

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Care Financing Administration**

[HCFA-4009-GNC]

RIN 0938-AJ88

Medicare Program; Criteria and Standards for Evaluating Intermediary and Carrier Performance During FY 2000**AGENCY:** Health Care Financing Administration (HCFA), 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 January 1, 2000. The results of these evaluations are considered whenever HCFA enters into, renews, or terminates an intermediary agreement or carrier contract or takes other contract actions (for example, assigning or reassigning providers or services to an intermediary or designating regional or national intermediaries).

This notice is published in accordance with sections 1816(f) and 1842(b)(2) of the Social Security Act. We are publishing for public comment in the **Federal Register** those criteria and standards against which we evaluate intermediaries and carriers.

DATES: The criteria and standards are effective January 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 January 3, 2000.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services (HHS), Attention: HCFA-4009-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, 20201, or 7500 Security Boulevard, Baltimore, Maryland 21244.

Because of the staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-4009-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, D.C., 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**

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 the Secretary of Health and Human Services. These agencies or organizations, known as fiscal intermediaries, determine whether medical services are covered under Medicare and determine correct payment amounts. The intermediaries then make payments to the health care providers 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. We evaluate intermediary performance through the contract management process.

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. We also evaluate carrier performance through the contract management process.

We are publishing the criteria and standards in the **Federal Register** in order to allow the public an opportunity to comment before implementation. In addition to the statutory requirement, our regulations at 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. Regulation 42 CFR 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 September 7, 1994 (59 FR 46258).

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

In those instances where we are unable to meet our goal of publishing the subject **Federal Register** notice before the beginning of the fiscal year, 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. Hence, any revised criteria and standards will measure performance prospectively; that is, we will not apply new measurements to assess performance on a retroactive basis.

Also, 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 mandate or Congressional action, there may be a need for changes that have direct impact upon the criteria and standards previously published, or which require the addition of new criteria or standards, or that cause the deletion of previously published criteria and standards. Should such changes be necessitated, we will issue a **Federal Register** notice prior to implementation of the changes. In all instances, necessary manual issuances will be published each year to ensure that the criteria and standards are implemented uniformly and accurately. Also, as in previous years, the **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. Criteria and Standards—General

Basic tenets 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. We have developed a contractor management program for FY 2000 that sets

expectations for the contractor; measures the performance of the contractor; evaluates the performance against the expectations; and, takes appropriate contract action based upon evaluation of the contractor's performance. 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 and HCFA directive. We ensure that contractors perform well and continually improve their performance. To better evaluate contractor performance, we are working to develop and refine measurable performance standards in key areas, and we will be facilitating the sharing of "best practices" among HCFA reviewers. We also are increasing the number of standardized evaluation protocols for use in FY 2000. We have structured contractor evaluation into five criteria designed to meet those objectives.

The first criterion in the FY 2000 contractor performance evaluation 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, and the accuracy of Explanations of Medicare Benefits. 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, and the percent of bills and claims paid with interest.

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 the rate of cases reversed by an Administrative Law Judge, the timeliness of intermediary reconsideration cases, the accuracy and timeliness of carrier reviews and hearings, and the accuracy and timeliness of carrier replies to beneficiary telephone inquiries. In FY 2000, customer feedback may be used to collect comparable data on customer satisfaction and identify areas in need of improvement. Among the specific contractor services that may be included in the evaluation process under the Customer Service criterion are: beneficiary relations; provider education; appropriate telephone

inquiry responses; and the tone and accuracy of all correspondence.

The third criterion is "Payment Safeguards," which evaluates whether the Medicare trust funds are safeguarded against inappropriate program expenditures. Intermediary and carrier performance may be evaluated in the areas of medical review, Medicare secondary payer, fraud and abuse, and audit and reimbursement. Mandated performance standards 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. Further evaluation in this criterion may include, but is not limited to, some core standards for Medical Review and Benefit Integrity.

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 payment of benefits and cost 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 Budget and Performance Requirements, and adherence to the Chief Financial Officers Act.

