Special Commission to Study Switching Medications
Report to the Massachusetts Legislature
April 3, 2018

EXECUTIVE SUMMARY

The Massachusetts legislature established a Special Commission to study medication switching by health insurers and pharmacy benefit managers (Commission). The Commission met throughout the second half of 2017 employing several methods to address the five charges placed before the Commission. The Commission conducted a literature review; created and/or evaluated 3 separate questionnaires (for patients, physicians, and health plans); convened a public listening session; and, conducted a data analysis using the Massachusetts All Payer Claims Database. The five charges to the Commission are:

(i) the frequency by which patients are switched from prescription medications to other medications for non-medical reasons and without the consent or notification of the patients' prescribing physicians; (ii) the frequency of a health provider prescribing an alternative drug in response to changes in health plan policies mid-year for non-medical reasons; (iii) evaluating the role of financial incentives to pharmacists and prescribers in prescription drug switching decisions, including but not limited to payment, fee, incentive or other contractual reward for choosing a drug alternative; (iv) determining the total cost to the Commonwealth when individuals are switched from prescription drugs that have been safe and effective, including but not limited to increased use of services, emergency rooms visits, inpatient hospital stays and outpatient office visits; and (v) identifying the patient populations most impacted by and vulnerable to being switched from prescription drugs for non-medical reasons.

The Commission encountered several limitations and could not fully address all of the charges however several themes were consistently identified and lead to a series of recommendations for the Legislature's consideration.

Themes:

- Patients and prescribers feel that non-medical switching interferes with the patient-physician relationship
- For patients who are stable on their medication regimens unplanned changes are disruptive and can be harmful particularly in certain vulnerable populations
- Health plan formulary changes should be systematic, predictable, and transparent.
    - Patients and prescribers are concerned about inadequate notice of medication changes
    - If medication changes are required by the health plan, patients should provide consent or have an efficient expedited appeals process
- Formularies are an important tool to help health plans manage plan costs

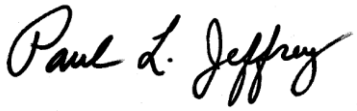
Recommendations: (See page 20 of Report)

- Establish or reinforce rules or guidelines to hold vulnerable patients harmless when the formulary status of a medication changes.
    - Define vulnerable populations
    - These rules may be different for changes within a plan year compared to across plan years, new member enrollment in a plan, or new prescriptions
- Reinforce rules or guidelines for timely notification of patients and providers when the formulary status of a medication changes

    - Strengthen the means of notification, including as it pertains to appeal rights
- Reinforce rules or guidelines for a timely and efficient appeals process including expedited review processes for vulnerable populations.
- Establish criteria for health plans to report to appropriate state agencies (e.g., Division of Insurance, Office of Patient Protection) the impact of medication switching for vulnerable populations.

The following report elaborates on the methods, findings, limitations and recommendations of the Commission. A series of appendices is attached to the report with further details concerning the sources used for the creation of this report.

Respectfully submitted,



Paul L. Jeffrey, PharmD
Chairperson, Special Commission to Study Switching Medications

INTRODUCTION/BACKGROUND

The Massachusetts legislature established a Special Commission to study medication switching by health insurers and pharmacy benefit managers (Commission). Secretary of Health and Human Services, Marylou Sudders, established the Commission in June 2017. The roster of Commissioners is contained in Appendix 1. The charge to the Commission follows:

Legal Authority: Section 195, Chapter 133 of the Acts of 2016

> There shall be a special commission to study the practice by health insurers and pharmacy benefit managers of switching, for non-medical reasons, individuals with complex or chronic diseases from safe and effective prescription medications to other medications. The commission shall investigate and study several areas including, but not limited to, the following: (i) the frequency by which patients are switched from prescription medications to other medications for non-medical reasons and without the consent or notification of the patients' prescribing physicians; (ii) the frequency of a health provider prescribing an alternative drug in response to changes in health plan policies mid-year for non-medical reasons; (iii) evaluating the role of financial incentives to pharmacists and prescribers in prescription drug switching decisions, including but not limited to payment, fee, incentive or other contractual reward for choosing a drug alternative; (iv) determining the total cost to the commonwealth when individuals are switched from prescription drugs that have been safe and effective, including but not limited to increased use of services, emergency rooms visits, inpatient hospital stays and outpatient office visits; and (v) identifying the patient populations most impacted by and vulnerable to being switched from prescription drugs for non-medical reasons. The Commission shall file a report on its findings and any accompanying recommendations to the joint committee on health care financing, the joint committee on financial services and the House and Senate Committees on Ways and Means on or before January 1, 2018.
>
> The Commission shall consist of the following members or their designees: the Secretary of Health and Human Services, who shall serve as Chair; the Executive Director of the Health Policy Commission; the Executive Director of the Center for Health Information and Analysis; 2 individuals with disabilities, one of whom shall be appointed by the Speaker of the House and one of whom shall be appointed by the Senate President; 2 individuals who are public policy or advocacy representatives for patient organizations with rare, complex or chronic diseases, one of whom shall be appointed by the Speaker of the House and one of whom shall be appointed by the Senate President and; 2 members appointed by the Governor, 1 of whom shall be an individual who is an actively practicing physician with expertise in the use and prescribing of complex specialty medications including biologics in the treatment of chronic autoimmune diseases and 1 individual who is an actively practicing physician with expertise in treating conditions for which treatment disruptions are likely to result in excess morbidity, disability, or demand of health care resources such as hospitalization, emergency or urgent care visits. The Commission may hold public meetings to solicit public input from interested parties in a manner and frequency to be determined by the Chair.

The Commission met several times over the ensuing months. The meeting minutes and other information is published on the Massachusetts state website at: https://www.mass.gov/lists/special-commission-to-study-switching-medications-meeting-minutes.

METHODS

The Commission determined that not all of the explicit charges could be accomplished because of various limitations which will be further described in the body of the report. A narrative is provided for each of the charges, (i) through (v), enumerated in the legislation. The Commission approached its charge in several segments of work:

- Literature Review and Environmental Scan
  - The Commissioners conducted a review of published literature pertinent to the topic to help identify the types of patients and categories of drugs of greatest concern related to medication switching. Appendix 2
  - An environmental scan of efforts by other entities (e.g., states, advocacy groups) to address concerns related to the charge. Appendix 3
- Stakeholder Input – The Commission sought input from various sectors of the healthcare community by using various questionnaires and a public listening session.
  - Three questionnaires were employed by the Commission. Two were developed by the Commission and one was utilized that was contemporaneously developed by another organization for the same purpose:
    - Patient Questionnaire - developed and administered by the Global Healthy Living Foundation (GHLF). Appendix 4, Section 2.1
    - Prescriber Questionnaire – administered with the assistance of the Massachusetts Medical Society (MMS). Appendix 5, Section 2.2
    - Health Plan Questionnaire – administered with the assistance of the Massachusetts Association of Health Plans (MAHP). Appendix 6, Section 2.3
  - Public Listening session – The Commission held a public listening session on November 13, 2017 to allow comments to be offered by the general public. The Commission was assisted in this regard by several advocacy groups. The testimony gathered at the listening session is summarized in Appendix 7, Section 3
- Data Analysis – After identifying the categories of patients and corresponding drug therapy, the Commission attempted to address its charge using data from the All Payer Claims Database (APCD) with the assistance of the Center for Health Information and Analysis (CHIA). The Commission acknowledged that pharmacy claims data, including the APCD pharmacy claims collected by CHIA, does not contain data elements that identify non-medical switches and therefore could not provide the level of specificity to directly answer the questions posed by the Legislature. Nonetheless an attempt was made to characterize the volume of activity attributable to medication switching. Section 4.

