

and should be submitted to the contact person below in advance of the meeting.

Contact Person for More Information:

Theodore M. Katz, M.P.A., Executive Secretary, NIOSH, CDC, 1600 Clifton Road NE., Mailstop: E-20, Atlanta, GA 30333, Telephone (513) 533-6800, Toll Free 1-800-CDC-INFO, E-mail ocas@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Dated: December 20, 2010.

Lorenzo J. Falgiano,

Acting Director, Management Analysis and Services Office Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-6041-NC]

Medicare Program: Solicitation of Comments Regarding Development of a Recovery Audit Contractor Program for the Medicare Part C and D Programs

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

ACTION: Request for information.

SUMMARY: This notice presents an approach and requests comments on the provision of the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), (collectively known as The Affordable Care Act (ACA)) that requires the expansion of the Recovery Audit Contractor (RAC) Program to the Medicare Part C and D programs.

DATES: *Comment Date:* To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 25, 2011.

ADDRESSES: In commenting, please refer to file code CMS-6041-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS-6041-NC, 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 to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-6041-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments only to one of the following addresses prior to the close of the comment period: a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey 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.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call (410) 786-9994 in advance to schedule your arrival with one of our staff members.

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

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

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

FOR FURTHER INFORMATION CONTACT: Cynthia Moreno (410) 786-1164.

SUPPLEMENTARY INFORMATION:

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.regulations.gov>. Follow the search instructions 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 three weeks after publication of a document, at the headquarters of CMS, 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

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) established the Medicare+Choice (M+C) program. Under section 1851(a)(1) of the Social Security Act (the Act), every individual with Medicare Parts A and B, except for individuals with end stage renal disease, could elect to receive benefits either through the original Medicare program or an M+C plan, if one was offered where the beneficiary lived. The primary goal of the M+C program was to provide Medicare beneficiaries with a wider range of health plan choices.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (Pub. L. 106-113), amended the M+C provisions of the BBA. Further amendments were made to the M+C program by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106-554), enacted December 21, 2000.

On December 8, 2003, the Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173). Title I of the MMA added new sections 1860D-1 through 1860D-42 to the Act creating the Medicare Prescription Drug Benefit (Part D) program, a landmark change to the Medicare program.

Sections 201 through 241 of Title II of the MMA made significant changes to the M+C program. As directed by Title II of the MMA, we renamed the M+C program the Medicare Advantage (MA) program. We also revised our regulations to include new payment and bidding provisions based largely on risk, to recognize the addition of regional Preferred Provider Organization plans, to address the provision of prescription

drug benefits under the Medicare Part D regulations, and to make other changes.

The MMA, at section 1860D–12(b)(3) of the Act, directed that specific aspects of the MA contracting requirements apply to the prescription drug plan benefit program. Consequently, the processes for contract determinations and the administrative appeal rights in the two programs are virtually identical.

We published the regulations implementing the MA and prescription drug benefit regulations separately, as proposed and final rules, though their development and publication were closely coordinated. On August 3, 2004, we published proposed rules for the MA program (69 FR 46866) and prescription drug benefit program (69 FR 46632). The final regulations implementing both programs, published on January 28, 2005 (70 FR 4588 and 70 FR 4194, respectively), reflect this similarity.

Section 306 of the MMA gave us authority to pilot a new contracting authority designed to detect improper payments. This MMA provision directed the Secretary to demonstrate the use of RACs in identifying Medicare fee-for-service (FFS) underpayments and overpayments and collecting Medicare overpayments. Overpayments and underpayments were identified through a careful review of individual Medicare claims to determine if the claims were medically necessary, correctly coded, and conformed to Medicare payment policy. An important characteristic of the RAC program is that RACs are paid contingency fees based on the overpayments collected from providers and for underpayments identified.

The initial demonstration project ran from 2005 to 2008 in California, New York, Florida, Massachusetts, South Carolina, and Arizona. One of the key objectives of the RAC demonstration program was to identify improper payments in Medicare FFS programs and implement corrective actions that will prevent future improper payments. We designed the demonstration to accomplish two specific goals: To demonstrate whether RACs can identify past improper payments in the Medicare FFS program (as specified in section 306 of the MMA); and to determine whether the RACs can provide information to CMS that could help prevent future improper payments. The demonstration proved to be successful, recovering \$992.7 million in gross overpayments, as well as identifying \$37.8 million in underpayments that were subsequently paid to providers.

The demonstration results showed the effectiveness of a recovery auditing program in Medicare Part A and Part B.

