Part III:

Medicaid Program

Part III:

Medicaid Program

Federal and State Partnership	1
Limit Enhanced Payments to Cost and Require That Medicaid Payments Returned by	
Public Providers Be Used To Offset the Federal Share	1
Improper Payments	7
Ensure Compliance With Requirements for Medicaid School-Based Health Services	
Prevent Duplicate Medicaid and Medicare Home Health Payments1	3
Enforce Federal Medicaid Payment Policies for Personal Care Services1	5
Prescription Drugs1	7
Ensure That Medicaid Reimbursement for Brand-Name Drugs Accurately Reflects Pharmacy Acquisition Costs1	7
Encourage States To Align Medicaid Generic Drug Pharmacy Reimbursements With Pharmacies' Acquisition Costs	.1
Establish a Connection Between the Calculations of Medicaid Drug Rebates and Drug Reimbursements	.5
Clarify and Improve Program Guidance to Drug Manufacturers on Average Manufacture Price Issues	7
Implement an Indexed Best-Price Calculation in the Medicaid Drug Rebate Program2	9
Extend Additional Rebate Payment Provisions to Generic Drugs	1
Identify Drugs That Are Ineligible for Federal Payments Under Medicaid	3
Medicaid Administration3	5
Enforce Federal Requirements for Submitting Medicaid Managed Care Encounter Data3	
Establish a National Medicaid Credit Balance Reporting Mechanism	7
Advise States of Their Authority To Collect From Noncustodial Parents With the Ability To Contribute Toward Their Children's Medicaid or Children's Health Insurance Program Costs	
Improve Medicaid Children's Access to Required Preventive Screening Services (New)4	1

Part III: Medicaid Program

Federal and State Partnership

Medicaid > Federal/State Partnership > Enhanced Payments

Limit Enhanced Payments to Cost and Require That Medicaid Payments Returned by Public Providers Be Used To Offset the Federal Share

Background: Title XIX of the Social Security Act authorizes Federal grants to States for Medicaid programs that provide medical assistance to certain low-income and disabled people. The Federal Government and States share in the administration and cost of the program. The Federal Government pays its share of medical assistance expenditures to the States according to a defined formula, which yields the Federal medical assistance percentage (FMAP). The FMAP can range from 50 percent to 83 percent, depending on each State's relative per capita income.

Medicaid is subject to upper payment limits (UPL). The UPL is an estimate of the maximum amount that would be paid to a category of Medicaid providers (usually hospitals and nursing homes) under payment principles established for the Medicare program. Generally, State payments that exceed UPLs do not qualify for Federal matching funds.

The differences between the States' allowable Medicaid payments and the UPLs are called enhanced payments. Under Medicaid UPL rules, States are permitted to provide enhanced payments to non-State-owned government providers, such as county or local public-owned nursing facilities and hospitals, and the enhanced payments qualify for Federal matching payments.

Findings: Audits issued in 2001 explored States' use of enhanced payments to local public-owned facilities. We found that the enhanced payments were not based on the actual cost of providing services to Medicaid beneficiaries; were not directly related to increasing the quality of care provided by the public facilities that received the enhanced payments; and were not always retained by the facilities to provide services to Medicaid beneficiaries

We found that some or all of the enhanced payments were returned by the providers to the States through intergovernmental transfers (exchanges of funds among or between different levels of government) to be put to other uses. The States were then able to use the funds for any purpose, including drawing down new Federal matching funds for Medicaid and other Federal programs. Some of the funds that were transferred back to the States were earmarked for use in health-care-related service areas but not necessarily for Medicaid-covered services approved in the State plans.

In effect, for the portions of the enhanced payments that were returned to the States, the States did not incur the health care expenditures for which Federal matching funds were claimed. As a result, the Federal Government and Federal taxpayers paid disproportionately more than their statutory share of Medicaid in those States without corresponding benefits to the intended beneficiaries.

We noted that accountability was generally lost at the point that funds were transferred to the States' general revenue accounts, thereby placing the funds at risk of being used for reasons other than their intended purpose.

Subsequently, we issued reports in 2004 and 2005 of audits of nursing facilities that were identified by State survey and certification reviewers as having serious deficiencies in patient care. The facilities had all been required to return substantial portions of their enhanced payments to the States to be used for other purposes. As a result, the facilities were underfunded. We recommended that the States allow the facilities to retain sufficient funding to cover the costs of providing an adequate level of care to their residents.

Recommendations: The Centers for Medicare & Medicaid Services (CMS) should (1) provide States with definitive guidance for calculating the UPL, which should include using facility-specific UPLs that are based on actual cost report data, and (2) require that the return of Medicaid payments by a county or local government to the State be declared a refund of those payments and thus be used to offset the Federal share generated by the original payment.

Savings: \$3.87 billion over 5 years*

*In its January 2007 Notice of Proposed Rulemaking, CMS estimated that if payments to providers operated by units of government were limited to cost and payments returned by providers were considered refunds, Federal Medicaid outlays would be reduced by \$120 million in the first year and by \$1.2 billion in the fifth year. CMS estimated that the final rule would result in a reduction of Federal Medicaid outlays of \$3.87 billion over 5 years.

Management Response Summary: In its comments on our September 2001 report, CMS partially concurred with our recommendations, stating that it would consider further reforms if it finds that States, under UPL rules, are continuing to use public health care facilities as transfer agents to leverage Federal Medicaid funding.

On January 18, 2007, CMS published a proposed rule at <u>72 Fed. Reg. 2236</u> that effectively addressed our concerns. The rule was proposed to "clarify the documentation required to support a certified public expenditure; limit reimbursement for health care providers that are operated by units of government to an amount that does not exceed the provider's cost; [and] require providers to receive and retain the full amount of total computable payments for services furnished under the approved State plan"

However, the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007, § 7002, prohibited implementation of CMS's proposed rule for 1 year following the date of the law's enactment on May 25, 2007. On May 29, 2007, CMS published a Final Rule With Comment Period at 72 Fed. Reg. 29748, that modified Medicaid reimbursement consistent with our recommendations.

On May 23, 2008, the U.S. District Court for the District of Columbia found that the Department of Health & Human Services (HHS) had violated the Congressional moratorium on finalization of the regulation in Public Law 110-28, vacated the rule, and remanded the matter to HHS. Accordingly, at 75 Fed. Reg 73972 (November 30, 2010), CMS formally withdrew the final rule and restored the previous regulation text so that the regulatory language impacted by the May 29, 2007, final rule would appear in the CFR as it did prior to issuance of the final rule.

The American Recovery and Reinvestment Act of 2009 (Recovery Act) provided that it was the sense of Congress that the Secretary of HHS should not promulgate the regulation.

In CMS's update of recommendations of this edition of the Compendium it had no new comments to offer on this matter.

Status: As an issue of accountability, we continue to monitor CMS's progress in limiting enhanced payments to public providers to cost and requiring that Medicaid payments returned by public providers be used to offset the Federal share. As we stated in June 2005 testimony before the Senate Committee on Finance (citation below), current policies and practices limit the ability of Congress, HHS, and State and local governments to manage, account for, and assess the benefits of Medicaid dollars.

