Increased Prescription Delivery Options At Same Cost For Health Plan Members (HB 2223)

Joint Commission on Health Care
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Study Mandate

- HB 2223 (Delegate O'Quinn) would have required health plans/Pharmaceutical Benefits Managers (PBMs) to permit filling of mail order prescriptions at network participating retail pharmacies:
  - With retail pharmacies reimbursed at "comparable" price to mail order, calculated on the same basis
  - Without imposing differential patient copayment, fee, condition
- SB 1741 was PBI'd in Education and Health and sent to JCHC for consideration

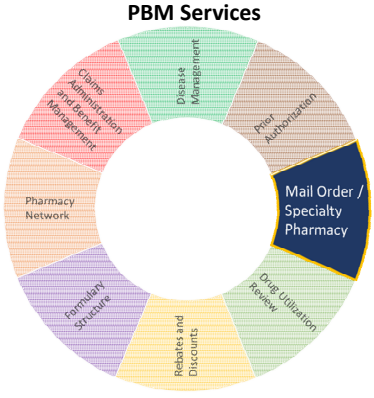
HB 2223 in context of Virginia Code

- HB 2223: type of "Any Willing Provider" (AWP) law focused on channel of distribution (mail order vs. retail)*
- VA "Freedom of Choice" Act (§§38.2-3407.7, 38.2-4209.1, 38.2-4312.1) currently allows patients to select any pharmacy (network or non-network) to receive pharmacy benefits
  - Insurer: prohibited from imposing differential patient copayment, fee, condition; must reimburse all pharmacies at network rate
  - Pharmacy must be willing to sign contract that insurer requires of all network pharmacies
  - **Mail order exception**: insurer can select single mail order provider as exclusive provider of mail order pharmacy services
  - HB 2223 would eliminate mail order exclusivity exception
    - Does not stipulate that pharmacy must be willing to sign contract that insurer requires of all network pharmacies
- VA Code (§38.2-3407.15:4) currently allows retail pharmacies to dispense by mail order on limited basis/as "ancillary service"

* See slide 17 in Appendix for additional detail

HB 2223 in context of PBM services

- Direct pharmacy dispensing (mail order/specialty) is common part of package of PBM services
- PBM-affiliated mail order dispensing may create conflict of interest (e.g., incentivizing use of mail order pharmacies regardless of benefit to plan sponsor or patient)
- Applicability of Federal Trade Commission (FTC) study (2005) on conflict of interest to current market unclear



  - FTC study conclusions: mail order pharmacy ownership "generally did not disadvantage plan sponsors" and "competition in this industry can afford plan sponsors with sufficient tools to safeguard their interests"
  - FTC letter to CMS (2014): "need for continued analysis of potential misalignment of incentives or conflicts of interest" in pharmacy plan design

Commonly cited advantages/disadvantages of mail order*

- Advantages – compared to retail, mail order pharmacies (with 90-day refills) have:
  - Lower dispensing costs due to high volume
  - Higher medication adherence rate
  - Lower medication dispensing error rate
- Disadvantages:
  - Mail order (with 90-day refills) results in higher medication wastage when patients switch
  - Customers prefer retail for 90-day prescriptions when offered similar pricing (e.g., copay) as mail order
  - Lower generic utilization

* See slide 18 in Appendix for additional detail

Key Considerations on HB 2223

Study questions addressed

- What effects could passage of HB 2223 have on prescription medicine costs and quality of services?
- Would legislative and/or regulatory changes be required to implement provisions of HB 2223?
- What alternative or additional approaches could address potential PBM conflicts of interest?

