

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAID AND MEDICAL ASSISTANCE
Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)

FINAL

ORDER

Pharmacy Value Based Purchasing (VBP)

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance initiated proceedings to amend Title XIX Medicaid State Plan regarding Pharmacy Value Based Purchasing (VBP), specifically, to participate in the Pharmacy Value Based Purchasing Program. The Department's proceedings to amend its regulations were initiated pursuant to 29 **Del.C.** §10114 and its authority as prescribed by 31 **Del.C.** §512.

The Department published its notice of proposed regulation changes pursuant to 29 **Del. C.** §10115 in the October 2023 *Delaware Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by October 31, 2023, at which time the Department would receive information, factual evidence, and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSAL

The purpose of this proposed regulation is to advise the public that Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) is proposing to amend Title XIX Medicaid State Plan regarding Pharmacy Value Based Purchasing (VBP).

Background

CMS has implemented Value Based Purchasing that has manufacturers reporting to the agency multiple best prices for a drug that is connected to a VBP arrangement (as defined at 42 CFR 447.502) and is made available to all states. The VBP arrangements will hold manufacturers more accountable for the clinical outcomes of their medications, while giving states the opportunity to earn additional rebates depending on how a drug works for patients. Delaware currently does not have a SPA that will allow participation in the VBP process.

Statutory Authority

42 CFR 447.502

Purpose

The purpose of this proposed regulation is to add language to the state Medicaid plan allowing Delaware to participate in the Pharmacy Value Based Purchasing program.

Summary of Proposed Changes

Effective October 1, 2023, the DHSS/DMMA proposes to amend Title XIX Medicaid State Plan to allow Pharmacy Value Based Purchasing.

Public Notice

In accordance with the *federal* public notice requirements established at Section 1902(a)(13)(A) of the Social Security Act and 42 CFR 440.386 and the *state* public notice requirements of Title 29, Chapter 101 of the **Delaware Code**, DHSS/DMMA gave public notice and provided an open comment period for 30 days to allow all stakeholders an opportunity to provide input on the proposed regulation. Comments were to have been received by 4:30 p.m. on October 31, 2023.

Centers for Medicare and Medicaid Services Review and Approval

The provisions of this state plan amendment (SPA) are subject to approval by the Centers for Medicare and Medicaid Services (CMS). The draft SPA page(s) may undergo further revisions before and after submittal to CMS based upon public comment and/or CMS feedback. The final version may be subject to significant change.

Provider Manuals and Communications Update

Also, there may be additional provider manuals that may require updates as a result of these changes. The applicable Delaware Medical Assistance Program (DMAP) Provider Policy Specific Manuals and/or Delaware Medical Assistance Portal will be updated. Manual updates, revised pages or additions to the provider manual are issued, as required, for new

policy, policy clarification, and/or revisions to the DMAP program. Provider billing guidelines or instructions to incorporate any new requirement may also be issued. A newsletter system is utilized to distribute new or revised manual material and to provide any other pertinent information regarding DMAP updates. DMAP updates are available on the Delaware Medical Assistance Portal website: <https://medicaid.dhss.delaware.gov/provider>

Fiscal Impact Statement

Projected impact is not available at this time. There is currently only one VBP offer available in the CMS MDRP Portal at the present and Delaware does not have plans to accept this offer at the present.

Summary of Comments Received with Agency Response and Explanation of Changes

Comment: There were comments supporting the proposed changes.

Agency response: DMMA appreciates the support.

DMMA is pleased to provide the opportunity to receive public comments and greatly appreciates the thoughtful input given by:

- State Council for Persons with Disabilities (SCPD)
- Governor's Advisory Council for Exceptional Citizens (GACEC)

FINDINGS OF FACT:

The Department has decided to finalize only the proposed changes set forth in Attachment 3.1-A, Page 5 Addendum, Continued 2, as set forth in the October 2023 Register of Regulations. The change set forth in Attachment 3.1-A, Page 5 Addendum, Continued 1, is not being finalized.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend Title XIX Medicaid State Plan regarding Pharmacy Value Based Purchasing (VBP), specifically, to participate in the Pharmacy Value Based Purchasing Program and shall be final effective December 11, 2023.

11/15/2023 | 5:53 PM EST

Date of Signature

Josette D. Manning Esq., Secretary, DHSS

Pharmacy Value Based Purchasing (VBP)

***Please Note: Due to the formatting requirements of the regulation, it is being attached here as a PDF document:**
[http://regulations.delaware.gov/register/december2023/proposed/Attachment 3.1-A page 5 Addendum 2 Amended.pdf](http://regulations.delaware.gov/register/december2023/proposed/Attachment_3.1-A_page_5_Addendum_2_Amended.pdf)

27 DE Reg. 430 (12/01/23) (Final)