AN EMPIRICAL EVALUATION OF PHARMACY "GAG" RULES IN THE U.S.

Farah Yehia, MPH[1] ; Jeromie Ballreich, PhD, MHS[2]

1-2. Department of Health Policy & Management, Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland.

Background

- Pharmacy Benefit Managers (PBMs) are intermediaries that negotiate prices with manufacturers on behalf of payers. But conflicts of interest surround PBMs' role.
- PBMs impose a "gag" clause forbidding pharmacist from telling consumer when cash price is lower than cost-sharing.
- Cost-sharing can be higher than cash price due to high list prices. The difference- 'claw back'- is said to be captured by the PBM.
- In a 2016 survey of community pharmacists, 58.1% of respondents reported that the gag clause in their contracts affected at least 10 or more transactions in the past month[1].
- Besides media reports, little empirical evidence on gag clauses exists to date.

Objective

- To estimate the frequency in which patients pay higher copay compared to pharmacy price
- To identify the most commonly involved drugs ("gag suspects")
- To examine characteristics of "gag suspect" drugs

Methods

- We used two datasets to evaluate patient cost-sharing and pharmacy price at the National Drug Code level.
  a. Patient-level cost was sourced from **IBM Truven Marketscan** (2014-2015). Transactions included copayment, coinsurance, and dispensing fee.
  b. Pharmacy prices were estimated based on acquisition costs from the **National Drug Acquisition Cost** Dataset and dispense fees (since Nov 2013)
  c. Drug characteristics were retrieved from Redbook (2016).
- The following variables were generated:
  a. Cost sharing= copayment + coinsurance → indicator of patient's OOP copay
  b. Total cost= NADAC + dispensing fee → Indicator of the true cash price
     ➢ *Since commercial dispensing fee may be subsidized (pharmacy charges lower dispensing fee and makes more $ on price spread), we stratified results by additional thresholds*
  c. Number of times the patient pays higher copay for drug (ie, total number of "Patient Worse Off" at drug level)
     ➢ *Stratified by 5 levels of patient worse off: >$0, $0-10, $10-20, $20-30, >$30*
  d. Number of times the patient pays higher copay for product (ie, total number of "Patient Worse Off" at the product (NDC desc) level)
  e. Weight variables= n# times patient pays higher copay for drug/n# fills per NDC
- Descriptive statistics and a Generalized Linear Regression Model (GLM) were run to address the research objectives.

Results

Table 1: Sample Characteristics

Variable	2014 n=109,845 Freq (%)	2015 n= 104,925 Freq (%)
Patient Worse Off Level		
PTX_WORSE_30_TOT	44,094 (40.14%)	39,717 (37.85%)
PTX_WORSE_20_TOT	48,598 (44.24%)	41,383 (39.44%)
PTX_WORSE_10_TOT	75,739 (68.95%)	68,583(65.36%)
PTX_WORSE_0_TOT	92,523 (84.23%)	87,700 (83.58%)
Drug involved= Yes	98,620 (89.78%)	94,020 (89.61%)
Drug type		
Multisource brand, generic	5,142 (4.68%)	4,341 (4.14%)
Multisource brand, no generic	827 (0.75%)	534 (0.51%)
Multisource generic	85,223 (77.58%)	82,057 (78.21%)
Other/unavailable	162 (0.15%)	6 (0.01%)
Over the counter	839 (0.76%)	821 (0.78%)
Single source brand	11,198 (10.19%)	10,108 (9.63%)
Single source generic	6,454 (5.88%)	7,058 (6.73%)
Maintenance indicator		
Primarily chronic	47,562 (43.3%)	45,758(43.61%)
Both acute & chronic	32,641 (29.72%)	31,045(29.59%)
Primarily acute	28,826 (26.24%)	27,316(26.03%)
Missing/other	816 (0.74%)	806(0.77%)
Therapeutic Group*		
(8) Central Nervous System	31,765 (28.92%)	30,704 (29.26%)
(7) Cardiovascular Agents	22,910 (20.86%)	21,924 (20.89%)
(20) Hormones & Synthetic Subst	11,615 (10.57%)	11,805 (11.25%)
(2) Anti-Infective Agents	9,419 (8.57%)	9,083 (8.66%)
(26) Skin & Mucous Membrane	8,304 (7.56%)	7,671 (7.31%)

*Only the top 5 therapeutic groups comprising over 75% of the data are reported in this table.