Related Reports:

2001 SEP	Review of Medicaid Enhanced Payments to Local Public Providers and the Use of Intergovernmental Transfers. A-03-00-00216 Report
2001 JUN	Medicaid Enhanced Payments to Hospitals and the Use of Intergovernmental Transfers in North Carolina. A-04-00-00140 Report
2001 MAY	Medicaid Enhanced Payments to Public Hospital Providers and the Use of Intergovernmental Transfers by the Alabama State Medicaid Agency. A-04-00-02169 Report
2001 MAR	Illinois' Use of Intergovernmental Transfers to Finance Enhanced Medicaid Payments to Cook County for Hospital Services. A-05-00-00056 Report
2001 MAR	Medicaid Supplemental Payments to Public Hospital District Nursing Facilities and the Use of Intergovernmental Transfers by Washington State. A-10-00-00011 Report
2001 FEB	The Commonwealth of Pennsylvania's Use of Intergovernmental Transfers to Finance Medicaid Supplementation Payments to County Nursing Facilities. A-03-00-00203 Report
2001 FEB	Medicaid Enhanced Payments to Public Providers and the Use of Intergovernmental Transfers by the State of Nebraska. A-07-00-02076 Report
2001 MAR	Medicaid Enhanced Payments to Public Providers and the Use of Intergovernmental Transfers by the Alabama State Medicaid Agency. A-04-00-02165 Report
See Also:	
2005 JUN	Office of Inspector General (OIG) Testimony Before the Senate Committee on Finance: Financing Mechanisms To Shift the Cost of Medicaid to the Federal Government Contrary to Federal and State Sharing Formulas. Testimony
2005 APR	Adequacy of New York State's Medicaid Payments to A. Holly Patterson Extended Care Facility. A-02-03-01004 Report
2005 MAR	Adequacy of Washington State's Payments to Newport Community Hospital, Long Term Care Unit. A-10-04-00001 Report
2005 MAR	Adequacy of Tennessee's Medicaid Payments to Nashville Metropolitan Bordeaux Hospital, Long-Term Care Unit. A-04-03-03023 Report

2004 JUN Adequacy of Medicaid Payments to Albany County Nursing Home. A-02-02-01020 Report

Improper Payments

Medicaid > Improper Payments > School-Based Services > State Claims for Federal Share Unallowable

Ensure Compliance With Requirements for Medicaid School-Based Health Services

Background: The Social Security Act, § 1903(c), provides that Medicaid payment for school-based health services is allowable for covered Medicaid services that are included in an individualized education plan or individualized family service plan established pursuant to the Individuals With Disabilities Education Act (IDEA). In August 1997, CMS issued a guide entitled *Medicaid and School Health: A Technical Assistance Guide*. According to the guide, school-based health services included in a child's plan may be covered if all relevant statutory and regulatory requirements are met.

Findings: Our reviews through fiscal year (FY) 2010 found that States' claims for the Federal share of Medicaid included school-based services that did not always fully comply with Federal and State standards. We identified Medicaid overpayments for school-based health services with the Federal share of the overpayments totaling an estimated \$1.4 billion. Many of the services claimed lacked a referral by an appropriate medical professional or were not provided by or under the direction of a qualified provider. These unallowable claims generally occurred because States did not provide sufficient guidance to and oversight of local education agencies, and rates were not developed in accordance with applicable Federal cost allocation requirements or CMS program guidelines.

Recommendations: States should (1) disseminate CMS guidance and other information to the local education agencies in a timely manner, (2) monitor local education agencies to ensure compliance with Federal and State requirements, and (3) help local education agencies develop written policies and procedures that require service providers to document all pertinent health services and retain those records for review.

Savings: TBD*

* Our reviews have identified Medicaid overpayments for school-based health services with the Federal share of the overpayments totaling an estimated \$1.4 billion.

Management Response Summary: CMS concurred with our recommendations to address overpayments and has taken recovery action, or claims have been settled by the Department of Justice (DOJ). We note through our continuing work in this area that

CMS has also undertaken a significant effort to bring State plans into compliance with Federal law, regulations, and policy in the coverage areas that pertain to Medicaid services delivered in school settings. In May 2010, CMS issued school-based services financial management review guide #28 for use by its staff, titled *Claims for IDEA-Related School Based Services*.

Status: We will continue to monitor CMS's efforts to ensure that States comply with our recommendations. Although CMS developed a review guide for its staff to use in reviewing school-based claims in May 2010, it has not yet taken steps to provide guidance for dissemination by States to local education agencies in an effort to reduce unallowable claims. Office of Inspector General (OIG) reviews that continue to identify unallowable claims point to the need for such guidance.

Related Reports:

2010 SEPT	Review of New Jersey's Medicaid School-Based Health Claims Submitted by Public Consulting Group, Inc. A-02-07-01052 Report
2010 APR	Review of New Jersey's Medicaid School-Based Health Claims Submitted by Maximus, Inc. A-02-07-01051 Report
2010 MAR	Review of Arizona's Medicaid Claims for School-Based Health Services A-09-07-00051 Report
2009 APR	Review of Timeliness of West Virginia's Retroactive Claims for Medicaid School-Based Services. A-03-06-00201 Report
2008 FEB	Review of New Jersey's Medicaid School-Based Rates. A-02-04-01017 Report
2007 OCT	Medicaid School-Based Services in Utah – Review of Payment Rates. A-07-06-04069 Report
2007 MAY	Review of Medicaid Reimbursement Rate for School-Based Health Services in Maryland. A-03-05-00206 Report
2006 DEC	Review of Nevada's Medicaid School-Based Administrative Expenditures for Calendar Years 2003 and 2004. A-09-05-00054 Report
2006 SEPT	Review of Medicaid School-Based Administrative Costs in Minnesota From July 1, 2003 June 30, 2004. A-05-05-00040 Report
2006 JUN	Review of Medicaid School-Based Services in Kansas-Bundled Rate Development. A-07-05-01018 Report

2006 MAY	Medicaid School-Based Services in Kansas-Adjustment of the Bundled Rates. A-07-06-01030 Report
2006 MAY	Review of Medicaid Claims for School-Based Health Services in New Jersey. A-02-03-01003 Report
2006 FEB	Review of School-Based Health Services in Kansas. A-07-03-00155 Report
2006 JAN	Audit of LaPorte Consortium's Administrative Costs Claimed for Medicaid School-Based Services. A-06-02-00051 Report
2005 DEC	Audit of Medicaid School-Based Services in Texas. A-06-02-00047 Report
2005 SEPT	Review of Medical Transportation Claims Made by the New York City Department of Education. A-02-03-01023 Report
2005 AUG	Review of Illinois Medicaid School-Based Administrative Costs for State Fiscal Year 2001. A-05-02-00050 Report
2005 JUN	Review of Medicaid Speech Claims Made by the New York City Department of Education. A-02-02-01029 Report
2005 APR	Medicaid School-Based Administrative Activities in Kansas. A-07-03-00154 Report
2005 JAN	Review of Vermont Medicaid School-Based Services for the Period October 2001 Through September 2002. A-01-03-00004 Report
2005 JAN	Review of Maine's Medicaid Retroactive Claims for School-Based Health Services, January 2001 Through June 2003. A-01-04-00004 Report
2004 SEP	Medicaid School-Based Health Services Administrative Costs - Massachusetts July 1999 Through June 2001. A-01-02-00016 Report
2004 AUG	Review of Medicaid Transportation Claims Made by School Health Providers in New York State. A-02-03-01008 Report
2004 MAY	Audit of Medicaid Fee-for-Service Payments to Local Education Agencies in North Carolina for the Period July 1, 1999 Through June 30, 2000. A-04-01-00005 Report
2004 FEB	Review of Medicaid Speech Claims Made by School Health Providers in New York State. A-02-02-01030 Report

