HAWAII HEALTH SYSTEMS
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COMPLIANCE ALERT 10-7

OIG and CMS Continue to Investigate Medicaid and Medicare Pharmaceutical Payments

The OIG continues to audit and make reports to CMS about the pricing and reimbursement of pharmaceuticals for Medicare and Medicaid reimbursement. The two reports summarized below are in addition to 14 other OIG reports comparing average sales price (ASP)to average manufacturer price (AMP). To date, CMS has not implemented sweeping changes to reimbursements as directed by the Deficit Reduction Act of 2005 (DRA). However, changes should be anticipated.

Section 1847A(d)(3) of the Social Security Act (the Act) requires that the OIG notify the Secretary of the Department of Health and Human Services if the (ASP) for a particular drug exceeds the drug's AMP by a threshold of 5 percent. If that threshold is met, the Act authorizes the Secretary to disregard the ASP for that drug and substitute the payment amount for the drug code with the lesser of the widely available market price for the drug (if any) or 103 percent of the AMP.

On January 20, 2010, the OIG released the two most recent reports concluding that state Medicaid programs may be significantly overpaying for prescription drugs based on its methodology for calculating the Medicaid Federal Upper Limit (FUL) reimbursement rate. Under current law, the FUL amount is calculated based on 150% of the lowest price published in national compendia. However, the DRA attempted to change the FUL methodology to calculate prices based on 250% of the lowest AMP.

The first report (OEI-03-08-00490) compared the FUL under the current pre-DRA method and the proposed AMP-based method for the 50 highest-expenditure FUL drugs during the fourth quarter of 2007. The report also compared prices for the average Part D pharmacy reimbursement amounts for all FUL drugs in the fourth quarter of 2007 and the retail price for any FUL drugs included in selected companies' discount generic programs.

The report found that for the time period audited, FUL amounts were more than four times higher than average pharmacy acquisition costs. The aggregate FUL

amounts were almost three times higher than average Part D payment amounts. And among individual products, the FUL amount was more than double the average Part D payment amount for 335 of the 572 drugs. In the aggregate, the FUL amounts were two times higher than prices available though retail discount generic programs for this time period.

The OIG also determined that calculating FUL amounts based on AMP was much closer to other available prices. The report estimated that the excess Medicaid expenditures due to the FUL methodology amounted to hundreds of millions of dollars. The report recommends that CMS "continue to work with Congress to identify strategies that would lower inflated Medicaid payments for multiple-source drugs."

The second report (OEI-02-07-00740) examined the effect of outliers on the FUL methodology. Under new DRA requirements, FUL amounts for most multiple-source drugs are to be based on 250 percent of the lowest reported AMP for each drug rather than 150 percent of the lowest prices published in the national compendia of drug cost information.

The OIG had previously found that the lowest AMP for many FUL drugs falls below pharmacy acquisition costs even when the 250 percent multiplier is applied. To address this, CMS announced plans to exclude the lowest AMP from the FUL calculation if it was more than 60% below the second-lowest AMP.

The OIG found that most outlier AMP amounts were accurate, but approximately 20 percent of the outlier AMPs for FUL drugs were inaccurate or potentially inaccurate. CMS plans to remove outlier AMPs from future FUL calculations and the OIG recommended that CMS:

- Examine the units of AMP submission for all FUL drugs before establishing FUL amounts
- Direct manufacturers to periodically examine their monthly AMP calculations to ensure accurate reporting of data
- Continue directing manufacturers to repot termination dates for discontinued drug products as soon as they are known.

Litigation by pharmaceutical trade associations has temporarily halted the implementation of the new FUL methodology as mandated by the DRA. Other recently posted OIG reports (OEI-03-09-00640, OEI 03-09-0340, and OEI-03-09-00490) continue to compare ASP and AMP for various quarters and note that millions of dollars could be saved by CMS if drug pricing were brought into line with current guidelines. It seems clear from the continuation of these reports

that CMS will be acting in the future to reduce payments as it implements the new FUL methodology.