



CURRENT FRAUD AND ABUSE ISSUES

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- I. Fraud and abuse issues – Health plan focus
  - A. Recipe for increased enforcement
    - Increasing portion of health care expenditures funded by government
    - Increasing fraud and abuse enforcement
    - Increasing portion of health expenditures funded by government flowing through health plans = increased fraud and abuse enforcement focused on health plans<sup>1</sup>
      - Medicare -- Medicare Advantage, PDPs and employer prescription drug benefit subsidy program
      - Medicaid
      - FEHBP
      - TriCare
  - B. Best predictors of enforcement targets
    - Cases already brought by the government
    - Cases government says it will look for
    - Follow the money
  - C. Key statutes
    - False Claims Act, 31 U.S.C. § 3729 et seq.<sup>2</sup>

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<sup>1</sup> This outline focuses on government fraud and abuse enforcement issues for health plans. It does not address private lawsuits, including pending and settled private class action suits in the Southern District of Florida and elsewhere in which health care providers have alleged a conspiracy among health insurance plans to diminish, delay and deny payments to providers.

<sup>2</sup> Because this outline focuses on exposure risks for health plans participating on government programs, it does not explore the important False Claims Act issues percolating from the decision of the Court of Appeals for the District of Columbia Circuit in *U.S. ex rel. Totten v. Bombardier Corporation*, 380 F.3d 488 (Aug. 29, 2004), cert. denied, 125 S.Ct. 2257 (2005) requiring submission of false claim to United States as element of False Claims Act violation. In

- Fraud against health benefit program, 18 U.S.C. § 1346
- Federal health benefit program anti-kickback law, 42 U.S.C. § 1320a-7b(b)
- Public Contract Anti-Kickback Act, 41 U.S.C. § 53

## II. Fraud and abuse enforcement actions

- *United States ex rel. Garner v. Anthem Insurance Companies Inc.*, S.D. Ohio No. 00-00463-SAS (settlement announced Aug. 8, 2005) [http://www.usdoj.gov/opa/pr/2005/August/05\\_civ\\_412.htm](http://www.usdoj.gov/opa/pr/2005/August/05_civ_412.htm) - Anthem Insurance Companies (“Anthem”) agreed to pay \$1.5 million to settle allegations, originally filed by a qui tam plaintiff, that from 1992 through 2002, it failed to pass on the full amount of OPM's proportionate share of rebates received by its affiliate Anthem Prescription Management on prescription drugs for FEHBP members and overcharged FEHBP by including impermissible profits in the cost of billed services from an affiliated company.
- *United States v. Americhoice of Pennsylvania, Inc.* (E.D. Pa. June 30, 2005). <http://www.usdoj.gov/usao/pae/News/Pr/2005/jun/ACPA%20settlement%20FINAL.pdf>. AmeriChoice agreed to pay \$1.6 million and enter into a corporate integrity agreement to resolve False Claims Act allegations relating to Medicare + Choice and Medicaid claims processing and coverage determinations. The government alleged that from September 1995 through June 1998, AmeriChoice failed to process or pay health care provider claims in a timely fashion. The

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*U.S. ex rel. Atkins v. McInteer*, 345 F.Supp.2d 1302 (N.D. Ala. 2004), the U.S. District Court for the Northern District of Alabama held that no False Claims Act action can lie when a nursing home provides inadequate care yet presents claims for payment to the Alabama Medicaid Agency, as the Alabama Medicaid Agency is neither the federal government nor a federal official, but merely a federal grantee. In a non-healthcare context, the U.S. District Court for the Eastern District of Louisiana in *U.S. ex rel. Rafizadeh v. Continental Common, Inc.*, 2005 WL 2061018 (2005), refused to grant the defendant's motion to dismiss a False Claims Act cause of action, but allowed the plaintiff to attempt to amend its complaint to more specifically plead how the defendant had presented claims to either the federal government or federal officials, and to specify which federal officials were presented with such claims.