2004 FEB	Audit of the Iowa Department of Human Services' Claim for Medicaid School-Based Administrative Costs. A-07-02-02099 Report
2004 FEB	Medicaid Payments for School-Based Health Services, Rhode Island, for the Period July 1999 Through June 2001. A-01-02-00014 Report
2004 JAN	Audit of Houston Administrative Costs Claimed for Medicaid School-Based Health Services. A-06-02-00037 Report
2003 DEC	Review of Illinois Medicaid School-Based Services for the Period July 1, 2000 Through June 30, 2001. A-05-02-00049 Report
2003 JUL	Review of Washington State's Medical Assistance Costs Claimed for School-Based Health Services Provided in State Fiscal Year 2000. A-10-02-00008 Report
2003 JUL	Medicaid Payments for School-Based Health Services - Massachusetts Division of Medical Assistance - July 1999 Through June 2000. A-01-02-00009 Report
2003 MAY	Review of Rate Setting Methodology Medicaid School-Based Child Health Program Costs Claimed by the Connecticut Department of Social Services July 1997 Through June 2001. A-01-02-00006 Report
2003 APR	Review of Payments for Transportation Services Made to Special Service School Districts Under New Jersey's Medicaid Program. A-02-02-01022 Report
2003 APR	Audit of Medicaid School-Based Services in Oklahoma. A-06-01-00083 Report
2003 MAR	Review of Medicaid School-Based Services Claimed During State Fiscal Year 2000 by Maryland's Medicaid Program. A-03-01-00224 Report
2003 MAR	Review of Wisconsin Medicaid School-Based Services Program for the Year Ending June 30, 2000. A-05-02-00023 Report
2002 DEC	Followup Review of a Finding Contained in a New York State Office of the State Comptroller Audit Report on Duplicate School Health Claims to Medicaid Made by the New York City Board of Education. A-02-02-01018 Report
2002 OCT	Audit of Oklahoma Medicaid School-Based Services Provided Free to Other Students and Not Exempt Under the Individuals with Disabilities Education Act. A-06-01-00077 Report

2002 AUG	Review of Oregon's Medicaid Payments for School-Based Health Services Direct Care in State Fiscal Year 2000. A-10-01-00006 Report
2002 JUN	Review of Medicaid School Based Child Health Service Costs Claimed by Connecticut Department of Social Services October 1999 - September 2000. A-01-01-00006 Report
2002 MAY	Review of Washington State's Administrative Costs Claimed for Medicaid School-Based Health Services in State Fiscal Year 2000. A-10-01-00011 Report
2001 NOV	Medicaid Monthly Payments for School-Based, Health-Related Services in North Carolina. A-04-00-02161 Report

Medicaid > Improper Payments > Home Care > Medicaid as Payer of Last Resort

Prevent Duplicate Medicaid and Medicare Home Health Payments

Background: Home health services are intended to restore health and minimize the effects of illness and disability, enabling beneficiaries to live in community settings and avoid institutionalization. Medicaid and Medicare pay home health providers for services specified in the plans of care for beneficiaries; however, both programs should not pay for the same supplies or services for the same beneficiaries. When Medicaid and Medicare cover particular supplies and services, Medicaid is the payer of last resort, and Medicare should pay first for services provided to individuals who meet dual-eligibility requirements. We examined Medicaid and Medicare claims during 2005 in five selected States to determine the extent to which improper home-health-related payments for dual-eligible beneficiaries occurred.

Findings: In four of the five States, we found that Medicaid inappropriately paid home health providers a combined \$1 million for claims for nonroutine medical supplies (e.g., catheters, dressings, syringes, and needles) and therapeutic services that were also paid by Medicare. This represented about 1 percent of the \$113 million that the four States spent on home health nonroutine medical supplies and therapeutic services.

We also found that in two States Medicaid paid \$6.6 million for routine medical supplies (e.g., cotton balls, gloves, and incontinence items) on the same dates that Medicare covered home health services, but the Medicaid claims data did not include enough information to determine whether the supplies qualified for Medicare payment.

We also found that each of the five States had established payment system edits to compare claims for home health services to Medicare eligibility information; however, incomplete eligibility information and payment system edit overrides resulted in inappropriate payments. States do not have direct access to Medicare prospective payment system (PPS) data that would provide information about whether and when a beneficiary is receiving Medicare-paid services.

The order of claims submission dates and dates of payment indicated that some home health providers were submitting Medicaid claims for medical supplies and therapeutic services when they had already received Medicare payments.

Recommendation: CMS should ensure that Medicaid does not pay providers for Medicare-paid nonroutine medical supplies and therapeutic services.

Savings: \$1 million*

*The estimate of \$1 million that Medicaid inappropriately paid for nonroutine medical supplies and therapeutic services in four of the five States reviewed in 2005 was not projected to all States.

Management Response Summary: CMS said that it "did not disagree" with our recommendation to ensure that Medicaid does not pay providers for Medicare-paid nonroutine medical supplies and therapeutic services and indicated that it recognized the importance of preventing duplicate Medicaid and Medicare billings. CMS's 2011 update of its response to this recommendation indicated that since the report was issued, many States have been able to obtain Medicare crossover claims data. Furthermore, CMS indicated that it is coordinating with State program integrity directors to identify additional data elements that can be used to correctly adjudicate Medicare and Medicaid crossover claims for home health services.

Status: We will continue to monitor CMS's actions to address duplicate claims for nonroutine medical supplies and therapeutic services.

Related Report:

2008 MAY Duplicate Medicaid and Medicare Home Health Payments: Medical Supplies and

Therapeutic Services.

OEI-07-06-00640 Report

See Also:

2009 FEB Memorandum Report: Medicaid and Medicare Home Health Payments for Skilled

Nursing and Home Health Aide Services.

OEI-07-06-00641 Report

Medicaid > Improper Payments > Personal Care Services

Enforce Federal Medicaid Payment Policies for Personal Care Services

Background: Personal care services (PCS) provide the elderly, people with disabilities, and individuals with chronic or temporary conditions with the assistance they need to remain in their homes or communities. State Medicaid programs may reimburse the cost of PCS for individuals who are not inpatients or residents of certain institutions but should not separately reimburse for PCS furnished during institutional stays (Social Security Act § 1905(a)(24); 42 CFR § 440.167: 42; CFR § 441.301(b)(1)(ii); and 42 CFR § 440.70(c)).

We reviewed Medicaid PCS and institutional claims and Medicare institutional claims for services provided from October 1 through December 31, 2005, in five States: Minnesota, New Mexico, North Carolina, Texas, and Washington. We compared the dates of service for paid PCS claims with the dates of service for paid Medicaid and Medicare institutional stays to identify Medicaid payments for PCS provided during institutional stays.

Findings: OIG found that in the first quarter of FY 2006, the five States reviewed paid nearly \$500,000 in error for PCS provided during periods of institutionalization.

Three of the five States had billing practices allowing PCS providers to bill for services on dates for which no PCS were provided, which could mean that nearly \$11 million in that quarter may have been paid in error.

Although all five States reported having Medicaid controls to prevent payments for PCS provided during institutional stays, the controls did not fully prevent erroneous payments.

Recommendations: CMS should (1) enforce Federal Medicaid payment policies that prohibit Medicaid reimbursement for PCS provided over a range of dates if the range includes dates on which the beneficiary was institutionalized and (2) work with States to reduce erroneous Medicaid payments for PCS provided during institutional stays.

Management Response Summary: CMS concurred with our second recommendation to reduce Medicaid payments for PCS provided during institutional stays. However, CMS did not concur with our recommendation to prohibit Federal Medicaid reimbursement for PCS claims billed with date ranges that include days on which no PCS were provided. CMS said that Federal reimbursement policies are

sufficient to prohibit such payments when States have effective controls in place. We revised the recommendation in the final report to say that CMS should enforce its policies. CMS's 2011 update of its response to our recommendations indicated that it is continuing to work with its regional offices and with the States on a solution for disseminating information to ensure that Medicaid does not pay for Medicare-paid services. In addition, CMS indicated that it has developed data-mining algorithms for Medicaid claims data to detect PCS provided during institutional stays in several States.

Status: We continue to encourage CMS to enforce policies to reduce erroneous Medicaid payments for PCS during institutional stays. As a related matter, OIG is conducting additional reviews to determine whether States' claims for the Federal share of PCS are appropriate, i.e., whether the services met Federal and State requirements.