FINDINGS

1. Literature Review (Appendix 2)

1.1 Patients most impacted from switching

We were not able to identify literature regarding which specific patients are most impacted by non-medical switching. However, the majority of studies found that focused on clinical and economic outcomes following non-medical switches were related to complex chronic diseases such as psychiatric, immune-mediated, and cardio-metabolic conditions. Patients with more simple chronic diseases, such as hypertension and hyperlipidemia, which are associated with relatively lower-cost therapies, may be less likely to be impacted by non-medical switching.

A systematic literature review identified 29 studies published between January 2000 and November 2015 that evaluated the impact of non-medical switching on clinical and economic outcomes, resource utilization and medication-taking behavior. The review included six disease categories: cardio-metabolic, immune-mediated, acid suppression, psychiatric, hormone replacement therapy, and pain. After analyzing 96 outcomes from the 29 studies, the authors concluded that non-medical switching was more often associated with a negative (33%) or neutral effect (55%) than a positive effect (12%) on a variety of important outcomes including clinical, resource utilization, economic, and medication-taking behavior outcomes. Among patients with a "well-controlled and stable" disease state, 68.8% had a negative association in one of the 32 outcomes when switched to another medical for a non-medical reason.[1]

In one study, electronic health records between 2007 and 2013 were analyzed retrospectively to evaluate the health care use and outcomes among patients that experienced a non-medical switch of their prescribed anti-tumor-necrosis-factor biological agent (anti-TNF) for cost containment reasons. Stable patients that experienced a non-medical switch were matched to patients who did not and rates of office visits, ER visits, hospitalizations, and medication-related adverse events were evaluated at time points up to one year. Office visits and medication-related adverse events (indicating increased side effects and diminished medication efficacy) were higher among the patients that experienced a non-medical switch ($p < 0.05$). Rates of ER use and hospitalizations were comparable.[2]

In regards to patients with psychiatric disorders, a case-control analysis was conducted to compare healthcare utilization and costs incurred by patients with major depressive disorder after being switched from escitalopram to another selective-serotonin-reuptake inhibitor (SSRI) for a non-medical reason. Switching for medical reasons was defined as switching within seven days after having a hospitalization, ER visit, or a psychotherapy visit. The study included 2,805 matched pairs after being identified in a database from 2003-2006. Compared to the controls, the patients that had experienced a non-medical switch to another SSRI had higher rates of all-cause and major depressive disorder-related hospitalizations and ER visits. A multivariate analysis was also conducted to determine healthcare costs between the two groups and found that the patients impacted from the non-medical switch had higher medical costs, drug costs, and total healthcare costs at an increase of +$138, +$149, and +$322 in comparison to the control group, respectively.[3] The study acknowledges limitations of a short observational period of three months, and the difficulty of accurately identifying non-medical reasons in a database.

Available literature on non-medical switching has important caveats, including frequent difficulty in accurately identifying non-medical reasons. Furthermore, many studies, including those described here, have funding or other involvement from the pharmaceutical industry, which can introduce bias in study design towards conclusions favorable to the use of high-cost drugs. However, literature suggests that for patients with complex chronic conditions, switching drugs for non-medical reasons is often associated with negative clinical and economic outcomes.

1.2 Laws related to switching

No current Massachusetts laws were found during the literature search regarding non-medical switching.

According to the Medicare Part D Manual, the Medicare Part D policies are as follows:

- Part D sponsors can expand coverage at any time by adding drugs, reducing cost-sharing, or deleting utilization management.
- Part D sponsors must seek CMS approval to remove a drug from the formulary, initiate higher cost-sharing, or new or more restrictive utilization management. Even if approved, affected enrollees are exempt from the change for the remainder of their plan year.
- Part D sponsors must provide 60 days of written notice of an approved negative change to affect enrollees.[4]

1.3 What other states do

An article published by the US Pain Foundation in February, 2017 summarized current state laws and proposed bills.[5] Seven states prevent pharmacy benefit managers from making formulary changes during a plan year that would not benefit enrollees, such as moving a medication to a higher tier or initiating a maximum coverage on a specific medication (FL, IL, MD, NM, NY, TN, TX). Other states allow formulary changes during the plan year, but require pharmacy benefit managers to notify their enrollees 60 or 90 days in advance of those changes (AK) and continue to cover their medication if still prescribed by their doctor (NJ, WA). Ultimately, there are a variety of different actions that states are taking to limit the potential negative impacts of non-medical switches.

The Office of Legislative Research for the State of Connecticut has prepared two Research Reports which are included as Appendices 9 and 10 for completeness. Many of the findings in the Connecticut reports are identified above by the Commission's research.

2. Questionnaires

2.1 Patient Questionnaire

Developed and analyzed by GHLF. The complete report is attached as Appendix 4. The Executive Summary follows:

Summary

A total of 260 Massachusetts residents started the online survey. Forty of the 260 participants did not complete the survey and 77 were disqualified for either not having a chronic or rare disease or for not experiencing a non-medical switch. The total number of participants who completed the survey is 143; only completed responses were analyzed.

Although respondents' individual diseases varied widely, five separate major classes were represented: mental health (35%), autoimmune (34%), neurological (29%), oncological (6%) and infectious (1%). A majority were female (73%), white (82%) and college educated (75%). There was an equal percentage (46%) of participants who were employed, either full-time, part-time, or self-employed, as there were participants who were unemployed. The majority of participants (64%) reported

having a household income of $50,000 or less per year. All types of insurance coverage were represented in our surveyed population. Private was held by the most number of respondents (43%), followed by public (36%), followed by a combination of private and public insurance (16%).

How many patients does non-medical switching negatively impact?

Results of this survey show that it is commonplace for chronic and rare disease patients in Massachusetts to experience mid-year changes in prescription medication coverage. Almost two-thirds (64%) reported that their insurance company switched their medication to a drug that was different from the one their physician prescribed as the result of a formulary change. Up to 65% of those patients did not have the opportunity to reject and/or decline the medication switch. In addition to these switches, nearly three-quarters (73%) reported that a mid-year change in insurance coverage resulted in their primary therapy becoming more expensive to obtain. The majority of respondents (66%) reported now paying more out-of-pocket for their prescribed medication, with 53% reporting to pay a lot more. Overall, two out of every three (68%) of our survey respondents reported being financially incentivized by their insurance companies to change their clinician-prescribed medication for non-medical reasons.

How does non-medical switching impact patient's treatment and health?