complaint also alleged that AmeriChoice did not report claims processing data accurately. Also see [http://www.oig.hhs.gov/fraud/cia/agreements/americhoice\\_of\\_pa\\_inc\\_06292005.pdf](http://www.oig.hhs.gov/fraud/cia/agreements/americhoice_of_pa_inc_06292005.pdf) (corporate integrity agreement addressing, inter alia, procedures for claims review and preventing billing for unallowable costs) (June 29, 2005)

- *United States v. Pacificare Health Systems* (April 2002) (\$87 million settlement of claim FEHBP contractor acquired by Pacificare set FEHBP premiums improperly from 1990-97. See Press Release, U.S. Dep't of Justice (Apr. 12, 2002), available at [http://www.usdoj.gov/opa/pr/2002/April/02\\_civ\\_217.htm](http://www.usdoj.gov/opa/pr/2002/April/02_civ_217.htm)
- *United States ex rel. Drescher v. Highmark, Inc.*, 305 F. Supp. 2d 451 (E.D. Pa. 2004). <http://www.paed.uscourts.gov/documents/opinions/04D0039P.pdf> United States joined a qui tam action against Highmark, sued as a Medicare fiscal intermediary and as a private health insurance company, for alleged violations of the FCA, as well as to recover overpayments made by Medicare pursuant to the Medicare Secondary Payer (MSP) statute, 42 U.S.C. §1395y(b)(2)(B)(ii), and for unjust enrichment and breach of contract. The qui tam relator had been a Highmark employee responsible for implementing a 1995 settlement agreement entered into by the government and Highmark's predecessors. Highmark allegedly violated the FCA as a private insurer by improperly paying MSP claims on a secondary basis that it should have paid on a primary basis, thereby causing providers and beneficiaries to submit false claims to the Medicare program for primary payment. Highmark allegedly obtained information to assist with submission of claims and then failed to integrate such steps into its internal systems. The court denied Highmark's motion to dismiss, and deferred ruling on separate claims that Highmark submitted false claims as a Medicare administrative contractor.
- *HealthAmerica Pennsylvania, Inc.* (Dec. 2003) (settlement of False Claims Act investigation with payment of over \$29 million by FEHBP contracting HMO. An audit conducted by the OPM Inspector General had identified alleged overcharges by the company in its FEHBP operations during contract years from 1993 through 1999, as well as potential false claims violations. Allegedly, HealthAmerica failed to apply a price reduction to the FEHBP that was comparable to the pricing it provided to commercial groups used as a contract price benchmark. The

government also expressed concern about demographic information HealthAmerica used in developing its rates. See Press Release, U.S. Dep't of Justice (Dec. 1, 2003), *available at* <http://www.usdoj.gov/usao/dc/press/03373.html>

- *United States v. AdvancePCS*, Civ. A. Nos. 02-CV-9236, 03-CV-5425 (E.D. Pa. Sept. 8, 2005) <http://www.usdoj.gov/usao/pae/News/Pr/2005/sep/pcs%20Consent%20Order.pdf> (consent order); <http://www.usdoj.gov/usao/pae/News/Pr/2005/sep/pcs%20settlement%20agreement.pdf> (civil settlement) -- \$137.5 million payment in resolution of False Claims Act and the Public Contract Anti-Kickback Law allegations concerning FEHBP and M+C (now MA) plans. The allegations focused on (1) payments made by pharmaceutical manufacturers to AdvancePCS via allegedly excessive administrative fees and over-priced products and services agreements as an improper reward for favorable treatment of the manufacturers' drugs in connection with contracts between AdvancePCS and health plan contractors under FEHBP and M + C plans (2) alleged payments by pharmaceutical manufacturers of flat fee lump sum and flat fee percentage rebate contracts for heavily utilized drugs as an improper reward for favorable treatment of those drugs in under FEHBP and M + C plans; and (3) alleged payments made by AdvancePCS to customers and potential customers that contracted with federally-funded healthcare plans to ensure that AdvancePCS was selected or retained as the PBM for the healthcare plan.
- *United States ex rel. Hunt v. Merck-Medco Managed Care LLC*, E.D. Pa., No. 00-CV-737,9/23/2004) (court dismisses constructive fraud and certain other parts of False Claims Act whistleblower case, but denied dismissal of allegations Medco paid kickbacks to a health plan and solicited and accepted kickbacks from drug companies. *United States v. Merck-Medco Managed Care, LLC*, No. 00-CV-737 (E.D. Pa., complaint filed, Sept. 29, 2003), *amended complaint filed* (Dec. 9, 2003) *available at* <http://www.usdoj.gov/usao/pae/News/Pr/2003/dec/Medcoamendedcomplaint.pdf>. A consent agreement settled one count, paralleling a separate settlement with a \$29.3 million payment to resolve state attorneys general allegations of fraud in connection with state Medicaid programs. *United States v. Merck-Medco Managed Care LLC*, E.D. Pa., No. 00-CV-737, *order filed* 4/26/04).