The Tax Relief and Health Care Act of 2006 (Pub. L. 109–432) gave the Secretary until January 1, 2010 to implement the national RAC program nationwide. As of October 29, 2009 the RAC FFS Medicare program was fully implemented. Currently, the RACs are reviewing all claim and provider types upon approval from us. The ACA makes a number of changes to Medicare programs, including Medicare Part C and Part D, to enhance the agency's current efforts to further reduce fraud, waste, and abuse in Medicare programs.

Section 6411(b) of ACA expands the use of RACs to all of Medicare (Title XVIII) amending the existing FFS RAC statute at section 1893(h) of the Act. The amendments to 1893(h) of the Act provide us with general authority to enter into contracts with RACs to identify overpayments and underpayments and recoup overpayments in Medicare Part C and Part D. In addition to the identification of underpayments and overpayments and the recoupment of overpayments, section 6411 of ACA also establishes special rules for Part C and Part D that require RACs to—

- Ensure that each MA plan and Part D plan has anti-fraud plans in place and to review the effectiveness of the anti-fraud plans;
- Examine claims for reinsurance payments to determine whether prescription drug plans submitting such claims incurred costs in excess of the allowable reinsurance costs permitted under the statute; and
- Review estimates submitted by prescription drug plans by private plans with respect to the enrollment of high cost beneficiaries (as defined by the Secretary) and to compare such estimates with the numbers of such beneficiaries actually enrolled by such plans.

II. Proposed Approach and Solicitation of Comments for Section 6411 of the Affordable Care Act

We want to utilize RAC overpayment and underpayment findings to reduce future improper payments in the Medicare Parts C and D programs. With that objective, we are interested in knowing how the RAC findings could be used to more accurately inform Medicare's reimbursement to Part C and Part D plans. Our current experience for utilizing RACs has been limited to the Medicare FFS model. Given the fundamental differences between Medicare FFS and the Medicare Parts C and D programs and since this is the first time we have attempted to expand RACs to other parts of the Medicare program, we are soliciting the views of

industry stakeholders on how to best implement the RAC program requirements established in section 6411(b) of the ACA for the Medicare Part C and Part D programs. We recognize that the payment structure in the Medicare Part C and Part D programs is different than in Medicare FFS, so we want to ensure that the RACs are utilized in the most efficient and appropriate manner to return any identified overpayments to the Medicare Trust Fund.

Based on the comments received from this solicitation, we may do further rulemaking on the development and implementation of requirements for RACs in the Part C and Part D programs. We are most interested in receiving comments on the following:

- Methods for RACs to identify underpayments and overpayments in the Medicare Part C and Part D programs.
- Utilizing a phased-in approach for RACs in the Medicare Part C and Part D programs, similar to the development of RACs in the Medicare FFS program.
- The criteria or qualifications necessary to enable a RAC to knowledgeably and appropriately review the payments in Medicare Part C and Part D plans. (We note that in order to meet the qualifications, the Medicare FFS RACs must obtain the services of certified coders, nurses, or therapists, and a Contractor Medical Director.)
- Specific conflict of interest rules that should apply to RACs for the Medicare Parts C and D programs.
- Establishing an oversight entity for Medicare Part C and Part D RAC Issue Approval. We are considering establishing a review board for the Part C and Part D RACs. (We note that FFS RACs have the authority to pursue clear-cut vulnerabilities that can lead to improper payments. However, for more complex vulnerabilities, a review board is utilized. This board decides whether FFS RACs can proceed with the proposed review.)
- Methods for resolving underpayments and how payments related to underpayments identified by the RAC would be implemented in the Part C and Part D programs.
- Potential for allowing Part C and Part D plans to use RACs within their own plans to identify overpayments in its operations. Working through us, the RAC contractor would come to an agreement with interested MA organizations (MAO) to conduct claims review. The claims review would be conducted on claims submitted to the MAO for payment to providers serving the MAO enrollees. The RAC would be paid by the MA organization on a

contingency fee basis and overpayments the MAO recoups as a result of the RAC activities would be retained by the MAO. In approaching this work, the RAC contractor would consider the use of complex and automated review of claims.

- Approaches to implementing the following special rules provisions of section 6411(b) of ACA:

++ We want to utilize RACs to ensure that each Part C and Part D plan has anti-fraud plans in place and to review the effectiveness of those anti-fraud plans. In accordance with section 1893(h) of the ACA, the RACs for the Part C and Part D programs would be paid on a contingency basis, as in the Medicare FFS program. We are interested in the industry's views on how to pay RACs on a contingency basis for reviewing anti-fraud plans in the Part C and Part D programs given there are no recoveries or overpayments resulting from a review of such plans. Should this contingency basis differ from how RACs are paid for reviewing Medicare FFS claims? If so, how?

