S.92: Section by section summary as amended by House Health Care

An act relating to prescription drug price transparency and cost containment

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Sec. 1. 18 V.S.A. § 4601 - Adds to definitions for chapter on prescription drug cost containment

- Adds new definitions and renumbers others
  - "Biological product" - uses definition from federal law, 42 U.S.C. § 262
  - "Interchangeable biological product" - means a biological product that the FDA has either licensed and found to be interchangeable with the reference product or has determined to be therapeutically equivalent in the latest FDA listing of generic drugs (which includes a few older biologics)
  - "Proper name" - the non-proprietary name of a biological product
  - "Reference product" - the biological product against which the interchangeable biological product was evaluated to determine its interchangeability

Sec. 2. 18 V.S.A. § 4605 - Substitution of interchangeable biological product

- Directs a pharmacist who receives a prescription for a biological product to select the lowest price interchangeable biological product, as is current law for prescription drugs and generics, ***unless***:
  - the prescriber instructs otherwise, or
  - the purchaser instructs otherwise and agrees to pay any additional cost
- Specifies that the requirements to substitute generic drugs and interchangeable biologics do not apply to Medicaid beneficiaries - the pharmacist must select the preferred brand-name or generic drug or biological product on DVHA's preferred drug list
- For interchangeable biological products, requires the pharmacist to notify the prescriber electronically within five business days about the specific biological product dispensed, including the product name and manufacturer
  - If a pharmacy is not capable of doing electronic notification, the pharmacist must communicate with prescriber by phone, fax, e-mail, etc.
  - If a prescription comes in to a pharmacy by means other than electronic prescribing, the pharmacist will notify the prescriber electronically unless the prescriber requests otherwise on the prescription
  - No requirement for the pharmacist to communicate information about the biological product dispensed if:
    - there is no FDA-approved interchangeable biological product for the prescribed biological product, or
    - the pharmacist is dispensing a refill and the product dispensed is the same product as was dispensed at the prior filling
- Requires the Board of Pharmacy to have a link on its website to the current lists of all FDA-approved interchangeable biological products

Sec. 3. 18 V.S.A. § 4606 - Dispense as written

- As currently applies to prescription drugs, the bill requires a pharmacist to dispense the biological product named in the prescription if the prescriber indicates "dispense as written" or similar language on the prescription
- Expands the scope of prescriptions on which a prescriber can indicate "dispense as written" or similar language to include electronic prescriptions

Sec. 4. 18 V.S.A. § 4607 - Information; labeling

- Adds biological products and interchangeable biological products, as applicable, to requirements for pharmacies to post information about the generic substitution law and to label prescription containers appropriately

Sec. 5. 18 V.S.A. § 4608 - Liability

- Adds interchangeable biological products to language specifying that a pharmacist's role in substituting a drug or product does not constitute the practice of medicine

Sec. 6. 8 V.S.A. § 4089i - Health insurance coverage

- Requires health insurance plans to apply the same cost-sharing requirements to interchangeable biological products as apply to generic drugs under the plan

Secs. 7-8. 8 V.S.A. § 4602 and 18 V.S.A. § 4636 - Health insurance plan reporting on prescription drugs

- Sec. 7 requires health insurers, as part of their premium rate filings, to report to the Green Mountain Care Board (GMCB):
  - for all covered prescription drugs dispensed for outpatient use:
    - percentage of premium rate attributable to prescription drugs for prior year for generic, brand-name (other than specialty) and specialty drugs
    - year-over-year change in per-member, per-month total health care spending for each category of prescription drugs
    - year-over-year change in per-member, per-month costs for prescription drugs compared to other components of the premium rate
  - their specialty tier formulary list
  - if available, the percentage of the premium rate attributable to prescription drugs administered in an outpatient health care setting that are part of medical benefit (instead of the prescription drug benefit)
  - their use of a pharmacy benefit manager, if any
- Sec. 8:
  - all insurers with more than 200 covered lives must report to the GMCB, for all covered prescription drugs provided in outpatient setting or sold in retail setting:
    - 25 most frequently prescribed drugs and average wholesale price (AWP) for each
    - 25 most costly drugs by total plan spending and AWP for each
    - 25 drugs with highest year-over-year price increases and AWP for each
  - GMCB must compile information into consumer-friendly report demonstrating overall impact of drug costs on health insurance premiums

