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Pharmacy Preferred Providers as Selected by Drug Manufacturers and Third Party Payers. Is There a Role for the Boards?

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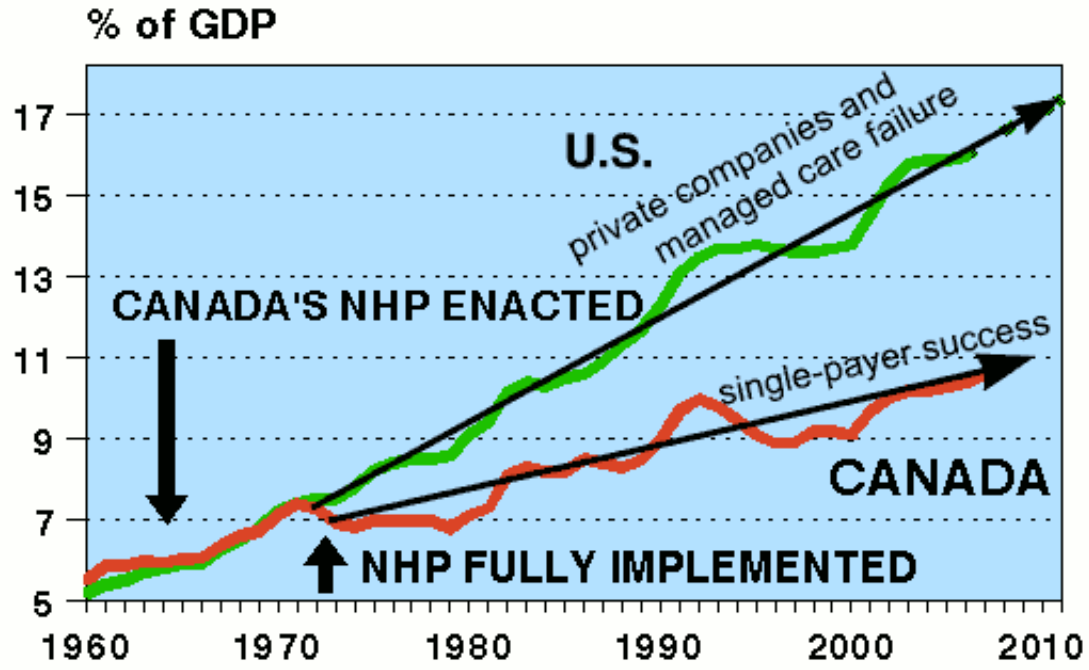
Health Costs as % of GDP:
U.S. & Canada, 1960-2010



Source: Statistics Canada, Canadian Inst. for Health Info., & NCHS/Commerce Dept

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UNITED STATES MILITARY

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CANADIAN MILITARY

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Pharmacy Preferred Providers as Selected by Drug Manufacturers and Third Party Payers. Is There a Role for the Boards?

- **Learning Objectives:**
  - Understand limited drug distribution systems established under a FDA required Risk Evaluation and Mitigation Strategy (REMS)
  - Discuss potential anti-trust concerns related to limited drug distribution systems established under a FDA required REMS
  - Describe preferred provider networks established by third-party payers
  - Understand legal and regulatory issues involving preferred provider networks in the United States

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- Two major reasons for use of limited distribution systems for pharmaceuticals in the United States:
  - Safety – Risk Evaluation and Mitigation Strategies (REMS)
  - Cost – Preferred Pharmacy Provider Networks

- Risk Evaluation and Mitigation Strategies (REMS)
  - Required risk management plans that use risk minimization strategies – beyond the professional labeling – to ensure that the benefits of certain prescription drugs outweigh their risks
  - Authorized by the Food and Drug Administration Amendments Act of 2007 (FDAAA)
    - But FDA earlier had required risk minimization strategies to be in place
      - e.g. clozapine – available only through a distribution system that ensures that WBC and ANC are monitored prior to the delivery of a supply of the drug
      - Risk Minimization Action Plans (RiskMAPs) – risk minimization guidances were issued in March 2005 after drugs like Lotronex and Rezulin were removed from the market