Of the 143 survey respondents:

- 48% tried multiple medications before finding another suitable drug that satisfactorily worked for them
- 70% reported that their new medication worked somewhat or much worse than the original prescribed medication
- 61% were switched to a medication that caused side effects
- 86% reported the side effects were worse compared to previous side effects
- 45% reported the side effects were much worse compared to previous side effects finding another suitable drug that satisfactorily worked for them
- 46% reported seeing their healthcare provider or going to the emergency room
- 18% were hospitalized as a result of complications from the switch
- 33% of respondents reported missing work due to the switch

Do insurers properly communicate formulary changes to patients?

When investigating communications by third-party payers to inform patients about formulary changes, our survey found close to half (42%) of all respondents reported never receiving any notifications, such as letters, emails, or phone calls, communicating details of their plan's formulary or changes being made to it.

When respondents experienced alterations to their plan's formulary, only a quarter (24%) reported their insurance company informed them of the altered coverage to their prescribed medication. A majority of respondents (68%) was informed by their

pharmacist, and a small percentage (5%) was informed by their physician.

How do patients feel about non-medical switching?

- 94% support legislation that would prohibit insurers from financially pressuring them to switch their physician prescribed medication for non-medical reasons
- 89% indicated that the out-of-pocket cost of medication was either a somewhat or an extremely important factor in their decision-making process

2.2 Health Plan Questionnaire (developed and analyzed by the Commission)

Summary

All six respondents update their formulary during the year, with three reporting monthly updates, one reporting quarterly updates, and two reporting bi-annual updates. All provide some form of patient notification. Notification mostly consists of direct mail and website updates (all six), although one plan also provides updates in its newsletter and one gives updates to providers. Given that all responding plans make formulary changes throughout the year, it is important to consider the effectiveness of appeals in determining the adequacy of the current system for patients, as well to consider the plans' ability to monitor implications of their formulary access.

Policies regarding holding patients harmless. Harvard Pilgrim Health Care (HPHC) has a reputation as a leader in drug management, including experimenting with innovative approaches to drug payments (e.g. developing value-based contracts with manufacturers) and developing a custom formulary. HPHC is the only plan respondent who explicitly holds the patient harmless in mid-plan year formulary updates. That is, they reported that they do not require switching for patients who are already using a drug.

Appeals process. Only two plans (including HPHC) are able to discriminate prior approval (PA) requests for therapeutic interchange versus requests for a priori clinical indications. However, HPHC is the only plan that reported tabulating the characteristics of PA requests, estimating that less than 10% (the lowest category) of PA requests are for therapeutic interchange.

While most plans reported an absolute PA denial rate of 10.1 – 50%, this question applies to PA denials across all reasons, not just therapeutic interchange. For the two plans that reported segmenting PA requests for therapeutic interchange, both reported an absolute denial rate for those requests of <10%, the lowest category. Therefore, while patients may have to engage in an appeals process to access their medications due to therapeutic interchange, which can present burdens for patients and providers, it appears that "best practice" plans do provide access to medications due to therapeutic interchange.

Ability to monitor effects of therapeutic interchange. Overall, plan efforts to monitor the effects of therapeutic interchange do not appear to be substantial. All respondents claim to monitor the impact of therapeutic exchange, but four out of six plans do not segment the reasons for PA, which could limit the ability to monitor impacts. Five of six plans report monitoring the impact of therapeutic exchange on pharmacy spending, but only half (three) report monitoring both medical and pharmacy impacts. None monitor

member or provider satisfaction, although these aspects can be more difficult to define. Furthermore, only two plans monitor abandoned prescriptions and only one monitors switching back to the original medication. None monitors revisits to health care providers, but some report that monitoring efforts vary by drug class.

Incentives. Two plans report providing incentives to promote therapeutic interchange, which in both cases consist of structuring lower copayments for preferred drugs. Only one plan reports prescriber incentives. This plan reported that it did not provide drug specific incentives, but rather providers are at risk for total spend, including drug spend. It is important to note that other plans likely do the same, but perhaps did not interpret the question about prescriber incentives as applying to total risk contracts. No plan reported pharmacy incentives.

2.3 Physician Questionnaire (developed and analyzed by Commission)

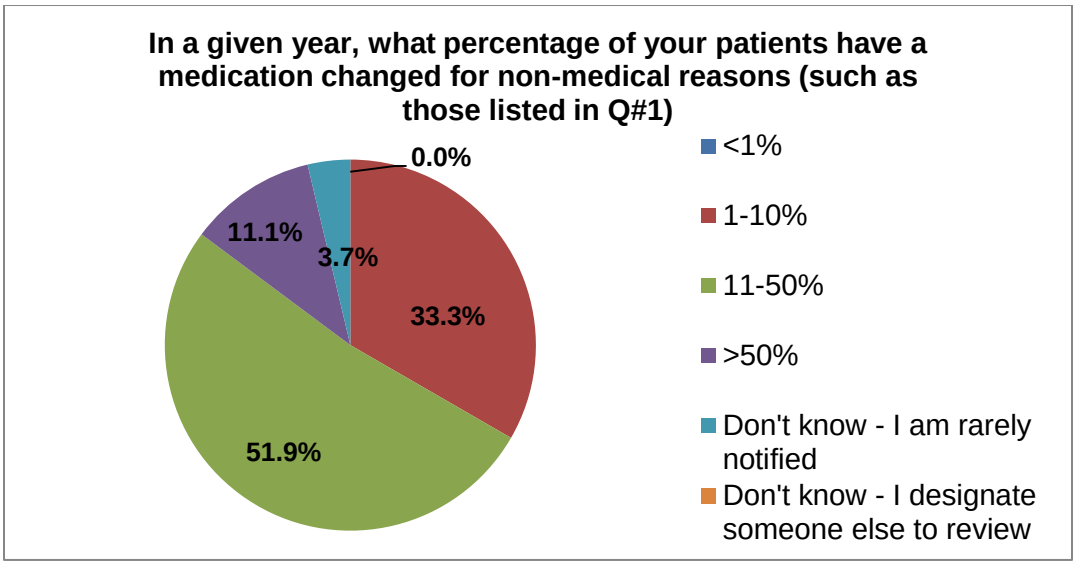
Summary

The Commission surveyed physicians to inform their experience with switching patients' medications. Of the 27 survey respondents, about half (13 or 48%) were in private practice, with most others (11 or 41%) belonging to a group practice, and a minority (3) or 11% practicing at an academic or teaching hospital. The physicians represented general medicine (18 or 67%), psychiatry (7 or 26%), neurology (1 or 4%), and surgery (1 or 4%). About half worked in a practice that participated in risk contracts (14 or 52%), with the remainder either not participating in a risk contract (6 or 22%) or did not know (7 or 26%).

1. ***Frequency of switching***

Results from the questionnaire suggest that patients in Massachusetts having a medication changed for non-medical reasons is a fairly common experience. About half of respondents reported that, in a given year, 11-50% of their patients had a medication changed for non-medical reasons (see **Exhibit 1**). While some respondents reported smaller shares of patients, other respondents reported larger shares. No respondent reported having no patients change medication for non-medical reasons in a given year. Note that this question could refer to a medication change for patients who were well maintained on a given medication, as well as patients starting a new medication for which the initial prescription was changed before it was filled.