Related Report:

2008 AUG Payments Made in Error for Personal Care Services During Institutional Stays. OEI-07-06-00620 Report

See Also:

2008 OCT More Than 24 Hours in a Day Billed for Personal Care Services in Four States. OEI-07-06-00621 Report

Prescription Drugs

Medicaid > Pharmacy Reimbursement > Brand-Name Drugs

Ensure That Medicaid Reimbursement for Brand-Name Drugs Accurately Reflects Pharmacy Acquisition Costs

Background: States generally reimburse pharmacies for brand-name drugs at the estimated acquisition costs (EAC) of the drugs plus a dispensing fee. State Medicaid agencies are responsible for determining the EAC. Historically, most States have based their EACs solely or in part on the average wholesale price (AWP) minus a percentage discount, which varies by State. The AWP is a list price compiled from manufacturers and other data sources by commercial organizations, e.g., First DataBank, for use by the pharmaceutical community. The AWP is not defined in law or regulation.

The majority of States have used the pricing compendium published by First DataBank as their source to obtain AWP data. In connection with a legal settlement, First DataBank announced that it will discontinue publishing the AWP no later than September 26, 2011. Although First DataBank will cease publication of the AWP, States may choose to obtain AWPs in pricing compendia published by other companies, such as Micromedex's Red Book. We are conducting a review to assess States' plans for selecting new pricing benchmarks, evaluate the advantages and disadvantages of replacing AWP with alternative approaches, and determine what guidance CMS has provided or anticipates providing to States related to these issues.

OIG produced significant work spanning two decades showing that the AWPs States used to estimate acquisition costs overstated the prices retail pharmacies paid to purchase drugs, resulting in inflated reimbursement rates and leading to excessive Medicaid expenditures for prescription drugs. OIG reports concluded that reliance on AWPs as a basis for drug reimbursement was fundamentally flawed and that AWPs exceeded other available pricing points.

Findings: In August 2001, OIG reported a significant difference between pharmacy acquisition costs for brand-name drugs and the AWPs for those drugs. We estimated that based on invoice prices, pharmacies' calendar year (CY) 1999 actual acquisition costs averaged 21.84 percent below AWP nationally. We calculated that Medicaid could have saved as much as \$1.08 billion for the 200 brand-name drugs with the greatest amount of Medicaid reimbursements for CY 1999. The savings amount was determined by multiplying the nationwide utilization for each drug by 11.53 percent of AWP, which represented the difference between the average pharmacy acquisition costs (AWP minus a 21.84 percent) and previous findings of average reimbursements (AWP minus 10.31 percent) for the drugs. Using a reduction in AWP of 21.84 percent rather than

10.31 percent for reimbursements would have resulted in savings of as much as \$1.08 billion in CY 1999.

An additional analysis in 2002 included both brand-name and generic drug data. We found that Medicaid could achieve more accurate alignments between reimbursements and pharmacy acquisition costs by separately evaluating reimbursement levels for four tiers of drugs: single-source brand-name drugs (innovators), innovator multiple-source drugs without Federal upper limits (FUL), non-innovator multiple-source drugs without FULs, and multiple-source drugs with FULs.

A single-source innovator drug is under patent protection and is produced by only one manufacturer. Upon expiration of the patent's exclusivity, generic versions of an innovator drug can be produced by other manufacturers, resulting in the original drug being categorized as an innovator multiple-source drug. FULs are maximum amounts that federally funded programs may pay for certain multiple-source drugs. Although our analysis compared pharmacy acquisition cost data with AWP, the four tier approach could be used in better aligning reimbursement rates using other benchmark prices as well.

Recommendation: CMS should encourage States to align pharmacy reimbursement more closely with the actual acquisition cost of brand-name drugs paid by pharmacies in their States, e.g., by implementing a four-tier approach to reimbursement consistent with our September 2002 additional analysis report).

Savings: \$1.08 billion*

*Estimated savings are based on a 21.84-percent average discount below AWP for the 200 brandname drugs with the highest Medicaid reimbursement for CY 1999. Potential savings would depend on current pharmacy acquisition costs and the pricing benchmarks that States use for reimbursements.

Management Response Summary: In its comments on our 2001 draft report, CMS concurred with our recommendation, stating that it was working with States to review their estimates of acquisition costs in light of our findings. The President's FY 2006 budget proposed requiring States to reimburse the Average Sales Price (ASP) of a drug to pharmacies for Medicaid drugs, plus a 6-percent fee for storage, dispensing, and counseling. ASP is the weighted average of all non-Federal sales from manufacturers, and is therefore a sound proxy for pharmacy acquisition cost. This reimbursement scenario would align pharmacy reimbursement with pharmacy acquisition cost and would create a more sustainable system. Reimbursing ASP plus 6 percent is consistent with Medicare reimbursement for Part B-covered drugs as established by the Medicare

Modernization Act. The HHS *Budget in Brief* estimated the proposal to save \$542 million in FY 2006 and \$5.4 billion over five years. The proposed legislative change was not enacted and was not included in subsequent Presidents' budgets.

We note that although little progress has been made at the Federal level to better align Medicaid drug reimbursements with actual acquisition costs, First DataBank's decision to no longer publish AWP data offers an opportunity for States to implement alternatives.

Status: We continue to monitor CMS's efforts to encourage States to improve Medicaid reimbursements for brand-name drugs. We plan to conduct an audit in FY 2011 that will compare pharmacies' actual acquisition costs with other benchmark prices such as wholesale acquisition costs and average manufacturer prices (AMP). We are also conducting a review to assess States' plans for selecting new pricing benchmarks, evaluate the advantages and disadvantages of replacing AWP with alternative approaches, and determine what guidance CMS has provided or anticipates providing to States related to these issues.

Related Reports:

2002 SEP	Medicaid Pharmacy—Additional Analyses of the Actual Acquisition Cost of
	Prescription Drug Products. A-06-02-00041 Report

2001 AUG Medicaid Pharmacy—Actual Acquisition Cost of Brand Name Prescription Drug Products. A-06-00-00023 Report

See Also:

2004 DEC	OIG Testimony Before the House Committee on Energy and Commerce,
	Subcommittee on Oversight and Investigations: "Medicaid is Paying Too
	Much for Prescription Drugs." <u>Testimony</u>

2002 MAR Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products. A-06-01-00053 Report

2001 SEP Medicaid's Use of Revised Average Wholesale Prices. OEI-03-01-00010 Report

Medicaid > Prescription Drugs > Pharmacy Reimbursement for Generic Drugs

Encourage States To Align Medicaid Generic Drug Pharmacy Reimbursements With Pharmacies' Acquisition Costs

Background: CMS sets FUL amounts (maximum amounts that federally funded programs may pay) for certain generic drugs or brand-name drugs with generic equivalents. Federal regulations cap aggregate Medicaid reimbursement for drugs with FULs at the FUL amounts plus a reasonable dispensing fee. Historically, FUL amounts have been set at 150 percent of the lowest published price (typically AWP or wholesaler acquisition cost) for the least costly, therapeutically equivalent products. The Affordable Care Act requires CMS to set FUL amounts at 175 percent of the volume-weighted AMP beginning October 1, 2010.

For drugs without FULs, Medicaid reimbursement is typically set at the lower of the estimated pharmacy acquisition cost plus a reasonable dispensing fee or the pharmacy's usual and customary charge. Most States estimate pharmacy acquisition cost using AWP minus a percentage discount, which varies by State. AWP is a published price that is not defined in law or regulation.

The majority of States have used the pricing compendium published by First DataBank as their source to obtain AWP data. In connection with a legal settlement, First DataBank announced that it will discontinue publishing the AWP no later than September 26, 2011. We are conducting a review to assess States' plans for selecting alternative data sources or pricing benchmarks, evaluate the advantages and disadvantages of replacing AWP with alternative approaches, and determine what guidance CMS has provided or anticipates providing to States related to these issues. The change presents an opportunity for States to implement alternative pricing benchmarks for drugs without FULs.