- Risk Evaluation and Mitigation Strategies (REMS)*
  - FDA can require a REMS if it determines safety measures, beyond the professional labeling, are needed to ensure that benefits outweigh risks
  - Drug manufacturers develop REMS programs, FDA reviews and approves them
  - FDA can require a REMS before or after a drug is approved
    - Before approval: If FDA determines REMS is necessary to ensure that the benefits of the drug outweigh the risk
    - Post-approval: If FDA becomes aware of new safety information* and determines REMS is necessary to ensure that the benefits of the drug outweigh the risks
  - REMS can be required for a single drug or a class of drugs
  - Healthcare professionals and distributors may need to follow specific safety procedures prior to prescribing, shipping, or dispensing the drug

* From A Brief Overview of Risk Evaluation & Mitigation Strategies (REMS) FDA Webinar

- Risk Evaluation and Mitigation Strategies (REMS)*
  - Elements of a REMS
    - Medication Guide – Document written for patients highlighting important safety information about the drug; must be distributed by the R.Ph. to every patient receiving the drug.
    - Communication Plan – Plan to educate healthcare professionals on the safe and appropriate use of the drug and consists of tools and materials that will be disseminated to the appropriate stakeholders.
    - Elements to Assure Safe Use (ETASU) – Strictly controlled systems or requirements put into place to enforce the appropriate use of a drug. Examples – physician certification requirements in order to prescribe the drug, patient enrollment in a central registry, ***distribution of the drug restricted to certain specialty pharmacies***, etc.
    - Implementation Plan – A description of how certain ETASUs will be implemented.

- Risk Evaluation and Mitigation Strategies (REMS)*
  - Current REMS
    - Individual REMS – 65 currently listed on FDA Web site.
      - Examples
        - Androgel (testosterone) 1% Gel – medication guide
        - Lotronex (alosetron hydrochloride) Tablets – medication guide, ETASU, implementation plan
        - Thalomid (thalidomide) Capsules – medication guide, ETASU, implementation plan
    - Shared REMS – 6 currently listed on FDA Web site
      - Examples
        - Extended-Release and Long-Acting Opioid Analgesics – medication guide, EASU
        - Isotretinoin iPLEDGE – medication guide, ETASU, implementation plan

- Risk Evaluation and Mitigation Strategies (REMS)*
  - Elements to Assure Safe Use – limited distribution example
    - Tracleer (bosentan)
      - Tracleer will only be dispensed by pharmacies, practitioners, hospitals and health care settings (dispensers) that are specially certified by Actelion. Tracleer Access Program (T.A.P.)
        - Outpatient Dispensing – Tracleer will only be dispensed by outpatient pharmacies that are specially certified. Actelion will ensure that, to be certified, pharmacies are under legal contract and will agree to adhere to multiple requirements: Accredo Health Group; Aetna; CVS Caremark; Curascript; Walgreens; CIGNA Healthcare/CIGNA Specialty Pharmacy Services
        - Inpatient Dispensing – Actelion will ensure that Tracleer is only dispensed in the inpatient setting by certified hospitals

- Risk Evaluation and Mitigation Strategies (REMS)*
  - Criticisms of REMS
    - They may not be effective
      - HHS OIG studied REMS and issued a report: "FDA Lacks Comprehensive Data to Determine Whether Risk Evaluation and Mitigation Strategies Improve Drug Safety". (February 2013)
        - Due to lack of comprehensive data, FDA "cannot ensure that the public is provided maximum protection from a drug's known or potential risks."
        - Because only 7 of 49 REMS were found to meet all of their goals and 21 were not, there were "questions about the effectiveness of REMS."
        - "FDA has not identified reliable methods for evaluating REMS."