<http://www.usdoj.gov/usao/pae/News/Pr/2004/apr/consentordermedco.pdf>

- *United States v. Humana, Inc.* (settlement June 5, 2000) (corporate integrity agreement at [http://www.oig.hhs.gov/fraud/cia/agreements/humana\\_060500.pdf](http://www.oig.hhs.gov/fraud/cia/agreements/humana_060500.pdf)) Humana paid \$14.5 million to settle allegations that it provided inaccurate payment information to Medicare from 1990 through 1998 for Medicare beneficiaries who were Medicare plan members incorrectly listed by the plans as dually eligible for both Medicare and Medicaid. The Medicare managed care program pays a higher monthly amount for dually eligible beneficiaries. Humana entered into a broad five-year corporate integrity agreement with the HHS OIG, addressing, enrollment, encounter, and adjusted community rate data , marketing/disenrollment and claims processing.
- *State of New York v. Fabrikant*, No. 7055-98 (N.Y. Sup. Ct. May 24, 1999) [http://www.oag.state.ny.us/press/1999/may/may24c\\_99.html](http://www.oag.state.ny.us/press/1999/may/may24c_99.html) – health plan and chief executive pled guilty to felony charges and paid \$375,000 fine to resolve charges of: (1) conspiracy to retain excessive Medicaid funds by removing thousands of beneficiaries from physician rosters, thereby avoiding making capitation payments to physicians who were compensated based upon the number of assigned patients; (2) false claims to Medicaid that the health plan was providing Medicaid recipients with access to primary care physicians; and (3) providing to Medicaid a false list of participating providers, which included non-participating physicians.
- *U.S. v. Wolf*, No. 97-10250-RCL (D. Mass. 1997) -- Blue Cross Blue Shield of Massachusetts’ “Blue Care 65” Medicare HMO reportedly paid a \$750,000 civil penalty for misrepresenting that certain providers were participating in its network.
- *United States ex rel. Tyson v. Amerigroup Illinois Inc.*, N.D. Ill., No. 02 C 6074 (N.D. Ill. April 2005) – State AG intervened in whistleblower suite accusing an Illinois HMO of defrauding Medicaid by submitting false claims by “cherry-picking” certain Medicaid patients and avoiding pregnant women and other seriously ill persons as a way to improve profits

- *U.S. v. Integrated Network Systems, Inc.*, (W.D. Wash. 1995) -- An individual was convicted and sentenced to 24 years imprisonment and he and the Integrated Network Systems PPO reportedly agreed to pay approximately \$2.5 million to settle a qui tam action. He and INS admitted to skimming \$1.4 million from health insurance companies. They negotiated discounts with medical center hospitals and agreed to pass on the discounted prices to various rural medical service bureaus which agreed to pay the discounted prices to defendants, who, in turn, were to pay those sums to the hospitals. Defendants allegedly cheated by quoting and collecting boosted prices from medical service bureaus and paying the lesser discounted sums to the hospitals. One of the victim medical service bureaus administered FEHBP claims under contract with the U.S. Office of Personnel Management. .  
<http://www.usdoj.gov/opa/health/hcf2.htm>

