



News Clips & Resources

Medicare & Medicaid

Health Care Cases Comprise Bulk of DOJ's Record Amount of Recoveries in Fiscal 2006

The Department of Justice recovered a record \$3.1 billion in false claims to the government in fiscal year 2006, with health care cases comprising a majority of the settlements and judgments, the enforcement agency announced Nov. 21.....4

Missouri Medical Supplier Sentenced To Prison Term for Role in Medicare Scam ST. LOUIS--

The owner of a medical supply company in the Kansas City, Mo., area was sentenced Nov. 20 to three years in prison without parole for his role in a multimillion-dollar Medicare scheme involving wheelchairs, U.S. Attorney for the Western District of Missouri Bradley J. Schlozman announced the same day.....4

Investigators, Compliance Officers Must Work Closely to Dig Up Part D Fraud, Meeting Told MARCO ISLAND, Fla.--

The government's fraud, waste, and abuse guidance to Part D plan providers will force special investigations units at private health insurers to work more closely with their organizations' compliance departments, an expert health care attorney said Nov. 16.....6

Texas Nursing Home Owner Pleads Guilty to Cheating Medicare, Medicaid HOUSTON--

A former owner of over 50 nursing homes in Texas and several other states Nov. 15 pleaded guilty to executing a scheme to defraud the Medicare and Medicaid programs of approximately \$4.2 million, U.S. Attorney for the Western District of Texas Johnny Sutton announced7

Report Says New York Paid \$3.6 Million In Medicaid Claims for Dead Beneficiaries ALBANY, N.Y.--

The New York state Medicaid program has paid \$3.6 million to providers for claims for deceased beneficiaries who died prior to falsely claimed dates of service, according to a Nov. 15 report from state Comptroller Alan G. Hevesi (D).8

U.S. Monitor Alleges N.J. Medical School Organized Illegal Patient Referral Scheme PHILADELPHIA--

Payments by the University of Medicine and Dentistry of New Jersey (UMDNJ) to 18 cardiologists beginning in 2003 violated federal laws barring the payment of kickbacks and referral fees, according to a Nov. 13 report9

GAO Says Medicare Improper Payments Cut, But Credits Estimating Methods, Not Controls Eighteen federal agencies--

including the Department of Health and Human Services--reported improper payments of more than \$38 billion for fiscal 2005, \$7 billion less than for fiscal 2004, due to fewer improper payments made by Medicare, the Government Accountability Office said in a report released Nov. 14.11

Kentucky Medical Supply Firm Charged With Cheating Federal Health Programs CINCINNATI--

A Louisville, Ky., medical appliance supplier, accused of billing for back braces more costly than those provided, was indicted Nov. 9 by a federal grand jury on six counts of Medicare and Medicaid fraud.....12

HHS May Require More Than Certificate Of Medical Necessity for Equipment Coverage

In an issue of first impression in all circuit courts, the U.S. Court of Appeals for the Eleventh Circuit found Nov. 3 that the health and human services secretary may require a durable medical equipment

supplier to submit additional evidence beyond a certificate of medical necessity (CMN) to show the equipment is medically reasonable and necessary, and therefore covered by Medicare Part B13

GAO Lays Out Road Map for Congressional Oversight of Medicare, Medicaid Changing the way Medicare pays providers to reward quality and efficiency and overhauling government efforts to improve financial management oversight of Medicaid are two of the many areas the Government Accountability Office suggests are prime for congressional oversight in the 110th Congress14

Fraud and Abuse

Medicare Drug Price Negotiation Threat to Industry Innovation, Report Says Allowing Medicare to negotiate prescription drug prices with drugmakers, as contemplated by incoming House Democrats, would reduce drug prices, but it also would cut research and development investment by pharmaceutical companies by about \$10 billion a year, according to a report scheduled to be released Nov. 28.16

CMS, Social Security Should Get Tax Access To Identify Low-Income People, Report Says Legislation is needed to allow the Centers for Medicare & Medicaid Services and the Social Security Administration to access tax information that would allow the two agencies to better identify individuals who are eligible for Part D low-income subsidies, the Department of Health and Human Services Office of Inspector General said in a Nov. 21 report.17

Canadian Pharmacists Seeking Export Ban On Prescription Drug Sales to United States OTTAWA--Associations representing Canadian pharmacists, supported by patient advocacy groups, are calling for the federal government to ban exports of prescription pharmaceuticals to the United States before the U.S. Congress moves to legalize cross-border drug sales.18

CMS Preparing to Begin Audits Of Medicare Drug Plan Sponsors The Centers for Medicare & Medicaid Services is preparing to begin regularly scheduled compliance audits of Medicare Part D plan sponsors, according to a recent memo to insurers.21

Study: 'Doughnut Hole' Coverage in 2007 To Grow, but Mostly Just for Generic Rx Although a growing number of Medicare drug plans will offer some "doughnut hole" coverage in 2007, many Medicare prescription drug benefit enrollees are expected to continue facing limited availability of plans with full gap coverage, according to an article in the Nov. 21 online edition of the journal *Health Affairs*.22

HHS Improperly Denied Medicare Coverage For Cardiac Devices, Court of Appeals Rules The Department of Health and Human Services improperly relied on an invalid rule when it denied a Connecticut hospital Medicare coverage for a series of treatments involving investigational cardiac devices that had not yet received premarket approval from the Food and Drug Administration, the U.S. Court of Appeals for the Second Circuit ruled Nov. 1623

Switch to Income-Based Part B Premium In 2007 Prompts Concerns by Key Senators Two key senators expressed concerns Nov. 17 about the government's ability to implement by January 2007 a new system for calculating Medicare Part B premiums for higher-income beneficiaries.25

Seniors Urged to Examine Drug Plan Options, As Open Enrollment Period for Part D Begins Beneficiaries enrolled in a Medicare Part D prescription drug plan need to re-examine their options for the upcoming year, because many drug plans have changed their coverage for 2007, according to Judith Stein, executive director of the Center for Medicare Advocacy.27


Senate Democrats Call on CMS to Limit 'Misleading' Marketing by Medicare Rx Plans
Senate Democrats are calling on the Centers for Medicare & Medicaid Services to revise Part D marketing guidelines to prohibit plans from using "misleading" language in marketing materials.28

USP Releases Draft Revisions to Model Guidelines for Medicare Rx Formularies The United States Pharmacopeia is seeking comments on its latest draft revisions to the Medicare Model Guidelines and Formulary Key Drug Types, released Nov. 10.28

Medicare & Medicaid

Health Care Cases Comprise Bulk of DOJ's Record Amount of Recoveries in Fiscal 2006

The Department of Justice recovered a record \$3.1 billion in false claims to the government in fiscal year 2006, with health care cases comprising a majority of the settlements and judgments, the enforcement agency announced Nov. 21.

The single largest recovery from was a \$920 million settlement with Tenet Healthcare Corp. in June to resolve claims brought by whistleblowers that hospital company billed for excessive Medicare outlier payments. The settlement also encompassed charges that Tenet paid kickbacks to doctors in return for patient referrals and that Tenet overcharged the government for certain Medicare services (No. 126 HCDR 6/30/2006 .

More than 70 percent of federal government recoveries in False Claims Act cases in 2006 were from health care cases, DOJ noted.

The second largest recovery in 2006, for \$565 million, was related to a non-health care False Claims Act case involving Boeing Co., a defense contractor, according to the DOJ release. Recoveries from defense industry contractors accounted the second largest category of false claims settlements and judgments, DOJ said.

"By any measure, it was a remarkable year," Assistant Attorney General Peter D. Keisler said. "Recoveries in health care fraud climbed more than a billion dollars over last year, and recoveries outside the health care arena--which accounted 28 percent of the total--increased by half a billion. Obviously, the system is working."

DOJ said that cases initiated by whistleblowers under the qui tam provisions in the False Claims Act accounted for nearly half the recoveries--\$1.3 billion.