- Risk Evaluation and Mitigation Strategies (REMS)*
  - Criticisms of REMS
    - Manufacturers may be using them to thwart competition
      - *Actelion Pharms Ltd. v. Apotex Inc* (U.S. District Court – District of NJ) – filed September, 2012.
        - Actavis, Apotex, and Roxane allege that Actelion imposed distribution restrictions preventing them from buying samples of Actelion's brand products (Tracleer and Zavesca) through customary distribution channels, and that Actelion refuses to sell the products directly
        - This prevents the plaintiffs from meeting FDA requirements for developing generic versions of these drugs – i.e. can't conduct bioequivalency studies without samples of branded products.
      - FTC amicus brief in Actelion:
        - Actelion's legal position, if adopted by the court, could pose a significant threat to competition in the pharmaceutical industry
        - Hatch-Waxman Act created a regulatory framework to encourage the introduction of low-cost generic drugs. Act cannot function as Congress intended if generic firms are unable to access samples of brand products

- Risk Evaluation and Mitigation Strategies (REMS)*
  - REMS & the Role of Boards of Pharmacy
    - Since federal law allows the FDA to require REMS and REMS can limit distribution of drugs to certain pharmacies – Boards can't require broader distribution.
    - Medication guides – part of the FDA approved labeling
      - Failure to distribute med guides could constitute misbranding
        - MN Stat. 151.36 – "A drug shall be deemed to be misbranded if . . . it otherwise fails to meet the labeling requirements of the federal act"
    - MN Rules 6800.2250 – unprofessional conduct includes . . . "the violation of any law, rule, regulation, or ordinance of the state or any of its political subdivisions, including the Board of Pharmacy, or the United States government, or any agency thereof relating to the practice of pharmacy".

- Preferred Pharmacy Provider Networks
  - Approximately 84% of Americans have health insurance
    - Most insured have some form of Rx drug coverage
      - 98% of privately insured
      - 90% of Medicare enrollees
      - 100% of Medicaid – categorically needy enrollees
    - Medicare Part D plans, most private insurers, and many state Medicaid agencies contract with pharmacy benefit managers (PBM) to process prescription claims and manage drug benefits
  - PBM approaches to cost cutting
    - Formulary development and management
    - Generic substitution
    - Manufacturer rebates and discounts
    - Mail order pharmacies
    - ***Networks of pharmacies***

- Preferred Pharmacy Provider Networks
  - Pharmacy network design options:
    - **Open Pharmacy Network** — consumer chooses any pharmacy in a plan's network. (Still most common).
    - **Preferred Pharmacy Network** —consumer has financial incentive to choose the dispensing pharmacy that reduces the payer's costs. (Less common, 40% of Medicare Part D enrollees in plan with preferred pharmacy network).
    - **Limited Pharmacy Network** — consumer must use a narrower network that includes only specifically designated pharmacies. AKA – restricted network. (Not yet common).

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- Preferred Pharmacy Provider Networks
  - "Any willing provider" statute and rules:
    - 32 states have some form of "any willing provider" law or rule that places limits of the ability of third-party payers to exclude providers from networks;
    - In District V (summaries of applicable laws)
      - Iowa – 514C.5: Policies or contracts providing for third-party payment may not require a beneficiary to order prescriptions by mail if the pharmacy chosen by the beneficiary agrees to comply with the same terms and conditions as the mail-order pharmacy.
      - Nebraska – 44-513.02: Beneficiaries shall not be required to obtain pharmaceutical services from mail-order in order to obtain reimbursement.
      - North Dakota – 26.1-36-12.2: Beneficiaries may choose any licensed pharmacy/pharmacist to provide services. Benefit differentials are prohibited. Licensed pharmacists who accept the terms may participate in the plan.

- Preferred Pharmacy Provider Networks
  - "Any willing provider" statute and rules:
    - In District V (summaries of applicable laws – cont.)
      - South Dakota – 58-18-37: Group health insurance policies may not refuse to accept licensed pharmacies/pharmacists as participating providers if they agree to the same terms and conditions offered to other providers of pharmacy services under the policy.
      - Minnesota – law appears to have been repealed in 2012.

- Preferred Pharmacy Provider Networks
  - "Any willing provider" statute and rules – limitations on state authority?
    - Employee Retirement Income Security Act of 1974 (ERISA)
      - Provisions concerning pension plans and health benefit plans
      - "Pre-emption clause": all state laws that relate to any employee benefit plan are pre-empted.
      - "Saving clause": states that nothing in ERISA "shall be construed to exempt or relieve any person from any law of any State which regulates insurance, banking, or securities."
      - "Deemer clause" – states insurance law cannot operate on employer self-funded benefit plans because they are deemed to not be "insurance".
        - Approx. 55% of health insurance plans in U.S. are self-funded.