Considerations on potential cost impacts

- Impact on future prescription costs likely depends on changes in mail order market concentration and inherent cost differentials between mail order/retail pharmacy-filled prescriptions
- Changes in market concentration may be mitigated by current demand for additional mail order options
  - Since 2018, Bureau of Insurance has received no complaints from consumers or pharmacists related to pharmacy benefits
  - Many consumers can currently fill 90-day prescriptions for same patient contribution as mail order through “90 Retail” networks
- Changes in market concentration may be limited if retail pharmacies are required to meet mail order terms and conditions
  - Other States’ experiences with AWP laws focused on mail order channel suggest limited change in market concentration when retail pharmacies required to meet mail order terms and conditions*
    - Legislative analysis of PA legislation found lack of widespread participation of retail pharmacies in mail order resulted in little impact
      - Likely due to limited scope of applicability (i.e., ERISA exemption), inability of retail pharmacies to meet mail order terms and conditions
- Inherent cost differentials may not impact payers
  - Evidence suggests mail order dispensing associated with lower costs overall/for patients but not necessarily for plan sponsor

* States include: NY, HI, PA, TX

Considerations on potential impact to quality of services

- PBM-pharmacy contracts contain process-related “terms and conditions” required for reimbursement (e.g., drug utilization evaluation, quality-of-care reviews, formulary compliance)
- Omission of requirement for retail pharmacies to adhere to mail order “terms and conditions” could adversely impact quality of some mail order covered services
  - Specialty drugs: Typical specialty pharmacy terms and conditions may be important for ensuring quality (e.g., 24/7 telephone access to pharmacists; adherence to storage, shipping and handling standards; tracking patient outcomes)
  - 90-day maintenance drugs: literature indicates modestly higher adherence when dispensed via mail order channel

If legislation similar in intent to HB 2223 is considered: Include provision requiring retail pharmacies to adhere to same terms and conditions as pharmacies providing mail order services

Considerations on compliance

- Consumer-focused provisions could be implemented without additional legislation/regulatory changes
  - BOI could verify that consumers were not prevented from filling mail order-covered prescriptions at retail pharmacies for same copay/fee/condition as mail order
- Implementation of PBM/pharmacy-focused provisions would require changes to existing BOI business practices
  - BOI does not currently conduct contract and/or claims comparisons focused on PBM reimbursement prices and basis of costs (e.g., MAC)
- BOI ability to license PBMs and obtain records via carriers would be required to ensure enforcement
  - PBMs not currently required by law to provide information to BOI (and PBM contracts with pharmacies not generally known to carriers)
  - Requiring carriers to have ability to access – and make available to BOI – all data related to prescription benefits provision would ensure ability to obtain relevant data for enforcement (e.g., PBM drug transaction/pricing data)
    - Requiring that data made available to BOI remain confidential would address PBM concerns about proprietary nature of data

If legislation similar in intent to HB 2223 is considered: Include provisions to license PBMs and require carriers to have ability to access/make available to BOI all data related to provision of prescription drug benefits

Additional considerations

- Selected HB 2223 requirements related to reimbursement price determination could be difficult to enforce
  - Determining whether retail reimbursement price is "comparable to" mail order price introduces degree of uncertainty
  - Drug manufacturer rebates – included as required component in calculation of reimbursement price – do not generally accrue directly to pharmacies
- Requirement to use the "same benchmark index" to reimburse pharmacies could be interpreted as price-fixing if not linked to determination of reimbursement price
- As noted in Fiscal Impact Statement:
  - Mail order exclusivity provision of Pharmacy Freedom of Choice Act would need to be eliminated
  - Exceptions would be required for selected prescriptions prohibited by federal law from dispensing from retail pharmacies (45 CFR 156.122)

If legislation similar in intent to HB 2223 is considered: 1) Require retail pharmacy be reimbursed a price "identical to" that of mail order, calculated to reflect all *direct* price inputs and based on the same benchmark index; 2) Eliminate mail order exclusivity provision from Pharmacy Freedom of Choice Act; 3) Exempt from provisions prescriptions federally prohibited from retail channel dispensing

Other States' approaches to addressing possible PBM conflicts of interest*

- "Anti-Steering" provisions
  - Example: PBMs prohibited from incentivizing patients to use PBM-owned pharmacies without written disclosure (LA)
- Reimbursing non-PBM-owned/-affiliated less than PBM-owned/-affiliated pharmacies for same service
  - Example: PBMs required to reimburse non-affiliated pharmacies at least as much as affiliated pharmacies for providing same services (AR)
- Ownership-related reimbursement reporting requirements
  - Example: Annual audit must report on differential payments to pharmacies based on ownership differences (TN)