Keisler applauded Senate Finance Committee Chairman Charles E. Grassley (R-Iowa) and Rep. Howard L. Berman (D-Calif.) for sponsoring the 1986 qui tam provisions, calling the False Claims Act "the government's primary weapon to fight fraud against the government."

In a separate release, Grassley said the qui tam provisions have "empowered whistleblowers to help fight fraud against the government."

"This law is one of the most powerful tools we have in rooting out waste, fraud and abuse in the federal government," Grassley said. "As these recoveries show, the False Claims Act has worked in the past, it works in the present, and will continue to protect taxpayer dollars long into the future."

Missouri Medical Supplier Sentenced To Prison Term for Role in Medicare Scam

ST. LOUIS--The owner of a medical supply company in the Kansas City, Mo., area was sentenced Nov. 20 to three years in prison without parole for his role in a multimillion-dollar Medicare scheme involving wheelchairs, U.S. Attorney for the Western District of Missouri Bradley J. Schlozman announced the same day (*United States v. Iloka*, D. Mo.,4:06-CR-00020-GAF, *sentencing* 11/20/06).

The owner, Godwin Iloka, was sentenced by Judge Gary A. Fenner of the U.S. District Court for the Western District of Missouri, to two years in prison for the Medicare scheme. In addition, Fenner revoked a sentence of supervised release Iloka was serving in connection with an unrelated credit card fraud case, and ordered him to serve a one-year prison sentence consecutively with the sentence for the Medicaid fraud scheme.

Fenner also ordered Iloka to forfeit his residence, three vehicles, and the funds in two bank accounts, all of which represented the proceeds from the scheme, the government said

According to a statement from Schlozman's office, Iloka pleaded guilty in July to his role in the powered-wheelchair scheme, which took place between January 2002 and September 2005. During that time, Iloka and his co-conspirators submitted more than \$5 million in fraudulent claims to Medicare on behalf of more than 1,000 Medicare recipients, the statement said. Through the scheme, the conspirators received more than \$2 million from Medicare.

For his part, Iloka admitted that he submitted claims to Medicare for power wheelchairs, but provided less expensive motorized scooters to the beneficiaries, a deception that was also used by his co-conspirators. Medicare sustained a loss of \$84,000 as a result from Iloka's conduct, the statement said.

Iloka also admitted to participating in three other fraud schemes, including a separate Medicare fraud scheme, a scheme to commit Social Security disability fraud, and a credit card fraud scheme.

Second Scheme: Custom Shoes

Prosecutors said that in the second Medicare fraud scheme, Iloka submitted claims to the program for custom-molded diabetic shoes, although he provided less-expensive standard diabetic shoes to the beneficiaries rather than the custom-molded kind. Medicare sustained a loss of \$165,000 as a result, the statement said.

Four of Iloka's co-conspirators are awaiting sentencing in the case. They are Kennedy Igbokwe, the owner of a medical supply company who was convicted Aug. 30 of health care fraud and money laundering; Kenneth Agugua, the owner of a medical supply company who pleaded guilty Aug. 23 to health care fraud; Amazair McAllister, a physician who pleaded guilty July 10 to health care fraud; and Ambrose Wotorson, a physician who pleaded guilty Feb. 24 to health-care fraud.

The case is being prosecuted by Gene Porter, senior litigation counsel in Schlozman's office.

Investigators, Compliance Officers Must Work Closely to Dig Up Part D Fraud, Meeting Told

MARCO ISLAND, Fla.--The government's fraud, waste, and abuse guidance to Part D plan providers will force special investigations units at private health insurers to work more closely with their organizations' compliance departments, an expert health care attorney said Nov. 16.

Complying with Part D rules issued by the Centers for Medicare & Medicaid Services means plans must undertake anti-fraud work in concert with compliance functions, attorney Kirk Nahra, Wiley Rein & Fielding LLP, Washington, told the National Health Care Anti-Fraud Association's 2006 Annual Training Conference. He said SIUs and compliance departments at private plans often operate entirely independent of one another.

Nahra said SIUs are best suited to handle anti-fraud matters, even though some of the Part D requirements are outside of corporate investigators' typical roles. CMS requires that Part D plans ensure that their third-party contractors also comply with Medicare rules, meaning plans have a greater role than ever before in "policing" their contractors.

Because SIUs generally already have good working relationships with law enforcers and are experienced identifying fraud outside their organizations, corporate investigators should work with compliance departments on Part D matters, he said.

Opportunity

Furthermore, he called the new Part D requirements an opportunity for SIUs to become involved in a broader range of activities and gain more exposure within their organizations.

Nahra explained that government law enforcers will rely on plan sponsors to identify fraud by other organizations, and will look to plans for information in investigations. He also warned that plans face "tremendous False Claims Act exposure" if they are not sufficiently watchful of third-party contractors.

As such, he noted, SIUs should develop ways to cooperate with law enforcement without "setting yourself up" for scrutiny.

The fraud, waste, and abuse guidance in the Part D manual (commonly referred to as Chapter 9 guidance) comprises mostly recommendations to plans; however, Nahra pointed out, the government will be auditing plans to ensure anti-fraud, waste, and abuse elements are in place. The guidance becomes effective Jan. 1, 2007.

"The government wants Part D sponsors to help with fraud investigations, but they're going to go after sponsors for any mistakes or problems--even for mistakes made by downstream contractors," Nahra said.

Reducing Risks

Developing strong, integrated Part D compliance and anti-fraud programs will reduce plans' risks and "buy you a lot of good will in the event of any investigations," he added.

Nahra said he did not believe it was possible for plans to do everything called for in the guidance "if you take it literally."

Instead, he suggested plans focus on what they can do well or easily, focus on responding and fixing specific problem situations, develop a reasonable anti-fraud approach, and develop a good cooperation strategy.

He also said plans should document their reasons for deciding not to undertake certain recommended guidance in Chapter 9.

The government's message about its expectations that plans develop compliance and anti-fraud plans that extend to downstream entities is "clearly threatening," Nahra said. However, he added, the government must also ensure the Part D program works and that means prosecutors can not "come down hard on everyone" without jeopardizing the stability of the benefit.

Texas Nursing Home Owner Pleads Guilty to Cheating Medicare, Medicaid

HOUSTON--A former owner of over 50 nursing homes in Texas and several other states Nov. 15 pleaded guilty to executing a scheme to defraud the Medicare and Medicaid programs of approximately \$4.2 million, U.S. Attorney for the Western District of Texas Johnny Sutton announced (*United States v. Lemon*, W.D. Tex., No. A-06-CR-260LY, *guilty plea* 11/15/06).

Defendant Rocky R. Lemon, the owner of TLC Health Care Inc. and TLC Health Care of Illinois Inc., admitted before Judge Lee Yeakel of the U.S. District Court for the Western District of Texas that he fraudulently diverted Medicare/Medicaid funds to his own use and benefit from at least September 1998 until April 2001.

Through a complex series of financial transactions, Lemon purchased and sold nursing homes and other assets using the Medicare/Medicaid funds and funneled net proceeds into his personal bank and brokerage accounts.

In 2001, Lemon abandoned all of his nursing care facilities in Texas, forcing state authorities to assume control and management of a number of facilities, Sutton said in a statement.

Sentencing is scheduled Feb. 9, 2007. The defendant faces up to 20 years in prison and a \$500,000 fine under federal sentencing guidelines.

Source: BNA

Report Says New York Paid \$3.6 Million In Medicaid Claims for Dead Beneficiaries


ALBANY, N.Y.--The New York state Medicaid program has paid \$3.6 million to providers for claims for deceased beneficiaries who died prior to falsely claimed dates of service, according to a Nov. 15 report from state Comptroller Alan G. Hevesi (D).

