Recently Issued Compendium of Unimplemented OIG Recommendations

On May 31, 2007, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued a Compendium of Unimplemented Recommendations (Compendium) made to the Centers for Medicaid and Medicare Services (CMS) and other government agencies. Previously, the OIG had issued these recommendations in two separate publications. The Red Book listed monetary recommendations while the Orange Book listed non-monetary recommendations meant to improve the operation of programs under HHS. This inaugural edition of the Compendium combines both the monetary and non-monetary recommendations along with previously made and new recommendations falling under both the monetary and non-monetary categories. This advisory briefly highlights a number of the OIG’s recommendations. The full Compendium can be accessed at: http://www.oig.hhs.gov/publications/docs/compendium/Compendium2007.pdf.

Priority Recommendations

The OIG organized its priority recommendations under three different target categories: (1) savings, (2) integrity and efficiency, and (3) quality of care. The OIG estimates that the priority recommendations listed under the savings category could save CMS $6.3 billion. The integrity and efficiency recommendations are intended to reduce the instances of fraud, waste and abuse and to increase the efficiency of HHS programs. Finally, the quality-of-care priority recommendations are designed to help the beneficiaries of these programs by protecting their health and safety.

Below, each of the recommendations falling under one of the OIG’s three subcategories of priority recommendations are noted by a footnote. These priority recommendations represent issues on which CMS and Congress may choose to focus their attention in the future, as they have been specifically identified as issues that would result in significant savings and increased effectiveness for HHS. We also include the recommendations that the OIG made along with its rationale for the recommendation and explain what steps CMS or other agencies have taken to implement the recommendations when they were originally made.
New Monetary Recommendations

Durable Medicare Equipment: Reduce the Rental Period for Medicare Home Oxygen Equipment

Recommendation: The OIG recommends that the current law limiting Medicare rental payments for home oxygen equipment to 36 months of continuous use be decreased.

- The president’s Fiscal Year 2007 budget recommended that Medicare limit its rental payments for home oxygen equipment to 13 months.

Recommendation: The OIG recommends that CMS determine the frequency of and reimbursement method for nonroutine servicing and maintenance of home oxygen equipment.

- CMS issued a proposed rule on August 3, 2006, asking for comments regarding the appropriate frequency of servicing home oxygen equipment.

Recommendation: The OIG recommends that CMS determine whether a new payment method for portable oxygen equipment is necessary.

- CMS issued a proposed rule on August 3, 2006, discussing an increase in the monthly payment for cylinder contents from $21 to $55.

Previous Monetary Recommendations

Medicare Hospitals: Revise Graduate Medical Education Payment Methodology

Recommendation: The OIG recommended that CMS revise two factors within the graduate medical education (GME) methodology used to compute the amount that Medicare reimburses hospitals for GME:

1. remove cost centers with less than 1 percent Medicare utilization from the calculation of GME base-year costs per resident; and

2. submit a legislative proposal to compute Medicare’s percentage of participation under the former method or a similarly comprehensive system, as it is currently based on inpatient data only.

- CMS did not agree with these recommendations.

End Stage Renal Disease: Reduce Medicare End Stage Renal Disease Payment Rates

Recommendation: The OIG recommended that CMS review and reduce the payment rate for outpatient dialysis treatments to better match what it believes is the actual average cost of treatment in the marketplace. The prospective payment rates are based on 1980 data and audited data from 1985 and 1989 demonstrates that the payment levels are much higher than the actual cost of dialysis treatments.

1 This is a priority recommendation listed by the OIG under the savings category.
CMS agreed that the composite payment rates should reflect the actual costs of outpatient dialysis treatments.

Medicare Reimbursement: Reinstate the Beneficiary Coinsurance and Deductible Provisions for Laboratory Services

**Recommendation:** The OIG recommended that CMS review the payments made to laboratories, in order to ensure that Medicare is not overpaying laboratories for the actual costs charged, and reinstate the coinsurance and deductible provisions to decrease the utilization of unnecessary services.

- Legislation was passed some time ago that reduced the prices of individual tests, but CMS continues to look at ways to reduce laboratory prices.

- CMS asserts it has taken steps to correct these problems and, as a result of the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, a competitive bidding demonstration for independent clinical laboratory services was scheduled to begin in April 2007, although it has not yet been implemented.

Medicaid Reimbursement: Require That Medicaid Reimbursement for Brand Name Drugs Accurately Reflects Pharmacy Acquisition Costs

**Recommendation:** The OIG recommended that CMS adopt a four-tier reimbursement system to ensure that the payments made to pharmacies are more consistent with what it believes is the actual acquisition cost of brand name drugs. The OIG estimates that the actual acquisition cost for brand name drugs was on average 21.84 percent below the average wholesale price whereas the average discount applied by the states was 10.31 percent.