The JCHC may wish to consider other or additional approaches focused on possible PBM ownership-related conflicts of interest, including legislation related to incentivizing patient choice, reimbursement differentials to pharmacies, and transparency reporting provisions

* See slides 19-20 in Appendix for additional detail

Policy Options

Policy Options

Policy Option(s)
Option 1: Take No Action
Option 2: Introduce legislation authorizing the Bureau of Insurance to license and regulate PBMs through insurance companies
Option 3: In conjunction with Option 2, introduce legislation based on HB 2223 that: • Requires retail pharmacies to adhere to same terms and conditions as mail order • Require retail pharmacy be reimbursed a price “identical to” that of mail order, calculated to reflect all direct price inputs and based on the same benchmark index • Eliminates mail order exclusivity provision in Pharmacy Freedom of Choice Act • Exempts prescriptions federally prohibited from retail channel dispensing • Requires carriers to have ability to access/make available to BOI all data related to provision of prescription drug benefits
Option 4: In conjunction with Option 2, introduce legislation that: • Option 4a: Prohibits PBMs from incentivizing use of PBM-owned or -affiliated pharmacies • Option 4b: Prohibits PBMs from reimbursing non-PBM-owned/-affiliated less than PBM-owned/-affiliated pharmacies for the same/equivalent services • Option 4c: Requires PBMs to make available to carriers/BOI data necessary to determine whether aggregate pharmacy reimbursement differentials exist based on ownership status (through annual audit report and/or de-identified/confidential claims-level data)

Public Comment

Written public comments on the proposed options may be submitted to JCHC by close of business on October 25, 2019.

Comments may be submitted via:

- E-mail: jchcpubliccomments@jchc.virginia.gov
- Fax: 804-786-5538
- Mail: Joint Commission on Health Care
  P.O. Box 1322
  Richmond, Virginia 23218

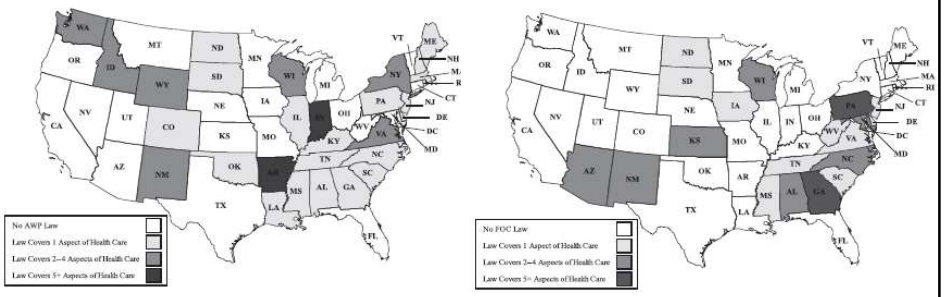
Comments will be provided to Commission members and summarized before they vote on the policy options during the JCHC's November 14th decision matrix meeting.

(All public comments are subject to FOIA release of records)

Appendix

Any Willing Provider (AWP)/Freedom of Choice (FOC) Laws

- ~ 30 States have pharmacy AWP laws, ~20 States have pharmacy FOC laws



Source: Klick and Wright

- Recent analysis found AWP laws associated with 5% increase in prescription drug spending, no significant effect of FOC laws
- Older analysis focused on pharmacy-specific AWP laws found modest association with higher drug expenditures

Evidence Base on Retail/Mail Order Pharmacies

- Costs
  - Mail order dispensing generally associated with lower costs overall/for patients but not consistently for plan sponsor
- Adherence
  - Strong evidence that patients using mail order are more adherent than retail channel
    - Estimates range from 3% to 12% greater adherence
    - Magnitude of differences narrow when mail-order channel incentives accounted for (e.g., greater days supply/lower copays)
  - Evidence that longer days supply associated with greater adherence
- Dispensing errors
  - Dispensing error rate at community pharmacies estimated at 1.5%, mail-order pharmacies estimated at 0.075%
    - Based on small body of research
- Generic utilization/substitution
  - Use of mail order pharmacy associated with lower rates of generic utilization, but ~90% of differences generic-dispensing rate may be driven by differences in therapeutic mix
  - Recent research suggests lower generic substitution with mail-order channel for certain therapeutic classes

