

Dated: September 25, 2007.

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*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1399-GNC]

RIN 0938-ZB02

### Medicare Program; Criteria and Standards for Evaluating Intermediary and Carrier Performance During Fiscal Year 2008

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

**ACTION:** General notice with comment period.

**SUMMARY:** This general notice with comment period describes the criteria and standards to be used for evaluating the performance of fiscal intermediaries (FI) and carriers in the administration of the Medicare program.

The results of these evaluations are considered whenever we enter into, renew, or terminate a FI agreement, carrier contract, or take other contract actions, for example, assigning or reassigning providers or services to a FI or designating regional or national intermediaries. We are requesting public comment on these criteria and standards.

**DATES:** *Effective Date:* The criteria and standards are effective on October 1, 2007.

*Comment Date:* To be assured consideration, comments must be no later than 5 p.m. on November 30, 2007.

**ADDRESSES:** In commenting, please refer to file code CMS-1399-GNC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1399-GNC, P.O. Box 8013, Baltimore, MD 21244-8013.

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

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1399-GNC Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

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

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

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

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

**FOR FURTHER INFORMATION CONTACT:** Lee Ann Crochunis, (410) 786-3363.

#### **SUPPLEMENTARY INFORMATION:**

*Submitting Comments:* We welcome comments from the public on all issues set forth in this notice to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-1399-GNC and the specific "issue identifier" that precedes the section on which you choose to comment.

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments

received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also 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 1-800-743-3951.

## I. Background

### A. Medicare 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 CMS. These agencies or organizations, known as fiscal intermediaries (FIs), determine whether medical services are covered under Medicare, determine correct payment amounts and then make payments to the health care providers (for example, hospitals, skilled nursing facilities (SNFs), and community mental health centers) on behalf of the beneficiaries. Section 1816(f) of the Act requires us to develop criteria, standards, and procedures to evaluate an FI's performance of its functions under its agreement.

Section 1816(e)(4) of the Act requires us to designate regional agencies or organizations, which are already Medicare FIs under section 1816 of the Act, to perform claim processing functions for freestanding home health agency (HHA) claims. We refer to these organizations as Regional Home Health Intermediaries (RHHIs) under the 42 CFR 421.117.

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

### B. Medicare Part B—Supplementary Medical Insurance

Under section 1842 of the Act, we are authorized to enter into contracts with carriers to fulfill various functions in the administration of Part B, Supplementary Medical Insurance of the Medicare program. Beneficiaries,

physicians, and suppliers of services submit claims to these carriers. The carriers determine whether the services are covered under Medicare and the amount payable for the services or supplies, and then make payment to the appropriate party.

Under section 1842(b)(2) of the Act, we are required to develop criteria, standards, and procedures to evaluate a carrier's performance of its functions under its contract. Evaluations of Medicare fee-for-service (FFS) contractor performance need not be limited to the current Federal Fiscal Year (FFY), other fixed term basis, or contract term. 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, § 421.120, § 421.122, and § 421.201, provide for publication of a **Federal Register** notice to announce criteria and standards for FIs and carriers before the beginning of each evaluation period. In the September 29, 2006 **Federal Register** (71 FR 57513), we published a general notice with comment the current criteria and standards for FIs and carriers.

To the extent possible, we make every effort to publish the criteria and standards before the beginning of the FFY, which is October 1. If we do not publish a **Federal Register** notice before the new FFY begins, readers may presume that until and unless notified otherwise, the criteria and standards that were in effect for the previous FFY 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 FFY, 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 beginning on the first day of the first month following publication of this notice in the **Federal Register**. Any revised criteria and standards will measure performance prospectively; that is, any new criteria and standards in the notice will be applied only to performance after the effective date listed on the notice.

