Office of the Registrar of Regulations,
Legislative Council,
State of Delaware

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)

ERRATA

ORDER

Pharmaceutical Services Reimbursement – 340B Drug Products
Title XIX Medicaid State Plan, Attachment 4.19-B Page 14

*** Please Note**: The submitted final regulation published in the February 1, 2016, Volume 19, Issue 8, of the Delaware *Register* by Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance (DMMA) amending the Delaware Title XIX Medicaid State Plan regarding Pharmaceutical Services, specifically, *to clarify reimbursement methodology for entities that purchase 340B drug product* erroneously contained language that was inadvertently added to the proposed regulation, published in the November 2015 *Register* (Volume 19, Issue 5).

This errata removes the inadvertently added language from the final regulation. This is a typographical error and therefore not a substantive change. For the current version of the Pharmaceutical Service Reimbursement – 340B Drug Products regulation, see http://regulations.delaware.gov/register/february2016/final/19%20DE%20Reg%20748%2002-01-16.pdf.

The effective date for the final order regulation appearing in the February *Register* remains the same, February 11, 2016. The effective date for the errata below is March 11, 2016.

FINDINGS OF FACT:

The Department finds that the errata to the final regulation regarding Pharmaceutical Services 340B exclusions is being corrected to remove a word that was inadvertently added to two (2) lines of the final regulation.

THEREFORE, IT IS ORDERED, that the errata to the final regulation amending the Delaware Title XIX Medicaid State Plan regarding Pharmaceutical Services, specifically, *to clarify reimbursement methodology for entities that purchase 340B drug products*, is corrected and shall be effective March 11, 2016.

Rita M. Landgraf, Secretary, DHSS
February 16, 2016

DMMA FINAL REGULATION #16-001
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STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES – OTHER TYPES OF CARE

REIMBURSEMENT FOR PHARMACEUTICALS

Overview
The Delaware Medical Assistance Program (DMAP) will reimburse pharmaceuticals using the lower of:

- The usual and customary (U & C) charge to the general public for the product,
- National Average Drug Acquisition Cost (NADAC) or if a NADAC is not available the Average Wholesale Price (AWP) minus 19%,
- A State-specific maximum allowable cost (DMAC) when the purchase price is not appropriately represented by either the NADAC or the Average Wholesale Price (AWP) minus 19%,
- The Federal Upper Limit (FUL) will not be used since the NADAC reflects the actual acquisition cost.

[~~Contracted e~~E]ntities that qualify for special purchasing under Section 602 of the Veterans Health Care Act of 1992 and entities exempt from the Robinson-Patman Price Discrimination Act of 1936 must charge the DMAP no more than their actual acquisition cost (AAC) plus a professional dispensing fee. The AAC must be supported by invoice and payment

documentation.

[~~Contracted~~ ~~e~~E]ntities that purchase Section 340B of the Public Health Service Act products are prohibited from using their stock for DMAP patients either directly or through coverage of the Managed Care Organization.

Professional Dispensing Fee
The professional dispensing fee rate is ten dollars ($10.00). There is one-time professional fee per thirty (30)-day period unless the class of drugs is routinely prescribed for a limited number of days.

Definitions
Delaware Maximum Allowable Cost (DMAC) - a maximum price set for reimbursement:

- when a single source product has Average Selling Prices provided by the manufacturer that indicates the AWP is exaggerated, or
- when the NADAC does not reflect the most current cost of a multiple source drug, or
- if a single provider agrees to a special price.

Any willing provider can dispense the product.

19 DE Reg. 800 (03/01/16) (Errata)