The four recommended tiers would be arranged as follows:

1. single-source innovator drugs;
2. multiple-source innovator drugs without federal upper payment limits (FUL);
3. multiple-source noninnovator drugs without FULs; and
4. multiple-source drugs with FULs.

- CMS agreed with the OIG on this recommendation and is currently reviewing the acquisition costs for drugs within the individual states.

- The president’s fiscal year 2006 budget included a legislative proposal that would have used manufacturers’ average sales price to determine the federal government’s share of Medicaid pharmacy payments. The president’s budget for fiscal year 2007 did not include this proposal.

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2 This is a priority recommendation listed by the OIG under the savings category.
Medicaid Reimbursement: Require That Medicaid Reimbursement for Generic Drugs Accurately Reflect Pharmacy Acquisition Costs

**Recommendation:** The OIG recommended that CMS adopt a four-tier reimbursement system to ensure that the payments made to pharmacies are more consistent with what it believes is the actual acquisition cost of generic drugs. The OIG estimates that the actual acquisition cost for generic drugs was on average 65.93 percent below the average wholesale price whereas the average discount applied by the states was 10.31 percent.

The four recommended tiers would be arranged as follows:

1. single-source innovator drugs;
2. multiple-source innovator drugs without FULs;
3. multiple-source noninnovator drugs without FULs; and
4. multiple-source drugs with FULs.

• CMS agreed with the OIG on this recommendation and is currently reviewing the acquisition costs for generic drugs within the individual states.

• The Deficit Reduction Act of 2005 set the FUL for Medicaid payments for generic drugs at 250 percent of the lowest average manufacturer price (AMP). The president’s 2007 budget proposes to limit the reimbursement for multiple-source drugs to 150 percent of the AMP.

Health Resources and Services: Eliminate Excessive Costs in the 340B Drug Discount Program

**Recommendation:** The OIG recommended that the Health Resources and Services Administration (HRSA) strengthen its oversight of the 340B Program by utilizing four steps:

1. establishing detailed standards to be used in the calculation of the 340B ceiling prices;
2. creating oversight mechanisms to ensure that the 340B calculations and prices charged are correct;
3. seeking to gain legislative authority to penalize entities who violate the Public Health Service Act; and
4. obtaining consistent unit-of-measure and package-size data in order to accurately reflect 340B ceiling prices.

• CMS entered into an Intra-Agency Agreement and Data Use Agreement with HRSA to facilitate the transmission of pricing data from CMS effective during fiscal year 2005 to HRSA. HRSA will continue to calculate 340B ceiling prices.

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3 This is a priority recommendation listed by the OIG under the savings category.
• CMS agreed to work with HRSA to reiterate the 30-day pricing data submission requirement for manufacturers. CMS has agreed to consider referral to the OIG of those who violate that requirement for possible penalties.

• HRSA agreed to list standards for 340B calculations on its Web site, look into the possibility of gaining the authority to levy penalties for violations of the Public Health Service Act and develop more detailed standards for the calculation of 340B ceiling prices.

New Non-Monetary Recommendations

Medicare Hospitals: Improve the Availability of Quality-of-Care Data in the Medicare End Stage Renal Disease Program

Recommendation: The OIG recommends that CMS develop facility-specific quality improvement information and increase its efforts to regularly collect data on all clinical performance measures identified by CMS to address quality of care issues in the End Stage Renal Disease Program (ESRD).

• In 2000, CMS stated that it was developing a Core Data Set project to regularly collect facility-specific data on a comprehensive set of clinical performance measures, but it has not yet been implemented.

• CMS published proposed revisions to the ESRD Conditions for Participation in February 2005, and a final rule is expected.

• To improve quality of care, CMS has developed clinical performance measures, defined a Core Data Set and proposed regulations requiring facilities to electronically submit all clinical performance measures on ESRD patients. CMS has also committed to developing a new information system called Consolidated Renal Operations in a Web-based Network (CROWN), which would consolidate existing data sources into one system. CMS expects CROWN to be completed in 2008.

Nursing Homes: Strengthen Oversight of Nursing Home Complaint Investigations

Recommendation: The OIG recommends that CMS increase its oversight of nursing home complaints by:

(1) ensuring that state agencies complete investigations of complaints that allege actual harm within 10 days;

(2) removing the two-week advance notice currently required in the State Operations Manual for the Federal Oversight and Support Survey in order that regional offices may review the most serious complaints; and

(3) increasing the amount of training for state agencies in complaint oversight and investigations.

4 This is a priority recommendation listed by the OIG under the quality of care category.
CMS plans to release a training video in 2007 regarding the handling of complaints and investigations.

In 2006, CMS adjusted the language of the State Performance Standard to coincide with the language of the State Operations Manual. (Importantly, the state agency is required to begin an onsite survey for nursing home intakes labeled “Non-Immediate Jeopardy-HIGH” within 10 working days.)


Recommendation: The OIG recommends that CMS strengthen the requirements for nursing home emergency plan certification by requiring that certain elements of the plan be specifically addressed. The OIG also recommends that states, local emergency entities and nursing facilities work together to create these plans.