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, Automated Data Processing (ADP) maintenance, and disaster recovery plans must be in place. It must also ensure that all necessary actions and system changes have been made and tested so that it is meeting established milestones along the critical path of HCFA's requirements for millennium compliance. Year 2000 compliant means information technology that accurately processes date and time data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the centuries (the years 1999 and 2000), and leap year calculations. Furthermore, Year 2000 compliant information technology, when used in combination with other information technology, must accurately process date and time data if

the other information technology properly exchanges date and time data with it. 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. Administrative Activities evaluations may also include implementation reviews of performance improvement plans, change management plans, 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 the Secretary 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 such regional intermediaries (*i.e.*, RHHIs) to not more than ten (see 42 CFR 421.117 and the Final Rule published in the **Federal Register** on May 19, 1988 (53 FR 17936) for more details about the RHHIs).

In addition, section 1816(e)(4) of the Act requires the Secretary to develop criteria and standards in order to determine whether to designate an agency or organization to perform services with respect to hospital affiliated HHAs. We have developed separate measures for RHHIs in order to evaluate the distinct RHHI functions. These functions include the bills processing of 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 a number of instances, we identify a HCFA 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 1400 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 an 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 HCFA regional offices maintain all Medicare manuals for public inspection. To find the location of the nearest available HCFA regional office, individuals may call the **FOR FURTHER INFORMATION CONTACT** individual listed at the beginning of this notice. That individual can also provide information about purchasing or subscribing to the various Medicare manuals.

III. Criteria and Standards for Intermediaries

Claims Processing Criterion

The Claims Processing criterion contains 4 mandated standards.

Standard 1—95% 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% 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 Judges (ALJ) is acceptable. HCFA has defined an acceptable reversal rate as one that is at or below 5.0%.

Standard 4—75% of reconsiderations are processed within 60 days and 90% 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;
- Attainment of Electronic Media Claims goals;
- Establishment and maintenance of relationship with Common Working File Host;
- Management of shared processing sub-contract; and
- Analysis and validation of data.

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 and shared with individual contractors.

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

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

Payment Safeguards Criterion

The Payment Safeguard criterion contains 2 mandated standards.

Standard 1—Decisions of 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.

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

- Medical Review. We may evaluate if the fiscal intermediary—

+ Increased the effectiveness of medical review payment safeguard activities;

+ Exercised accurate and defensible decision making on medical reviews;

+ Educated and communicated effectively with the provider and supplier community;

+ Collaborated with other internal components and external entities to ensure correct claims payment, and to address situations of fraud, waste, and abuse.

• Audit and Reimbursement. We may—

+ Assess the quality of a fiscal intermediary's activities in the audit and settlement of Medicare cost reports; and

+ Assess the timeliness of Medicare cost report settlements and the accuracy by which a fiscal intermediary has established interim provider payments.

• Medicare Secondary Payer. We may—

+ Review the intermediary's MSP processes in administering the program and for identifying and recovering mistaken Medicare payments in accordance with MIM, Part 3, §§ 3400ff and 3600ff, and pertinent HCFA instructions and transmittals;

+ Develop outcome measures to assess the intermediary's accuracy in reporting savings and to determine if claim development procedures are followed;

+ Evaluate the accuracy and timeliness of claims payment and determine if the Common Working File, internal systems and required software are utilized as prescribed; and

+ Evaluate the contractor's ability to prioritize and process recoveries in compliance with instructions, determine if recoveries of all payers are processed equally, and ensure that audit trail documentation exists.

• Fraud and Abuse. We may evaluate if the fiscal intermediary—

+ Used proactive and reactive techniques in the detection and development of potential fraud cases;

+ Used other corrective and preventive actions (such as payment suspensions, Civil Monetary Penalties (CMPs), overpayment assessments, prepayment or post-payment claims reviews, system fixes, claim denials, etc.);

+ Properly developed fraud cases for referral to the Office of the Inspector General, HHS; and

+ Maintained a good working relationship and extensive networking with both internal components and external partners.

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 HCFA.

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

- Adherence to approved budget;
- Compliance with the Budget and Performance Requirements;
- Adherence to the Chief Financial Officers Act; and
- Control of administrative cost and benefit payments.

Administrative Activities Criterion

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

A contractor must efficiently and effectively manage its operations to assure constant improvement in the way it does business. Proper systems security, ADP maintenance, and disaster recovery plans must be in place. It must also ensure that all necessary actions and system changes have been made and tested so that it is meeting established milestones along the critical path of HCFA's requirements for millennium compliance. Year 2000 compliant means information technology that accurately processes date and time data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the centuries (the years 1999 and 2000), and leap year calculations. Furthermore, Year 2000 compliant information technology, when used in combination with other information technology, must accurately process date and time data if the other information technology properly exchanges date and time data with it. A contractor must also test standard system changes to ensure the accurate implementation of HCFA instructions.