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

impact on the criteria and standards previously published, or that require the addition of new criteria or standards, or that cause the deletion of previously published criteria and standards. If we must make these changes, we will publish an amended **Federal Register** notice before implementation of the changes. In all instances, necessary manual issuances will be published to ensure that the criteria and standards are applied uniformly and accurately. Also, as in previous years, this **Federal Register** notice will be republished and the effective date revised if changes are warranted as a result of the public comments received on the criteria and standards.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173) was enacted on December 8, 2003. Section 911 of the MMA establishes the Medicare FFS Contracting Reform (MCR) initiative that will be implemented over the next several years. This provision requires that we use competitive procedures to replace our current FIs and carriers with Medicare Administrative Contractors (MACs). The MMA requires that we compete and transition all work to MACs by October 1, 2011.

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

### **II. Analysis of and Response to Public Comments Received on FY 2007 Criteria and Standards**

We received five comments in response to the September 29, 2006 **Federal Register** general notice with comment. All comments were reviewed, but none necessitated reissuance of the FY 2007 Criteria and Standards. Comments submitted did not pertain specifically to the FY 2007 Criteria and Standards.

### **III. Criteria and Standards—General**

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

Basic principles of the Medicare program are to pay claims promptly and accurately, and to foster good beneficiary and provider relations. Contractors must administer the Medicare program efficiently and economically. The goal of performance

evaluation is to ensure that contractors meet their contractual obligations. We measure contractor performance to ensure that contractors do what is required of them by statute, regulation, contract, and our directives.

We have developed a contractor oversight program for FY 2008 that outlines what is expected of the contractor; measures the performance of the contractor; evaluates the contractor's performance against those expectations; and provides for appropriate contract action based upon the evaluation of the contractor's performance.

As a means to monitor the accuracy of Medicare FFS payments, we have established the Comprehensive Error Rate Testing (CERT) program that measures and reports error rates for claims payment decisions made by carriers and FIs. Since November 2003, the CERT program has been measuring and reporting claims payment error rates for each individual carrier. FI-specific rates became available November 2004.

These rates measure not only how well contractors are doing at implementing automated review edits and identifying which claims to subject to manual medical review, but they also measure the impact of the contractor's provider outreach/education, as well as the effectiveness of the contractor's provider call center(s). We will use these contractor-specific error rates as a means to evaluate a contractor's performance.

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

In addition to evaluating performance based upon our expectations for FY 2008, we may also conduct follow-up evaluations throughout FY 2008 of areas in which contractor performance was out of compliance with statute, regulations, and our performance expectations during prior review years where contractors were required to submit a Performance Improvement Plan (PIP).

We may also utilize Statement of Auditing Standards-70 (SAS-70) reviews as a means to evaluate

contractors in some or all business functions.

In FY 2001, we established the Contractor Rebuttal Process as a commitment to continual improvement of contractor performance evaluation (CPE). We will continue the use of this process in FY 2008. The Contractor Rebuttal Process provides the contractors an opportunity to submit a written rebuttal of CPE findings of fact. Whenever we conduct an evaluation of contractor operations, contractors have 7 calendar days from the date of the CPE review exit conference to submit a written rebuttal. The CPE review team or, if appropriate, the individual reviewer considers the contents of the rebuttal before the issuance of the final CPE report to the contractor.

The FY 2008 CPE for FIs and carriers is structured into five criteria designed to meet the stated objectives. The first criterion, claims processing, measures contractual performance against claims processing accuracy and timeliness requirements, as well as activities in handling appeals. Within the claims processing criterion, we have identified those performance standards that are mandated by legislation, regulation, or judicial decision. These standards include claims processing timeliness, the accuracy of Medicare Summary Notices (MSNs), the timeliness of FI and carrier redeterminations, and the appropriateness of the reading level and content of FI and carrier redetermination letters. Further evaluation in the claims processing criterion may include, but is not limited to, the accuracy of claims processing, the percent of claims paid with interest, the accuracy of redeterminations, timeliness of forwarding case files to and effectuation of Qualified Independent Contractor (QIC) decisions, and effectuation of administrative law judge (ALJ) decisions.