Results

Table 2: Top 10 Products with Highest Count* of Patients Worse Off in 2014

Product (ndc_desc)	RANK	NDCS	>$30	$20-$30	$20-$10	$10-0	Any amount
AMLODIPINE BESYLATE 10 MG TAB	1	331	8,829	2,093	22,345	171,598	204,865
MELOXICAM 15 MG TABLET	2	177	6,323	1,927	17,585	296,135	321,970
ATORVASTATIN 40 MG TABLET	3	185	5,619	5,390	33,775	280,573	325,357
OMEPRAZOLE DR 40 MG CAPSULE	4	245	4,646	521	3,501	96,306	104,974
CARVEDILOL 25 MG TABLET	5	194	4,607	4,808	35,925	441,626	486,966
LOSARTAN POTASSIUM 50 MG TAB	6	315	4,482	3,075	22,988	293,420	323,965
LISINOPRIL-HYDROCHLOROTHIAZIDE 20-25 MG TAB	7	114	4,050	4,409	22,972	302,731	334,162
SYNTHROID 100 MCG TABLET	8	35	3,825	2,928	22,027	257,078	285,858
BUPROPION SR 150 MG TABLET	9	84	2,793	2,817	19,898	262,681	288,189
VALACYCLOVIR HCL 500 MG TABLET	10	227	2,793	2,817	19,898	262,681	288,189

*Ranked by count of patient-worse-off level ">30$", to represent most burdensome drugs on out-of-pocket expenditure

Table 3: Top 10 Products with Highest Count* of Patients Worse Off in 2015

Product (ndc_desc)	RANK	NDCS	>$30	$20-$30	$20-$10	$10-0	Any amount
FLUTICASONE PROP 50 MCG SPRAY	1	60	7,589	948	9,763	281,340	299,640
METOPROLOL TARTRATE 50 MG TAB	2	151	6,539	3,537	10,376	173,626	194,078
PRAVASTATIN SODIUM 40 MG TAB	3	162	5,458	332	1,427	37,496	44,713
OMEPRAZOLE DR 20 MG CAPSULE	4	271	4,464	2,317	9,282	202,183	218,246
ONDANSETRON HCL 4 MG TABLET	5	108	3,366	1,711	11,428	271,659	288,164
PROAIR HFA 90 MCG INHALER	6	12	2,712	1,530	7,196	130,709	142,147
DULOXETINE HCL DR 60 MG CAP	7	236	2,712	1,530	7,196	130,709	142,147
ATORVASTATIN 80 MG TABLET	8	145	2,254	2,889	12,699	210,459	228,301
BUPROPION HCL XL 300 MG TABLET	9	142	1,919	946	5,540	117,248	125,653
VOLTAREN 1% GEL	10	12	1,881	2,119	11,025	157,648	172,673

Table 4: GLM proportion of times patient pays higher copay than total cost for a drug (weight_NDC) (model with lowest AIC is shown)

Odds Ratio	Model A
Drug type	
Multisource generic (3) (reference)	--
Multisource brand, generic (1)	.142***(.134-.151)
Multisource brand, no generic (2)	.150***(.118-.191)
Other/unavailable (4)	3.56e-06***(1.60e-06- 7.95e-06)
Over the Counter (5)	.364***(.322-.411)
Single source brand (6)	.0431***(.041-.045)
Single source generic (7)	.080***(.075-.085)
Maintenance indicator	
Primarily chronic (1) (reference)	--
Both acute & chronic (2)	.854***(.832-.877)
Primarily acute (3)	1.115***(1.083-1.148)
Missing/other (4)	.325***(.269-.392)
Number of manufacturers	.999***(.999-.999)
Number of drugs in therapeutic group	.999(.999-1.000)
Constant	.865 (.494-1.515)
Observations	104,925
AIC	69,364.93
BIC	69,680.44

*Therapeutic group included in model but not presented in table

Discussion & Future Directions

- Our study provides empirical evidence to suspect the gag rule is widely exercised. Among drug types, generic drugs seem to be especially involved.
- In almost 37% of drug fills made in 2015, patients were made worse off by the copay by more than $30. In 2014, patients were made worse off by more than $30 in almost 40% of transactions.
- Multisource generic category is significantly associated with increased odds of weight_NDC, compared to every other drug type category.
- Drugs for Primarily Acute indications have significantly increased odds of weight_NDC, compared to Primarily Chronic indications.
- Future work should involve validating results of "gag suspect" drugs with local pharmacies and a group of clinicians.

Acknowledgments

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References
(1) NCPA(2017, June 28). Pharmacists survey: Prescription drug costs skewed by fees on pharmacies, patients. Retrieved from: www.ncpanet.org/newsroom/news-releases/2016/06/28/pharmacists-survey-prescription-drug-costs-skewed-by-fees-on-pharmacies-patients