



STATE OF DELAWARE  
**STATE COUNCIL FOR PERSONS WITH DISABILITIES**  
MARGARET M. O'NEILL BUILDING  
410 FEDERAL STREET, SUITE 1  
DOVER, DE 19901

VOICE: (302) 739-3620  
TTY/TDD: (302) 739-3699  
FAX: (302) 739-6704

**MEMORANDUM**

DATE: November 24, 2015

TO: Mr. Glyne Williams  
Planning, Policy and Quality Unit

FROM: Ms. Daniese McMullin-Powell, Chairperson  
State Council for Persons with Disabilities

RE: 19 DE Reg. 369 (DMMA Proposed Medicaid Outpatient Drug Reimbursement Regulation)

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health and Social Services/Division of Medicaid and Medical Assistance's (DMMAs) proposal to adopt some discrete changes to its reimbursement standards for prescription drugs. The proposed regulation was published as 19 DE Reg. 369 in the November 1, 2015 issue of the Register of Regulations. SCPD has the following observations.

As background, federal law authorizes states to negotiate rebate agreements with drug manufacturers. Federal law (340B program) also requires drug manufacturers to enter into agreements with HRSA to provide discounts on drugs to covered entities. The interplay of these laws is complicated. However, State Medicaid agencies must exclude from State rebate requests drugs that have already by discounted under the 340B program:

State Medicaid agencies should exclude claims for 340B purchased drugs (340B claims) from Medicaid rebate requests to prevent subjecting drug manufacturers to duplicate discounts (i.e. selling 340B-purchased drugs to covered entities at the discounted ceiling prices and providing Medicaid rebates on the same drugs).

In practice, drug manufacturers are contesting State rebate requests based on their perception that the drugs have already been discounted under the 340B program. DMMA recites as follows:

Drug manufacturers use the potential for a 340B discounted price to dispute rebate payments.

DMMA has determined that its providers do not generally use 340B discounted drugs for Medicaid patients:

To date, with few exceptions, every contracted entity listed on the 340B participating providers' file has responded in writing that they do not use these products for Delaware Medicaid patients.

To obviate drug manufacturer argument, DMMA is amending the State Plan to categorically bar providers from using 340B discounted drugs for Medicaid patients:

Entities that purchase Section 340B of the Public Health Services products are prohibited from using their stock for DMAP patients either directly or through coverage of the Managed Care Organization.

SCPD endorses the proposed regulation since the proposed regulation should remove an impediment to drug manufacturer rebate payments to the State.

Thank you for your consideration and please contact SCPD if you have any questions or comments regarding our observations or position on the proposed regulation.

cc: Mr. Stephen Groff  
Mr. Brian Hartman, Esq.  
Governor's Advisory Council for Exceptional Citizens  
Developmental Disabilities Council

19reg369 dmma-medicare outpatient drug reimbursement 11-25-15