The report, which is based on an audit of Medicaid payments from April 1, 2003, to Feb. 3, 2006, found that Medicaid paid claims for care of 4,277 deceased beneficiaries. Among the most egregious examples was \$22,046 in prescription drug claims to a pharmacy over several months and \$14,537 paid to a nursing home for two years after the beneficiary's death.

The report attributed the errors primarily to inadequate oversight by the state Department of Health over the county government agencies that administer Medicaid on the local level. The report said local governments failed to consistently match death records, welfare records, and other information with Medicaid eligibility files.

The report made a number of recommendations about how the state could improve oversight over the process of determining who is eligible for Medicaid benefits.

Federal IG Found Problems in Other States

The report comes about one month after the Department of Health and Human Services Office of Inspector General issued a report finding that Medicaid programs in 10 states, including New York, have paid millions of dollars to health care providers for services claimed to have been provided after beneficiaries died (No. 199 HCDR 10/16/06 )

"Generally, the department's monitoring and oversight of the initial eligibility determination and recertification processes were working as intended," the New York state report said.

"However, information provided to the department and local districts after initial eligibility determination and subsequent recertification was not always used to identify ineligible beneficiaries and discontinue Medicaid benefits when appropriate in a timely manner."

N.Y. Health Department Taking Remedial Action

The state Health Department, in a prepared response to the report, said it generally agreed with the report's main conclusions. The department's Office of Medicaid Management currently is working on a plan to run daily comparisons of data from the Office of Vital Records and Medicaid files to identify deceased beneficiaries, it said.

"While they represent a very small percentage of Medicaid cases, the department agrees with the findings of the audit as they pertain to areas that would benefit from more attention, such as maintenance of more consistent supporting documentation and increased coordination with outside resources such as Vital Records," the department said in a response by Dennis P. Whalen, the executive deputy health commissioner.

New York's Medicaid program has about 4.1 million beneficiaries and costs state, local, and federal governments about \$45 billion per year.

Other points in the report include:

- Medicaid paid \$4.3 million for emergency medical assistance without the certification needed from physicians to continue eligibility.
- Medicaid paid \$2 million for emergency medical services that were provided after the allowable 90-day period of eligibility expired.
- Local governments lacked a Social Security number or had an incorrect SSN for 175,939 Medicaid beneficiaries.

A copy of the New York state report is available at:

<http://www.osc.state.ny.us/audits/allaudits/093007/05s42.pdf>


U.S. Monitor Alleges N.J. Medical School Organized Illegal Patient Referral Scheme

PHILADELPHIA--Payments by the University of Medicine and Dentistry of New Jersey (UMDNJ) to 18 cardiologists beginning in 2003 violated federal laws barring the payment of kickbacks and referral fees, according to a Nov. 13 report by the federal monitor overseeing UMDNJ operations.

"These payments were disguised as 'salaries,' and were not paid for medical services," federal monitor Herbert J. Stern said in his report to U.S. Attorney for the District of New Jersey Christopher J. Christie. "They were nothing more than referral fees paid to doctors in order to induce them to bring their patients to UMDNJ. These payments were and are illegal under federal law."

Stern pegged the "potential total of fraud and abuse" at \$84.5 million, including \$5.7 million in allegedly illegal payments to the 18 doctors and nearly \$80 million in possible fines and penalties under the Stark physician self-referral and anti-kickback laws.

Cardiology Program Investigation

The 29-page report details the findings of an investigation of UMDNJ's cardiology program by the federal monitor. The monitor was appointed in December 2005 to enforce compliance with a deferred prosecution agreement that allowed UMDNJ to avoid criminal prosecution for health care fraud in connection with its alleged double-billing of Medicaid for physician services in outpatient clinics (No. 247 HCDR 12/28/05 ).

According to the report, the alleged kickback/referral scheme was devised by UMDNJ administrators in 2002 to save the cardiac surgery unit, where the volume of procedures had been below the minimum required under state licensure standards for several years.

UMDNJ had been advised by state health regulators that it would lose its license to perform cardiac surgery if it failed to meet the minimum volume standards by the end of 2003.

To boost patient volume, UMDNJ hired community cardiologists as part-time "clinical associate professors" at salaries close to those of its full-time cardiology faculty members, although the part-timers performed minimal or no services for the university, according to the report.

Although many of them had never used University Hospital before, they began referring hundreds of patients to UMDNJ after they were hired, the report said. In addition to being paid as much as \$180,000 a year by UMDNJ, they continued to collect from Medicare, Medicaid, and private insurers for performing clinical services, according to the report.

The report said it was clear from e-mails and other written communications by UMDNJ administrators that "the primary intent of hiring these doctors was to capture referrals of cardiac services from them."

Cover Up Alleged

The federal monitor said UMDNJ administrators not only hatched and implemented the allegedly illegal scheme, but later covered it up by paying a \$2.2 million settlement in June 2006 to a whistleblower who claimed he was fired for protesting the scheme (*Arora v. UMDNJ*, N.J. Super. Ct. Law Div. Essex Cty., No C-322-03, *settled* 6/16/06).

UMDNJ violated the terms of the deferred prosecution agreement by failing to alert the monitor and the U.S. attorney of the whistleblower's existence and allegations, according to the report, which said the monitor's staff learned of the settlement by reading about it in the *New Jersey Law Journal*.

"UMDNJ failed to reveal the existence of the settlement to the monitor even after its outside counsel informed UMDNJ that the admissions made by UMDNJ employees under sworn testimony proved that there were violations of federal law," the report said.

UMDNJ legal counsel never investigated the concerns raised by outside counsel in a March 2006 analysis of settlement considerations with regard to the whistleblower lawsuit, according to the report, which said UMDNJ as recently as July 2006 hired a community cardiologist for a part-time position paying \$225,000 a year.

Report to Be Validated

UMDNJ said in a statement that it is moving as quickly as possible to validate the assertions in the report and halt any violations that are found. The university said an outside consultant will review all

physician compensation arrangements at University Hospital/New Jersey Medical School and the findings will be shared with the monitor.

The university said the substance of the complaints in the whistleblower lawsuit, including the allegations concerning possible Stark law and anti-kickback violations, were transmitted to the monitor's office in January.

Although its legal counsel erred in failing to report the substance of the proposed settlement to the monitor's office or to UMDNJ management and the Board of Trustees, "there was no affirmative effort to conceal the substance of the settlement, which was made widely available to the legal community in *The New Jersey Law Journal*," UMDNJ said.

UMDNJ said it will recommend that the Board of Trustees adopt all the recommendations in the monitor's report to strengthen adherence to the deferred prosecution agreement.

Among other things, the report recommended a procedure to be followed in any proposed settlement involving a payment of more than \$100,000 to ensure accountability.

The report said the ongoing investigation by the monitor's office will seek to determine the "extent of the violations of federal law and the extent to which UMDNJ has failed to comply " with the deferred prosecution agreement.

Text of the Nov. 13 interim report of the federal monitor for the University of Medicine and Dentistry of New Jersey, redacted for public review, along with 421 pages of exhibits, is available at <http://www.umdnj.edu/home2web/federalmonitor/pdf/report111406c.pdf>.

GAO Says Medicare Improper Payments Cut, But Credits Estimating Methods, Not Controls

Eighteen federal agencies--including the Department of Health and Human Services--reported improper payments of more than \$38 billion for fiscal 2005, \$7 billion less than for fiscal 2004, due to fewer improper payments made by Medicare, the Government Accountability Office said in a report released Nov. 14.

GAO said that while Medicare reported \$7 billion less in improper payments for fiscal 2005, the reported reduction "mainly resulted from a change to Medicare's estimating methodology rather than from improved payment controls. GAO released information about Medicare overpayments earlier this year.

"Regardless of whether prior year estimates were reliable, the reported reduction is unlikely to represent a measurable improvement in internal control and accountability given that the HHS's [Office of Inspector General] continued to cite the integrity of Medicare payments as a top management challenge" for fiscal 2005, said the report, *Improper Payments; Agencies' Fiscal Year 2005 Reporting Under the Improper Payment Information Act Remains Incomplete* (GAO-07-92).