The second criterion, customer service, assesses the adequacy of the service provided to customers by the contractor in its administration of the Medicare program. Functions that may be evaluated under this criterion include, but will not be limited to, the following: (1) Timeliness and accuracy of all correspondence to providers; (2) monitoring the quality of replies provided by the contractor's provider telephone customer service representatives (quality call monitoring); and (3) provider outreach and education activities.

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

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

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

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

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

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

The fifth and final criterion, administrative activities, measures a contractor's administrative management of the Medicare program. A contractor must efficiently and effectively manage its operations. Proper systems security (general and application controls), Automated Data Processing (ADP) maintenance, and disaster recovery plans must be in place. A contractor's evaluation under the administrative

activities criterion may include, but is not limited to, establishment, application, documentation, and effectiveness of internal controls that are essential in all aspects of a contractor's operation, as well as the degree to which the contractor cooperates with us in complying with the Federal Managers' Financial Integrity Act of 1982 (FMFIA). Administrative activities evaluations may also include reviews related to contractor implementation of our general instructions and data and reporting requirements.

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

In sections IV. through VI. of this notice, we list the criteria and standards to be used for evaluating the performance of intermediaries, RHHIs, and carriers.

#### **IV. Criteria and Standards for Fiscal Intermediaries**

[If you choose to comment on issues in this section, please include the caption "Criteria and Standards for Intermediaries" at the beginning of your comments.]

##### *A. Claims Processing Criterion*

The claims processing criterion contains the following three mandated standards:

Standard 1. Not less than 95.0 percent of clean electronically submitted nonperiodic interim payment claims are paid within statutorily specified timeframes. Clean claims are defined as claims that do not require Medicare FIs to investigate or develop outside of their Medicare operations on a prepayment basis. Specifically, the Act specifies that clean nonperiodic interim payment electronic claims be paid no earlier than the 14th day after the date of receipt, and that interest is payable for any clean claims if payment is not issued by the 31st day after the date of receipt.

Standard 2. Redetermination letters prepared in response to beneficiary initiated appeal requests are written in a manner calculated to be understood by the beneficiary. Letters must contain the required elements as specified in § 405.956.

Standard 3. All redeterminations must be concluded and mailed within 60 days of receipt of the request, unless the party submits documentation after the request, in which case the decision-making timeframe is extended for up to 14 calendar days for each submission.

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

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

- Accuracy of claims processing.
- Remittance advice transactions.
- Establishment and maintenance of a relationship with Common Working File (CWF) Host.
- Accuracy of redetermination decisions.
- QIC case file requirements.
- Accuracy and timeliness of processing appeals as set forth in part 405, subpart I (§ 405.900 et seq.).

#### **B. Customer Service Criterion**

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

- Maintaining a properly programmed interactive voice response system to assist with inquiries.
- Performing quality call monitoring.
- Training customer service representatives.
- Entering valid call center performance data in the customer service assessment and management system or its successor the provider inquiry evaluation system.
- Providing timely and accurate written replies to providers that address the concerns raised and are written with an appropriate customer-friendly tone and clarity.
- Ensuring written correspondence is evaluated for quality.
- Conducting provider outreach and education-activities.
- Effectively maintaining an Internet Web site dedicated to furnishing providers and physicians timely, accurate, and useful Medicare program information.

#### **C. Payment Safeguards Criterion**

The Payment Safeguard criterion contains the following two mandated standards:

Standard 1. Decisions on SNF demand bills are accurate.

Standard 2. TEFRA target rate adjustments, exceptions, and exemptions are processed within mandated timeframes. 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.

