***CONFIDENTIAL***

# LEGISLATIVE BILL REVIEW FORM: 2016

**Bill Number:**_____**S.216**_____ **Name of Bill:**___**An act relating to prescription drug formularies**____

**Agency/ Dept:**_____**AHS/DVHA**_____ **Author of Bill Review:**____**Susan Coburn, Addie Strumolo, Lindsay Parker**___

**Date of Bill Review:**__**5/11/2016**__ **Related Bills and Key Players** _____

**Status of Bill: (check one):** _____**Upon Introduction** _____ **As passed by 1st body** _**X**_**As passed by both**

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**Recommended Position:**

_____**Support** _____**Oppose** __**X**_**Remain Neutral** _____**Support with modifications identified in #8 below**

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## Analysis of Bill

1. **Summary of bill and issue it addresses.** *Describe what the bill is intended to accomplish and why.*

   S.216, as passed by the Senate and House, intends to create transparency of prescription drug costs and formularies from all insurers.

   The following provisions proposed in S.216 impact the Department of Vermont Health Access (DVHA):

   - **Section 2 – Pharmaceutical Cost Transparency.** GMCB, in collaboration with DVHA, shall identify 15 prescription drugs that represent high spend drugs for the State. GMCB must provide this list of drugs to the Office of the Attorney General.

     For each prescription drug on this list, the Office of the Attorney General must require that drug manufacturers provide information and supporting documentation needed to justify any increases in wholesale acquisition costs. By December 1 each year, the Attorney General, in consultation with DVHA, will report to the General Assembly on the information received from manufacturers.

   - **Section 3 – Prescription Drug Formularies; Rulemaking**. Directs the Commissioner of the Department of Financial Regulation to adopt administrative rules, by January 1, 2017, to require insurance issuers, which offer plans through the exchange, to provide information about prescription drug formularies available to enrollees, potential enrollees and health care providers. Rules require that the formulary is posted online in a standard format, updated "frequently" and includes drugs covered, cost sharing amounts, drug tiers, prior authorization, step therapy and utilization management.

   - **Section 4 – 340B Drug Dispensing Fees.** Requires DVHA to change 340B dispensing fees from $15 to $4.75. This change in dispensing fees will not apply to FQHCs or Planned Parenthood.

- **Section 5 – 340B Drug Reimbursement; Report.** Requires DVHA to report to the designated legislative committees (HHC, SHW, SFC) by March 15, 2017 on findings and recommendations related to:
    - Formula used by other states' Medicaid programs to reimburse covered entities that use 340B pricing for dispensing prescription drugs to Medicaid beneficiaries;
    - Advantages and disadvantages of using the same dispensing fee in VT Medicaid's reimbursement formula for 340B prescription drugs as DVHA uses to pay for non-340B prescription drugs under the Medicaid program; and
    - Benefits of 340B drug pricing to consumers, other payers, and the overall health care system.

- **Section 6 – Out-of-Pocket Prescription Drug Limits; 2018 Pilot Reports.** Addresses but does not amend prescription drug out of pocket limit ("Rx MOOP") established in 8 V.S.A. § 4089i, by

Advisory Group (a)-(c)

- Establishing an advisory group to develop options for bronze-level qualified health benefit plans (QHPs) to be offered on the Vermont Health Benefit Exchange for the 2018 plan year, including one or more bronze QHP that exceeds the statutory Rx MOOP and two or more that meet it.
- Requiring DVHA to present the advisory group's recommendations to the GMCB when establishing standard QHP designs for 2018.

QHP certification (d)

- Requiring QHP issuers to seek GMCB approval to modify the statutory Rx MOOP for one or more non-standard bronze-level QHPs.
- Allowing GMCB to approve modifications to the statutory Rx MOOP for the 2018 plan year only.
- Requiring DVHA to certify at least two standard bronze QHPs that meet the statutory Rx MOOP for the 2018 plan year as long as they are federally compliant.
- Allowing DVHA to certify one or more bronze QHPs with modified Rx MOOPs for the 2018 plan year only.

Re-enrollment (e)

- Requiring issuers to renew 2016 and 2017 bronze QHP enrollees who met the Rx MOOP in 2016 into a bronze plan with the statutory Rx MOOP for 2018, and to notice such enrollees about the availability of bronze plans with a modified Rx MOOP prior to reenrollment.

ACA Waiver Study (f)

- Directing the Director of Health Care Reform (AOA) to determine whether HHS could waive bronze AV requirements/MOOP under the ACA, and to present findings and waiver considerations to the Health Reform Oversight Committee by Oct 1, 2016.
- If AOA has found that HHS has the authority, directing DVHA to apply for such a waiver to preserve the availability of bronze QHPs that meet the statutory Rx MOOP by March 1, 2017.

