

**DRAFT AFFORDABLE CARE ACT THREE-MONTH ROLLING AVERAGE
FEDERAL UPPER LIMIT (FUL)
METHODOLOGY AND DATA ELEMENTS GUIDE**

The Affordable Care Act modified the previous statutory provisions that required the Secretary to establish a Federal Upper Limit (FUL) on multiple source drugs. Effective October 1, 2010, the Social Security Act was revised to require that the Secretary calculate a FUL as no less than 175 percent of the weighted average (determined on the basis of manufacturer utilization) of the most recently reported monthly average manufacturer prices (AMP) for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. In order to facilitate this change, the Centers for Medicare & Medicaid Services (CMS) issued draft AMP-based FUL reimbursement files for multiple source drugs, including the draft methodology used to calculate the FULs in accordance with the Affordable Care Act, beginning with the July 2011 data reporting period.

We solicited and received comments on the draft AMP-based FUL files, and in response, we have developed a draft three-month rolling average FUL, consisting of the weighted average of the current and the two previous monthly draft AMP-based FULs. We are posting the draft three-month rolling average FUL file, for review and comment only, beginning with the July 2012 draft file.

We encourage review and comment on all aspects of the draft three-month rolling average FULs, and we note the following two issues. First, we are providing a draft three-month rolling average FUL only where we have three months (current and two previous months) of manufacturer reported and certified data for the applicable multiple source drugs. Therefore, there may not be an exact match, and in some cases a fewer number of drug groups with a draft three-month rolling average FUL, compared to the draft AMP-based FUL. Second, while we expect the draft three-month rolling average FUL to fluctuate to a lesser degree from month-to-month compared to the fluctuations we have observed in the draft monthly AMP-based FUL, the draft three-month rolling average FULs incorporates pricing data older than the current monthly pricing that may be less reflective of pharmacies' current purchase prices.

Draft Affordable Care Act Three-Month Rolling Average FUL Methodology

CMS uses the following data sources to calculate a draft three-month rolling average FUL:

- The Food and Drug Administration (FDA) online databases
- A National Drug Pricing Compendium
- Drug Data Reporting for Medicaid system reported and certified data

The draft three-month rolling average FUL is calculated using the manufacturer reported and certified AMP and AMP unit data for the FUL product groups that have a published monthly draft AMP-based FUL price for the current and previous two months. In cases where there is not a one-to-one match in the FUL product group national drug codes (NDC) over the three-month period, we do not calculate a draft three-month rolling average FUL.

The following methodology is used to calculate the draft three-month rolling average FUL:

1. Calculate the weighted average of the three monthly AMPs (current month and the two previous months) for each NDC in the FUL product group.
2. Then, calculate the weighted average for all of the NDCs in the FUL product group for the three-month period based on the weighted average of each NDC.
3. Multiply the weighted average in # 2 above by 175 percent.

Per our guidelines for the draft AMP-based FUL, at this time, we are not publishing a draft three-month rolling average FUL for the following:

- Any FUL product group that does not contain at least three innovator multiple source drug products (I) and/or non-innovator (N) multiple source drug products at the NDC -9 level, that are therapeutically equivalent, (A-rated) with three monthly AMP prices with AMP units greater than zero reported and certified by manufacturers to calculate the weighted average of monthly AMPs
- Certain inhalation, infusion, instilled, implanted, or injectable drugs (the 5i drugs)
- Any FUL product group that we have identified as not having AMP or AMP unit data that has been reported and certified by the manufacturer
- Any FUL product group where all manufacturers within the FUL group do not report the same unit type

Draft Affordable Care Act Three-Month Rolling Average FUL Data Elements Guide

File: Draft Three-Month Rolling Average FULs - Month/Year

This file includes four worksheets.

Summary – of each draft three-month rolling average FUL product group

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- Draft Monthly AMP-based FUL (two months previous)
- Draft Monthly AMP-based FUL (previous month)
- Draft Monthly AMP-based FUL (current month)
- Draft Three-Month Rolling Average FUL

Extreme Details – listing of NDCs within all FUL Product Groups

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- Medicaid Drug Rebate (MDR) Unit Type
- Three-Month Rolling Average FUL Aberrant Code
- Draft Three-Month Rolling Average FUL
- Package Size
- NDC
- Drug Category -Single source (S), (I) or (N)
- A-rated - Yes or No
- MDR Units per Package Size (UPPS)
- MDR Termination Date

Changes – for each current Draft Three-Month Rolling Average FUL group that had a change from the prior month's Draft Three-Month Rolling Average FUL group

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- MDR Unit Type

- Current month Draft Three-Month Rolling Average FUL
- Previous month Draft Three-Month Rolling Average FUL

Aberrant Codes – reference for Draft Three-Month Rolling Average FUL

- 0 = Draft three-month rolling average FUL was successfully calculated
- 1 = FUL product group was added in the last two months, and thus is new within the three-month period. There must be three monthly periods of data to calculate a draft three-month rolling average FUL.
- 2 = FUL product group was excluded from a FULs price calculation in at least one of the three monthly periods due to there being less than three FDA Orange Book therapeutic equivalents for the product group.
- 3 = FUL product group did not have a draft AMP-based FUL aberrant code zero (0) in all three periods.
- 4 = At least one drug product in the FUL product group was not reported for the two previous months but was reported in the current month and this drug product was neither added to MDR between the previous and current FULs cycles nor did this drug product have a market date in the current month.
- 5 = At least one drug product in the FUL product group was not reported two months ago or in the current month, but was reported last month.
- 6 = At least one drug product in the FUL product group was not reported two months ago but was reported last month and in the current month, and drug product was neither added to MDR between the two previous months nor had a market date for the previous month.
- 7 = At least one drug product in the FUL product group was not reported in the previous month and current month, but was reported two months ago and the drug product was not terminated two months ago.
- 8 = At least one drug product in the FUL product group was not reported in the previous month but was reported two months ago and in the current month.
- 9 = At least one drug product in the FUL product group was not reported in the current month but was reported two months ago and last month and the drug product was not terminated last month.