NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

History of AMP-Based Federal Upper Limits Timeline

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Starting with the Deficit Reduction Act of 2005 (DRA), Congress has passed legislation that made changes to how Federal Upper Limits (FUL) are calculated. The DRA legislation dramatically reduced the FULs for the federal matching rates as the basis of the payment for generic drugs under Medicaid.

The statutory authority provided by provisions in the Affordable Care Act (ACA) changed the average manufacturer price (AMP)-based reimbursement system created by the DRA and helped provide for more accurate pharmacy reimbursement. Below is a timeline outlining the ten-year history of AMP-based FULs.

February 2006:
Congress enacted the DRA which changed the way FULs were calculated. The DRA defined AMP to include sales outside the retail class of trade (mail, long-term care, etc.), calculated FULs at 250% of lowest AMP, and allowed states to set FULs when there are two equivalent drug products. In addition, the DRA also allowed CMS to post brand and generic AMPs on a public website for access by states and allowed CMS to collect and provide retail survey price (RSP) to the states.

December 2006:
CMS posted the "Medicaid Program; Prescription Drugs Proposed Rule" in the Federal Register. This proposed rule would implement the provisions of the DRA pertaining to prescription drugs under the Medicaid program. The final rule was published July 2007.

December 2007:
A federal court issued a temporary injunction which halted CMS' implementation of the agency's AMP rule as result of a lawsuit filed by NACDS and the NCPA. The court order prohibited CMS from using the AMP data as calculated under the rule to set FULs pending resolution of the lawsuit. It also prohibited the publishing of the erroneously calculated AMP data by CMS or the distribution of the data to the states. CMS did not appeal the decision. While the lawsuit temporarily halted CMS from implementing its own unlawful AMP rule, it did not address the underlying statutory issue of using AMP to set federal upper limits as established under the DRA. The injunction created the opportunity to find a long-term solution.

July 2008:
Congress enacted the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) which implemented a statutory delay of AMP provided by DRA. Section 203 of MIPPA prohibited both the use and disclosure of AMPs until October 1, 2009. This

delay of the implementation of the AMP rule and the prohibition of public posting of AMPs also allowed Congress to determine a fair and appropriate benchmark for determining Medicaid reimbursement to retail pharmacies.

August 2008:
As a result of MIPPA delaying calculation of AMP-based FULS, CMS resumed calculation of FULs based on the pre-DRA methodology, which was based on 150% of the lowest published price (AWP and WAC) from all compendia on products that were available from three or more sources and rated therapeutically equivalent by the FDA.

March 2010:
Congress passed the Affordable Care Act (ACA) and changed the methodology for setting Medicaid generic drug reimbursement from the DRA method to no less than 175% of the weighted average AMP.

September 2010/ November 2010:
CMS published a proposed rule to withdraw existing regulations regarding the determination of AMP, multiple source drugs, and FUL requirements. This rule would ultimately delete the definition of AMP, delete the definition of multiple source drugs, and delete the FUL requirements. In their place, CMS proposed to require manufacturers to rely on the new statutory definitions of AMP, wholesaler, and retail community pharmacy as enacted by the ACA until new interpretive regulations are promulgated. The rule did not include any substantive guidance interpreting the new statutory definitions and did not express any of the agency's thinking on how manufacturers were to calculate AMP going forward. The final rule was published in November 2010 and at that time CMS discontinued calculating FULs using the pre-DRA methodology.

September 2011:
CMS began calculating draft monthly AMP-based FULs that represent the weighted average of monthly AMPs in a FUL group as enacted by ACA. CMS issued draft AMP-based FUL reimbursement files (for review and comment only) for multiple source drugs, including the draft methodology used to calculate the FULs. For the draft FULs, monthly AMPs for individual drugs were not/are not posted. Rather, only the weighted average of monthly AMPs in a FUL group is posted.

February 2012:
CMS published the Covered Outpatient Drugs Proposed Rule in the Federal Register which would implement the provisions enacted by the ACA to allow CMS to calculate AMP-based FULs based on no less than 175% of the weighted average AMP. The comment deadline for the proposed rule was April 2012.

October 2012:
CMS began calculating a three- month rolling average AMP-based FULs. CMS had received numerous comments that the draft AMP-based FULs fluctuates on a month-to-month basis and that these fluctuations may create problems for pharmacies because they

will be unable to predict resulting state reimbursement rates. In response to those comments, CMS developed a draft three-month rolling average FUL consisting of the weighted average of the current and two previous monthly draft AMP-based FULs.

November 2013:
CMS announced further delay of the final AMP-based FULs until July 2014. At this time CMS continued to post monthly and three-month rolling average AMP-based FULs for review and comment.

April/May 2014:
HHS Secretary Sebelius receives bipartisan letters from 9 Senators and 49 members of the House of Representatives urging CMS to provide a one-year transition period for the states to implement the proposed Medicaid Covered Outpatient Drugs Final Rule and make corresponding dispensing fee changes.

June 2014:
CMS announced that they would not be publishing and implementing the final AMP-based FULs in July, as they had previously stated in November 2013. At that time, CMS did not provide a new date for the final FULs and corresponding guidance. In its announcement, CMS indicated that it remained committed to ensuring that guidance is provided to states with sufficient time to implement the FULs. CMS further stated that it expects to provide a new finalization date for the FULs when it releases this subsequent guidance to states.

November 2014:
CMS released an informational bulletin informing stakeholders of the anticipated finalization of the ACA FULs. In this bulletin CMS stated that they expected to release the finalized AMP-based FULs at or about the same time that they publish the Medicaid Covered Outpatient Drugs Final Rule (CMS-2345-F). At that time, CMS also stated plans to issue formal detailed guidance to the states to implement the AMP-based FULs which would include the information that the states will need to include in their state plan amendments, including detailed timelines for compliance.

April 2015:
HHS Secretary Burwell receives bipartisan letters from 10 Senators and 54 members of the House of Representatives urging CMS to protect beneficiary access through fair and accurate pharmacy reimbursement as well as provide at least a year-long transition period for the states to implement the proposed Medicaid Covered Outpatient Drugs Final Rule.

August 2015:
On August 4, CMS submitted the final Covered Outpatient Drug Rule to the Office of Management and Budget (OMB) for review. Once submitted the OMB has up to 90 days for review and comments. The review process may be shorter or longer depending on conversations between the agency and the department.

January 2016:
On January 21, the *Federal Register* posted CMS' "Covered Outpatient Drugs Final Rule with Comment" (CMS-2345-FC). NACDS members are immediately reviewing this rule, which was posted by the *Federal Register*.