

NEWSSTAND

Healthcare Update - Healthcare News From Capitol Hill and The Department of Health and Human Services

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CMS PROPOSES CHANGES TO PRESCRIPTION DRUG PRICING REGULATIONS:

In early September, the Centers for Medicare and Medicaid Services (CMS) released a proposed rule that seeks to repeal specific elements of Medicaid prescription drug regulations that were published in 2007.

The proposed rule would apply to provisions that were challenged in court by pharmacy groups following the initial 2007 implementation of the regulations, and that were also acted on legislatively in 2008, when a moratorium was imposed by Congress.

Specifically, CMS' latest proposed rule would repeal three elements of the 2007 Medicaid regulations:

- The federal upper limit – the maximum reimbursement rate – for generic drugs;
- The method for determining a drug's average manufacturing price (AMP); and
- The definition of multiple source (generic) drugs.

In changing the AMP and multiple source drug definitions – as mandated by recent healthcare overhaul legislation – CMS stated that drug manufacturers “would be advised to base their AMP calculations in accordance with the definitions set forth in section 1927 of the [Social Security] Act, instead of the AMP and AMP-related definitions provided in existing regulations and guidance.”

Further, CMS' proposed rule stated that the maximum reimbursement rate for multiple source drugs is “to be no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis.”

Those wishing to submit comments on the proposed rule must do so by October 4.

REPORT DETAILING FUTURE HEALTHCARE SPENDING RELEASED:

Expected trends in healthcare spending and enrollment over the next decade – following the recent enactment of healthcare overhaul legislation (Public Law 111-148) – was the subject of a new report by CMS, released on September 9.

In its report, the agency estimated that healthcare spending will increase slightly over the next decade, rising by an average annual rate of 6.3 percent from 2010 to 2019. By 2019, the spending will account for nearly one-fifth of the nation's Gross Domestic Product – up 0.3 percentage points from estimates made prior to the enactment of healthcare reform.

Logically, CMS stated that increased health insurance coverage will account for the increased spending, offset by reductions to Medicare and decreased provider reimbursements under Medicaid. In addition, the increased coverage will account for lower out-of-pocket spending rates for individuals.

Enrollment in Medicaid and the Children's Health Insurance Program (CHIP) will increase, and spending for the two programs will make up nearly 20 percent of national healthcare spending by 2019, according to the report. This estimate is two percentage points higher than before the enactment of healthcare reform.

In total, it will cost \$71.1 billion to implement healthcare reform measures over 10 years, according to CMS. This total includes \$37.7 billion in federal and state outlays in order to implement and operate the new health insurance exchanges, \$31 billion in Medicaid administrative costs, and \$2.4 billion for the Department of Health and Human Services.

NEXT STEPS:

We continue to follow news from CMS as the implementation of healthcare reform moves forward, and continue to monitor Congress as other related matters arise. We will provide timely updates as such developments occur.

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Should you have any questions on the content of this advisory, or wish to discuss any other healthcare related issue, please contact those listed below or call the Edwards Angell Palmer & Dodge LLP attorney responsible for your affairs.

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