 synergistically activates p53 dependent transcription of 14–3–3σ gene. These observations demonstrate the role of 14–3–3σ, and the interaction of BRCA1, p53, and 14–3–3σ in neoplastic conditions, such as breast cancer or ovarian cancer.

The technology disclosed in the E–307–00/0 patent application is directed to a method to identify an agent that modulates 14–3–3σ. The 14–3–3σ checkpoint control gene is significantly downregulated in BRCA1 -/-cells. The method includes incubating the agent and a sample of interest, wherein the sample is capable of expressing 14–3–3σ, under conditions sufficient to allow the compound of interest to interact with the sample, and determining the effect of the compound on the expression or activity of 14–3–3σ. The effect of an agent on the interaction of 14–3–3σ with p53 and/or BRCA1 can also be assessed. A method is also provided for determining the prognosis of a subject diagnosed with a 14–3–3σ-associated disorder. The method includes contacting a sample from the subject with a reagent that binds to 14–3–3σ, detecting binding of the reagent to 14–3–3σ; and correlating the binding of the reagent to the sample with the prognosis of the disorder. The method can also include detecting p53 and/or BRCA1 mutations.

The above mentioned invention is available for licensing on an exclusive or non-exclusive basis.

Dated: October 23, 2000.

Jack Spiegel,

Director, Division of Technology Development & Transfer, Office of Technology Transfer.

[FR Doc. 00–27890 Filed 10–30–00; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Director's Council of Public Representatives, October 31–November 1, 2000, National Institutes of Health, 9000 Rockville Pike, Building 31, Conference Room 6, Bethesda, MD 20982 which was published in the **Federal Register** on October 10, 2000, 65 FR 60200–60201.

The dates, times, and location of the meeting are the same but the agenda has changed to discuss human research protections and medical applications research. The meeting is open to the public.