

The following comments were raised by various stakeholders regarding the issuance of the draft Affordable Care Act Federal Upper Limit (FUL).

Disclaimer: These responses are limited to and based upon the facts as described in the inquiries and have no applicability to a different set of facts even if such facts appear similar in nature or scope. These responses are also not considered to be an advisory opinions under Section 1128D(b) of the Social Security Act since only the Inspector General of the U.S. Department of Health and Human Services has been authorized to issue advisory opinions related to health care fraud and abuse under that section.

AFFORDABLE CARE ACT – DRAFT FEDERAL UPPER LIMIT (FUL) POLICY INQUIRIES

Subject	Comment	Response
Comment Deadline	Is there a deadline for comments on the draft Affordable Care Act FULs?	No. We encourage you to submit your comments as soon as possible so that we may consider them before we publish the final Affordable Care Act FULs. Please submit your comments to FUL@cms.hhs.gov .
Implementation of the Affordable Care Act FUL	We urge CMS to forego its plans for periodically releasing FULs and weighted average manufacturer prices (AMP) in draft format, at least until it finalizes regulations implementing section 2503 of the Affordable Care Act.	Section 2503(d) of the Affordable Care Act specifies that the FULs amendments "shall take effect ... without regard to whether or not final regulations to carry out such amendments have been promulgated...". Accordingly, we do not plan to wait for the issuance of the final regulation before publishing FULs.
The Affordable Care Act FUL and Average Acquisition Cost (AAC)	What is the role of State AAC and the FUL? Will the AAC prices in States such as Alabama be subject to the lower of the FUL or AAC?	Payment for Medicaid covered drugs is dependent on the methodologies set forth in the State plan. The FUL is established as an aggregate upper limit and depending on the State plan, States generally have the flexibility to determine actual reimbursement for specific drugs provided the total reimbursement for drugs subject to the FUL does not exceed the FUL in the aggregate.
Publication of FUL Prices	Should the absence of a reported price for a drug in a given period be interpreted to mean its previously reported price should be continued? Or should it be eliminated? For instance, a product has a reported January FUL of \$1.00 but <i>no</i> reported price in February. Does that mean the \$1.00 price is still in effect or is there no FUL on this product in February?	If a drug product is subject to a FUL, the FUL price will appear in each published update and that price will remain in effect until the next published update. Further, if the FUL price on a drug changes from a previous update, the price change will be noted on the FUL Computation file under a "Changes" tab in the current monthly file. In the case where a drug product is subject to a FUL, and in the next publication it does not meet the criteria to be subject to a FUL, the previous FUL no longer applies.

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Changes in Draft ACA FUL Pricing	A comparison of the draft Affordable Care Act FULs released by the agency in September 2011 to the draft Affordable Care Act FULs released in October 2011 reveals changes and may exemplify the volatile nature of the AMP, and its use as a reimbursement benchmark.	The use of the AMP as a reimbursement benchmark for the FUL is required by Section 2503 of the Affordable Care Act. We expect that the AMP and resultant FUL, based on sales data, will experience fluctuation from month to month based on the changes in drug prices that occur in the market.
Data Matching and Compendia	To the extent that CMS relies on national drug pricing compendia to assign drug products to FUL groups, steps need to be taken to ensure the accuracy of the selected reference's data. For example, an extended release drug should not be grouped with a non-extended release drug.	CMS is aware of discrepancies within some FUL groups, and we are taking steps to identify and resolve these discrepancies.