The amount of improper payments did not include Medicaid or the State Children's Health Insurance Program, which will begin reporting its error rate in fiscal 2007, GAO said.

Fiscal 2005 was the second year that federal agencies were required to report improper payment information under the Improper Payments Information Act of 2002.

Agencies must perform four steps to address improper payment reporting requirements, including perform a risk assessment, estimate improper payments for risk-susceptible programs, implement plans to reduce improper payments for such payments over \$10 million, and annually report on estimates and actions to reduce them, the report said.

Of the 35 agencies reviewed by GAO, 23 had performed risk assessments for their programs, it added.

The report was prepared for several lawmakers, including House Government Reform Chairman Thomas M. Davis (R-Va.).

The report is available at <http://www.gao.gov/new.items/d0792.pdf>.

Kentucky Medical Supply Firm Charged With Cheating Federal Health Programs

CINCINNATI--A Louisville, Ky., medical appliance supplier, accused of billing for back braces more costly than those provided, was indicted Nov. 9 by a federal grand jury on six counts of Medicare and Medicaid fraud (*United States v. Conti*, W.D. Ky., No. 3:06-cr-00152-TBR, *indictment* 11/9/06).

Conti Medical Concepts and owner Anthony J. Conti were charged with altering medical records, giving a kickback to a doctor, and conspiracy to commit fraud by billing the federal health plans for a back brace called Pro-Fitt while providing patients with a less expensive brace called V-Loc.

This scheme was in effect from August 1997 through April 2003, alleges the indictment filed in U.S. District Court for the Western District of Kentucky. In the fall of 2002, Medicare initiated a review of braces provided by suppliers using certain billing codes, including Conti Medical Concepts; shortly thereafter, Medicare began denying some of Conti's claims and the company began furnishing a brace meeting the Pro-Fitt definition, which had a higher profit margin.

According to the indictment, Conti Medical Concepts altered medical records to cover up fraudulent billings, in some cases cutting physician signatures from durable medical equipment prescriptions and pasting them onto others, and offered a local doctor a \$4,350 television to induce patient referrals.

The firm's owner has pleaded not guilty to the charges. If Conti is found guilty on all counts, he could face 5 years in federal prison and fines exceeding \$500,000.

Steven Romines, attorney for Conti Medical Concepts, said the indictment stems from a misunderstanding over billing codes caused, in part, when the brace manufacturer changed the name, but doctors kept prescribing it under the old name.

The indictment comes two years after federal and state agents searched Conti Medical Concepts' office for evidence of health care fraud.

A hearing on reciprocal discovery is scheduled for Nov. 30.

Source: BNA

HHS May Require More Than Certificate Of Medical Necessity for Equipment Coverage

In an issue of first impression in all circuit courts, the U.S. Court of Appeals for the Eleventh Circuit found Nov. 3 that the health and human services secretary may require a durable medical equipment supplier to submit additional evidence beyond a certificate of medical necessity (CMN) to show the equipment is medically reasonable and necessary, and therefore covered by Medicare Part B (*Gulfcoast Medical Supply Inc. v. HHS*, 11th Cir., No. 05-16935, 11/3/06).

The court concluded that the Medicare Act unambiguously permits Medicare Part B carriers and the HHS secretary to require suppliers to submit evidence of medical necessity beyond a CMN. The appeals court rejected the argument by Gulfcoast Medical Supply Inc., a Florida-based supplier of durable medical equipment, that the HHS secretary has no discretion to request additional medical necessity documentation beyond a CMN.

"If, as Gulfcoast suggests, the carriers and the Secretary have no discretion to request any evidence of medical necessity apart from the CMNs already submitted by the suppliers, such audits would be rendered useless," the per curiam opinion said. "Moreover, were we to adopt Gulfcoast's position, the Secretary would effectively lack the discretion to deny any claim so long as a supplier could find a physician--even a dishonest or incompetent one--to sign a CMN."

Medicare Overpayment

The Medicare Part B carrier, Palmetto Government Benefits Administrators, concluded that Medicare had overpaid Gulfcoast \$280,574 after finding that services for certain randomly selected beneficiaries were not supported by documents in their medical records and that at least half of those whose records were examined did not need a power wheelchair. Gulfcoast appealed the determination by Palmetto before an administrative law judge of the HHS Departmental Appeals Board.

The ALJ rejected Gulfcoast's argument that because it submitted a CMN signed by a physician for each of the challenged claims, Palmetto lacked discretion to reject those claims on the basis of additional evidence. The ALJ found that overpayments were correctly assessed in 17 cases, but incorrectly in six others and, therefore, ordered Palmetto to recalculate the total overpayment.

Gulfcoast appealed to the U.S. District Court for the Middle District of Florida, which affirmed the ALJ's decision. Gulfcoast then appealed to the Eleventh Circuit. Gulfcoast argued that Part B does not require a supplier to submit additional medical documentation beyond the CMN to prove medical reasonableness and necessity and the secretary lacked discretion to reject the claims on the basis of the additional records and interviews conducted by Palmetto.

Act's Definition of Certificate

Gulfcoast relied on the Medicare Act's definition of a certificate of medical necessity: as "a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." (42 U.S.C. §1395m(j)(2)(B)).

However, the appeals court determined that contrary to Gulfcoast's assertion, the Medicare statute does not unambiguously preclude the secretary from requiring a supplier to submit information beyond a CMN to prove medical reasonableness and necessity. Further, the appeals court found that Gulfcoast failed to show any other section of the Medicare Act that suggested the secretary may not require a supplier to supplement a CMN with other documentation.

"[A] CMN is an optional pre-payment tool designed primarily to reduce paperwork and to streamline the processing of claims. Section 1395m(j)(2)(A) restricts the supplier's ability to fill out a CMN in advance, no doubt in order to ensure that CMNs are not abused," the Eleventh Circuit determined. "It would be incoherent to construe [the statute], a subsection restricting the use of CMNs and clearly indicating that they are voluntary, to also make CMNs the exclusive means for proving medical necessity."

The appeals court found that Palmetto and the secretary acted reasonably in assuming the authority to require additional documentation from Gulfcoast. The Eleventh Circuit concluded that, because Medicare is a complex and highly technical regulatory program, judicial deference to the secretary's discretionary decisions in this area was all the more warranted.

Beverly A. Pohl, with Broad & Cassel, Fort Lauderdale, Fla., and Derek T. Ho, with Kellogg, Huber, Hansen, Todd, Evans & Figel PLLC, Washington, represented Gulfcoast. Paul I. Perez Jr., assistant U.S. attorney with the Middle District of Florida, Tampa, Fla., and Anthony John Steinmeyer, Department of Justice Civil Appellate Division, Washington, represented the HHS secretary.

The court's decision is available at <http://www.ca11.uscourts.gov/opinions/ops/200516935.pdf>.

GAO Lays Out Road Map for Congressional Oversight of Medicare, Medicaid

Changing the way Medicare pays providers to reward quality and efficiency and overhauling government efforts to improve financial management oversight of Medicaid are two of the many

areas the Government Accountability Office suggests are prime for congressional oversight in the 110th Congress.

In a letter sent Nov. 17 to congressional leaders, GAO officials also urged Congress to limit Medicaid payments to government facilities to the costs of providing services — a step GAO said would “curtail states’ use of financing schemes to inappropriately obtain federal matching funds.”

The Medicare and Medicaid proposals were part of a sweeping list GAO provided to lawmakers. The report recommends several changes to the budget process, including setting spending caps, establishing “pay as you go” budget rules, and reviewing the use of supplemental spending bills and earmarks.

“We cannot afford to continue business as usual in Washington, given our current deficit and growing long-term fiscal challenges,” Comptroller General David M. Walker wrote to Capitol Hill.