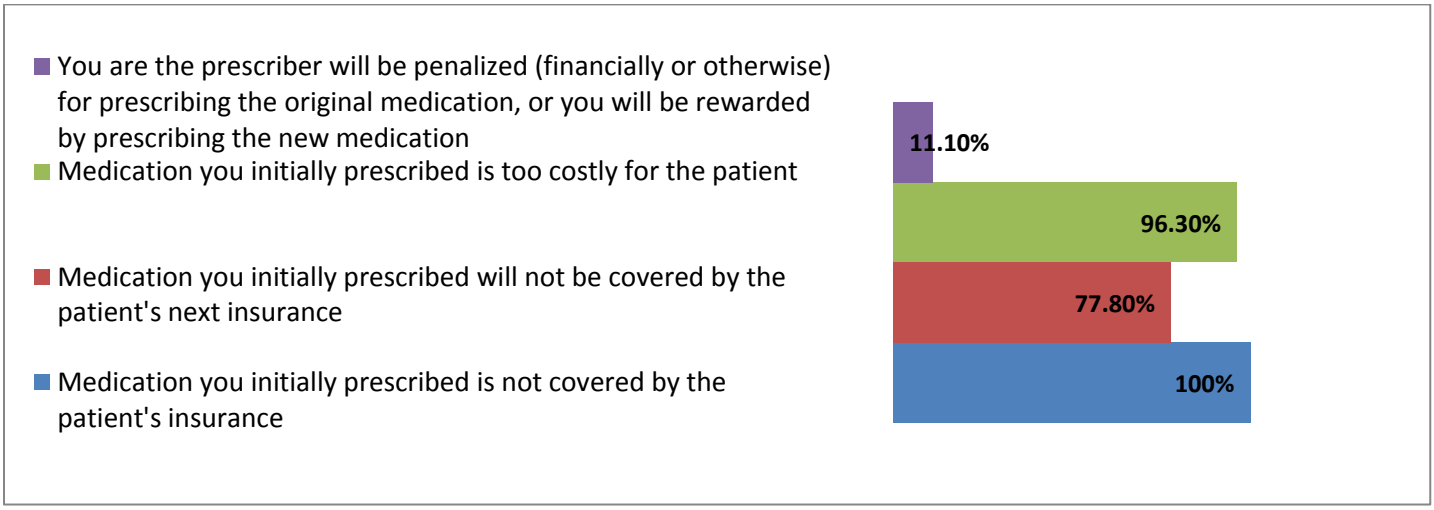
Exhibit 1



2. *Reasons for switching medications:*

Respondents cited the common reasons for non-medical medication switching included cost to the patient, lack of coverage by the patient's insurance or change in the patient's insurance (see **Exhibit 2**). All 27 respondents reported switching a patient's prescription because the medication initially prescribed was not covered by the patient's insurance. 26 respondents (96.3%) reported switching a patient's prescription because the medication initially prescribed was too costly for the patient. Twenty one (21) respondents (77.8%) reported switching a patient's prescription because the patient's insurance changed (77%). Three (3) respondents (11.1%) reported switching a patient's prescription because they would be penalized (financially or otherwise) for prescribing the original medication or would be rewarded for prescribing the new medication. Of these 3 respondents, 1 was in private practice and said their practice did not participate in risk contracts. The other 2 were in group practices and did participate in risk contracts.

Exhibit 2



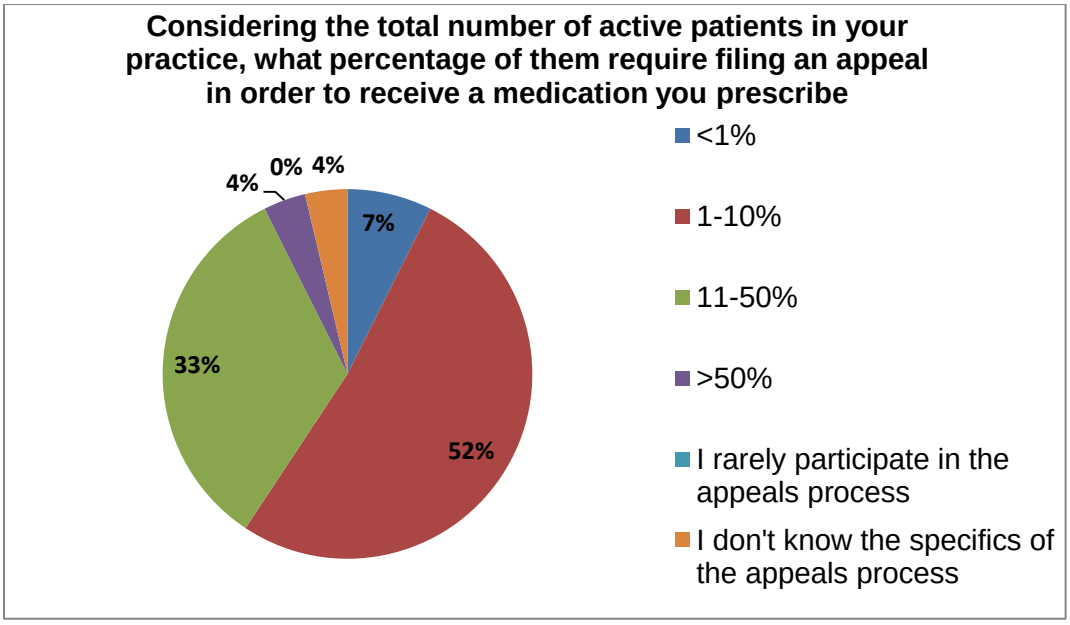
3. Knowledge of appeals processes

- 59.3% of respondents (16) knew about the medication appeals process for their insurance plans.
- 47% of respondents (11) did not know.

4. Patients requiring appeals

Survey data also indicates that many physician practices have a large share of patients who require filing an appeal in order to receive their medications (see **Exhibit 3**). While about half of physicians reported a relatively small share of members (1-10%) needing an appeal, about a third of physicians reported a relatively large share of members (11-50%) needing an appeal to receive their medication. These results suggest that the process to secure the appropriate medication for a patient may represent a large burden for some practices.

Exhibit 3



3. Listening Session

Summary

The Commission held a public listening session on November 13, 2017 to allow comments to be offered by the general public. There were 14 members of the public in attendance including patients and representatives from advocacy groups. Eight people gave oral testimony, two written testimonies were submitted at the session, and three people submitted testimony through an email box.

There were several main themes that arose from those testimonies.

- People on medications for certain chronic health conditions can be at risk of their health being destabilized as a result of changing medications. We heard testimony that drugs are not interchangeable and should not be as easily subject to non-medical switching

for the following conditions: Epilepsy, Multiple Sclerosis, Hemophilia and (Rheumatoid) Arthritis.

- Switching medications for people with certain chronic conditions can potentially increase medical costs including ambulance, emergency room visits, doctor visits, that outweigh the monthly expense to the plan of keeping that individual on their prescribed medication.

- Speakers understood that health plans change coverage for medications mid-year to accommodate market changes. However, they expressed that costs should not be passed on to patients who signed up for the plan assuming that the drug they needed would be on the formulary at a certain rate.