HCFA's evaluation of a contractor under the Administrative Activities criterion may include, but is not limited to, reviews of the contractor's—

- Systems security;
- ADP maintenance;
- Disaster recovery plan;
- Performance Improvement Plans implementation;
- Change Management Plan implementation;

- Data and reporting requirements implementation; and
- Internal controls establishment and use.

IV. Criteria and Standards for Carriers*Claims Processing Criterion*

The Claims Processing criterion contains 5 mandated standards.

Standard 1—95% 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% 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% of Explanations of Medicare Benefits (EOMBs) are properly generated.

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

Standard 5—90% 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;
- Attainment of Electronic Media Claims goals;
- Management of shared processing sub-contract;
- Establishment and maintenance of relationship with the Common Working File Host; and
- Analysis and validation of data.

Customer Service Criterion

The Customer Service criterion contains 1 mandated standard.

Standard 1—Telephone inquiries are answered timely.

Carriers are to achieve a monthly All Trunks Busy Rate of not more than 5%. 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.

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 report of contractor performance 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;
- Accuracy, clearness, and timeliness of responses to written inquiries with appropriate customer-friendly tone and clarity;
- Establishment and maintenance of relationships with professional and beneficiary organizations and using focus groups; and
- Conduct of educational and outreach efforts.

Payment Safeguards Criterion

Carrier functions that may be reviewed under this criterion include, but are not limited to—

- Medical Review. We may evaluate if the carrier —
 - + Increased the effectiveness of medical review payment safeguard activities;
 - + Exercised accurate and defensible decision making on medical reviews;
 - + Effectively educated and communicated with the provider and supplier community;
 - + Collaborated with other internal components and external entities to ensure correct claims payment, and to address situations of fraud, waste, and abuse.
- Medicare Secondary Payer. We may—
 - + Review the carrier's MSP processes in administering the program and for identifying and recovering mistaken Medicare payments in accordance with the Medicare Carriers Manual (MCM, Part 3, §§ 3375, 4306.3, and 4307–4308.1), and pertinent HCFA instructions and transmittals;
 - + Develop outcome measures to assess the carrier's accuracy in reporting savings and to determine if claim development procedures are followed;
 - + Evaluate the accuracy and timeliness of claims payment and determine if the Common Working File, internal systems and required software are utilized as prescribed; and
 - + Evaluate the contractor's ability to prioritize and process recoveries in compliance with instructions, determine if recoveries of all payers are processed equally, and ensure that audit trail documentation exists.
- Fraud and Abuse. We may evaluate if the carrier —

- + Used proactive and reactive techniques in the detection and development of potential fraud cases;
- + Used other corrective and preventive actions (such as payment suspensions, CMPs, overpayment assessments, education, pre-payment or post-payment claims reviews, system fixes, edits, claim denials, etc.);
- + Properly developed fraud cases for referral to the Office of the Inspector General, HHS;
- + Maintained a good working relationship and extensive networking with both internal components and external partners.

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 HCFA.

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

- Compliance with the Budget and Performance Requirements;
- Adherence to approved budget;
- Adherence to the Chief Financial Officers Act; and
- Control of administrative cost and benefit payments.

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 operation, its system of internal controls and its compliance with HCFA's directives and initiatives.

A contractor must efficiently and effectively manage its operations to assure constant improvement in the way it does business. Proper systems security, ADP maintenance, and disaster recovery plans must be in place. It must also ensure that all necessary actions and system changes have been made and tested so that it is meeting established milestones along the critical path of HCFA's requirements for millennium compliance. Year 2000 compliant means information technology that accurately processes date and time data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the centuries (the years 1999 and 2000), and leap year calculations. Furthermore, Year 2000 compliant information technology, when used in combination with other information technology, must accurately process date and time data if the other information technology

properly exchanges date and time data with it. Also, a contractor must test standard system changes to ensure accurate implementation of HCFA instructions.

A carrier's evaluation under this criterion may include, but is not limited to, reviews of—

- Proper systems security;
- ADP maintenance;
- Disaster recovery plan;
- Performance improvement plans implementation;
- Change management plan implementation;
- Data and reporting requirements implementation; and
- Internal controls establishment and use.