GAO recommends that Congress take on the difficult task of overhauling entitlement programs that will eat up more of the budget in coming years with the retirement of the baby boomer generation. “Absent reform, Medicare’s and Medicaid’s long-term fiscal sustainability for supporting health care for elderly, disabled and low-income Americans is in jeopardy,” according to GAO.

In 2006, Medicare spending is estimated to be 3.2 percent of the gross domestic product, or the total amount of domestic economic activity, and the figure is expected to increase to 7.3 percent by 2035. With about 42 million beneficiaries and \$330 billion in 2005 spending, plus the addition of the Medicare prescription benefit this year, “the program’s size and complexity make it vulnerable to improper payments and inefficient payment systems,” according to GAO.

Medicaid, the federal-state health insurance program that serves about 56 million poor and disabled Americans, also is at risk of increased and inappropriate federal spending, GAO noted. Medicaid consists of more than 50 distinct programs. Joint federal/state expenditures for fiscal year 2004 are estimated to be \$298 billion and federal expenditures are projected to double in a decade. The federal government pays from 50 percent to 83 percent of each state’s reported Medicaid expenditures.

Other recommendations from GAO include:

- Assessing the Centers for Medicare and Medicaid Services’ managerial oversight of Medicare, including efforts to ensure program integrity and provide information to assist beneficiaries in making choices about the prescription drug benefit.
- Ensuring that initiatives to restructure Medicaid eligibility and benefits are consistent with the administration’s goal of budget neutrality for the federal government.

- From CQ Top Docs: [GAO Letter to Congress](#) (pdf)

Source: Congressional Quarterly

Fraud & Abuse

Medicare Drug Price Negotiation Threat to Industry Innovation, Report Says

Allowing Medicare to negotiate prescription drug prices with drugmakers, as contemplated by incoming House Democrats, would reduce drug prices, but it also would cut research and development investment by pharmaceutical companies by about \$10 billion a year, according to a report scheduled to be released Nov. 28.

The report by the think tank Manhattan Institute said drug prices would be lowered by about 21.8 percent between 2007 and 2025 by allowing Medicare to bargain with drugmakers.

Prices would be lowered because Medicare would be able to leverage the market as the single largest purchaser of prescription drugs in the United States, according to the report, *The Human Cost of Federal Price Negotiations: The Medicare Prescription Drug Benefit and Pharmaceutical Innovation*.

House Democrats have said that a bill allowing Medicare to negotiate for lower prescription drug prices likely will be brought up shortly after they assume power in January 2007.

Congressional Democrats have criticized the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which created the Medicare drug benefit, for preventing Medicare from negotiating lower drug prices with drugmakers, saying seniors' drug costs could be cut by price negotiations. Republicans have maintained that competition built into the drug program is working to lower costs, removing the need for federal intervention.

It is unclear whether legislation allowing Medicare to negotiate lower drug prices would clear the new Democrat-majority Senate, and President Bush likely would veto such legislation.

Reduced Economic Returns

While price discounts would cut drug costs, the report said, they "clearly would have an additional effect: They would reduce the economic returns to investment in the research and development of new and improved drugs. So one important concern raised by the possibility of federal price negotiations for drugs is a decline in that research and development, and thus in pharmaceutical innovation."

The report said federal negotiators "would have incentives to favor price reductions at the expense of more-inclusive drug formularies. This greater willingness of federal officials to exclude drugs from formularies would lower drug prices below those that otherwise would be set by the market. This, in turn, would reduce incentives for the capital market to invest in research and development of new medicines."

The report said the reduction in drug prices could be interpreted as an "implicit tax" on drug companies. This tax would reduce research and development annually by between \$5.6 billion to \$11.6 billion, with about \$10 billion the most likely figure, it said.

This reduction in research and development would result in a loss of between six and 12 new medicines a year, costing Americans "about 5 million life-years annually," it added.

"The fiscal crisis inherent in Medicare is far greater than the short-term savings that federal price negotiations might yield, but the resulting longer-term costs caused by reduced pharmaceutical innovation are large," the report concluded. "So once again, we are confronted with a stark choice: Cheap drugs in the here and now would prove expensive indeed tomorrow."

The Manhattan Institute describes itself as a think tank "whose mission is to develop and disseminate new ideas that foster greater economic choice and individual responsibility."

A spokesman for incoming House Speaker Nancy J. Pelosi (D-Calif.) could not be reached for comment.

The report will be available at http://www.manhattan-institute.org/pdf/mpr_03.pdf.

CMS, Social Security Should Get Tax Access To Identify Low-Income People, Report Says

Legislation is needed to allow the Centers for Medicare & Medicaid Services and the Social Security Administration to access tax information that would allow the two agencies to better identify individuals who are eligible for Part D low-income subsidies, the Department of Health and Human Services Office of Inspector General said in a Nov. 21 report.

Currently, Internal Revenue Service rules prohibit the sharing with SSA beneficiaries' tax records until a beneficiary completes a subsidy application that releases the IRS to share such information, the HHS OIG said in its report, *Identifying Beneficiaries Eligible for the Medicare Part D Low-Income Subsidy* (OEI-03-06-00120).

SSA attempted to access earnings data from the IRS that would have specifically identified individuals who likely would qualify for low-income subsidies, thus allowing the agency to more directly target individuals who would most benefit from the subsidy program, the OIG explained.

However, the IRS objected to the use of personally identifying tax data for Medicare Part D (drug benefit) low-income subsidy outreach efforts, saying it is authorized to release such information only with the taxpayer's approval or where a specific statutory exception exists, the report stated.

SSA instead relied on other financial data to target potentially eligible low-income recipients, but SSA overestimated the population of individuals who might be eligible because it did "not have comprehensive income data for these beneficiaries."

CMS also does not have access to data allowing it to more specifically target outreach to low-income beneficiaries, the OIG noted.

Access Like MSP Program Needed

The OIG suggested that the IRS be allowed by statute to share tax data with the Medicare and Social Security agencies for the purposes of identifying low-income beneficiaries in much the same way similar data is shared under the Medicare Secondary Payer program.

In that case, a statutory exception under the Omnibus Budget Reconciliation Act of 1989 allows IRS, CMS, and SSA to share data about Medicare beneficiaries and their spouses to appropriately identify cases in which another health insurer should have been the primary payer of services, rather than Medicare, the OIG explained.

"Legislation that would allow data sharing among CMS, SSA, and IRS would help to create a more accurate pool of potentially eligible beneficiaries," the OIG said. "The identification of these beneficiaries would allow for a more targeted and effective outreach effort to ensure that all those who qualify for the subsidy receive this important assistance. Without knowing the true population of potentially eligible beneficiaries, it is difficult to judge the success of current outreach and enrollment efforts."

Grassley Cautious About Tax Information

Senate Finance Committee Chairman Charles E. Grassley (R-Iowa) said in a Nov. 21 release that CMS and SSA "worked hard to get beneficiaries signed up for the extra help," but that many individuals who would qualify have not applied for the Part D subsidies.

Grassley said he welcomed the opportunity to work with CMS, SSA, and the IRS on better identifying beneficiaries who should be receiving Part D low-income subsidies, but said he was cautious about the use of tax information to do so.

"Any change in rules regarding disclosure of tax information must be considered very carefully," he said.

The HHS OIG report is available at <http://www.oig.hhs.gov/oei/reports/oei-03-06-00120.pdf>.

Canadian Pharmacists Seeking Export Ban On Prescription Drug Sales to United States

OTTAWA--Associations representing Canadian pharmacists, supported by patient advocacy groups, are calling for the federal government to ban exports of prescription pharmaceuticals to the United States before the U.S. Congress moves to legalize cross-border drug sales.

Senior congressmen have indicated that legalizing imports of Canadian prescription drugs will be a priority for the now Democrat-dominated Congress when it resumes sitting in February, raising the specter of an increase in Canadian exports that could threaten Canadians' access to needed drugs, a pharmacy coalition said in a Nov. 22 letter to federal Health Minister Tony Clement.