++ The statute requires that we use RACs to examine claims for reinsurance payments to determine whether Part D plans submitting such claims incurred costs in excess of the allowable reinsurance costs permitted under the statute. Under the Part D statute, Part D plans legitimately incur costs in excess of allowable reinsurance costs during the catastrophic phase of the benefit. In the catastrophic phase of the defined standard benefit, 80 percent of the negotiated price is paid by Federal reinsurance, 15 percent is the responsibility of the sponsor (and is incorporated into their bid for the direct subsidy) and 5 percent is the responsibility of the beneficiary. Prospective reinsurance payments to plans are based on plans' estimates of reinsurance costs and, as required by statute, we reconcile these prospective reinsurance payments for sponsors with actual reinsurance costs. Given this annual reconciliation process, requiring RACs to review the accuracy of the prospective reinsurance payments is less likely to result in recovery of overpayments.

However, we are considering having RACs examine the accuracy and completeness of sponsors' reporting of Direct and Indirect Remuneration (DIR). The DIR information reported by plans includes rebates paid by pharmaceutical manufacturers, as well as other remuneration received by the plan that has the effect of reducing their drug costs, and is used as a factor in our payment calculations to Part D plans. Under-reporting of DIR by plans would

overstate plans' drug costs, including in the catastrophic phase of the benefit, and would result in an overpayment to the plan. We are interested in receiving comments on how RACs could be used to review the accuracy and completeness of DIR information provided to us by plans.

++ The statute also requires that we use RACs to review estimates submitted by Part D plans with respect to enrollment of high cost beneficiaries. A Part D sponsor's estimates for the enrollment of high cost beneficiaries may impact the reinsurance estimates in their Part D bids and thus, the prospective reinsurance subsidy payments they receive from us. However, given the structure of the Part D program that requires us to reconcile reinsurance subsidy payments against a Part D sponsor's actual costs, requiring RACs to undertake this activity is less likely to result in recovery of any reinsurance overpayments. However, as noted previously, we are interested in receiving comments on how RACs might be used to identify overpayments and underpayments associated with DIR reporting.

++ We are interested in learning about successful overpayment recoupment models in managed care that may already exist in the commercial sector and to what extent these models are applicable to Part C. Successfully integrating RACs into Part C presents a particular challenge because of how Part C payments are paid. Under the statutory payment formula, plans are paid on a capitated basis. Therefore, the plan, not the government, is at direct risk for any overpayments and underpayments made to its providers. We are interested in learning whether and how other purchasers have identified overpayments and underpayments made by capitated plans and to what extent savings were shared between the plan and the purchaser.

- Any additional information concerning the development of a RAC program in Medicare Part C and Part D and how we can establish the required program elements to protect the Medicare Parts C and D programs from fraud, waste, and abuse.

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

Dated: December 8, 2010.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Head Start; Statement of Organization, Functions, and Delegations of Authority

AGENCY: Administration for Children and Families, HHS.

ACTION: Notice.

SUMMARY: Statement of Organizations, Functions, and Delegations of Authority. The Administration for Children and Families (ACF) has reorganized the Office of Head Start (OHS). This reorganization creates the Grants and Contracts Division and the State Initiatives Division. It renames the Educational Development and Partnership Division, titling it the Education and Comprehensive Services Division. It also renames the Immediate Office of Head Start, the Office of the Director. Additionally, it renames the Policy and Budget Division, the Policy and Planning Division.

FOR FURTHER INFORMATION CONTACT: Yvette Sanchez-Fuentes, Office of the Director, Office of Head Start, 1250 Maryland Avenue, SW., Washington, DC 20024, 202-205-8573.

This notice amends Part K of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Administration for Children and Families (ACF) as follows: Chapter KU, Office of Head Start (OHS), as last amended 71 FR 59117-59123, October 6, 2006.

I. Under Chapter, KU, Office of Head Start, delete KU in its entirety and replace with the following:

KU.00 MISSION. The Office of Head Start (OHS) advises the Assistant Secretary for Children and Families on issues regarding the Head Start program (including Early Head Start). OHS develops legislative and budgetary proposals; identifies areas for research, demonstration and developmental activities; presents operational planning objectives and initiatives relating to Head Start and Early Head Start to the Assistant Secretary; and oversees the progress of approved activities. It provides leadership and coordination for the activities of the Head Start program in the ACF Central Office including the Head Start Regional Program Units. OHS represents Head Start in inter-agency activities with other Federal and non-Federal organizations.

KU.10 ORGANIZATION. OHS is headed by a director who reports