Findings: A March 2002 OIG report on State pharmacy reimbursement formulas and pharmacy acquisition costs estimated that pharmacies' actual acquisition costs for generic drugs averaged 65.93 percent below the AWP in CY 1999. We estimated that changing the reimbursement policy to more accurately reflect pharmacies' actual acquisition costs could have saved the Medicaid program as much as \$470 million for the 200 generic drugs with the highest Medicaid reimbursement for CY 1999.

An additional analysis in 2002 included both brand-name and generic drug data. We found that Medicaid could achieve more accurate alignments between reimbursements and pharmacy acquisition costs by separately evaluating reimbursement levels for four specific tiers of drugs.

A 2005 report compared Medicaid FUL amounts to AMPs for the third quarter of 2004. AMPs are statutorily defined prices based on drug sales to the retail class of trade. We found that overall, FUL amounts for generic drug products were five times higher than the average AMP amounts for the same products in the third quarter of 2004. During the same period, the FUL amount was, on average, 22 times higher than the lowest reported AMP.

In 2007, we reported that FUL amounts set under the existing calculation method were more than double the average pharmacy acquisition costs in the second quarter of 2006.

In 2009, we found that existing FULs in the fourth quarter of 2007 were more than four times higher than average pharmacy acquisition costs for 50 high-expenditure FUL drugs, almost three times higher than average Part D payment amounts for 572 FUL drugs, and twice as high as retail prices for 291 drugs available through discount generic programs.

Recommendations: CMS should (1) encourage the States to align Medicaid generic drug pharmacy reimbursements more closely with the actual acquisition costs paid by pharmacies in their States (e.g., by implementing a four-tier approach to setting reimbursements consistent with our September 2002 additional analysis report).

Savings: TBD*

*Savings not estimated. Reimbursements for generic drugs without FULs may be affected by implementing alternative pricing benchmarks beginning in October 2011, and reimbursement for drugs with FULs will change by implementation of the Affordable Care Act.

Management Response Summary: In its comments on our March 2002 report, CMS concurred with our recommendation, indicating that it would work with States to strongly encourage them to review their estimates. CMS also concurred with the findings of the 2005 report stating that Congress should take action to ensure that Medicaid reimbursement amounts more closely relate to actual transaction prices.

The Deficit Reduction Act of 2005 (DRA) changed the FUL calculation for generic drugs, capping Medicaid drug reimbursement at 250 percent of the lowest AMP for a therapeutically equivalent version of a drug. CMS promulgated a final rule pursuant to this change at 72 Fed. Reg. 39142 (July 17, 2007), 42 CFR Part 447. This rule was scheduled to take effect on January 1, 2008. However, in December 2007, a Federal judge issued a preliminary injunction prohibiting CMS from implementing the provisions of the rule.

In April 2008, CMS told us that it would follow up to ensure that States take OIG's findings into account. Our 2009 report recommended that CMS should continue to work with Congress to identify strategies that would lower inflated Medicaid payments for generic drugs. CMS concurred with our recommendation and stated that our findings supported the agency's belief that AMP-based FULs more accurately reflect acquisition costs and prices used in other programs.

Effective October 1, 2010, section 2503(a)(1) of the Affordable Care Act modified the previous statutory provisions for FULs under the DRA by revising the Social Security Act, § 1927(e)(5), to establish FULs as no less than 175 percent of the weighted average of the most recently reported monthly AMPs. CMS published a final rule at 75 Fed. Reg. 69591 (November 15, 2010) to withdraw those parts of the 2007 final rule that established upper limits for multiple-source drugs and revised the definition of AMP.

Status: We will continue to monitor reimbursements of Medicaid generic drugs that have (or do not have) FULs to determine whether the calculation methods lead to reimbursement amounts that more accurately reflect pharmacy acquisition costs.

Related Reports:

2009 AUG	A Comparison of Medicaid Federal Upper Limit Amounts to Acquisition Costs, Medicare Payment Amounts, and Retail Prices. OEI-03-08-00490 Report
2007 JUN	Deficit Reduction Act of 2005: Impact on the Medicaid Federal Upper Limit Program. OEI-03-06-00400 Report
2005 JUN	Comparison of Medicaid Federal Upper Limit Amounts to Average Manufacturer Prices. OEI-03-05-00110 Report
2002 SEP	Medicaid Pharmacy—Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products. A-06-02-00041 Report
2002 MAR	Medicaid Pharmacy—Actual Acquisition Cost of Generic Prescription Drug Products. A-06-01-00053 Report

See Also:

2004 DEC OIG Testimony Before the House Committee on Energy and Commerce,

Subcommittee on Oversight and Investigations: "Medicaid is Paying Too

Much for Prescription Drugs." Testimony

2001 SEP Medicaid's Use of Revised Average Wholesale Prices. OEI-03-01-00010

Report

Medicaid > Prescription Drugs > Rebate Program

Establish a Connection Between the Calculations of Medicaid Drug Rebates and Drug Reimbursements

Background: The Omnibus Budget Reconciliation Act of 1990 (OBRA 1990) authorized States to collect rebates from drug manufacturers for drug purchases made under the Medicaid program. Medicaid overspending occurs because of an inconsistency between the key values used for calculating rebates and reimbursements.

Medicaid requires that rebates be based on a specifically designated value, AMP, while, at the same time, allowing reimbursements to be calculated using other values (usually a discounted AWP). This creates a situation whereby fluctuations in reimbursements do not result in a corresponding adjustment in the associated rebates. The inconsistency between the key values used for calculating rebates and reimbursements causes overspending for drugs. When a State increases its payments for a drug, it does not receive a correspondingly higher rebate on that drug purchase because there is no connection between the reimbursement and rebate calculations. Legislation would be needed to establish the connection.

Findings: Our 1998 review of this matter considered the fact that most States calculate reimbursement for drugs without FULs on EACs based on AWP. Therefore, we explored the effect of basing rebates on AWP instead of AMP. We concluded that requiring manufacturers to pay Medicaid drug rebates using the same basis as Medicaid's reimbursements to pharmacies would establish a much-needed connection between the calculation of Medicaid drug rebates and the calculation of Medicaid reimbursement for drugs at the pharmacy level. Although the 1998 review analyzed an AWP/AWP scenario, other matching alignments (e.g., AMP/AMP) could also be considered.

Recommendations: CMS should (1) seek legislation that would require Medicaid drug rebates and reimbursements to be developed using the same basis or (2) review viable alternatives to the current program.

Savings: TBD*

*We estimated that if rebates had been based on AWP (instead of on the statutorily required AMP) for CY 1994 through CY 1996, Medicaid would have achieved more than \$1 billion in added rebates for only the top 100 Medicaid-reimbursed brand-name drugs.

Management Response Summary: At the time of our report in 1998, CMS did not concur with our recommendation, stating that it did not believe that a legislative proposal was feasible

In 2005, Section 6001 of the DRA amended the Social Security Act to require that CMS provide States with AMP data. We note that although the DRA did not require States to use AMP data in determining reimbursement, the dissemination of AMP data would have provided States with a new pricing source for establishing EAC. Making AMP available would have enabled States to use monthly AMP data when setting Medicaid reimbursement rates for prescription drugs. The DRA, in effect, provided States an opportunity to establish the critical connection between the calculation of rebates and reimbursements. CMS promulgated a corresponding final rule; however, a Federal injunction prohibited its implementation.

Subsequently, section 2503 of the Affordable Care Act modified the DRA requirement in a way that will limit the availability of AMP information to the States for reimbursement or other purposes. The Affordable Care Act requires CMS to publish weighted AMPs for certain multiple-source drugs, instead of publishing AMPs for all drugs.

Status: We are concerned that until States use the same basis in their rebate and reimbursement formulas, fluctuations in reimbursements will not result in a corresponding adjustment in the associated rebates. We continue to monitor this issue.

Related Report:

1998 May Need to Establish Connection Between the Calculation of Medicaid Drug Rebates

and Reimbursement for Medicaid Drugs.