"We represent Canadian pharmacists, members of the supply chain, and patients who believe that the government should institute an immediate, simple, and straightforward ban on the export, both bulk and retail, of prescription drugs produced for Canadians," said the letter, signed by the Canadian Pharmacists Association, Ontario Pharmacists Association, Best Medicines Coalition, and Canadian Association for Pharmacy Distribution Management.

Canadian Supply 'Would Only Last 38 Days.'

"[We] believe that neither Canada's drug supply, nor its drug price control regime, could be sustained under the pressure of U.S. demand if the drug imports from Canada were legalized. An authoritative U.S. study concluded that Canada's drug supply would only last 38 days in the face of full-blown U.S. bulk importation."

There also are bills before Congress and state legislatures that would legalize for the first time unlimited purchases of Canada's prescription drugs in bulk by wholesalers, health maintenance organizations, chain and banner self-distributing pharmacies, buying groups, and independent pharmacies, which could open the door for 119 million Americans to legally purchase lower-cost prescription drugs from Canada, it said. Without a ban on bulk exports, any Canadian pharmacy could re-route its drug inventory to the United States to generate more profit, a practice known as "arbitrage", it said.

"The cross-border drug trade requires the government's immediate attention. We believe that acting only after a drug shortage is identified, or U.S. bills are passed, is not an adequate response by the government. Canada needs to stop the cross-border drug trade before, rather than after, the United States legalizes drug imports from Canada," it said.


No Plans for Immediate Ban

The letter asks the health minister to meet with the groups' representatives within the next two weeks. A spokesman for Clement, who would not comment on whether a meeting will be arranged, told reporters Nov. 22 that the government has no plans to legislate a pharmaceutical export ban, but will continue to closely monitor drug export levels and take quick action if shortages occur.

"[Clement] has it in his power to take action if necessary, but there has not been any law passed in the United States," said spokesman Erik Waddell. "There is no threat to the Canadian supply, but we are ready to act if there is."

The Ontario Pharmacists' Association had released Oct. 11 an open letter to the federal health minister also indicating that its members are "gravely concerned" about the imminent threat to

Canada's prescription drug supply posed by legislative changes and relaxed enforcement measures in the United States.

A deal struck by congressional leaders in late September to permit U.S. citizens to carry a 90-day personal supply of prescription drugs into the United States through "foot traffic" import (No. 194 HCDR 10/6/06 ) was compounded by the Department of Homeland Security's decision directing Customs and Border Protection agents to stop, effective Oct. 9, confiscating drugs ordered via the Internet and mailed to Americans, said the letter signed by Marc Kealey, the association's chief executive officer.

"Our pharmacists do not want to become America's drug store," the letter said. "Our job is to provide medications and expertise to Canadian patients, not provide solutions for the shortcomings of the U.S. health care system and its problem with high drug costs."

Fraud Risks

The decision to permit Internet ordering of prescription drugs is particularly alarming because it encourages fraud by offshore criminals posing as Canadian pharmacists and selling counterfeit drugs to U.S. consumers, the open letter said. That poses a health and safety threat to both American and Canadian patients who rely on the reputation of Canadian pharmacists, it said. "U.S. customs statistics on mail-order seizures show at least 10 percent of packages purportedly from Canadian Internet pharmacies contain counterfeit drugs," it said.

That letter also criticized the Canadian government for standing "idly by" while U.S. actions have threatened the Canadian prescription drug supply and raised national security vulnerabilities. "We respectfully call on the government of Canada to take immediate action to protect Canada's prescription drug supply by banning prescription drug sales to U.S. patients by all means, including 'foot traffic', Internet, and mail order," it said.

Internet Pharmacies May Have to Close

Meanwhile, Internet-based pharmacies based in the Canadian province of Manitoba have warned that they will be forced to close or move their operations if the provincial government implements proposed new legislation governing pharmaceutical sales.

Bill 41, which would overhaul the province's 1992 Pharmaceutical Act, would give too much power to the provincial pharmacy regulatory body and make it nearly impossible for Internet and mail-order pharmacies to stay in business, Troy Harwood-Jones, president of the Manitoba International Pharmacists Association, said Nov. 21.

The legislation would give the Manitoba Pharmaceutical Association the power to go on "fishing expeditions" looking for noncompliance with provincial regulations by Internet-based pharmacies, rather than having to wait to respond to specific complaints, as is the current practice, Harwood-Jones said. "The industry is very nervous," he said.

The legislation also would make it mandatory for pharmacies to carry liability insurance, a serious issue for Internet-based pharmacies because they have been unable to secure such insurance because they sell drugs to uninsured and under-insured Americans. It also would amend the definition of prescribing physician to eliminate the current practice of having Canadian doctors co-sign prescriptions written by U.S. doctors.

The provincial pharmacy association, meanwhile, has expressed strong support for the legislation. "It provides appropriate tools for the regulator to ensure safe, legal, and ethical practice in the profession," the association said in a statement.

CMS Preparing to Begin Audits Of Medicare Drug Plan Sponsors

The Centers for Medicare & Medicaid Services is preparing to begin regularly scheduled compliance audits of Medicare Part D plan sponsors, according to a recent memo to insurers.

The audits will cover randomized chapters in the final audit guides for prescription drug plans and Medicare Advantage plans with prescription drug plans, both released in April, CMS Plan Oversight & Accountability Group Director Cynthia Tudor told plan sponsors in a Nov. 13 memo.

CMS will contact plans nine weeks prior to a scheduled audit to set up audit dates and discuss audit logistics, Tudor said. Within three weeks of the audit, plans will receive written notification of the audit guide chapters that will be covered in the audit and an initial request for documents to be covered in the audit.

Most audits likely will be so-called desk audits, those not performed at the plan sponsor's site, she added. Desk audits are expected to take about one month to complete, and onsite audits are expected to take no more than one week to complete, according to the memo.

"Sponsors are expected to have key staff responsible for compliance and operations in the area(s) selected for audit available during that time," the memo stated.

Tudor said plans' abilities to provide to auditors documents that demonstrate compliance with Part D requirements was a "critical component" of the audit process. She explained that plans would be given a list of "exact" documents necessary for the audits.

CMS also will attempt to time Part D audits with Part C (Medicare Advantage) audits "especially for sponsors who have the same staff involved in any particular function scheduled for audit," Tudor said.

The PDP audit guide is available at <http://www.cms.bhs.gov/PrescriptionDrugCovContra/Downloads/PDPAuditGuide.pdf>. The MA-PDP audit guide is available at <http://www.cms.bhs.gov/PrescriptionDrugCovContra/Downloads/MAPDAuditGuide.pdf>

Study: 'Doughnut Hole' Coverage in 2007 To Grow, but Mostly Just for Generic Rx

Although a growing number of Medicare drug plans will offer some "doughnut hole" coverage in 2007, many Medicare prescription drug benefit enrollees are expected to continue facing limited availability of plans with full gap coverage, according to an article in the Nov. 21 online edition of the journal *Health Affairs*.

More Medicare Part D plans will offer generic-only coverage in the gap in 2007 than in 2006, but the range of plans with full coverage of branded and generic drugs will remain limited, the authors said in "Status Report on Medicare Part D Enrollment in 2006: Analysis of Plan-Specific Market Share and Coverage."

In fact, at least one of the largest players in the full gap coverage market in 2006 will limit its offerings in 2007, the article stated. The drug plan Humana PDP Complete in 2006 had the highest enrollment of beneficiaries with access to full gap coverage. For 2007, though, the plan changed its benefit design to cover just generic medications in the doughnut hole.

"Beneficiaries will have greater access to plans with gap coverage in 2007, but this is primarily because more plans will offer generic-only coverage," the authors said.