- data must be aggregated and not reveal information as specific to a particular plan
- GMCB must publish the report on its website annually by January 1

Sec. 9. 18 V.S.A. § 4635 - Prescription drug price transparency

- Expands provisions of prescription drug price transparency law passed in 2016
- Requires DVHA to create an annual list of 10 drugs for which the *wholesale acquisition cost* (WAC) has increased by 50% or more over the past 5 years or 15% or more over the past calendar year
    - must include at least one generic and one brand-name drug
    - must show percentage of WAC increase for each drug on the list
    - must be ranked from largest to smallest WAC increase
    - must indicate whether each drug is on the list because of its 5-year cost increase or its one-year cost increase, or both
    - must include DVHA's total expenditure on each listed drug during past year
- Requires DVHA to create an annual list of 10 drugs for which DVHA's *net cost* after rebates has increased by 50% or more over the past 5 years or 15% or more over the past calendar year
    - must include at least one generic and one brand-name drug
    - must be ranked from largest to smallest net cost increase
    - must indicate whether each drug is on the list because of its 5-year cost increase or its one-year cost increase, or both
- Requires health insurers with more than 5,000 covered lives to create an annual list of 10 drugs for which their *net cost* after rebates has increased by 50% or more over the past 5 years or 15% or more over the past calendar year
    - must include at least one generic and one brand-name drug
    - must be ranked from largest to smallest net cost increase
    - must indicate whether each drug is on the list because of its 5-year cost increase or its one-year cost increase, or both
    - must include the insurer's total expenditure for each drug on the list during the past calendar year
- DVHA and the health insurers must provide the lists to the Attorney General's Office (AGO) and GMCB annually by June 1; AGO and GMCB must post on their websites
- Of the drugs listed by DVHA and the insurers based on net cost increases, the AGO must identify 15 drugs as follows:
    - of drugs appearing on more than one list, the top 15 drugs on which the most money was paid across all payers during the previous calendar year
    - if there are fewer than 15 drugs in the first group, then the drugs on which any payer paid the most during the previous calendar year until reach 15 drugs total
- For the 15 drugs on the AGO's list, the AGO must require the manufacturer to provide a justification for the price increase(s) over the specific period
- The manufacturer must also provide a separate version of the justification that will be made public on AGO's and GMCB's websites
    - if the manufacturer needs to redact information as proprietary or confidential, must explain each redaction to the AGO; subject to AGO approval

Sec. 10. 18 V.S.A. § 4637 - Notice of new high-cost drugs

- Requires prescription drug manufacturers to notify AGO in writing if introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold for specialty drugs under Medicare Part D ($670 in 2017)
- Within 30 days after notification, manufacturer must provide to AGO:
    - description of marketing and pricing plans for drug launch in the U.S. and internationally
    - estimated volume of patients who may be prescribed the drug
    - whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval
    - date and price of acquisition if the manufacturer did not develop the drug
- Manufacturer may limit information reported to that in public domain/publicly available
- AGO must publish information on its website at least quarterly
    - must be published in a manner that identifies information on a per-drug basis
    - cannot be aggregated in a manner that would not allow identification of a drug
- Gives AGO enforcement authority

Sec. 11. 18 V.S.A. § 9473 - Banning pharmacist gag clauses in PBM contracts

- Bars pharmacy benefit managers (PBMs) from prohibiting/penalizing a pharmacy or pharmacist for providing information to an insured regarding the insured's cost-sharing amount for a prescription drug
- Bars PBMs from prohibiting/penalizing a pharmacy or pharmacist for disclosing to an insured the cash price for a prescription drug or for selling a lower cost drug if one is available

Sec. 7. Effective dates

- The bill takes effect on passage, except:
    - the biologics sections take effect on July 1, 2018
    - the pharmacist disclosure section takes effect on July 1, 2018 and applies to all contracts taking effect on or after that date