A-06-97-00052 Report

See Also:

2004 DEC OIG Testimony Before the House Committee on Energy and Commerce,

Subcommittee on Oversight and Investigations: "Medicaid is Paying Too

Much for Prescription Drugs." Testimony

Medicaid > Prescription Drugs > Rebate Program

Clarify and Improve Program Guidance to Drug Manufacturers on Average Manufacture Price Issues

Background: The Social Security Act, § 1927, requires drug manufacturers to enter into and comply with rebate agreements with the Secretary of HHS for States to receive Federal funds for a manufacturer's covered outpatient prescription drugs. The Secretary may also authorize States to enter into direct agreements with drug manufacturers.

Pursuant to section 1927, manufacturers are required to report their AMPs to CMS for each covered outpatient drug for a base period. The manufacturer is required to report on a quarterly basis the AMP and the best price for each covered outpatient drug. Section 6001 of the DRA required OIG to review the requirements for and the manner in which AMPs are determined under section 1927 and to recommend appropriate changes.

Findings: Requirements for determining certain aspects of AMPs are not clear and comprehensive, and manufacturers' methods of calculating AMPs are inconsistent. OIG focused primarily on how manufacturers calculate AMP and found that interpretations of AMP requirements differ among manufacturers. Our findings demonstrated the need to clarify the definition of "retail class of trade" and the treatment of pharmacy benefit manager rebates and Medicaid sales in AMP calculations. Many of our AMP-related reports contain proprietary information and are therefore not available to the public.

Our work related to the use of the AMP by CMS and other agencies highlights the need to consider the timeliness and accuracy of manufacturer-reported AMPs. Consistent with our findings, industry groups also emphasized the need to clarify certain AMP requirements.

Recommendations: CMS should (1) clarify requirements with regard to the definition of "retail class of trade" and the treatment of pharmacy benefit manager rebates and Medicaid sales; (2) consider addressing issues raised by industry groups, such as administrative and service fees, lagged price concessions and returned goods, the frequency of AMP reporting, AMP restatements, and baseline AMPs; and (3) encourage States to analyze the relationship between AMP and pharmacy acquisition costs to ensure that the Medicaid program appropriately reimburses pharmacies for EACs.

Management Response Summary: CMS concurred with our recommendations. Pursuant to AMP-related provisions of the DRA, CMS promulgated a final rule at

<u>72 Fed. Reg. 39142</u> (July 17, 2007), 42 CFR Part 447. This rule was scheduled to take effect on January 1, 2008. However, in December 2007, a Federal judge issued a preliminary injunction prohibiting CMS from implementing the provisions of the rule. Subsequently, CMS published a final rule at <u>75 Fed. Reg. 69591</u> (November 15, 2010) to withdraw those parts of the 2007 final rule that established upper limits for multiple-source drugs and revised the definition of AMP.

Status: OIG audits continue to identify variations among calculation methods, and we continue to recommend that CMS provide oversight to ensure that methods used to calculate AMPs are consistent among manufacturers. We plan additional reviews in FY 2011 of selected drug manufacturers to evaluate methodologies they use to calculate the AMP and best price for rebate and reimbursement purposes.

Related Reports:

2006 MAY Determining Average Manufacturers Prices for Prescription Drugs Under the Deficit Reduction Act of 2005. A-06-06-00063 Report

1992 NOV Drug Rebates: The Health Care Financing Administration Needs to Provide
Additional Guidance to Drug Manufacturers to Better Implement the Program.
A-06-91-00092 Report

See Also:

2005 JUL Multistate Review of Medicaid Drug Rebate Programs. A-06-03-00048
Report

2004 DEC OIG Testimony Before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations: "Medicaid is Paying Too Much for Prescription Drugs." <u>Testimony</u> Medicaid > Prescription Drugs > Rebate Program

Implement an Indexed Best-Price Calculation in the Medicaid Drug Rebate Program

Background: OBRA 1990 authorized States to collect rebates from drug manufacturers for drug purchases made under the Medicaid program. Rebates are calculated using the AMP, the manufacturer's best price, and other factors. To discourage drug manufacturers from raising prices, the basic rebate amount for brand-name drugs is increased by the amount that the AMP increases over and above the Consumer Price Index (CPI) for all urban consumers. However, no similar indexing of best price is made, even though best price is part of the basic rebate calculation for brand-name drugs.

Findings: Since the inception of the Medicaid drug rebate program, drug manufacturers have consistently increased best prices in excess of the CPI for all urban consumers. To determine the potential effect of increases in best price (beyond the rate of inflation) on rebates, we calculated the difference in rebates that would have resulted from using an indexed best price. We estimated that in 1993, drug rebates would have increased by about \$123 million for the 406 drugs included in our review.

Recommendation: CMS should pursue legislation to index the best-price calculation in the Medicaid drug rebate program to the CPI-urban.

Savings: \$123 million*

*This savings estimate is based on the best-price indexing in 1993 of the 406 drugs included in our review.

Management Response Summary: CMS did not concur with our recommendation. In its comments on our 2002 *Red Book*, CMS said that it believed that savings would be achieved through a President's budget proposal for a legislative change that would have based the Medicaid drug rebate on the difference between AWP and the best price of the drug. However, the proposal was not enacted. In November 2008, CMS noted that the Administration's position, as reflected in the FY 2008 President's budget, was to eliminate the best price; however, this proposal also was not enacted.

Status: We plan to continue monitoring the drug rebate program through audits focusing on enhancing the collection of rebates and providing potential savings to the rebate program. The main issue has not been addressed. Brand-name drugs are indexed, and we have suggested a similar calculation for generic drugs.

Related Report:

1995 OCT Special Report for the Ranking Member of the Senate Special Committee on

Aging: Potential Impact on the Use of an Indexed Best Price Calculation in the

Medicaid Drug Rebate Program. A-06-94-00039 Report

See Also:

2004 DEC OIG Testimony Before the House Committee on Energy and Commerce,

Subcommittee on Oversight and Investigations: "Medicaid is Paying Too

Much for Prescription Drugs." Testimony

Medicaid > Prescription Drugs > Rebate Program

Extend Additional Rebate Payment Provisions to Generic Drugs

Background: For covered outpatient drugs to be eligible for Federal Medicaid funding, the manufacturers must enter into rebate agreements that are administered by CMS and pay quarterly rebates to the States. The Social Security Act, § 1927(b)(3), requires participating manufacturers to report quarterly to CMS the AMP for covered outpatient drugs. The Social Security Act requires the payment of additional rebates for single-source and innovator multiple-source drugs (collectively, "brand-name drugs") under certain situations. For these brand-name drugs, section 1927(c)(2) requires manufacturers to pay an additional rebate when the AMP for a drug increases more than a specified inflation factor. Generally, the amount of the additional rebate is based on the amount by which the drug's reported AMP exceeds its inflation-adjusted baseline AMP, and manufacturers pay the additional rebate for each unit of the drug reimbursed by Medicaid. There is no similar inflation-based rebate provision for noninnovator (generic) drugs.

Findings: From 1991 through 2004, we found that generic drug price increases exceeded the specified statutory inflation factor applicable to brand-name drugs for 35 percent of the quarterly AMPs we reviewed. If the provision for brand-name drugs were extended to generic drugs, the Medicaid program would receive additional rebates. We calculated that by applying the method in the Social Security Act for calculating additional rebates on brand-name drugs to generic drugs, the Medicaid program would have received \$966 million in additional rebates for the top 200 generic drugs, ranked by Medicaid reimbursement, from 1991 through 2004.

Recommendation: CMS should consider seeking legislative authority to extend the additional rebate provisions to generic drugs.

Savings: \$966 million*

*We calculated that the Medicaid program would have received \$966 million in additional rebates for the top 200 generic drugs, ranked by Medicaid reimbursement, from 1991 through 2004.