### III. Contractual and regulatory deficiency allegations

- *Healthcare U.S.A. of Missouri v. Nixon*, Mo. Cir. Ct., No 01 cc 001930 (Dec. 19, 2002) (\$1.1 million settlement resolves claim plan breached Medicaid contractual duty to perform lead screenings)
- *Dick v. Community Health Plan of the Rockies*, No. 01 cv 1265, Colo. Dist. Ct. (filed March 22, 2001) (Medicaid settles allegations that its mailroom staff were purposefully discarding and hiding provider claims in alleged effort to delay payments; personnel were allegedly instructed by management that if providers questioned the delay they should be informed that the claims were never received)
- *In re Americhoice of New Jersey, Inc.* (N.J. Dep't of Health and Senior Services May 2005) (order assessing \$275,000 in penalties for alleged failures in record-keeping, customer service, quality improvement, inappropriate billing, sentinel event tracking, medical director clinical leadership and direction and leadership, and procedures for determining clinical appropriateness of certain formulary drugs)  
[http://www.state.nj.us/dobi/acrobat/omc/omcorder05\\_01.pdf](http://www.state.nj.us/dobi/acrobat/omc/omcorder05_01.pdf)
- *In re Humana Medical Plan, Inc.* (Fla. Att. Gen. June 2001) (\$8 million overpayment refund paid in settlement of alleged overcharges in relation to members dually enrolled in both

Medicaid and Medicare managed care plans. , our Florida subsidiary, Humana Medical Plan, Inc., reached an agreement with the Florida Attorney General's office to reimburse \$8 million in overpayments in connection with members who were enrolled in both Medicaid and Medicare managed care plans.

- HHS Office of Inspector General – Audit, "Review of PacifiCare of Colorado's Modifications To Its 2004 Adjusted Community Rate Proposal Under The Medicare Prescription Drug, Improvement, and Modernization Act," (A-09-05-00077), March 20, 2006  
<http://www.oig.hhs.gov/oas/reports/region9/90500077.pdf>
- HHS Office of Inspector General – Audit, "Duplicate Medicare Payments to Cost-Based Health Maintenance Organization Plans for John Deere Health Plan, Inc., for the Fiscal Years 2000 Through 2003," (A-05-05-00043), Sept. 12, 2005,  
<http://www.oig.hhs.gov/oas/reports/region5/50500043.pdf>
- HHS Office of Inspector General – Audit, "Duplicate Medicare Payments to Cost-Based Health Maintenance Organizations Plans for Arnett Health Plan, Inc. for the Fiscal Years 2000, Through 2003," (A-05-05-00044), Sept. 9, 2005,  
<http://www.oig.hhs.gov/oas/reports/region5/50500044.pdf>
- HHS Office of Inspector General – Audit, "Review of Humana Health Plan of Texas, Inc.'s Modifications to Its 2001 Adjusted Community Rate Proposal Under the Benefits Improvement and Protection Act of 2000," (A-06-03-00027), July 8, 2005,  
<http://www.oig.hhs.gov/oas/reports/region6/60300027.pdf>
- Group Health Incorporated, Office of Personnel Management Office of Inspector General, "FEHBP experience rated contract audit Report No. 1D-80-00-04-058" ( June 20, 2005) (questioned costs included \$4,784,436 for claim payments allegedly not properly coordinated with Medicare; \$1,341,765 for unreturned uncashed health benefit checks, and \$145,238 for lost investment income on uncashed checks that were either not returned to the FEHBP or not returned in a timely manner; \$457,579 for duplicate claim payments; \$329,566 for unreturned program integrity recoveries; \$289,993 for executive compensation over-charges; and \$290,853 for Disease Management Program undercharges. Also, as regards pharmacy benefit rebates, GHI allegedly did not return \$1,519,511 in rebates to the FEHBP and GHI returned over \$5 million in rebates untimely to the FEHBP GHI agreed with \$8,120,495 of the

questioned charges. See Office of Personnel Management, Office of the Inspector General, Semi-Annual Report, April 1, 2005 – September 30, 2005 at p.5  
<http://www.opm.gov/oig/pdf/OPMSAR33.pdf>