Other States' Approaches to Addressing Possible PBM Conflicts of Interest (all 2019)

- AR, SC: PBMs required to reimburse non-affiliated pharmacies at least as much as itself/affiliated pharmacies for providing same services
- GA: Prohibits PBMs from advertising/marketing/promoting affiliates to current/prospective patients
- LA: Prohibits directly/indirectly steering/incentivizing patients to use pharmacies in which PBM has ownership interest/control without written disclosure acknowledged by patient (e.g., differential premiums, deductibles, co-pays, co-insurance)
- LA: Prohibits fees not apparent at time of claims processing/not reported on remittance advice of adjudicated claim
- MN:
  - PBMs must make available to plan sponsors (upon request) and insurance commissioner de-identified claims-level information, including whether the pharmacy making the claim is: under common control/ownership of PBM; a mail order pharmacy
  - PBMs with ownership interests in pharmacies must disclose to plan sponsor differences between amount paid to pharmacy/charged to sponsor
  - PBMs prohibited from incentivizing members from using pharmacies in which PBM has ownership interest (e.g., differential premiums, deductibles, co-pays, co-insurance)

Other States' Approaches to Addressing Possible PBM Conflicts of Interest (all 2019)

- NM: For generics, PBMs required to reimburse non-affiliated pharmacies at least as much as affiliated pharmacies for providing same/equivalent service
- OK: PBMs prohibited from:
  - Naming specific pharmacies, hospitals, providers on mail/ID cards unless all network pharmacies, hospitals, providers are named
  - Lower reimbursement to non-PBM-owned/-affiliated pharmacies for same service as in PBM-owned/-affiliated pharmacies
  - Retroactively denying/reducing reimbursement for covered service after adjudicating claim unless claim was fraudulent/contained errors
- SC:
  - Pharmacy participation in networks with different accreditation / certification standards cannot be tied to PBM affiliation status
- TN:
  - Annual audit must report on differential payments to pharmacies based on ownership differences
  - PBMs required to reimburse non-affiliated pharmacies at least as much as itself/affiliated pharmacies for providing same drug, dispensed product or service

References

References

Slide 4 (HB 2223 in context of PBM services)

- Carroll, N., 2006. Mail-Service Pharmacy Savings: A Conclusion in Search of Evidence. *Journal of Managed Care Pharmacy*, 12, pp.164–166.
- Federal Trade Commission, 2005. *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, Federal Trade Commission.
- Gavil, A., Gaynor, M. & Feinstein, D., 2014. *Re: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs*, Federal Trade Commission Office of Policy Planning, Bureau of Competition, and Bureau of Economics.

References

Slides 5, 18 (Commonly cited advantages/disadvantages of mail order; Evidence Base on Retail/Mail Order Pharmacies)

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- Johnsrud, M., Lawson, K. & Shepherd, M., 2007. Comparison of Mail-Order With Community Pharmacy in Plan Sponsor Cost and Member Cost in Two Large Pharmacy Benefit Plans. *Journal of Managed Care Pharmacy*, 13, pp.122–134.

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Slides 5, 18 (Commonly cited advantages/disadvantages of mail order; Evidence Base on Retail/Mail Order Pharmacies) (continued)

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- Murphy, P., Khandelwal, N. & Duncan, I., 2012. Comparing Medication Wastage by Fill Quantity and Fulfillment Channel. *Am J Pharm Benefits*, 4, pp.e166–e171.
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- Wosinska, M. & Huckman, R., 2004. Generic Dispensing And Substitution In Mail And Retail Pharmacies. *Health Affairs*, w4, pp.409–416.