- Changes to plan design or drug tiers may result in patients having to pay more for medications, find an alternate therapy, or forego treatment altogether. This can result in stable patients losing access to their medications.
    - *One patient testified that her doctor switched her medication for medical reasons. The new medication worked well. Her insurance had covered it, but then the second time she got a dose the insurance company sent her an invoice for $40,000. This was resolved later when her doctor's office appealed the rejection but created quite bit of angst for this patient.*

- Plans should ensure existing enrollees in a health plan have continued access to their covered treatments within the plan year by requiring plans to provide continued access to stable patients.

- Speakers recommended having no mid-year changes without consent of the physician and patient. Given that this might not occur, plans should give adequate notification to physicians and patients to prepare for any changes.

- We heard that having an appeals process may not be a sufficient protection for people because this can be a lengthy process.

Specific concerns were raised by about switching for people with Epilepsy.

- People living with epilepsy who have their medications switched, or who experience a delay in accessing their medication, are at a high risk for developing breakthrough seizures and related complications including death.

- Patients also testified that, seizures can often result in significant social, legal, and developmental consequences including loss of one's driver's license, loss of employment, and loss of self-esteem.

- Slight changes in the amount of medication received by a person with epilepsy can mean the difference between a fully controlled condition and breakthrough seizures.
    - *One patient testified about being put on a generic drug required by their health plan and being told he should not be concerned about the switch. He stated that "Later, the next day, I would take my morning dose and go on with my day. I never saw that afternoon. I awoke the following day in a hospital bed. My doctor kept me for four days until she was certain that once again I was at least stable".*

A physician representing the American College of Asthma and Immunology spoke about devices used to deliver certain drugs for Asthma, and injectable adrenaline devices that are for the treatment of anaphylaxis and issues he encounters when the preferred device is difficult for his patients, many who are children to use.

- *The way the provider generally finds out about a switch for injectable adrenaline is when the pharmacy sends a fax stating that the patient's medication requires prior authorization. He stated that he has rules in his office that no switches to the generic or other changes in medicines are made until his office talks to the patient to see if there are other inexpensive drugs that may work better for the patient. Getting PAs to address these issues is time consuming for this office.*

4. Data Analysis

Summary

Overview of Pharmacy Claims Analysis

The Commission was tasked with studying the frequency by which patients are switched from prescription medications to other medication for non-medical reasons and without the consent or notification of the patients' prescribing physicians as well as determining the total cost to the commonwealth when individuals are switched from prescription drugs that have been safe and effective, including increases in the use of services, emergency room visits, inpatient hospital stays and outpatient visits. The Commission inquired whether the Massachusetts All Payer Claims Database (MA APCD) could support the analytic tasks outlined in the legislation, but after some preliminary investigation it became apparent that there are neither indicators nor flags in the pharmacy claims that identify when prescriptions have been changed for non-medical reasons, thereby making fulfillment of the analytic tasks through the use of the MA APCD pharmacy claims extremely challenging.

The Commission did perform a high level analysis of fully-insured commercial MA APCD pharmacy claims data (Massachusetts residents only) for three large health plans in an effort to estimate the scope of non-medical switching by Massachusetts health plans. In the first step of the analysis, drugs within the ten specified pharmaceutical classes were flagged as potential non-medical switches when there was a significant decrease in the number of claims from SFY2014 to SFY2015. The highlighted drugs were forwarded to a clinical expert (pharmacist or physician) for review to determine if the decline in the number of claims was likely due to a non-medical switch. The clinical feedback was then applied to the summary data and the percentage of claims associated with possible non-medical switching was calculated for each of the ten pharmaceutical classes for all three health plans.

The ten First Databank Pharmaceutical Classes that were the focus of the analysis were selected by Commission because patients using these classes of drugs were identified through the literature review or through the public listening session as being particularly vulnerable to changes to their medications. The ten pharmaceutical classes include:

- Drugs Acting on Non-Autonomic Nervous System (MS Drugs)
- Adrenergics Drugs (Epi-Pen)

- Drugs Affecting primarily Trachea/Bronchi (Advair, Albuterol)
- Anti-Convulsant Drugs (gabapentin)
- Anti-Hyperglycemic Drugs (Humalog, Invokana)
- Anti-Neoplastic Drugs (Letrozole)
- Anti-Viral Agents (Harvoni, Sovaldi)
- Blood and Blood Replacement Preparations
- Drugs Acting Principally on Joint (Arava, Humira, naproxen)
- Psychoactive Drugs (Abilify, bupropion)

The ten pharmaceutical drug classes represented 33% of the total pharmacy claims for the three large commercial health plans in SFY2015 and 58% of the total drug spend or allowed amount for the same period (Figure 1 and Figure 2).