IV. Fraud and abuse enforcement targets under Medicare Advantage and Medicare Part D

A. Getting into trouble

1. Of course that's cheating
2. That's way sloppy!
3. They cheated, and you helped it happen
4. Your statement led to someone else's false claim
5. You may not have realized that was cheating, but ....
6. Combination(s) of above, such as:
  - You were careless and helped others cheat in a way that you may not have realized was cheating....
7. Watch out for unanticipated issues in relation to employer drug plan 28% subsidy; if cost tracking is not as rigorous as is maintained for a Part D plan, there could be risk of liability for knowingly causing submission of a false claim by the employer
8. Specific risks –
  - a. underutilization and denial of necessary covered medical care;
  - b. systemic effort to move high-risk managed care patients out of managed care plans (enrolment/disenrollment fraud);
  - c. “cherry-picking” or recruitment of healthier-than-average enrollees through improper screening (enrollment fraud)
  - d. failure to provide beneficiaries' services advertised or mandated;
  - e. systemic denial of promised treatment or benefits or systemic delays in providing treatment or benefit information;
  - f. unreasonable times and distances for appointments to prevent beneficiaries from obtaining services;
  - g. misrepresentations in “encounter data” or other data submitted to the government and utilized to determine rates;
  - h. submission of falsely elevated cost data to government to justify higher payments (or submitted to employer, and utilized to determine 28% subsidy);

- i. failure to assign revenues and expenses to appropriate “claims cost” or “administrative” buckets, resulting in inaccurate bid submissions or subsidy calculations
- j. fraudulent subcontracts
- k. improper beneficiary inducements to enrollment
- l. misrepresentations in enrollment data (e.g., mis-reporting of enrollee characteristics) to increase payments
- m. misrepresentations to the government or to federal program beneficiaries in marketing or other materials regarding:
  - 1. quality of healthcare services or benefits;
  - 2. competence of participating providers or the size or composition of provider networks; and
  - 3. access to healthcare services

B. Centers for Medicare and Medicaid Services, Prescription Drug Benefit Manual, Chapter 9 – Part D Program to Control Fraud, Waste and Abuse

<http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManualChapter9FWA.pdf>.

1. Part D sponsor abuse
  - Failure to provide medically necessary services
  - Marketing schemes
  - Improper bid submissions
  - Payments for excluded drugs
  - Multiple billing
  - Non-compendium payments
  - Inappropriate formulary decisions
  - Inappropriate enrollment/disenrollment
  - Appeals process handled incorrectly
  - Adverse selection
  - False information
  - Delinquent reimbursements
  - Duplicative premiums
  - Excessive premiums
  - Inaccuracies in eligibility or coordination of benefits
  - Incorrect calculation of TrOOP
  - Inaccurate data submission
  - Catastrophic coverage manipulation
  - Failure to disclose or misrepresentation of rebates, discounts or price concessions
    - Bait and switch pricing

- Manipulation of low-income subsidy enrollees
2. PBM abuse
- *Prescription drug switching*: The PBM receives a payment to switch a beneficiary from one drug to another or influence the prescriber to switch the patient to a different drug.
  - *Unlawful remuneration*: PBM receives unlawful remuneration in order to steer a beneficiary toward a certain plan or drug, or for formulary placement. Includes unlawful remuneration from vendors beyond switching fees.
  - *Inappropriate formulary decisions*: PBMs or their P&T Committees make formulary decisions where cost takes precedence over clinical efficacy and appropriateness of formulary drugs.
  - *Prescription drug shorting*
  - *Failure to offer negotiated prices*
3. Pharmacy abuse
- *Inappropriate billing practices*:
    - Incorrectly billing for secondary payers to receive increased reimbursement
    - Billing for non-existent prescriptions
    - Billing multiple payers for the same prescriptions
    - Billing for brand when generics are dispensed
    - Billing for non-covered prescriptions as covered items
    - Billing for prescriptions that are never picked up (*i.e.*, not reversing claims that are processed when prescriptions are filled but never picked up)
    - Billing based on “gang visits,” *e.g.*, a pharmacist visits a nursing home and bills for numerous pharmaceutical prescriptions without furnishing any specific service to individual patients.
    - Inappropriate use of dispense as written (“DAW”) codes
  - *Prescription drug shorting*
  - *Bait and switch pricing*
  - *Prescription forging or altering*
  - *Dispensing expired or adulterated prescription drugs*
  - *Prescription refill errors*
  - *Illegal remuneration schemes*:
    - Pharmacy is offered, paid, solicits, or receives unlawful remuneration to induce or reward the pharmacy to switch patients to different drugs, influence prescribers to prescribe different drugs, or steer patients to Plans.