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

- Audit and Reimbursement
  - + Performing the activities specified in our general instructions for conducting audit and settlement of Medicare cost reports.
  - + Establishing accurate interim payments.
- Medical Review
  - + Increasing the effectiveness of medical review activities.
  - + Exercising accurate and defensible decision-making on medical reviews.
  - + Collaborating with other internal components and external entities to ensure the effectiveness of medical review activities.
- Medicare Secondary Payer
  - + Accurately following MSP claim development and edit procedures.
  - + Auditing hospital files and claims to determine that claims are being filed to Medicare appropriately.
  - + Supporting the Coordination of Benefits Contractor's efforts to identify responsible payers primary to Medicare.
  - + Supporting the MSP Recovery functions for provider, physician or other supplier debts and duplicate provider, physician or other supplier payments.
  - + Accurately reporting MSP savings.
- Overpayments
  - + Collecting and referring Medicare debts in a timely manner.
  - + Accurately reporting and collecting overpayments.
  - + Adhering to our instructions for management of Medicare Trust Fund debts.
- Provider Enrollment
  - + Complying with assignment of staff to the provider enrollment function and training the staff in procedures and verification techniques.
  - + Complying with the operational standards relevant to the process for enrolling providers.

#### **D. Fiscal Responsibility Criterion**

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

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

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

#### **E. Administrative Activities Criterion**

We may measure an FI'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 FI'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. A FI must also test system changes to ensure the accurate implementation of our instructions.

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

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

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

[If you choose to comment on issues in this section, please include the caption "Criteria and Standards for RHHIs" at the beginning of your comments.]

The following three standards are mandated for the RHHI criterion:

Standard 1. Not less than 95.0 percent of clean electronically submitted nonperiodic interim payment home health and hospice claims are paid within statutorily specified timeframes. Clean claims are defined as claims that do not require Medicare FIs to investigate or develop them outside of their Medicare operations on a prepayment basis. Specifically, the statute specifies that clean non-periodic interim payment electronic claims be paid no earlier than the 14th day after the date of receipt, and that interest is payable for any clean claims if payment

is not issued by the 31st day after the date of receipt.

Standard 2. Redetermination letters prepared in response to beneficiary initiated appeal requests are written in a manner calculated to be understood by the beneficiary. Letters must contain the required elements as specified in § 405.956.

Standard 3: All redeterminations must be concluded and mailed within 60 days of receipt of the request, unless the party submits documentation after the request, in which case the decision-making timeframe is extended for up to 14 calendar days for each submission.

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

## VI. Criteria and Standards for Carriers

[If you choose to comment on issues in this section, please include the caption "Criteria and Standards for Carriers" at the beginning of your comments.]

### A. Claims Processing Criterion

The claims processing criterion contains the following four mandated standards:

Standard 1. Not less than 95.0 percent of clean electronically submitted claims are processed within statutorily specified timeframes. Clean claims are defined as claims that do not require Medicare carriers to investigate or develop outside of their Medicare operations on a prepayment basis. Specifically, the Act specifies that clean non-periodic interim payment electronic claims be paid no earlier than the 14th day after the date of receipt, and that interest is payable for any clean claims if payment is not issued by the 31st day after the date of receipt.

Standard 2. Ninety-eight percent of MSNs are properly generated. Our expectation is that MSN messages are accurately reflecting the services provided.

Standard 3. Redetermination letters prepared in response to beneficiary initiated appeal requests are written in a manner calculated to be understood by the beneficiary. Letters must contain the required elements as specified in § 405.956.

Standard 4. All redeterminations must be concluded and mailed within 60 days of receipt of the request, unless the party submits documentation after the request, in which case the decision-

making timeframe is extended for up to 14 calendar days for each submission.

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

- Accuracy of claims processing.
- Remittance advice transactions.
- Establishment and maintenance of relationship with Common Working File (CWF) Host.
- Accuracy of redetermination decisions.
- QIC case file requirements.
- Accuracy and timeliness of processing appeals as set forth in part 405, subpart I (§ 405.900 et seq.).

