DRAFT AFFORDABLE CARE ACT FEDERAL UPPER LIMIT (FUL) METHODOLOGY AND DATA ELEMENTS GUIDE TO THE DRAFT FUL FILES

The Affordable Care Act modified the previous statutory provisions that 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 FULs 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). In order to facilitate this change, the Centers for Medicare & Medicaid Services (CMS) is issuing draft FUL reimbursement files (for review and comment only), for multiple source drugs, including the draft methodology used to calculate the FULs in accordance with the Affordable Care Act. These draft FUL prices are based on the most recently reported monthly AMP and AMP unit data. For example, we used the monthly AMP and AMP unit data for covered outpatient drugs that manufacturers reported to CMS for the month of August 2011 to develop the files that we released in October 2011. We are not posting monthly AMPs for individual drugs on any of the draft FUL files. Rather, we are posting the weighted average of monthly AMPs in a FUL group. Further, we note that 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 by such date." Please note that the draft FULs do not apply to B-rated drugs.

Starting with the files that we post to our website in January 2012 (based on the monthly AMP and AMP unit data for covered outpatient drugs that manufacturers reported to CMS starting with the month of October 2011), we changed the information technology system and grouping methodology we use to establish a FUL Product Group and assign national drug codes (NDC) to each of those groups. This has alleviated the need for an Unmatched File.

To begin our implementation of these changes, we are posting to our website the Draft Affordable Care Act FUL Methodology and Data Elements Guide to the Draft FUL files along with the below two draft files of Affordable Care Act FULs.

1. Draft Affordable Care Act FUL File
2. Draft Affordable Care Act FUL Computation File

Draft Affordable Care Act Federal Upper Limit Methodology

CMS used the following data sources to calculate a draft Affordable Care Act FUL:

- The Food and Drug Administration
- A National Drug Pricing Compendium
- Drug Data Reporting for Medicaid (DDR) system

The methodology CMS used for establishing the draft Affordable Care Act FULs is explained below.

- Include all brand, innovator (I) and generic, non-innovator (N) pharmaceutically and therapeutically equivalent ("A" rated) multiple source drugs when calculating the weighted average of monthly AMPs
- Not include formulations of the drug that are not rated by the Food and Drug Administration (FDA) as pharmaceutically and therapeutically equivalent to the reference listed drug, ("A" rated) in the calculation of the FUL, or apply the FUL to those formulations that are not "A" rated, e.g., "B" rated drugs
- Use the manufacturer reported and certified monthly AMPs
- Use the monthly AMP units reported and certified by manufacturers to calculate the weighted average of monthly AMPs in a FUL group
- Require that there be at least three (I) and/or (N) drug products at the NDC-9 level, that are "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
- Establish the FUL at 175 percent of the weighted average of monthly AMPs in the FUL group
- Not use the AMP of a terminated drug
- Establish the FUL as an aggregate upper limit

Initially a FUL will not be published for the following:

- Any FUL group that does not contain at least three (I) and/or (N) drug products at the NDC -9 level, that are "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 5 "I" drugs)
- Any FUL group that we have identified as not having AMP or AMP unit data that has been reported and certified by the manufacturer
- Any FUL group where all manufacturers within the FUL group do not report the same unit type

Affordable Care Act Federal Upper Limit Data Elements Guide
To The Draft FUL Files

FILE #1 - Draft Affordable Care Act FUL Month/Year

This file includes the draft Affordable Care Act (ACA) FUL groups that have a FUL price calculated

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- ACA FUL
- Monthly Weighted Average AMP

FILE #2 - Draft Affordable Care Act Federal Upper Limit Computation Month/Year

Summary – of each draft Affordable Care Act FUL product group (may or may not have a published FUL price – See aberrant code)

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- Aberrant Code
- ACA FUL
- Monthly Weighted Average AMP
- Show Details – links to NDCs in Summary tab

Extreme Details – listing of NDCs to corresponding Summary file

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- Aberrant Code
- Medicaid Drug Rebate (MDR) Unit Type
- ACA FUL
- Package Size
- NDC
- Monthly AMP – Reported (R) or Not Reported (NR)

- AMP Units – Reported (R) or Not Reported (NR)
- Drug Category (Single source (S), innovator-multiple source (I), or noninnovator multiple source (N))
- MDR Therapeutic Equivalency Code (TEC)
- MDR Units per Package Size (UPPS)
- MDR Termination (Term) Date