- *TrOOP manipulation*
- *Failure to offer negotiated prices*

4. Manufacturer abuse

- Lack of integrity of data to establish payment and/or determine reimbursement
- Kickbacks, inducements, and other illegal remuneration
- Formulary and formulary support activities:
  - inappropriate relationships with formulary committee members
  - payments to PBMs, and formulary placement payments in order to have manufacturer's products included on a Plan's formulary
- Inappropriate relationships with physicians
- Illegal off-label promotion
- Illegal usage of free samples

V. Department of Health & Human Services Office of Inspector General Work Plan for Fiscal Year 2006, Medicare Managed Care <http://www.oig.hhs.gov/publications/docs/workplan/2006/WorkPlanFY2006.pdf>

A. Medicare Advantage

○ *Enrollee Access to Negotiated Prices for Covered Part D Drugs:*

The OIG is investigating whether Medicare Advantage and Part D enrollees are being given access to negotiated prices for covered drugs, including all discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, regardless of whether the drug was paid for under the benefit.

○ *Regional Plan Stabilization Fund:* The OIG is assessing compliance with MMA requirements and CMS guidance pertaining to the establishment and management of the "Regional Plan Stabilization Fund," including the adequacy, propriety, and timeliness of CMS's review processes for evaluating Managed Care Organization (MCO) proposals and the awarding of stabilization funds.

○ *Adjusted Community Rate Proposals:* In a review carried over from the 2003 Work Plan, the OIG is examining whether modifications of the 2001 and 2004 Adjusted Community Rate Proposals were properly supported. MCOs may make one or more of the following proposals: reduced beneficiary premiums; reduced beneficiary cost sharing; enhanced benefits; additional payment amounts received after March 1, 2001 placed in a Benefit Stabilization Fund; or additional payment amounts used to retain providers or expand a provider

network, as long as the stabilization or enhancement does not result in increased premiums, increased cost sharing, or reduced benefits. The OIG is verifying documentation that MCOs used the additional payments in accordance with these requirements and properly documented changes in adjusted community rate values to reflect updated per-month-per member cost, utilization, and membership assumptions.

- *Follow-up on Adjusted Community Proposals:* The OIG is examining CMS's actions to resolve the problems identified in prior audits of adjusted community rate proposals to ensure that future proposals are accurate and that repayments or enhanced benefits are provided to account for audit findings.

- *Administrative Costs:* Using the Federal Employees Health Benefits guidelines, the OIG is examining the administrative accounts currently claimed by MCOs. This is, in part, in response to Congress's expressed interest in how MCOs determine funding amounts to meet administrative costs, which must be allocable, reasonable, and limited under the program.

- *Managed Care Encounter Data:* The OIG is assessing the accuracy of Part A encounter data on Medicare beneficiaries. MCOs are required to submit this data for CMS's use in developing a portion of each organization's monthly capitation rate, the risk-adjusted portion that will eventually comprise 100 percent of the monthly rate. As a result, incorrect encounter data could have a significant impact on future Medicare reimbursement.

- *Enhanced Managed Care Payments:* The OIG is completing several reviews determining whether CMS made proper enhanced capitation payments to MCOs. The OIG review focuses on the accuracy of controls at both CMS and the MCOs regarding special status categories, such as ESRD status, dual eligibles, and institutionalized beneficiaries, warranting these enhanced payments.