Figure 1

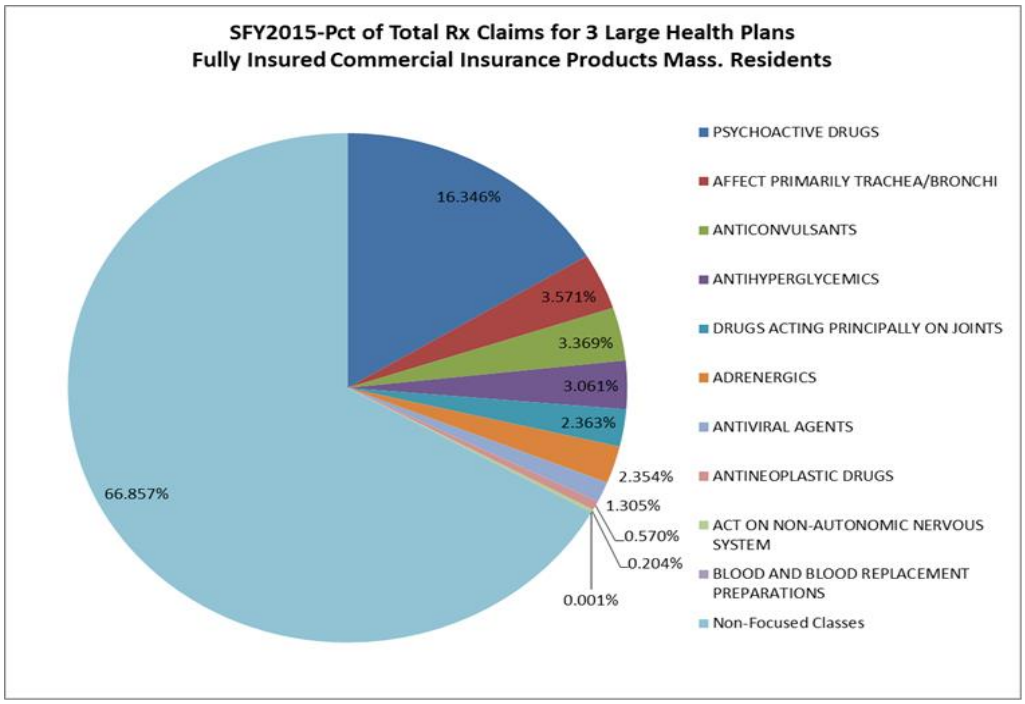


Figure 2

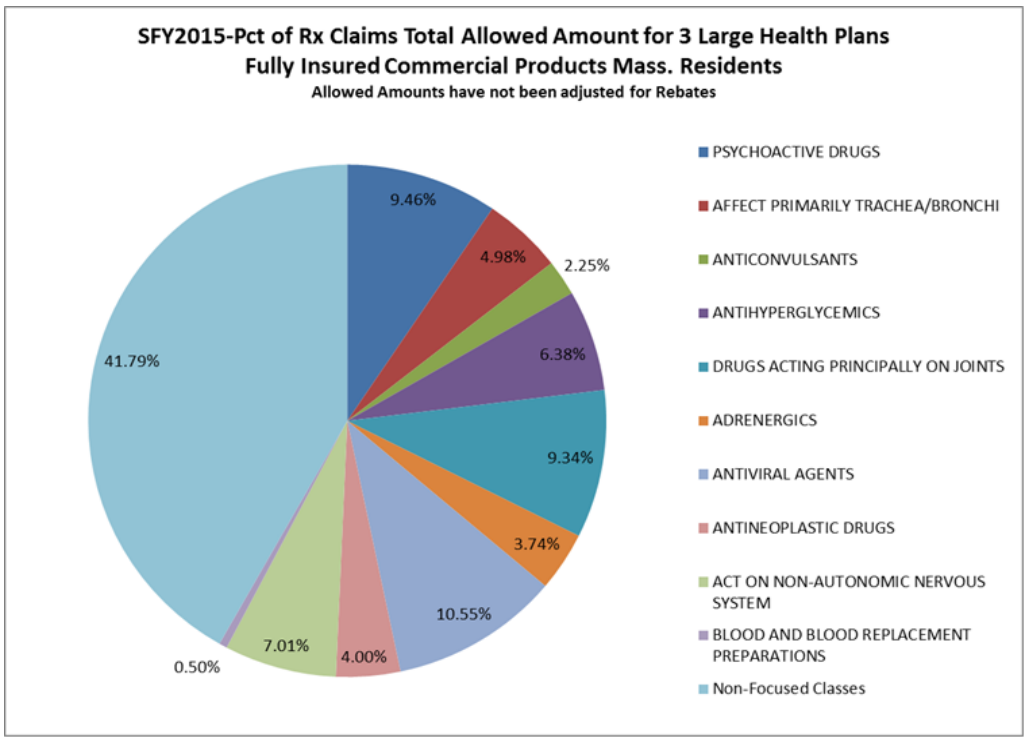


Table 1 summarizes which of the pharmaceutical drug classes by health plan appeared to have had some level of non-medical switches based on both a decline in number of claims between SFY2014 and 2015 and input from clinical experts. The estimated percentage of claims that were possibly associated with non-medical changes between SFY2014 and SFY2015 are also displayed.

Table 1-Possible Indication of Non-Medical Switch within Selected Drug Class and Estimated Percentage of Claims within Drug Class that were switched for Non-Medical reasons between SFY2014 and SFY2015

Ten Selected Drug Classes	Health Plan A	Health Plan B	Health Plan C
Drugs Acting on Non-Autonomic Nervous System	Yes/ 2%	Yes / 4%	Yes / 4%
Adrenergics Drugs	No	No	No
Drugs Affecting primarily Trachea/Bronchi	No	Yes / <1%	Yes / 2%
Anti-Convulsants Drugs	No	No	No
Anti-Hyperglycemics Drugs	Yes / 3%	Yes / 1%	Yes / 3%
Anti-Neoplastic Drugs	No	No	No
Anti-Viral Agents	No	No	No
Blood and Blood Replacement Preparations	No	No	No
Drugs Acting Principally on Joint	No	No	No
Psychoactive Drugs	Yes / <1%	Yes / 1%	Yes / <1%

After clinical review of the MA APCD commercial pharmacy claims summary files, there appeared to have been non-medical switching of drugs within pharmaceutical class between SFY2014 and SFY2015 for the three large private health plans included in the analysis. All three health plans appeared to have had non-medical switching within the following

pharmaceutical classes: Drugs Acting on Non-Autonomic Nervous System including Multiple Sclerosis Drugs; Anti-Hyperglycemic Drugs; and Psychoactive Drugs. Two of the health plans also had possible non-medical switching for Drugs affecting the Trachea/Bronchi.

The non-medical switching appeared to have affected between <1% to 4% of the claims within each of the pharmaceutical classes where a non-medical switch was potentially identified. Changes from one generic drug to another generic drug within the same drug class were not counted as a non-medical switch.

In order to perform longitudinal cost and utilization studies of patients who have experienced non-medical switching, the health plans would have to provide additional data (e.g. formulary data at the National Drug Code level with begin and end dates) that support the identification of non-medical switching within the pharmacy claims data.

REVIEW OF CHARGES TO COMMISSION

(i) the frequency by which patients are switched from prescription medications to other medications for non-medical reasons and without the consent or notification of the patients' prescribing physicians.

Results from the questionnaires suggest that patients in Massachusetts having a medication changed for non-medical reasons are a fairly common experience. The physician survey identified over half of the respondents reporting 11-50% of their patients having medications switched because of plan formulary changes. The patient survey disclosed almost two-thirds (64%) of respondents reported that their insurance company switched their medication to a drug that was different from the one their physician prescribed as the result of a formulary change. Both physicians and patients report relatively high rates of not being notified of formulary-based medication changes despite the health plans universally reporting that members and prescribers are notified through a variety of means. Patients also reported they frequently did not consent to the required medication change.

The health plan questionnaire responses disclosed some variability among the reporting plans' ability to discriminate utilization management activities directly attributable to therapeutic interchange (an indicator of non-medical switching). The plans generally reported between 10 and 50% of therapeutic categories being candidates for therapeutic interchange. Only one plan tabulated prior authorization (PA) requests attributable to therapeutic interchange and reported that to be less than 10% of its PA volume. Several plans reported the denial rate for PA appeals for therapeutic interchange was fewer than 10%. Given the size of the populations served by these health plans, these findings would support the premise that switching medications for non-medical purposes is a common occurrence in the Commonwealth.

Additionally, the Commission's efforts to quantify the rate and impact of non-medical medication switching were confounded by the absence of any indicator/marker in the data in the MA APCD, or any large database for that matter, that would address this question. The MA APCD analysis identified certain therapeutic categories for which the data suggested the possibility of between 1-4% of claims being switched for non-medical reasons. The Commission has low confidence in the methodology to support this hypothesis.

(ii) the frequency of a health provider prescribing an alternative drug in response to changes in health plan policies mid-year for non-medical reasons.

The Commission was not able to determine the frequency of medication switching in the middle of a plan year. Once again no data in the MA APCD would answer this question. That said, five of the 6 plans responding to the questionnaire do make mid-year formulary changes and determine, based on the situation, if members must switch. Only one plan categorically permits members to remain on their stable therapy during a mid-year formulary change.