V. Regional Home Health Intermediaries' (RHHIs') Criterion

The following standards are mandated for the Regional Home Health Intermediaries' criterion:

Standard 1—95% of clean electronically submitted non-PIP HHA/hospice bills paid within statutorily specified time frames. 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% of clean paper non-PIP HHA/hospice 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—75% of HHA/hospice reconsiderations are processed within 60 days and 90% 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.

VI. Action Based on Performance Evaluations

A contractor's performance is evaluated against applicable program requirements for each criterion. Each contractor must certify that all information submitted to HCFA relating to the contractor management process, including without limitation all records, reports, files, papers and other information, 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 contractor 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. Such 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 Performance Improvement Plan for each program deficiency identified. The contractor will be monitored to ensure effective and efficient compliance with the performance improvement plan, and to ensure improved performance where 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 which 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 which the Secretary finds to be reasonable and adequate to meet the cost which must be incurred by an efficiently and economically operated intermediary or carrier, such high costs may also be grounds for adverse action.

VII. 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.

We have reviewed this notice under the threshold criteria of Executive Order 13132 of August 4, 1999, Federalism, published in the **Federal Register** on August 10, 1999 (64 FR 43255). The Executive Order is effective November 2, 1999, which is 90 days after the date of this Order. We have determined that the notice does not significantly affect the rights, roles, and responsibilities of States.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million in any one year. This

notice will not have an effect on the governments mentioned, and the private sector costs will not be greater than the \$100 million threshold.

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

Dated: October 6, 1999.

Michael M. Hash,

Deputy Administrator, Health Care Financing Administration.

[FR Doc. 99-31361 Filed 12-2-99; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Invention; Availability for Licensing: "Novel Method and Composition to Induce Apoptosis in Tumor Cells"

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, 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.

SUPPLEMENTARY INFORMATION: Invention Title: "Anti-Notch-1 Monoclonal Antibodies for Inducing Cellular Differentiation and Apoptosis" Inventors: Drs. Lucio L Miele (U.S.F.D.A.) and Chana Y. Fuchs (U.S.F.D.A.) USPA SN: 60/124,119—Filed with the U.S.P.T.O. March 12, 1999

Apoptosis or programmed cell death is caused by many anti-tumor drugs and by radiation therapy. These treatment modalities cause apoptosis in tumor cells and in many normal cells in the body. As cancer cells progress towards more aggressive forms, they often become highly resistant to drug or radiation-induced apoptosis, generally

through the loss of function p53, a gene which can trigger apoptosis in response to DNA damage. Thus, novel strategies to induce apoptosis in tumor cells, especially p53-deficient cells, is an attractive and an active area of research.

Notch-1 is expressed at high levels in several human tumors. However, its function in tumor cells has not been characterized. So far, its role in maintaining tumor cell survival has not been identified. Using a model constituted by a p53-deficient mouse leukemia cell line, PHS scientists found that: (1) Antisense synthetic DNA oligonucleotides and stable incorporation of an antisense gene (a model for gene therapy) targeting notch-1, when given together with a differentiation-inducing antitumor drug, cause the cells to respond by massive apoptosis rather than differentiation; (2) stable incorporation of an antisense notch-1 gene increases apoptosis in these cells even in the absence of any antitumor drugs. This suggests that antisense notch-1 treatment, by antisense oligonucleotides or by gene therapy, may be used alone or together with anti-cancer drugs to cause apoptosis in tumor cells.

The notch gene belongs to a family of epidermal growth factor ("EGF") like homeotic genes, which encode transmembrane proteins with a variable number of cysteine-rich EGF-like repeats in the extracellular region. Four notch genes have been described in mammals, which include notch-1, notch-2, notch-3, and notch-4 (Int-3), which have been implicated in the differentiation of the nervous system and other structures. The EGF-like proteins Delta and Serrate have been identified as ligands of notch-1.

Mature notch proteins are heterodimeric receptors derived from the cleavage of notch pre-proteins into an extracellular subunit (N^{EC}) containing multiple EGF-Like repeats and a transmembrane subunit including intracellular region (Ntm). Notch activation results from the binding of ligands expressed by neighboring cells, and signaling from activated notch involves network of transcription regulators.

Alteration of notch-1 signaling or expression may contribute to tumorigenesis. Deletions of the extracellular portion of human notch-1 are associated with about 10% of the cases of T-Cell acute lymphoblastic leukemia. Truncated forms of notch-1 cause T-Cell lymphomas when introduced into mouse bone marrow stem cells and are oncogenic in rat kidney cells. The human notch-1 gene is in a chromosomal region (9q34)