CMS strongly agrees with this recommendation and has taken multiple steps to increase the amount of oversight and direction for nursing home emergency plans. Specifically, CMS is looking to strengthen the federal certification standards for emergency plans.

Previous Non-Monetary Recommendations

End Stage Renal Disease: Improve Quality Improvement Processes in Dialysis Facilities

Recommendation: The OIG recommended that CMS revise the Conditions for Coverage to require facility medical directors to exercise leadership in quality improvement; require dialysis facilities to conduct their own quality improvement projects; examine ways to foster the commitment of attending physicians to performance measures; develop more effective intervention strategies for facilities; and work with corporations to share experiences and minimize reporting burdens on dialysis facilities.

CMS agreed with the majority of these recommendations.

The Conditions for Coverage proposed rule was published in February 2005, had a 90-day public comment period and has not yet been published as a final regulation. The proposed conditions would require an outcome-oriented Quality Assessment and Performance Improvement (QAPI) program, increased participation of attending physicians in patient care and supporting the facility’s QAPI program, a larger medical director role and electronic clinical measure reporting.
Medicare Reimbursement: Strengthen Managed Care (Part C) and Prescription Drug (Part D) Benefit Payment Cycles

**Recommendation:** The OIG recommended that CMS review and strengthen its policy of oversight for managed care and prescription drug payments in order to reduce the amount of payment errors.

Specifically, the OIG recommends the following changes:

1. Update the management system so that appropriate information for oversight is provided;
2. Ensure that standard documentation and retention policies are in place to aid in the regional office monitoring reviews of managed care organizations;
3. Adjust the procedures for regional office monitoring of demonstration projects to address the individual risks and requirements of each project;
4. Identify incorrect payment trends or errors by compiling lists of beneficiary data and payment information;
5. Strengthen the payment authorization process by compiling a log to document payment anomalies and errors along with conducting reconciliation of all authorized payments; and
6. Create a plan to reconcile beneficiary data with plan payments, including all plan-level adjustments.

- CMS took action to increase the amount of oversight and auditing of the Prescription Drug Benefit.
- CMS has developed error rates for Part C, Part D and the Retiree Drug Subsidy Program.

**Conclusion**

The issues identified in this advisory only highlight a small number of the OIG’s Unimplemented Recommendations in the voluminous Compendium. As noted previously, the OIG’s priority recommendations, monetary and non-monetary, represent issues that CMS and Congress may choose to focus their attention on in the future as they have been specifically identified by the OIG as issues that would result in significant savings and issues that would increase the effectiveness of HHS programs.
If you have any questions or would like additional information, please contact your Alston & Bird attorney or a member of our Health Care Group.

Atlanta Office

Robert C. Lower  
404.881.7455  
robert.lower@alston.com

Kevin E. Grady  
404.881.7164  
kevin.grady@alston.com

Dawnmarie R. Matlock  
404.881.4253  
dawnmarie.matlock@alston.com

Michelle A. Williams  
404.881.7594  
michelle.williams@alston.com

Donna P. Bergeson  
404.881.7278  
donna.bergeson@alston.com

Gina G. Greenwood  
404.881.4698  
gina.greenwood@alston.com

Jack S. Schroder  
404.881.7685  
jack.schroder@alston.com

Angela T. Burnette  
404.881.7665  
angie.burnette@alston.com

Jeffrey K. Hester  
404.881.4254  
jeff.hester@alston.com

Robert D. Stone  
404.881.7270  
robert.stone@alston.com

Washington Office

Peter M. Kazon  
202.756.3334  
peter.kazon@alston.com

Tamara Rae Carty  
202.756.3489  
tamara.carty@alston.com

Marc J. Scheineson  
202.756.3465  
marc.scheineson@alston.com

Timothy P. Trysla  
202.756.3420  
timothy.trysla@alston.com

Jacqueline C. Baratian  
Counsel  
202.756.3484  
jacqueline.baratian@alston.com

Stephanie A. Kennan  
Senior Public Policy Advisor  
202.756.3159  
stephanie.kennan@alston.com

Donald E. Segal  
202.756.3449  
donald.segal@alston.com

Jennifer E. Bell  
Senior Public Policy Advisor  
202.756.3416  
jennifer.bell@alston.com

Mark Rayder  
Senior Public Policy Advisor  
202.756.3562  
mark.rayder@alston.com

Thomas A. Scully  
202.756.3459  
thomas.scully@alston.com

Jennifer L. Butler  
202.756.3326  
jennifer.butler@alston.com

Colin T. Roskey  
202.756.3436  
colin.roskey@alston.com

Julie K. Tibbets  
202.756.3444  
 julie.tibbets@alston.com

Marilyn Yager  
Senior Public Policy Advisor  
202.756.3341  
marilyn.yager@alston.com

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