In 2006, nearly half of all enrollees--more than 10 million--had no gap coverage, according to the report. Of the 52 percent with full Medicare prescription drug coverage through the gap, most were low-income enrollees who qualified for coverage in the doughnut hole, according to the article authored by Juliette Cubanski, principal policy analyst with the Henry J. Kaiser Family Foundation in Washington, and Patricia Neuman, vice president and director of the Medicare Policy Project at the Kaiser Family Foundation, also in Washington.

In addition, most non-low-income enrollees who had doughnut hole coverage in 2006 were in plans that offered generic-only coverage gap coverage, Cubanski and Neuman found.

More Evaluation Needed to Pick Plans

The study concluded that beneficiaries largely chose plans in 2006 based on name recognition and low premiums, but that in future plan years enrollees should more closely consider their coverage gap needs when selecting a Part D plan.

"Going forward, it will be important for beneficiaries to evaluate their choices carefully, since some beneficiaries might be better off in plans that charge higher premiums but provide full-year coverage with no doughnut hole," Cubanski said.

The article also reiterated previous findings that Part D enrollment in 2006 was concentrated in a few plans, and that most enrollees selected stand-alone prescription drug plans versus Medicare Advantage (managed care) plans with drug coverage.

Nevertheless, Cubanski and Neuman noted that MA enrollment has "gained ground in recent years" and that insurers may be attracting beneficiaries to their PDP offerings with the intent of later migrating them to a managed care plan with drug coverage.

Plans' success in enrolling beneficiaries in 2006 for Medicare drug coverage is a positive sign for the future of the program, the authors said in the article.

"Part D sponsors clearly met--if not exceeded--congressional expectations by providing beneficiaries access to numerous drug plan choices in 2006 and even more for 2007," Cubanski and Neuman wrote.

It is unclear, though, how plans will fare past the 2007 plan year when fewer federal reimbursement incentives will exist in the Part D market.

"The robust response from insurers in Part D in 2006 and 2007 is at least partly attributable to their drive to gain market share in Medicare given limited opportunities for growth in other sectors, and to payment policies that encourage plan participation and mitigate risk, including reinsurance and risk corridors," the study stated.

The Health Affairs article is available at <http://content.healthaffairs.org/cgi/content/abstract/blthaff.26.1.w1>.

HHS Improperly Denied Medicare Coverage For Cardiac Devices, Court of Appeals Rules

The Department of Health and Human Services improperly relied on an invalid rule when it denied a Connecticut hospital Medicare coverage for a series of treatments involving investigational cardiac devices that had not yet received premarket approval from the Food and Drug Administration, the U.S. Court of Appeals for the Second Circuit ruled Nov. 16 (*Yale-New Haven Hospital v. Leavitt*, 2nd Cir., No. 05-1224-cv, 11/16/06).

The HHS Secretary "altered" its "historical practice" of conducting a device-by-device review of a product's safety and efficacy when it adopted a "per se" rule in its 1986 Medicare reimbursement manual that removed Medicare coverage of investigation devices, Chief Judge Dennis Jacobs said, writing for the Court of Appeals. The 1986 manual provision "is unenforceable because the Secretary did not satisfactorily explain his reasons for its promulgation," Jacobs said.

Jacobs vacated the ruling of the U.S. District Court for the District of Connecticut--which had reversed HHS's decision to deny Yale New-Haven Hospital \$1.5 million in Medicare reimbursement claims--and remanded the case back to the federal agency. HHS must adjudicate Yale's claims under the rules and procedures in place at the time the claims were submitted, Jacobs said.

Regulation Change Requires Explanation

An agency cannot alter its historical course and rescind a rule without "supply[ing] a reasoned analysis for the change," Jacobs explained, quoting *Motor Vehicle Manufacturers Association of the United*

States Inc. v. State Farm Mutual Auto. Ins. Co., 463 U.S. 29 at 41-42 (1983). Absent such analysis, the promulgation of new regulations is arbitrary and capricious, he said.

Between 1994 and 1995, Yale submitted 49 Medicare claims on behalf of 48 different beneficiaries in clinical trials who received implantable cardioverter-defibrillator devices to treat their irregular heart rhythm. Although the device manufacturer had not yet received premarket approval from the FDA, Jacobs said the agency had granted an investigational device exemption to allow the cardiac devices to be sold to hospitals and physicians for use in clinical trials.

Prior to 1986, the Health Care Financing Administration (now known as the Centers for Medicare & Medicaid Services), which administered Medicare on behalf of HHS, allowed Medicare coverage for investigational medical devices that were considered "safe and effective," Jacobs said.

"The 1986 Manual Provision--telling [Medicare fiscal] intermediaries that there is not coverage unless treatment received FDA premarket approval--was an evident change of course," the chief judge said, and one that HHS must explain.

HHS also failed to explain the linkage between FDA approval and the 1986 standard it adopted, Jacobs noted. "We cannot clearly discern why the standard adopted by the Secretary was FDA premarket approval, given that such a standard likely excludes numerous devices that would be the most appropriate treatments for certain patients," he said.

The rule change is "not the type of self-explanatory, unremarkable application of governing law" that would allow the court to uphold the agency's denial of Yale's claims, Jacobs concluded.

Jacobs added that the 1986 manual provision was superseded in 1995, when the agency issued final regulations governing investigational devices.

Leonard C. Homer, an attorney with Ober Kaler, Grimes & Shriver, in Baltimore, who represented Yale said the court's ruling provides two "primary lessons" for the government.

First, HHS cannot arbitrarily change its position, as it did here, Homer told BNA. Second, Medicare's legislative history demonstrates that, if a coverage decision is to "lean" one way or the other, it should lean toward affording coverage, rather than denying it.

Related FCA Claims 'Gone.'

In a separate ruling issued the same day, Jacobs dismissed a related False Claims Act qui tam action filed against Yale and 131 other hospitals (*United States v. The Baylor University Medical Center*, 2nd Cir., No. 05-2951-cv, 11/16/06).

Relator Kevin Cosens, a former medical device salesman, initially brought the whistleblower action in March 1994, and the government intervened in 2002. Cosens alleged that the hospitals violated the FCA when they sought reimbursement for services involving the investigational cardiac devices, in contravention of the 1986 rule change.

Jacobs said the qui tam action was time-barred. The government's complaints-in-intervention alleged that the hospitals made their last false claims in 1995, according to Jacobs. As a result, the FCA's six-year statute of limitations period (31 U.S.C. §3731(b)) had expired by the time the government chose to intervene in 2002.

With these two rulings, the FCA case "is gone," Homer told BNA. Even without the application of the statute of limitations, if, as Jacobs ruled in the *Yale* case, the government cannot rely on the 1986 manual provision, they no longer have a basis to deny the hospital's claims or argue that the hospital's claims are false under the FCA, he said.

Prior to the present decisions by the Court of Appeals, the government already had negotiated settlements with a number of hospitals, recovering more than \$45 million.

The hospitals that settled early took their chances, Homer said. The qui tam action went on for 10 years, he said, and they wanted to get any potential liability off their books.

Full text of the Yale decision is available at <http://op.bna.com/bl.nsf/r?Open=thyd-6vqkwp>. Full text of the Baylor University Medical Center decision is available at <http://op.bna.com/bl.nsf/r?Open=thyd-6vqs9l>.

Switch to Income-Based Part B Premium In 2007 Prompts Concerns by Key Senators

Two key senators expressed concerns Nov. 17 about the government's ability to implement by January 2007 a new system for calculating Medicare Part B premiums for higher-income beneficiaries.

Sens. Charles Grassley (R-Iowa) and Max Baucus (D-Mont.) cited new Government Accountability Office findings on the Social Security Administration's ability to successfully implement income-related Medicare Part B premiums, as required under a 2003 law. Grassley and Baucus are the chairman and ranking minority member of the Senate Finance Committee, respectively.