Changes – for each draft Affordable Care Act FUL group that had a change in the FUL from the prior month

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- MDR Unit Type
- Current ACA FUL
- Prior month ACA FUL

Unit Type Issues – All manufacturers within the draft FUL group are not reporting using the same unit type

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- Aberrant Code
- MDR Unit Type
- ACA FUL
- Package Size
- NDC
- Monthly AMP – R or NR
- AMP Units – R or NR
- Drug Category Code
- MDR TEC
- MDR UPPS
- MDR Term Date

Each Groups – Certain products reported and certified as EACH currently excluded from draft Affordable Care Act FUL calculation

- Product Group
- Ingredient
- Strength
- Dosage

- Route
- Aberrant Code
- MDR Unit Type
- ACA FUL
- Package Size
- NDC
- Monthly AMP – R or NR
- AMP Units – R or NR
- Drug Category Code
- MDR TEC
- MDR UPPS
- MDR Term Date

Inhalation, Infusion, Instilled, Implanted, Or Injectable Drug – (5 "I" Drugs) – Certain products that are considered to be 5 "I" drugs which currently will not have a draft Affordable Care Act FUL

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- Aberrant Code
- MDR Unit Type
- ACA FUL
- Package Size
- NDC
- Monthly AMP – R or NR
- AMP Units – R or NR
- Drug Category Code
- MDR TEC
- MDR UPPS
- MDR Term Date

Non "A" Rated NDCs – each reported and certified NDC that is not therapeutically equivalent

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- Aberrant Code
- MDR Unit Type
- ACA FUL
- Package Size

- NDC
- Monthly AMP – R or NR
- AMP Units – R or NR
- Drug Category Code
- MDR TEC
- MDR UPPS
- MDR Term Date

Not Reported (NR) AMP – within the draft Affordable Care Act FUL group, at least one manufacturer has not reported and certified monthly AMP pricing for their drug product

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- Aberrant Code
- MDR Unit Type
- ACA FUL
- Package Size
- NDC
- Monthly AMP – R or NR
- AMP Units – R or NR
- Drug Category Code
- MDR TEC
- MDR UPPS
- MDR Term Date

Single Source ("S") Drugs – each NDC that is reported and certified by the manufacturer as a single source drug and not included in the calculation of the draft Affordable Care Act FUL

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- Aberrant Code
- MDR Unit Type
- ACA FUL
- Package Size
- NDC
- Monthly AMP – R or NR
- AMP Units – R or NR
- Drug Category Code
- MDR TEC
- MDR UPPS

- MDR Term Date

Bioequivalent Groups – Draft Affordable Care Act FUL groups that are established with an alternative therapeutic equivalence code

- Product Group
- Ingredient
- Strength
- Dosage
- Route
- FDA TEC

Aberrant Codes - Provides a cross walk of the aberrant code and a description of what the code represents

- **0** = all criteria in place to establish a FUL
- **1** = Inconsistent Unit Type – all manufacturers within the FUL group are not reporting using the same unit type.
- **2** = < 3 NDC 9s –less than three suppliers of the drug for this FUL group
- **3** = <3 TEC As – FDA has rated less than three TE formulations for this FUL drug group
- **4** = <3AMPs >0- less than three distinct monthly AMPs greater than zero have been reported and certified by the labeler at the NDC-9 level for this FUL group
- **5** = <3AMP units > 0 –less than three distinct monthly AMP units greater than zero have been reported and certified by the labeler at the NDC-9 level for this FUL group
- **6** = <3NDC-9s, with TEC A and AMP greater than zero and AMP units greater than zero – less than three distinct, FDA rated TE products with monthly AMP and AMP units have been reported and certified by the labeler at the NDC-9 level for this FUL group
- **7** = Unit Type "EA" – certain products reported and certified with a unit type of "EACH" currently excluded from a FUL calculation
- **8** = Route Exceptions – certain products that are generally considered to be inhalation, infusion, instilled, implanted, or injectable drugs (5 "I" drugs) currently excluded from a FUL calculation
- **9** = Not Reported AMP exists – within the FUL drug group, at least one manufacturer has not reported and certified monthly AMP and AMP units for a drug product