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

Date of Bill Review: 4/4/2016 **Related Bills and Key Players** _____

Status of Bill: (check one): _____Upon Introduction __X__ As passed by 1st body _____As passed by both

Recommended Position:

_____Support _____Oppose __X_Remain Neutral _____Support with modifications identified in #8 below

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 the Senate, intends to create transparency of prescription drug formularies from all insurers.

   Section 1 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 2 requires the Department of Vermont Health Access (DVHA) to use the same dispensing fees for 340B drugs as used to pay for non-340B prescription drugs under Medicaid. Effective upon passage of bill.

   Section 3 requires DVHA to determine the formula used by other state Medicaid programs that use 340B pricing for dispensing prescription drugs, and to submit a report of findings, financial implications, and any recommendations for modifications to Vermont's 340B reimbursement to the House Committee on Health Care and Senate Committee on Health and Welfare by January 15, 2017.

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

   Medicaid

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Legislation is not needed for Medicaid to use the same dispensing fees for 340B drugs or to conduct a report on the topic.
Effective July 1, 2009, the approved Medicaid state plan dispensing fee is $4.75 for Vermont pharmacies. A state plan amendment or rule changes are not needed for this legislation.

Medicaid is not listed as an insurer in the bill as passed the Senate for the purpose of Section 1(g) for prescription drug formularies.

Medicaid drug formularies are made publically available:

- http://dvha.vermont.gov/for-providers/smacweblist-20160115.pdf
- http://ovha.vermont.gov/for-providers/preferred-drug-list-clinical-criteria

Medicaid cost sharing is as follows:

Medicaid Cost share (if no Medicare Part D coverage)	**Prescription usual and customary charge**
$1	<$30
$2	$30-$50
$3	>$50

Qualified Health Plans

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, 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.

[1] 45 CFR 156.122

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

Section 1

Medicaid

The bill does not include Vermont Medicaid as an insurer for noticing formulary.

If it is included DVHA does not currently have a way for beneficiaries to determine the cost share they would pay for a medication based on the usual and customary charge. There would be administrative costs involved with stratifying the cost sharing.

Medicaid cost sharing is nominal with a maximum of $3 prescription co-payment, if no Medicare Part D coverage.

Qualified Health Plans

If enacted, DVHA would want to 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. It would also need to make sure related requirements in its QHP certification administrative rule remain consistent with any DFR rules on this topic.

Section 2

The dispensing fee for non-340B drugs is $4.75 and for 340B is $15.

There is the potential for savings associated with lowering the dispensing fee to $4.75 for all drugs.

The potential annual cost savings based on CY2015 claims are:

$358,966 gross
$161,427 state
$197,539 federal

There is no requirement for facilities to participate in the 340B program. Facilities could choose to opt out of the 340B rebate program. Facilities opting out of the 340B rebate program would lower the potential cost savings for DVHA because DVHA would see a decrease in savings on the net cost of the drug (including dispensing fee). DVHA will not get the better drug pricing that's associated with 340B discounts. DVHA would not have to pay the $15 dispensing fee, but for some drugs, DVHA's net cost for drugs is higher than the 340B net cost.

The shared savings is equal to 10% of the fee or up to $3 per claim. Most are paid at $3 per claim plus the dispensing fee.

CY 2015	Current Process ($15, or $30 for compounded drugs)	$4.75 Dispensing Fee	POTENTIAL SAVINGS with $4.75 Dispensing Fee

Total # Claims	32130	32130	
Total Amount Paid	$ 7,506,908.97	$ 7,506,908.97	
Enhanced Dispensing Fee	$ 511,584.00	$ 152,617.50	**$ 358,966.50**
340B Cost of those Claims	$ 3,754,223.30	$ 3,754,223.30	

The administration of 340B is complex and utilizes a full-time staff person at HP.

Section 3
Gathering information and preparing a reimbursement report requires DVHA staff time and resources. CMS Rule 2345 for covered outpatient drugs requires states to review pharmacy reimbursement methodologies and may change how states operate. States (including Vermont) must submit state plan amendments to CMS for an effective date of April 2017. Implementation of these regulations by other state Medicaid programs will impact recommendations that DVHA makes in the report requested by the legislature. DVHA recommends that the submission date for the report be changed to July 1, 2017 to allow for analysis and review of other state practices.

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.

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

If the dispensing fee is lowered, it is unknown if hospitals and FQHCs would choose to opt out of the program.

The 340B dispensing fee change would not apply to Planned Parenthood. They are not paid a dispensing fee and are paid a higher rate of shared savings. Their perspective is unknown.

6. **Other Stakeholders:**

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

For qualified health plans, beneficiaries with high out-of-pocket costs for prescription medications will appreciate the transparency. They 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, 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 these changes because the changes may pose substantial administrative cost and burden.

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

   DVHA is neutral on this bill. Changing the dispensing fee, as proposed in this bill, represents potential for cost savings for VT Medicaid. However, implementing a change to dispensing fees, and researching and writing a report to the legislature regarding dispensing fees 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.*

   DVHA proposes the following modification to the bill:
   - Sec 3. Change the reporting date to July 1, 2017 to allow for review of other state's implementation of federal regulations under CMS 2345 for covered outpatient drugs.

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:*** 4/15/16

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