INFORMATIONAL LETTER NO.1646

DATE: March 30, 2016

TO: Iowa Medicaid Pharmacies

FROM: Iowa Department of Human Services (DHS), Iowa Medicaid Enterprise (IME)

RE: Updated - Federal Upper Limit (FUL) Pharmacy Reimbursement

EFFECTIVE: May 1, 2016

Informational Letter 1250 dated June 21, 2013, provided information on the FUL Pharmacy reimbursement process through Iowa Medicaid, including the FUL override. This letter is intended to update the FUL information and process, based on the recent release of final federal regulations regarding this program.

1) Rate Setting
   i. The Centers for Medicare and Medicaid Services (CMS) is responsible for establishing the FUL rates.
   ii. Process:
      1. The Affordable Care Act (ACA) revised the FUL rates to be set at no less than 175 percent of the weighted average (determined on the basis of 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.
      2. In the final regulation, CMS finalized an exception to calculating the FUL at this amount, using the methodology found at 42 CFR 447.514(b)(2), as referenced on the Medicaid.gov website Affordable Care Act – Federal Upper Limits.
      3. CMS will establish a FUL for each multiple source drug for which the Food and Drug Administration (FDA) has rated at least three or more drugs therapeutically and pharmaceutically equivalent (A-rated only), regardless of whether all such additional formulations are rated as such.
      4. All covered outpatient drugs with the same ingredient, route, strength, and dosage form are included in a FUL group, which includes both prescription and over-the-counter drugs.
   iii. State Requirement: The federal FUL regulations require states to meet the FULs in the aggregate. In order to assure that Iowa meets the FULs in the

aggregate, Iowa’s federally approved state plan for medical assistance, which is the basis for federal funding of the state program, provides as follows:

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The amount of payment shall be based on several factors, subject to the upper limits in 42 CFR 447.500-520 as amended.

a. Reimbursement for covered prescription and nonprescription drugs shall be the lowest of the following as of the date of dispensing:

(1) “Estimated acquisition cost (EAC),” defined as the average Actual Acquisition Cost (AAC), as determined from surveys of Iowa Medicaid enrolled pharmacies, plus the professional dispensing fee. If no AAC is available, the EAC will be defined as the Wholesale Acquisition Cost (WAC), as published by Medi-Span.

(2) “Federal upper limit (FUL),” defined as the upper limit for multiple source drugs established in accordance with the methodology of the Centers for Medicare and Medicaid Services as described in 42 CFR 447.514, plus the professional dispensing fee.

(3) Submitted charge, representing the provider’s usual and customary charge for the drug.

b. Professional Dispensing Fee: The professional dispensing fee is based on the cost of dispensing survey which must be completed by all medical assistance program participating pharmacies every two years beginning in 2014. For services rendered on or after August 1, 2014, the professional dispensing fee is $11.73.

c. Subject to prior authorization requirements, if a physician certifies in the physician’s handwriting that, in the physician’s medical judgment, a specific brand is medically necessary for the particular recipient, the FUL does not apply and the payment equals the lesser of EAC or submitted charges.

iv. Draft/Final ACA FUL Files:

1. CMS published the initial draft ACA FUL files calculated in accordance with the Medicaid Covered Outpatient Drug final rule with comment (CMS-2345-FC) on the Medicaid.gov website Affordable Care Act – Federal Upper Limits on January 27, 2016, and February 25, 2016.

2. The final ACA FULs will be published in late March 2016 and will be effective on April 1, 2016, to coincide with the effective date of the final rule with comment.
v. Effective Date: States will have up to 30 days from the April 1, 2016, effective date to implement the ACA FULs.

vi. Pre-ACA FULs: Once the final regulation is effective, CMS will remove the FULs that are currently in effect, which were last updated on September 25, 2009.

2) Reimbursement: Pursuant to its federally approved state plan, Iowa Medicaid reimbursement methodology is to pay the lesser of:
   i. Ingredient cost, based on average actual acquisition cost (AAC) (or Wholesale Acquisition Cost (WAC), if AAC is not available), plus professional dispensing fee;
   ii. Any FUL, plus professional dispensing fee; or
   iii. Usual & Customary (U&C) charge.
With an exception from FUL for specific brands certified as medically necessary.

3) Update:
   i. Effective for claims with dates of service May 1, 2016, and thereafter, the Iowa Medicaid FUL override process will be terminated with the implementation of the ACA FULs, as indicated in the Informational Letter 12501.
   ii. Iowa Medicaid will continue to evaluate the ACA FULs as files become available and rates become final.

4) Pharmacy Reimbursement Contact Information:
   i. Concerns regarding specific ACA FUL rates should be directed to CMS by email at FUL@cms.hhs.gov.
   ii. For pharmacy reimbursement concerns other than ACA FUL rates contact:

   Myers and Stauffer LC-Pharmacy Unit
   9265 Counselors Row, Suite 100
   Indianapolis, IN 46240
   Phone: 800-591-1183
   Fax: 317-571-8481
   Email: pharmacy@mslc.com
   Website: http://www.mslc.com/Iowa