Reports (g)-(h)

- Requiring DVHA to report to legislative committees (HHC, SHW, SFC) by February 15, 2017 on 2014-2017 bronze cost share trends, 2018 bronze cost share amounts (lowered due to modified Rx MOOP), comparison of bronze QHPs, information about the advisory group's process and information considered in Rx MOOP modification bronze cost share information from FFM states compared to VHC bronze QHPs, and VHC outreach and education plan for bronze QHP enrollees.
- Requiring DVHA to report to legislative committees (HHC, SHW, SFC) by February 1, 2018 on bronze enrollment trends and advisory group recommendations regarding the continuation of Rx MOOP at 8 V.S.A. § 4089i.

- **Section 7 -** Bill shall take effect on passage.

**2. Is there a need for this bill?** *Please explain why or why not.*

**Sections 2, 4 & 5**

No. Legislation is not needed for DVHA to collaborate with GMCB and the Office of the Attorney General on prescription drug costs and spend. Nor is legislation needed for DVHA to change drug dispensing fees or to study the 340B program, potential modifications to the program, and impacts to VT Medicaid.

**Section 3 – DFR Rulemaking re: Prescription Drug Formularies**

No. Formulary transparency standards already exist for issuers of qualified health plans (QHPs) offered through Vermont Health Connect.[1] Under federal rules, QHPs must:

- Submit formulary drug list to the Exchange or the State
- Publish an up-to-date, accurate, and complete list of all covered drugs on its formulary drug list, including any tiering structure that it has adopted and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the State, the Exchange, HHS, the U.S. Office of Personnel Management, and the general public. A formulary drug list is easily accessible when:
    - It can be viewed on the plan's public Web site through a clearly identifiable link or tab without requiring an individual to create or access an account or enter a policy number; and
    - If an issuer offers more than one plan, when an individual can easily discern which formulary drug list applies to which plan.

An exchange will then post QHP formularies on its website. Vermont Health Connect does so by linking to the formularies so that enrollees access information that the issuer is responsible for updating continually.

S.216 would require Department of Financial Regulation (DFR) to adopt additional rules around formulary transparency for QHPs, including a standard format for online posting and the inclusion of information related to prior authorization, step therapy, and utilization management requirements. The rest of the requirements in the bill are duplicative of the federal regulations.

**Section 6 – Out of Pocket Prescription Drug Limits**

Yes. Introducing flexibility into the establishment of out of pocket maximums for prescription drugs (Rx MOOP) in the individual and small groups markets will allow VHC to offer QHPs that better suit customer needs. While it is an important consumer protection, the combination of the statutory Rx MOOP with ACA AV requirements has had unintended consequences affecting QHPs. These consequences include higher cost-share required in other service categories to compensate for the Rx MOOP cap, increased utilization of non-generic prescriptions once the Rx MOOP is met, even reports of Medicare-eligible QHP enrollees remaining on QHPs rather than enrolling in a Medicare Part D plan (and possibly being subject to a Medicare penalty). This issue has come up repeatedly during the GMCB's QHP design approval process, and addressing this provision could benefit the state and other stakeholders including enrollees in Vermont QHPs.

[1] 45 CFR 156.122

**3. What are likely to be the fiscal and programmatic implications of this bill for this Department?**

**Section 2**
DVHA anticipates allocating staff time to consulting with GMCB and the Office of the Attorney General on the report mandated in this section. This represents new work for DVHA; the Department hopes it will be reasonably limited in scope with GMCB and the Attorney General as leads on the report.

**Section 3**
DVHA will work closely with DFR to coordinate any changes to formulary posting requirements so that it can continue to provide direct access to the issuer's formulary information through links on the VHC website. DVHA will also need to make sure related requirements in its QHP certification administrative rule remain consistent with any DFR rules on this topic.

**Sections 4 & 5**
Changing the dispensing fees for 340B drugs from $15 to $4.75 will be a substantial administrative lift for DVHA; it will require DVHA staff time and resources.

As shared with the legislature, DVHA is concerned with the mandated change to dispensing fees for two reasons: 1) Timing – there is a federal regulation that will force VT Medicaid to change dispensing fees by 2017, and 2) Risk of entities carving out – projected cost savings for DVHA at risk if entities carve out of 340B program, and its unknown what entities will do.