### B. Customer Service Criterion

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

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

- Maintaining a properly programmed interactive voice response system to assist with inquiries.
- Performing quality call monitoring.
- Training customer service representatives.
- Entering valid call center performance data in the customer service assessment and management system or its successor the provider inquiry evaluation system.
- Providing timely and accurate written replies to providers that address the concerns raised and are written with an appropriate customer-friendly tone and clarity.
- Ensuring written correspondence is evaluated for quality.
- Conducting provider outreach and education, activities.
- Effectively maintaining an Internet Web site dedicated to furnishing providers timely, accurate, and useful Medicare program information.

### C. Payment Safeguards Criterion

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

- Medical Review
  - + Increasing the effectiveness of medical review activities.
  - + Exercising accurate and defensible decision-making on medical reviews.
  - + Collaborating with other internal components and external entities to ensure the effectiveness of medical review activities.

- Medicare Secondary Payer
  - + Accurately following MSP claim development/edit procedures.
  - + Supporting the Coordination of Benefits Contractor's efforts to identify responsible payers primary to Medicare.
  - + Supporting the Medicare Secondary Payer Recovery functions for provider, physician or other supplier debts and duplicate provider, physician or other supplier payments.
  - + Accurately reporting MSP savings.
- Overpayments
  - + Collecting and referring Medicare debts in a timely manner.
  - + Accurately reporting and collecting overpayments.
  - + Compliance with our instructions for management of Medicare Trust Fund debts.
- Provider Enrollment
  - + Complying with assignment of staff to the provider enrollment function and training staff in procedures and verification techniques.
  - + Complying with the operational standards relevant to the process for enrolling suppliers.

### D. Fiscal Responsibility Criterion

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

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

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

### E. Administrative Activities Criterion

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

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

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

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

### VII. Action Based on Performance Evaluations

[If you choose to comment on this section, please include the caption "Action Based on Performance Evaluations" at the beginning of your comments.]

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

If a contractor meets the level of performance required by operational instructions, it meets the requirements of that criterion. When we determine a contractor is not meeting performance requirements, we will use the terms "major nonconformance" or "minor nonconformance" to classify our findings. A major nonconformance is a nonconformance that is likely to result

in failure of the supplies or services, or to materially reduce the usability of the supplies or services for their intended purpose. A minor nonconformance is a nonconformance that is not likely to materially reduce the usability of the supplies or services for their intended purpose, or is a departure from established standards having little bearing on the effective use or operation of the supplies or services. The contractor will be required to develop and implement PIPs for findings determined to be either a major or minor nonconformance. The contractor will be monitored to ensure effective and efficient compliance with the PIP, and to ensure improved performance when requirements are not met.

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

- Entering into, renewing, or terminating agreements or contracts with contractors; and
- Deciding other contract actions for intermediaries and carriers (such as deletion of an automatic renewal clause). These decisions are made on a case-by-case basis and depend primarily on the nature and degree of performance. More specifically, these decisions depend on the following:
  - + Relative overall performance compared to other contractors.
  - + Number of criteria in which nonconformance occurs.
  - + Extent of each nonconformance.
  - + Relative significance of the requirement for which nonconformance occurs within the overall evaluation program.
  - + Efforts to improve program quality, service, and efficiency.
  - + Deciding the assignment or reassignment of providers and designation of regional or national intermediaries for classes of providers.

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

In addition, if the cost incurred by the FIs, RHHI, 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 FIs or carrier, these high costs may also be grounds for adverse action.

### VIII. Collection of Information Requirements

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

### IX. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are unable to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "Comment Date" section of this notice, and, if we proceed with a subsequent document, we will respond to the comments in the section entitled as "Analysis of and Response to Public Comments Received on FY 2008 Criteria and Standards" of that document.

**Authority:** Sections 1816(f), 1834(a)(12), and 1842(b) of the Social Security Act (42 U.S.C. 1395h(f), 1395m(a)(12), and 1395u(b)). (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance, and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 24, 2007.

**Leslie V. Norwalk,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

**Editorial Note:** This document was received at the Office of the Federal Register on September 26, 2007.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0353]

### Drug Products Containing Hydrocodone; Enforcement Action Dates

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its intention to take enforcement action, as described in this notice, against