(iii) Evaluating the role of financial incentives to pharmacists and prescribers in prescription drug switching decisions, including but not limited to payment, fee, incentive or other contractual reward for choosing a drug alternative;

The Commission found little evidence of financial incentives provided to prescribers to encourage switching medications for non-medical reasons. One health plan reported a broad, non-specific, incentive to prescribers who are at financial risk wherein the risk includes pharmaceutical spending. In the physician questionnaire, three respondents reported they would be penalized (financially or otherwise) for prescribing the original medication or would be rewarded for prescribing the new medication, however these reports were not further characterized.

It is common knowledge that health plans promote the most cost effective, therapeutically appropriate medications. The resulting financial savings may benefit consumers by reducing premiums and/or increasing access to high-cost prescription drugs. Plans determine financial preference either by identifying the least costly medications within a therapeutic category or entering into a contract with a manufacturer for discounts linked to formulary status. The Commission did not further investigate these well-established industry practices.

The Commission has not found evidence of actions on the part of pharmacists to warrant attention in recommendations on that sector, particularly given that any medication switching suggested by a pharmacist would require the prescriber to change the medication, so a natural stop-gap exists.

(iv) "determining the total cost to the commonwealth when individuals are switched from prescription drugs that have been safe and effective, including but not limited to increased use of services, emergency rooms visits, inpatient hospital stays and outpatient office visits";

The Commission was not able to answer this question because of data limitations. A small number of studies identified in the literature review have determined the impacts of non-medical switching on the consumption of other health care services. The results of these studies could not legitimately be extrapolated to the Commonwealth because of local data limitations, as well as limitations inherent in the study designs. The patient questionnaire reported high rates of adverse outcomes, including utilization of other healthcare services, by respondents.

(v) "identifying the patient populations most impacted by and vulnerable to being switched from prescription drugs for non-medical reason

The Commission identified several patient populations and/or therapeutic categories of drugs where non-medical switching could pose the greatest risk to patients. The literature review, questionnaires, and listening session lead to similar conclusions concerning the most vulnerable patients. The most frequent mentions in the Commission's review were complex chronic conditions such as neurological, auto-immune diseases and mental health conditions. More specific disease states such as epilepsy, hemophilia and multiple sclerosis were also

frequently mentioned and would be a subset of the non-specific categories mentioned in the previous sentence. It was difficult for the Commission to narrow down some of the higher risk disease states/therapeutic drug categories when references were made by various stakeholders to very broad categories, for example "behavioral health". Although mental health is frequently mentioned as a high risk category, the Commission received little direct testimony and reviewed studies with conflicting results concerning the risks of non-medical switching. These same populations of patients are also potentially vulnerable to other types of medication switches that were not addressed by the Commission: *a priori* (or pre-emptive) switches wherein the initial prescribed medication is compelled to be switched by the formulary strategy of the plan, and brand-to-generic switches which are mandated by consumer protection laws and the pharmacy practice act.

The Commission has been using the dyad of disease states-therapeutic drug categories to describe the potentially most vulnerable patient populations. The reason for the dual designation is that not every drug that could be used in the treatment of a particular disease state presents the same potential risk related to non-medical switching. Likewise, not every therapeutic category poses the same risk when used to treat different conditions. Medication switching concerns arise almost exclusively in the context of chronic diseases. The most compelling factor for risk from medication switching appears to depend on the complexity of the individual disease and/or patient. An illustrative example within the mental health area might be: the use of Selective Serotonin Reuptake Inhibitors (SSRIs, such as Celexa™) may pose little risk related to formulary switches in the management of chronic anxiety, but a more profound risk when used for major depressive disorder.

The following list is not exhaustive and not necessarily in priority order:

- Anti-epileptic Drugs (AEDs) – some of the most compelling testimony evaluated by the Commission related to this condition/drug pairing.
- Immune-mediated Diseases/Biologicals - this broad category of diseases and related drug therapy would include, but not be limited to, the following:
    - Multiple Sclerosis Drug Therapy – several different categories of drugs are used to treat MS, including biologicals.
    - Rheumatoid Arthritis – e.g., Anti-TNF drugs such as Humira™
    - Crohn's Disease - e.g., Anti-TNF drugs such as Humira™
- Mental Health – e.g, antipsychotics, antidepressants

Other disease/drug categories that were mentioned, but less frequently than those above included: cardio-metabolic diseases, oncology, infectious diseases, acid-suppression, and pain.

LIMITATIONS

The report of the Special Commission is bounded by certain limitations. The Commission was not funded and encountered time and financial constraints.

- The Commission did not have access to sufficiently detailed data to fulfill several of the charges to the Commission. Prescription drug databases, including the Massachusetts All Payer Claims Database (APCD), do not contain any indicator of the reason for a medication change. Although the Commission could identify certain instances of a medication change within therapeutic category, the reason for the change could not be established.
    - A more rigorous analysis using patient-level data and a methodology that would elucidate the reasons for a medication switch and whether that switch

lead to adverse outcomes, and quantifying same, was not possible given the constraints of resources.

- The sample size of the survey was small and the survey was only disseminated through the Massachusetts Patient Access and Safety Coalition. A larger sample size with random sampling across patient populations would have been preferable.
- The literature review the Commission conducted was thorough but not exhaustive. For example, the Commission did not attempt to independently ascertain the scientific quality of the literature reports (e.g., to detect statistical flaws, bias).
- Although the input from stakeholders was very useful to the Commission it was not balanced by countervailing views.
    - The questionnaires utilized by the Commission were not validated survey instruments. The questionnaires were directionally biased to elicit problems attributable to non-medical switching. Furthermore, the method of distribution of the questionnaires and the audience targeted were constrained by Commission resources.
    - Similarly, the public listening session was attended primarily by patients and advocacy groups opposed to non-medical medication switching.
- Despite hearing testimony that medication switching attributable to brand-to-generic switches could be problematic, particularly to patients with epilepsy, such switches are outside the scope of the Commission's charge.

RECOMMENDATIONS

Several themes emerged from the investigations by the Commission that establish the basis for the proposed recommendations the General Court may consider. The Commission is cognizant of the need to manage the cost of pharmaceuticals and the value formulary management systems bring to bear on containing health care costs. Modifications of the authority of health plans to utilize formulary management tools should consider a fair balance of the needs of the individual patient and the needs of the health care system to contain burgeoning healthcare costs. The Commission also recognizes that patients adherent to an effective stable therapeutic regimen provide the optimal clinical and economic outcomes.

- Patients and prescribers feel that non-medical switching interferes with the patient-physician relationship
- For patients who are stable on their medication regimens unplanned changes are disruptive and can be harmful
    - Such unplanned changes can result in physical, psychological and financial distress
    - An untoward outcome of such switching appears to be more problematic in certain disease states/therapeutic drug categories than others (vulnerable populations).
- Health plan formulary changes should be systematic, predictable, and transparent.
    - Patients and prescribers are concerned about inadequate notice of medication changes
    - If medication changes are required by the health plan, patients should provide consent or have an efficient expedited appeals process
- Formularies are an important tool to help health plans manage costs
    - Health plans typically change their formularies on an annual basis (plan year changes); however mid-year changes are made to accommodate market changes (e.g., newly marketed drugs, price increases).