- Not good timing for legislative mandate because there is a new federal regulation (CMS-2345-FC) for outpatient drugs that requires states to review pharmacy reimbursement methodologies. With implementation of this federal regulation VT Medicaid expects to move to actual acquisition cost (AAC) for all pharmacies and will likely need to adjust drug dispensing fees (perhaps up to $12 for all drugs). This federally mandated change will happen by April 2017, regardless of this new state directive.

- Any anticipated cost savings resulting from lowering the 340B dispensing fee comes with the disclaimer that it is difficult to predict how many covered entities may carve out of the 340B program. Depending on if, and how many, entities carved out of the program, DVHA may not realize the cost savings estimated or may see costs lost. DVHA estimates that there is on average 2-3% net cost savings with the 340B program. For context, DVHA only spent $7 million in the 340B program, compared to 200 million pharmacy budget.

As a result of the new federal regulation, States (including Vermont) must submit state plan amendments to CMS with an effective date of April 2017. Implementation of the federal regulations by other state Medicaid programs will impact recommendations that DVHA makes in the requested legislative report.

**Section 6**
Although this section includes programmatic requirements for DVHA related to QHP plan design, approval, and certification, much of this work will fit into DVHA's existing annual plan management cycle and not require additional resources, with the following exceptions:

A QHP advisory group is already in existence; however, it will need to be expanded to include all the members required under this legislation and to convene at least six times prior to submission of plan designs for GMCB approval. DVHA plan management staff will need to support this process and likely host the meetings.

The waiver study and application in section (f) and required reports in sections (g) and (h) are new and will require additional staff time. DVHA will need to expand the scope of the contract with its actuarial vendor to support these.

4. **What might be the fiscal and programmatic implications of this bill for other departments in state government, and what is likely to be their perspective on it?**

DFR is tasked with rulemaking for prescription drug formularies under Section 3. DFR will also review and approve the forms for QHPs with modified Rx MOOP under Section 6.

GMCB is tasked with leading report on pharmaceutical drug costs. GMCB will work in collaboration with DVHA and the Office of the Attorney General. GMCB will also review and approve the QHP plan designs featuring modified Rx MOOP under Section 6.

AOA is tasked with directing the ACA waiver study in Section 6, in consultation with DHVA and Leg Council.

5. **What might be the fiscal and programmatic implications of this bill for others, and what is likely to be their perspective on it?** (f*or example, public, municipalities, organizations, business, regulated entities, etc)*

QHP issuers may oppose Section 3 (formulary transparency rules) because of the increased regulatory burden and duplication with federal requirements.

QHP issuers will support Section 6 (flexibility around the statutory Rx MOOP) because they will be able to offer different bronze QHP designs for 2018. QHP issuers will have to support the 2018 reenrollment parameters established in Section 6 (e) by noticing those bronze QHP enrollees who met the Rx MOOP in 2016. QHP issuers as well as other stakeholders were involved in the development of this legislation with AOA.

6. **Other Stakeholders:**

**6.1 Who else is likely to support the proposal and why?**

Beneficiaries of QHPs with high out-of-pocket costs for prescription medications will likely support Section 3 (single prescription drug formularies) and appreciate how the transparency of information informs their decisions as health care consumers. Beneficiaries may save money by not choosing to have a prescription filled because of high out of pocket costs. They may also request a different medication with lower out of pocket costs from their physician.

Providers will likely support the proposal outlined in Section 3 (single prescription drug formularies) as it will allow them to take cost sharing into account proactively, rather than having to re-prescribe

following a beneficiary trying to pick up a costly script at a pharmacy and calling back for another prescription.

**6.2 Who else is likely to oppose the proposal and why?**

Insurers and pharmacy benefit managers may not support the changes proposed in Sections 3 (single prescription drug formularies) because the changes to publicly shared information may pose substantial administrative cost and burden.

7. **Rationale for recommendation:** *Justify recommendation stated above.*

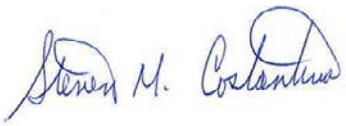
DVHA remains neutral on this bill. Mandated legislative reports require additional staff time and resources.

8. **Specific modifications that would be needed to recommend support of this bill***: Not meant to rewrite bill, but rather, an opportunity to identify simple modifications that would change recommended position.*

None.

9. **Will this bill create a new board or commission AND/OR add or remove appointees to an existing one? If so, which one and how many?**

No.

***Secretary/Commissioner has reviewed this document: _***  ***__ Date: 5/12/16_____***

*Please return this bill review as a Microsoft Word document to Jahala.Dudley@vermont.gov & Jessica.Mishaan@vermont.gov*