A statement from the committee said, "In a review requested by the Senators ... the GAO found that the short time frame before the change is scheduled to take effect and heavy workload challenges could affect SSA's ability to successfully calculate the new premiums." SSA typically deducts the premiums from checks.

While the Centers for Medicare & Medicaid Services administers the Medicare program, the SSA is responsible for determining and assessing Medicare Part B income-based premiums, once CMS has set the standard premium amount for the year, according to a Nov. 17 GAO letter to the two senators that contains the findings.

Grassley said, "Three years ago Congress acted to help ensure the long-term sustainability of the Medicare program by asking those who can afford it to help out and pay an increased premium for Medicare Part B." The Iowa Republican said the new findings from GAO show that "SSA, IRS, and CMS need to get together in these next critical weeks to make sure the system works and

beneficiaries are charged the correct premium." Grassley noted that there were "similar problems with the withholding of Part D [drug benefit] premiums earlier this year."

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the premiums are set to change from one flat premium to a system of income-related premiums, beginning Jan. 1, 2007. The Medicare Part B premiums will be calculated based on tax information that the SSA receives from the Internal Revenue Service, according to the Senate committee. If a beneficiary's income is above the threshold of \$80,000 for single filers or \$160,000 for married filers, SSA will then calculate the amount a beneficiary has to pay in addition to the standard monthly Medicare Part B premium, which is \$93.50 for 2007, the committee said.

Baucus, the incoming chair of the Finance panel for the next Congress, said GAO's findings indicate that "the Social Security Administration has been working hard under severe time constraints to make sure that this process runs without problems, but I am still concerned that time is too short. I urge the SSA--in conjunction with CMS and IRS--to continue its serious efforts to ensure that the process runs smoothly."

GAO Findings

GAO said, "At this writing, SSA is still in the process of calculating premiums and expects to finish this task by mid-November. Once the calculations are completed, SSA will include the new premium in its cost of living adjustment notices, which will be mailed to affected beneficiaries in late November."

GAO added, "Despite SSA's planning efforts, there are various issues that could affect its implementation of income-based premiums. For example, SSA has about a month to determine and assess the premiums, and faces an anticipated field office workload increase when beneficiaries contact them for help in understanding the higher premiums or challenging the premium assessment."

The GAO letter to the two senators noted that Medicare Part B is a voluntary program administered by CMS that covers doctors' services, certain outpatient services, and other care.

"Currently, Medicare Part B beneficiaries generally pay a flat premium of 25 percent (the standard monthly premium) of the cost of the program, with the remaining 75 percent subsidized by the federal government," GAO said.

With the change under the 2003 law, the premiums for some high-income beneficiaries could rise over three years to as much as 80 percent of the full program costs, GAO noted.

GAO said in its correspondence that of the 40.7 million projected Medicare Part B beneficiaries in 2007, about 1.65 million of them will pay a higher income-based premium. "Some of these beneficiaries may not yet be aware they will be affected by the income-based premium," GAO noted.

The report is available at <http://www.gao.gov/new.items/d07228r.pdf>.

Seniors Urged to Examine Drug Plan Options, As Open Enrollment Period for Part D Begins

Beneficiaries enrolled in a Medicare Part D prescription drug plan need to re-examine their options for the upcoming year, because many drug plans have changed their coverage for 2007, according to Judith Stein, executive director of the Center for Medicare Advocacy.

The Part D program "is a new program every year," and people need to look at their plan anew each year, even if they are happy with their current plan, Stein said. Some prescription drug plans "are quite different," with new formularies, higher copayments and premiums, and no coverage in the so-called doughnut hole for brand-name drugs, she said.

Leslie Norwalk, acting administrator for the Centers for Medicare & Medicaid Services, agreed that "some plans have moved around a little bit." But overall, the landscape of choices is not that different from last year, she said. Nevertheless, beneficiaries may want to look to see if their drug plan for 2007 is right for what they need, she said.

The two made their comments at a Webcast sponsored by the Kaiser Family Foundation to discuss the open enrollment period for Part D. The open enrollment period begins Nov. 15 and runs through Dec. 31.

Coverage Changes for 2007

CMS has asked plan providers to send out an annual notice to indicate any changes to their drug plans for 2007, Norwalk said.

For 2007, nearly all beneficiaries will have an option for brand-name and generic drug coverage in the doughnut hole gap, she said, but it may not be offered by the same companies as in 2006. In addition, there are more plans with no deductibles for 2007, as well as an increase in the number of plans offering more formularies, she added.

According to Juliette Cubanski, principal policy analyst for the Kaiser Family Foundation's Medicare Policy Project, more plans in 2007 offer coverage in the doughnut hole, but coverage is primarily for generics only. Only about 1 percent of plans offer full coverage for generics and brand-name drugs, she said, adding that beneficiaries who want that type of coverage may "have to shop around."

Norwalk said approximately 288,000 beneficiaries who are eligible for the low-income subsidy under the Part D program, or those who are eligible for both Medicare and Medicaid (the dual eligibles), will need to be moved to a new plan. She said CMS automatically would assign those beneficiaries to a new plan to preserve their low-income subsidy, unless the individual chooses to stay with their current plan or moves to a new one.

Comparing Part D Plans

Beneficiaries first should get a sense of what their prescriptions are, Norwalk said. Then they can call CMS at 1-800-MEDICARE, or log on to <http://www.medicare.gov/>, to compare all the available plans in their area. Beneficiaries can compare plans that offer the drugs that they need at the pharmacy they use and even look at a graph of approximately how much they will spend each month under a particular plan, Norwalk said.

If beneficiaries choose to enroll in a new plan, they will be disenrolled automatically from their old plan, Norwalk said. At that same time, those individuals who are happy with their plan for 2007 do not have to do anything, and they will be re-enrolled in the same plan, she said.

Stein said beneficiaries should look at more than the amount of the monthly premium or initial deductible. Individuals should look to see what drugs are covered, if there is coverage in the doughnut hole, and whether the plan includes utilization management tools that may require beneficiaries to go through step therapy, pay higher copayments, or set limits on drug quantity, she said.

Source: BNA

Senate Democrats Call on CMS to Limit 'Misleading' Marketing by Medicare Rx Plans

Senate Democrats are calling on the Centers for Medicare & Medicaid Services to revise Part D marketing guidelines to prohibit plans from using "misleading" language in marketing materials.

In a Nov. 13 letter to CMS, Sens. Byron Dorgan (D-N.D.), Debbie Stabenow (D-Mich.), Jeff Bingaman (D-N.M.), and 13 other Senate lawmakers said marketing language that describes plans as "complete, premier, or gold" can deceptively lead beneficiaries to believe that coverage offered by an insurer meets all their needs, even though the plans may have "significant gaps in coverage." The letter especially was critical of such language used in plan names.

The group specifically called on CMS to block plan providers from sending the so-called confusing and misleading information to beneficiaries.

Furthermore, Dorgan said, CMS should require insurers disclose in marketing materials any coverage gaps in the plans they offer.

"Many of these drug plans have been named in such a way that they are at best confusing, and at worst deliberately misleading," Dorgan said.

Source: BNA

USP Releases Draft Revisions to Model Guidelines for Medicare Rx Formularies

The United States Pharmacopeia is seeking comments on its latest draft revisions to the Medicare Model Guidelines and Formulary Key Drug Types, released Nov. 10.

The USP model guidelines are used by the Centers for Medicare & Medicaid Services and Part D plan providers for determining appropriate Medicare Rx formularies.

Among changes to the guidelines was the addition of a number of vaccines to the listing of key formulary drug types.

USP also created a drug listing table with examples of drugs that could be assigned to each category, class, or formulary key drug type. However, USP noted, the list is not a formulary, nor does it include all possible drugs that could populate those categories.

Comments to USP will be incorporated into the final model guidance, expected to be delivered to CMS by Feb. 5, 2007.

The draft revised guidance and drug listing table are available at <http://www.usp.org/healthcareInfo/mmg/forPublicComment.html>.