The recommendations, in general, speak to providing greater assurances that formulary-driven medication switches be systematic, adequately communicated, and provide reasonable exceptions for patients stabilized on chronic medications. Many such protections currently exist in Massachusetts by regulation or best practice application but could be enhanced.

Recommendations

1. Establish rules or guidelines to hold patients harmless when the formulary status of a medication changes:

   NOTE: The Commission discussed but did not reach consensus on the most appropriate mechanism to ensure the continuation of stable medication regimens for vulnerable populations, particularly across plan years or for new enrollees. The Commission struggled with balancing the need to preserve the positive impact (fiscal and other) of sound formulary management practices with the need for vulnerable patient protection. Legislation may be needed to ensure proposed patient protections.

   Define stability rules and high risk therapeutic categories

   1.1. Within a plan year patients should not be mandated to switch a stable medication. Plans should establish clinically sound rules to determine which disease states/therapeutic drug categories are automatically or expeditiously exempted from non-medical switching.
      1.1.1. In those circumstances qualifying for an exemption, patients should not be required to pay a higher co-pay if the medication moves to a higher copay tier (or other out-of-pocket increase in cost).
      1.1.2. When the formulary changes, plans should continue to provide the stable medication pending the resolution of any appeals the patient may invoke.

   1.2. Establish or clarify rules regarding maintenance of stable medication as eligibility for medical necessity at the start of a new plan year (this principle could also apply to patients enrolling in a new plan):
      1.2.1. Across plan years, the plans should view stable medication regimens favorably as qualifying criteria for medical necessity, and as part of the assessment, apply clinically sound parameters for stability and risk.

2. Reinforce rules or guidelines for timely notification of patients and providers when the formulary status of a medication changes unless the formulary change is favorable to the plan members (e.g., addition of a drug to the formulary).

   Clarify notification rules for formulary changes and appeals

   2.1. Current rules require plans to notify providers and members 30 to 60 days in advance of formulary changes, however patients report being unaware of such changes.
      2.1.1. Plans should identify the member's preferred method of notification (e.g, phone/text/email) as a means to communicate formulary changes.
      2.1.2. Notification of mid-year formulary changes should emphasize the member's appeal rights. The notification of the opportunity to appeal should be written in

plain language, clearing explaining the member's rights and provide a phone number to respond to appellants questions.

3. Reinforce rules or guidelines for a timely and efficient appeals process.

   Define the turn-around time for an appeal of a medication switch for vulnerable populations

   3.1. Current rules allow for an expedited review (3 days) if required by the patient or the prescriber. This information should be emphasized as noted in 2.1.1 above.
      3.1.1. Consideration should be given to requiring expedited review for high risk therapeutic categories
   3.2. In the circumstance when the initial medication prescribed for a plan member is not preferred by the plan's formulary and is subjected to a management control (e.g., prior authorization), the plan should be required to adjudicate an appeal with a rapid turnaround.

4. State agencies (Division of Insurance, Office of Patient Protection) should monitor formulary-related appeals. Health plans should monitor the impact of medication switching for vulnerable populations.

   Create a limited set of measures plans must report to identify the frequency and outcome of formulary-based medication switches

   4.1. Plans should be able to distinguish between medication changes that occur subsequent to various types of formulary and benefit manipulations to better assess the impact of non-medical switching on vulnerable populations.

DISCUSSION

Plans can update formularies throughout the plan year, and plans have an appeals process for therapeutic interchange. However, navigating a system of prior authorizations and appeals can be confusing and time-consuming for patients and providers, and any denial of continuation of a medication on which a patient is well-maintained can have potentially adverse effects on patient health, particularly for patients who are medically vulnerable. It is difficult to conclude how switching medications for non-medical reasons impacts total cost of care in Massachusetts. Limited literature suggests that this practice may increase total costs of care in some cases, but it is difficult to generalize the specific findings to the broader population in the Commonwealth for whom these policies would apply.

With respect to a plan's ability to change its formulary within the plan year, the ability to adjust a formulary within the year provides plans with an important tool to respond to changes in the market (e.g. introduction of new competitors, price increases from manufacturers, etc), and provide them with negotiating leverage with manufacturers, which can help slow the growth in drug prices and insurance premiums for all consumers. CHIA and Health Policy Commission research indicates that drug spending has been the highest sector of commercial health care spending growth in Massachusetts in recent years, and mid-single digit annual growth is expected over the next decade (Health Policy Commission, 2016 Cost Trends Report). Maximizing the tools available to plans to combat drug spending growth is a highly important component of achieving affordable health care for all in Massachusetts. However, consumers are locked into their plan for the year, and they may choose their plans for the year

based on the formulary that is presented to them. Importantly, for patients who are well-maintained on a particular drug, the ability to have continued access to that drug may be a major factor in their decisions. Therefore, changing a formulary – and particularly creating substantive barriers to access of a drug on which patients are well-maintained – may run counter to the goal of having a transparent and fair health insurance marketplace.

Patients could still face adverse effects if plans discontinue coverage of a drug at the end of a plan year, if patients don't have access to other plans that include the drug on their formulary. Based on the literature search, it appears that no state mandates coverage across plan years. In Texas, a bill to do so was proposed, but it did not pass. This provision is supported by the Epilepsy Foundation of New England, which provided us with model legislation. Patient access to medications on which they are well-maintained must be carefully balanced with concern for the impact on health care costs and premium growth for all consumers, as well as concerns that this new precedent could be applied more broadly and impact plan's ability to manage costs through negotiating annually with providers through tiering and limited network access, or applied to a broader set of drugs than is absolutely necessary. An alternative to commercial plans covering drugs across plan years could be a state-funded drug assistance program on a very limited basis – perhaps added to the state AIDS drug assistance program, or another comparable program, if one exists.

Also, we have not found evidence of actions on the part of pharmacists to warrant attention in recommendations on that sector, particularly given that any medication switching suggested by a pharmacist would require the prescriber to change the medication, so a natural stop-gap exists

CONSIDERATIONS FOR FURTHER STUDY

- Consider a more rigorous analysis using patient-level data to address the questions the Commission could not answer because of the data limitations the Commission experienced.
- Develop a methodology that would clarify the reasons for a medication switch and whether that switch lead to adverse outcomes, and quantifying same.
- Explore what is adequate notification for members when plans intend to switch a patient who is stable on her/his medication.
- Determine how to address patients with complex or chronic diseases when they are starting on a medication that conflicts with the formulary strategy of a new health plan, or a new plan year.

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4. Medicare Part D Manual: http://www.cms.gov.

5. https://uspainfoundation.org/news/non-medical-switching-bills-announced-three-states/

APPENDICES (See attached zipped file)

1. Commission Members Roster
2. Literature Review Results
3. Environmental Scan
   - 3.1. AIMED Alliance Model Legislation
   - 3.2. Proposed 2017 Texas Legislation
   - 3.3. IfPA Healthcare Analytics Brief: Cost-Motivated Treatment Changes and Non-Medical Switching
   - 3.4. Connecticut Brief 1
   - 3.5. Connecticut Brief 2
4. GHLF Massachusetts Patient Access & Safety Coalition Questionnaire
5. Physician Questionnaire Results
6. Health Plan Questionnaire Results
7. Summary of Listening Session Testimony