- Preferred Pharmacy Provider Networks
  - "Any willing provider" statute and rules – limitations on state authority?
    - Employee Retirement Income Security Act of 1974 (ERISA)
      - *Kentucky Association of Health Plans v. Miller*, 123 S. Ct. 1471 (2003)
        - Health plans challenged Kentucky's any willing provider law claiming that the ERISA "saving clause" didn't apply because the law didn't apply to only insurers
        - Supreme Court unanimously upheld Kentucky law

- Preferred Pharmacy Provider Networks
  - "Any willing provider" statute and rules – limitations on state authority?
    - CMS Medicare Part D Regulations
      - The Medicare Modernization Act contains an any willing provider clause: "A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan."
      - CMS regulations allow for the formation of preferred pharmacy networks:
        - 42 C.F.R. §423.120(a)(9) – A Part D sponsor . . . may reduce copayments or coinsurance for covered Part D drugs obtained through a preferred pharmacy relative to the copayments or coinsurance applicable for such drugs when obtained through a non-preferred pharmacy.
        - In effect since 2006 – but first PDP to establish a preferred pharmacy network was the Humana Walmart-Preferred Rx Plan in 2011. Have been several other plans since then.

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- Preferred Pharmacy Provider Networks
  - "Any willing provider" statute and rules – limitations on state authority?
    - CMS Medicare Part D Regulations
      - *Southwest Pharmacy Solutions Inc. v. Centers For Medicare and Medicaid Services* (5th U.S. Circuit Court of Appeals, No. 12-40097, 05-01-2013)
        - Independent pharmacies challenged CMS regulation.
        - 5th Circuit upheld lower courts dismissal because plaintiffs had not exhausted administrative remedies before filing a claim in federal court
      - *Farmville Discount Drug, Inc. et al v. Sebelius et al* (North Carolina Eastern District Court)
        - Four independent pharmacies challenged CMS regulation. Dismissed – March, 2013
        - Appeal filed in 4th Circuit Court on April 26, 2013

- Preferred Pharmacy Provider Networks
  - "Any willing provider" statute and rules – limitations on state authority?
    - CMS Medicare Part D Regulations
      - Latest CMS "Final Call" letter – issued n April, 2013 for 2014 Plan Year
        - We have begun to scrutinize Part D drug costs in PDPs with preferred networks, and comparing these to costs in the non-preferred networks, as well as to costs in PDPs without preferred networks
        - We strongly believe that including any pharmacy that can meet the terms and conditions of the preferred arrangements in the sponsor's preferred network is the best way to encourage price competition and lower costs in the Part D program

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- Preferred Pharmacy Provider Networks
  - Preferred Pharmacy Provider Networks & The Boards
    - Is there a role for Boards?
    - Board regulation of PBMs?
      - Carmen Catizone: "Similarly, if a PBM is engaged in the practice of pharmacy, it should be regulated by the board of pharmacy fairly, objectively and competently."
      - National Community Pharmacy Association – Boards have a role in making sure that PBM decisions are in the best interest of patients
      - Pharmaceutical Care Management Association – have Boards regulate PBMs is like "letting the fox guard the henhouse."
      - Federal Trade Commission – could increase costs if Boards disclose pricing information
      - Mississippi is the only state in which PBMs are regulated by the Board
      - At least three other states considering it: Oregon, Oklahoma and Hawaii

- Preferred Pharmacy Provider Networks
  - Preferred Pharmacy Provider Networks & The Boards
    - Is there a role for Boards?
    - Questions to consider:
      - Are Boards equipped to regulate PBMs?
        - Appropriate expertise?
        - Adequate resources – including staff?
      - PBMs focus on costs – but can some PBM practices be a risk to patients' health – e.g. inappropriate PA leading to lack of access to drugs?
      - Is it possible to craft legislation authorizing a Board to regulate PBMs – while still offering protections to PBMs (e.g. making pricing and contracting data non-public)?

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- Contact Information

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