Management Response Summary: CMS said that it could not commit to pursuing the legislative change because at the time of our report, it did not have sufficient time to assess the impact of recent changes to the Medicaid prescription drug program required by the DRA. However, CMS indicated that it would consider our recommendation as it considers future legislative proposals. In December 2009, CMS told us that it continues to consider all improvements to the Medicaid drug rebate program, including seeking legislative change when CMS believes it is appropriate.

Status: We will continue to monitor CMS's progress in seeking legislation and other improvements toward implementing the recommendation.

Related Report:

2007 OCT Review of Generic Drug Price Increases. A-06-07-00042 Report

Medicaid > Prescription Drugs > Rebate Program

Identify Drugs That Are Ineligible for Federal Payments Under Medicaid

Background: For Federal payments to be available for covered outpatient drugs provided under Medicaid, the Social Security Act, §§ 1927(a)(1) and (b)(1), requires drug manufacturers to (1) enter into rebate agreements with the Secretary of HHS and (2) pay quarterly rebates to State Medicaid agencies. Covered outpatient drugs must be approved by the Food and Drug Administration (FDA) for safety and effectiveness, with certain exceptions, to qualify for Federal payments. As set forth in section 1927(b)(3), manufacturers must provide CMS with the AMP,¹ by national drug code (NDC), for each of their covered outpatient drugs. The rebate amount for a drug is based in part on whether it is categorized as an innovator or noninnovator product. Innovator products are generally subject to higher reimbursement. Manufacturers provide CMS with the drug categorization in conjunction with AMP data. We compared drug categorizations in CMS's fourth quarter 2007 AMP file to drug categorizations in two national compendia. A compendium is a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium.

Findings: We found that most AMP file drug categorizations matched the categorizations in two national compendia. For 90 percent of NDCs in our comparison, the drug categorizations in the fourth-quarter 2007 AMP file were the same as the categorizations in the national compendia. However, drug categorizations did not match for 10 percent of NDCs. Overall, these nonmatching NDCs were associated with 3 percent of total fourth-quarter 2007 Medicaid expenditures for the NDCs under review. A manual review of 75 high-expenditure nonmatching NDCs revealed that 32 NDCs were for drugs that had not been approved by FDA. Medicaid paid \$20 million for these drugs in the fourth quarter of 2007.

In addition, a substantial number of NDCs were excluded from the drug categorization comparison, primarily because of missing data. We were unable to compare drug categorizations for 42 percent of NDCs with fourth-quarter 2007 Medicaid utilization for several reasons: (1) the NDCs were not listed in the AMP file, (2) the NDCs were not listed in one or both of the two national drug compendia, or (3) the NDCs had drug categorizations that differed in the two national compendia.

 $^{^{1}}$ In December 2007, the U.S. District Court for the District of Columbia preliminarily enjoined the implementation of AMP-based FULs.

Recommendation: CMS should work closely with FDA to identify any potentially problematic Medicaid payments for drugs that have not been approved by FDA.

Savings: \$20 million*

*Based on OIG analysis of 2007 fourth-quarter Medicaid expenditures.

Management Response Summary: In its response to our recommendation, CMS said that it has worked and will continue to work closely with FDA to identify potentially problematic Medicaid payments for drugs that do not meet the definition of a covered outpatient drug for the purposes of the Medicaid drug rebate program. CMS explained that FDA provides it with information on unapproved drugs that may be ineligible for coverage and that CMS reviews the information to determine whether action should be taken to remove these drugs from the list of covered drugs.

Status: We continue to encourage CMS to work closely with FDA to identify potentially problematic Medicaid payments for drugs that have not been approved by FDA. We will continue to monitor CMS's progress through current work.

Related Report:

2009 JUL Accuracy of Drug Categorizations for Medicaid Rebates.

OEI-03-08-00300 Report

Medicaid Administration

Medicaid > Managed Care Encounter Data

Enforce Federal Requirements for Submitting Medicaid Managed Care Encounter Data

Background: Encounter data are the primary records of Medicaid services provided to beneficiaries enrolled in capitated Medicaid managed care. As of 2006, 65 percent of the 45.6 million Medicaid beneficiaries were receiving all or part of their health care services through Medicaid managed care. The Balanced Budget Act of 1997 (BBA) requires that Medicaid claims submitted to CMS "on or after January 1, 1999, provide for electronic transmission of claims data in the format specified by the Secretary of HHS and consistent with the Medicaid Statistical Information System (MSIS)." As the only national database of Medicaid claims and beneficiary eligibility information, the MSIS is used by CMS to manage, analyze, and disseminate information on Medicaid beneficiaries, services, and payments. The MSIS is also widely used for research and policy analysis by public and private organizations and may also be used for detecting fraud, waste, and abuse. The MSIS must include encounter data to be representative of Medicaid beneficiaries and services.

Findings: We found that the 40 States with capitated Medicaid managed care collect encounter data from managed care organizations (MCO); however, the usefulness of the MSIS is limited because CMS does not enforce encounter data requirements.

Recommendation: CMS should enforce Federal requirements that States include encounter data in MSIS submissions.

Management Response Summary: CMS concurred with our recommendation. CMS's 2011 update of its response to our recommendation stated that it intends to increase efforts to consistently enforce the Federal reporting requirements for encounter data and that it will review statutory and regulatory authorities to determine areas in which it can strengthen the reporting of this data.

Status: Section 6402(c) of the Affordable Care Act authorizes the Secretary to withhold the Federal matching payment for States that fail to report enrollee encounter data in the MSIS. We will monitor CMS's efforts in the implementation of its planned actions and promulgation of Federal regulations regarding section 6402(c).

Related Report:

2009 MAY Medicaid Managed Care Encounter Data: Collection and Use. OEI-07-06-00540 Report

Medicaid > Administration > Credit Balances

Establish a National Medicaid Credit Balance Reporting Mechanism

Background: CMS does not require State agencies to routinely monitor providers' efforts to identify and refund Medicaid credit balances in patient accounts. Credit balances generally occur when the reimbursement that a provider receives for services provided to a Medicaid beneficiary exceeds the charges billed, such as when a provider receives a duplicate payment for the same service from the Medicaid program or a third-party payer.

Findings: Two of our reports have indicated that significant outstanding Medicaid credit balances exist nationwide. Between May 1992 and March 1993, we reported that many State agencies' efforts were inadequate to ensure that, nationwide, providers were identifying the majority of Medicaid credit balances and remitting overpayments in a timely manner.

Recommendations: CMS should (1) establish a national Medicaid credit balance reporting mechanism similar to that used for Medicare Part A and (2) require its regional offices to actively monitor the reporting mechanism that is established.

Savings: TBD*

*Savings not estimated.

Management Response Summary: When commenting on our 1995 report, CMS concurred with our recommendation to establish a national Medicaid credit balance reporting mechanism similar to that used for Medicare Part A. However, CMS decided not to do so, citing the uncertain and minimal savings potential; the Administration's commitment to enhancing States' flexibility; and, specifically, avoiding the imposition of an unfunded mandate.

In 2010, CMS described actions it had taken to update and issue its financial management review guide addressing Medicaid provider overpayments, to develop an annual work plan for reviewing high-risk financial management areas, and to establish overpayment reporting mechanisms in the CMS-64 expenditure reports. However, CMS has not implemented a credit balance reporting mechanism, citing cost-effectiveness issues.

Status: We continue to recommend that CMS establish a national Medicaid credit balance reporting mechanism and require its regional offices to monitor reporting. We

are conducting audit work in the Medicaid credit balance area to update our work. Based on our audit results, we will update or delete this item accordingly.