- *Duplicate Medicare Fee-for-Service Payments:* The OIG is investigating whether duplicate Medicare fee-for-service payments were made to providers for beneficiaries enrolled in MCOs operating under a risk-based contract, including whether CMS or its intermediaries have sufficient controls in place to prevent such duplicate payments.

- *Marketing Practices by Managed Care Organizations:* The OIG is examining whether Medicare MCOs market their plans pursuant to CMS guidelines and how CMS monitors compliance. CMS prohibits discriminatory marketing activities that include selectively enrolling beneficiaries through monetary inducements, soliciting enrollment

door-to-door, and using providers to distribute or accept plan materials. The OIG is concerned about this issue because a prior study found that 43 percent of beneficiaries were asked about health problems when applying with an MCO.

- *Medicare Capitation Payments to Managed Care Plans After a Beneficiary's Death:* The OIG is examining to what extent payments are made to MA plans for deceased beneficiaries, the CMS processes that identify MA overpayments due to beneficiary deaths, and what portion of those payments are subsequently recovered by CMS.

- *Medicare Advantage Regional Plans: Availability, Physician Participation, and Beneficiary Enrollment in Rural Areas:* The OIG is examining the availability of regional MA plans to rural beneficiaries, the extent to which rural beneficiaries enroll in MA plans, and whether physician practices in rural areas participate in regional MA plans.

- *Dissemination of Beneficiary Information Materials by Medicare Advantage Prescription Drug Plans:* The OIG is examining the extent to which MA-PD plans meet statutory and regulatory requirements regarding the content of materials distributed to beneficiaries, and whether MA-PD marketing materials comply with CMS guidelines.

#### B. Medicare Part D Administration

- *CMS Program Integrity Safeguards for Medicare Drug Plan Applicants:* The OIG is assessing the safeguards that CMS uses to confirm that drug plan applicants qualify to provide Part D benefits and whether CMS sufficiently addresses program integrity concerns associated with the sponsors who apply to offer drug plan benefits. The OIG also is reviewing the regulations and guidance associated with the application process with an eye to business integrity and compliance.

- *Beneficiary Awareness of the Medicare Part D Low-income Subsidy:* The OIG is evaluating whether beneficiaries are aware of the Part D low-income subsidy and analyze the methods used to educate beneficiaries about the subsidy. *Tracking Beneficiaries' True Out-of-pocket Costs for Part D Prescription Drug*

- *Coverage:* The OIG will examine CMS's oversight of the calculation of true out-of-pocket expenses that qualify toward catastrophic coverage and the accuracy of tracking these expenses in the Coordination of Benefits system. *Prescription Drug Plan and Marketing Materials for Prescription Drug Benefits:* The OIG is examining prescription drug plan marketing materials to ensure that they are clear and understandable to Medicare beneficiaries and in compliance with regulations and guidance.

- *Auto-enrollment of Dual Eligibles into Medicare Part D Plans:* The OIG is studying CMS's auto-enrollment of dually eligibles, the

proportion of dually eligibles that selected their own plan, and those who are not enrolled in any Part D plan.

- *Medicare Prescription Drug Benefit Pharmacy Access in Rural Areas:* The OIG is studying Part D pharmacies in rural areas to ensure that there is sufficient beneficiary access and that the drug plans comply with minimum pharmacy access requirements. *Monitoring Fluctuation in Drug Prices Under Prescription Drug Plans and Medicare Advantage Prescription Drug Plans:* The OIG is studying fluctuations in drug prices and price variation patterns under the PDPs and Medicare Advantage Prescription Drug plans (MA-PDs).

- *Coordination and Oversight of Medicare Part B and D to Avoid Duplicate Payments:* The OIG is examining Part D and Part B oversight to ensure that it will prevent duplicate payment for drugs.

- *Enrollee Access to Negotiated Prices for Covered Part D Drugs:* The OIG is investigating whether Medicare Advantage and Part D enrollees are being given access to negotiated prices for covered drugs, including all discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, regardless of whether the drug was paid for under the benefit.