References

Slide 8 (Considerations on potential cost impacts)

- Legislative Budget and Finance Committee, 2015. *Impact of Act 2012-207 on Access to Retail Pharmacies and Cost of Prescription Medications*, Pennsylvania General Assembly.
- References on previous two slides

Slide 9 (Considerations on potential impact to quality of services)

- Khandelwal, N. et al., 2011. Medication Adherence for 90-Day Quantities of Medication Dispensed Through Retail and Mail Order Pharmacies. *The American Journal of Managed Care*, 17, pp.e427–e434.
- Visante, 2014. *Proposed New York Legislation Could Increase Prescription Drug Costs $6 Billion Over 10 Years*, Visante.

Slide 17 (Any Willing Provider (AWP)/Freedom of Choice (FOC) Laws)

- Klick, J. & Wright, J., 2015. The Effect of AnyWilling Provider and Freedom of Choice Laws on Prescription Drug Expenditures. *American Law and Economics Review*, 17, pp.192–213.
- Durrance, C., 2009. The Impact of Pharmacy-Specific Any Willing-Provider Legislation on Prescription Drug Expenditures. *Atlantic Economic Journal*, 37, pp.409–423.

HB 2223

A BILL to amend the Code of Virginia by adding a section numbered ***38.2-3407.15:5****, relating to pharmacy services; mail order and delivery; pharmacy benefits managers.*Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered **38.2-3407.15:5** as follows:

§ ***38.2-3407.15:5****. Access to retail community pharmacies.*

A. As used in this section:

"Carrier" has the same meaning ascribed thereto in subsection A of § ***38.2-3407.15****.*

"Covered individual" means an individual receiving prescription medication coverage or reimbursement provided by a pharmacy benefit manager or a carrier under a health benefit plan.

"Health benefit plan" has the same meaning ascribed thereto in § ***38.2-3438****.*

"Mail order pharmacy" means a pharmacy whose primary business is to receive prescriptions by mail or through electronic submissions and to dispense medication to covered individuals through the use of the United States mail or other common or contract carrier services and provides any consultation with covered individuals electronically rather than face-to-face.

"Pharmacy benefits manager" or "PBM" means a person that performs pharmacy benefits management. "Pharmacy benefits manager" includes a person acting for a PBM in a contractual or employment relationship in the performance of pharmacy benefits management for a carrier, nonprofit hospital, or third-party payor under a health program administered by the Commonwealth.

"Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a carrier for the benefit of covered individuals.

"Retail community pharmacy" means a pharmacy that is open to the public, serves walk-in customers, and makes available face-to-face consultations between licensed pharmacists and persons to whom medications are dispensed.

HB 2223 (continued)

B. Every carrier shall, as applicable, (i) administer its health benefit plans in a manner consistent with the following criteria and (ii) include the following provisions in each provider contract addressing the provision of pharmacy benefits management that the carrier or the carrier's pharmacy benefits manager enters into with a pharmacy or the pharmacy's contracting agent:

1. Each covered individual shall be permitted to fill any mail order-covered prescription, at the covered individual's option, at any mail order pharmacy or network participating retail community pharmacy if the network participating retail community pharmacy agrees to accept a price that is comparable to that of the mail order pharmacy, calculated to reflect all drug manufacturer's rebates, direct and indirect administrative fees, costs and any remuneration;

2. The PBM or carrier shall not impose a differential copayment, additional fee, or other condition on any covered individual who elects to fill his prescription at an in-network retail community pharmacy that is not similarly imposed on covered individuals electing to fill a prescription from a mail order pharmacy; and

3. The PBM shall utilize the same benchmark index, including the same average wholesale price, maximum allowable cost, and national prescription drug codes, to reimburse all pharmacies participating in the health benefit plan regardless of whether a pharmacy is a mail order pharmacy or a retail community pharmacy.

C. This section shall not apply with respect to claims under an employee benefit plan under the Employee Retirement Income Security Act of 1974, Medicaid, or Medicare Part D.

D. This section shall apply with respect to contracts with a PBM entered into, amended, extended, or renewed on or after January 1, 2020.

E. Pursuant to the authority granted by § 38.2-223, the Commission may promulgate such rules and regulations as it may deem necessary to implement this section.

F. The Commission shall have no jurisdiction to adjudicate individual controversies arising out of this section.

Joint Commission on Health Care

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