Related Reports:

1995 MAY Quarterly Credit Balance Reporting Requirements for Medicaid.

A-05-93-00107 Report

1993 MAR Nationwide Audit of Medicaid Credit Balances. A-04-92-01023 Report

Medicaid > Administration > Third-Party Liability

Advise States of Their Authority To Collect From Noncustodial Parents With the Ability To Contribute Toward Their Children's Medicaid or Children's Health Insurance Program Costs

Background: Regulations require State agencies operating child support enforcement programs pursuant to Title IV-D of the Social Security Act to petition the court or administrative authority, unless the custodial parent and children have satisfactory health insurance other than Medicaid, to include health insurance that is available to the noncustodial parent at reasonable cost in new or modified orders for support. Title XXI of the Social Security Act, which authorizes the Children's Health Insurance program (CHIP), is silent with regard to collecting CHIP costs from noncustodial parents who have medical support orders.

Findings: States can reduce State and Federal Medicaid costs by increasing the number of noncustodial parents who provide medical support for their children. Although Federal regulations authorize States to recover Medicaid costs from third-party payers, Title IV-D regulations do not provide specific guidance for collecting Medicaid costs from noncustodial parents who have the financial ability to pay and who do not have affordable employer-sponsored health coverage available. Medicaid regulations do not address how State Medicaid agencies should coordinate with State Title IV-D agencies or how the States should establish and administer Medicaid fee-for-service (FFS) recoveries.

States also have an opportunity to enroll uninsured Title IV-D children in CHIP and provide a means for noncustodial parents to fulfill their medical support obligations. Unlike Federal Medicaid laws, CHIP laws are silent with regard to an "assignment of rights" that would allow States to recover children's medical expenses from their noncustodial parents. Although some States have taken steps to collect CHIP costs from noncustodial parents, others have questioned their authority to do so or expressed concern about the costs that would be incurred.

Recommendations: CMS should (1) clarify third-party liability regulations to help State Medicaid agencies coordinate with State Title IV-D agencies to collect Medicaid costs from noncustodial parents with medical support orders; (2) seek legislation that would allow States to accumulate medical support payments to offset Medicaid FFS costs for a reasonable period; (3) determine whether more Federal funds are needed to help States interface their Title IV-D and CHIP databases; (4) implement a process to collect CHIP costs from noncustodial parents; and (5) as appropriate, provide funds for this purpose.

Savings: \$99 million – Medicaid* \$14 million – CHIP**

*Based on an eight-State review, we estimated that Title IV-D children who were enrolled in Medicaid had noncustodial parents who were financially able to contribute \$99 million based on the most recent data available from each State in 2001 or 2002.

**Based on an eight-State review, we estimated that Title IV-D children who received CHIP benefits had noncustodial parents who could potentially contribute \$14 million toward the CHIP premiums based on the most recent data available from each State in 2001 or 2002.

Management Response Summary: CMS did not concur with our recommendation to clarify third-party liability regulations; it agreed, however, to work with us to draft legislation to allow States to accumulate medical support payments because Federal laws and regulations prohibit States from accumulating additional medical support payments. CMS did not concur with our recommendations that issuing formal guidance on CHIP costs was necessary but agreed to alert States to their option to pursue the Federal and State shares of these costs. After our reports were issued, CMS told us during a series of Medical Support Collaboration meetings sponsored by the Administration for Children & Families (ACF) in 2005 that it had provided guidance to States on the collection of Medicaid costs from available employer-sponsored health care coverage of noncustodial parents and on their authority under Federal law to collect CHIP costs from noncustodial parents. CMS also noted that States had the authority to fund the administrative costs of building an infrastructure with the State Title IV-D agency under their 10-percent administrative CHIP cap and recognized that there is no mechanism in CHIP to provide States with more funding if they spend funds up to the cap.

Status: We continue to recommend that CMS consider alternatives to ensure that States receive adequate funds, especially if States are at or near their 10-percent administrative cap.

Related Reports:

2005 JUN Eight-State Review of the Ability of Noncustodial Parents To Contribute Toward the Medical Costs of Title IV-D Children That Were Paid Under the Medicaid Program. A-01-03-02501 Report

2005 MAY Eight-State Review of the Ability of Noncustodial Parents To Contribute Toward the Medical Costs of Title IV-D Children Under the State Children's Health Insurance Program. A-01-03-02502 Report

Medicaid > Medicaid Administration > Children's Health Screening

Improve Medicaid Children's Access to Required Preventive Screening Services (New)

Background: Services provided under Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit are intended to screen, diagnose, and treat children eligible for EPSDT services at early, regular intervals to avoid or minimize childhood illness. The EPSDT services cover four health-related areas: medical, vision, hearing, and dental. Our review focused on medical, vision, and hearing screenings. Only medical screenings have components specifically required by the statute. Complete medical screenings under the EPSDT benefit must include the following five age-appropriate components: a comprehensive health and developmental history, a comprehensive unclothed physical examination, appropriate immunizations according to age and health history, appropriate laboratory tests, and health education.

Findings: Most Medicaid-covered children in nine selected States are not fully benefiting from Medicaid's EPSDT comprehensive screening services. Seventy-six percent of children, or 2.7 million children, in 9 selected States did not receive all required medical, vision, and hearing screenings. Forty-one percent of children did not receive any required medical screenings. In addition, more than half of children did not receive any required vision or hearing screenings. Of the 55 percent of children in the nine States who received a medical screening during the review period, 59 percent lacked at least one component of a complete medical screening. The component that screenings were most often missing was appropriate laboratory tests.

Two primary factors contributed to this problem: children did not receive the correct number of each type of screening, and when children received medical screenings, the screenings were often incomplete. These two factors taken together indicate that very few children received the correct number of complete screenings required by law. Officials from all nine selected States identified strategies to improve participation in the EPSDT and the completeness of medical screenings. The disconnect between States' efforts to improve the EPSDT program and the low number of children receiving required screenings is difficult to account for, but indicates that additional efforts are required.

Recommendations: CMS should (1) require States to report vision and hearing screenings, (2) collaborate with States and providers to develop effective strategies to encourage beneficiary participation in EPSDT screenings, (3) collaborate with States and providers to develop education and incentives for providers to encourage complete medical screenings, and (4) identify and

disseminate promising State practices for increasing children's participation in EPSDT screenings and providers' delivery of complete medical screenings.

Management Response Summary: CMS concurred with our recommendations and stated that it is undertaking efforts in conjunction with States and national experts to improve the provision of EPSDT services. CMS also stated that a National EPSDT Improvement Workgroup has been formed and is tasked with making recommendations on improving EPSDT data collection opportunities. CMS plans to encourage individual States to submit promising practices for increasing participation in EPSDT screening and will post these on its Web site.

Status: We will continue to monitor CMS's implementation of our recommendations.

Related Reports:

2010 MAY	Most Medicaid Children in Nine States Are Not Receiving All Required Preventive Screening Services. OEI-05-08-00520 Report
2005 JUL	Children's Use of Health Services While in Foster Care: Common Themes. OEI-07-00-00645 Report
See Also:	
2005 JUN	Children's Use of Health Services While in Foster Care: New York. OEI-02-00-00362 Report
2005 JAN	Children's Use of Health Services While in Foster Care: Georgia. OEI-07-00-00644 Report
2004 AUG	Children's Use of Health Services While in Foster Care: North Dakota. OEI-07-00-00643 Report
2004 JUN	Foster Care Children's Use of Medicaid Services in Oregon. OEI-02-00-00363 Report
2004 FEB	Children's Use of Health Services While in Foster Care: Texas. OEI-07-00-00641 Report
2004 FEB	Children's Use of Health Services While in Foster Care: Illinois. OEI-07-00-00642 Report
2003 AUG	Children's Use of Health Services While in Foster Care: Kansas. OEI-07-00-00640 Report

2003 JUL	Foster Care Children's Use of Medicaid Services in New Jersey. OEI-02-00-00360 Report
1997 MAY	Medicaid Managed Care and EPSDT. OEI-05-93-00290 Report
1992 AUG	Early and Periodic Screening, Diagnosis, and Treatment (EPSDT)—Performance Measurement. OEI-07-90-00130 Report