- *Prescription Drug Plans' Use of Formularies:* The OIG is investigating whether (1) the Pharmacy and Therapeutics committees that construct the formularies, (2) the breadth and depth of drugs in the formularies, and (3) the beneficiary management tools (including exception and appeal rights) conform to rules and regulations.

- *Coordination Between State Pharmaceutical Assistance Programs and Medicare Part D:* The OIG is examining the coordination between State Pharmaceutical Assistance Programs and Part D to identify whether beneficiaries are able to obtain needed assistance and appropriate drug coverage.

- *Prescription Drug Plans' and Medicare Advantage Plans' Implementation of Required Programs to Deter Fraud, Waste, and Abuse:* Following an OIG inspection to assess program integrity safeguards in the PDP and MA-PD application process, the OIG will evaluate PDPs' and MA-PDs' implementation of required programs to deter fraud, waste, and abuse, and CMS programs' integrity systems to oversee the PDP and MA-PD programs.

- *Prescription Drug Cards:* The OIG is reviewing the processes and controls for the prescription drug discount card program, specifically addressing general and application system controls at CMS and for some program sponsors, identifying whether controls are in place to minimize fraud, waste, and abuse in transitional assistance payments. The discount program ended January 2006, and the OIG

will present the results of its review as a "lessons learned" for use in the full prescription drug benefit.

- *Employer Subsidies for Drug Coverage:* The OIG is assessing the strength of the controls that CMS will implement to administer employer subsidies to sponsors of qualified retiree prescription drug plans by verifying some of the sponsors' data, both the actuarial equivalency and qualified retiree information.

- *Medicare Part D Drug Benefit Payments:* The OIG is sampling Part D beneficiaries' claim files to determine whether controls have been implemented and is working to ensure that (1) benefits are paid on behalf of eligible beneficiaries and (2) Medicare, as well as the beneficiaries paid appropriate amounts for drug coverage.

- *State Contribution to Drug Benefit Costs Assumed by Medicare:* The OIG is reviewing the data used to calculate states' contribution payments, calculation of those payments, the states' payment amounts, and CMS and state controls related to contribution payments, in order to determine states' compliance with laws and regulations requiring them to make monthly payments under the MMA.

- *Medicare Part D Risk-sharing Payments and Recoveries:* The OIG is determining whether CMS and the prescription drug plans have established adequate controls over Part D risk-sharing payments and recoveries to ensure that (1) the plans submit accurate and timely information to CMS; (2) CMS calculations are performed in accordance with applicable laws and regulations; and (3) payments and recoveries are made in accordance with applicable laws and regulations.

- *Prescription Drug Benefit:* Many Medicare Advantage (MA) organizations currently offer a prescription drug benefit as a supplemental benefit when expected Medicare payments exceeded Medicare costs. While any supplemental benefits (prescription drug benefit under Part D or as an additional benefit under an MA plan) offered by the plan may be viewed as a single package of supplemental benefits, the two types of supplemental benefits are considered separately for bidding. The OIG is examining the bidding of prescription drugs when these two scenarios are present. It also is examining the impact of the amount a beneficiary must spend on Part D covered drugs to reach catastrophic coverage of prescription drugs available under an MA-sponsored plan and any other drug benefit provided as an additional benefit.

## VI. Further resources:

- HHS Office of Inspector General, “Compliance Program Guidance for Medicare+Choice Organizations Offering Coordinated Care Plans,” 64 Fed. Reg. 61,893 (Nov. 15, 1999)  
<http://oig.hhs.gov/fraud/docs/complianceguidance/111599.pdf>
- Thomas R. Judd and Sarah Elizabeth Jones, *Health Care Fraud in a Managed Care Environment*, National Association of Attorneys General, April 1996
- Department of Health and Human Services Office of Inspector General, OEI-07-96-00250, “Medicaid Managed Care Fraud and Abuse,” June 1999 <http://oig.hhs.gov/oei/reports/oei-07-96-00250.pdf>
- “Guidelines for Addressing Fraud and Abuse in Medicaid Managed Care,” A Product of the National Medicaid Fraud & Abuse Initiative, October 2000  
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