Division of Medicaid
Office of the Governor
State of Mississippi
Drug Utilization Review (DUR) Board Meeting

MISSISSIPPI DIVISION OF
MEDICAID

January 21, 2016 at 2:00pm

Woolfolk Building, Room 117

Jackson, MS

Prepared by:

MS|DUR Evidence-Based DUR Initiative
The University of Mississippi School of Pharmacy

Drug Utilization Review Board

Allison Bell, Pharm.D.
University of MS School of Pharmacy
2500 North State St.
Jackson, MS 39216
Term Expires: June 30, 2018

James R. “Beau” Cox, Pharm.D. (**Co-Chair**)
Tara Pharmacy
110 Metroplex Blvd., Suite H
Pearl, MS 39208
Term Expires: June 30, 2016

Logan Davis, Pharm.D., MBA
Vital Care, Inc.
1170 NE Industrial Park Rd
Meridian, MS 39301
Term Expires: June 30, 2016

Antoinette M. Hubble, M.D.
McComb Children's Clinic
300 Rawls Dr. Ste 100
McComb, MS 39648
Term Expires: June 30, 2017

Cherise McIntosh, Pharm.D.
UMC Dept of Pharmacy
2500 North State St.
Jackson, MS 39216
Term Expires: June 30, 2017

Jason Parham, M.D.
UMMC Department of Medicine
2500 North State Street
Jackson, MS 39216
Term Expires: June 30, 2016

Bobby Proctor, M.D.
Laurel Family Clinic
1440 Jefferson St.
Laurel, MS 39440
Term Expires: June 30, 2016

Janet Ricks, D.O.
UMMC, Family Medicine
2500 North State Street
Jackson, MS 39216
Term Expires: June 30, 2018

Sue H. Simmons, M.D.
Maben Medical Clinic
49 Turner St.
Maben, MS 39750
Term Expires: June 30, 2018

Dennis Smith, R.Ph. (**Chair**)
Polk's Discount Pharmacy
1031 Star Rd
Brandon, MS 39042
Term Expires: June 30, 2017

Cynthia Undesser, M.D.
MS Children's Home Services
402 Wesley Ave
Jackson, MS 39202
Term Expires: June 30, 2017

Pearl Wales, Pharm.D.
Be Jay PE Pharmacy 1668
West Peace Street
Canton, MS 39047
Term Expires: June 30, 2018

2016 DUR Board Meeting Dates

January 21, 2016
April 14, 2016
July 21, 2016
September 29, 2016

As with any analysis, great efforts are made to ensure that the information reported in this document is accurate. The most recent administrative claims data available are being used at the time the reports are generated, which includes the most recent adjudication history. As a result, values may vary between reporting periods and between DUR Board meetings, reflecting updated reversals and claims adjustments.

Unless otherwise indicated, all MS-DUR analyses are conducted for the entire Mississippi Medicaid program including beneficiaries receiving services through the Medicaid fee-for-service (FFS) and the two Mississippi Medicaid Coordinated Care Organizations (CCOs). When dollar figures are reported, the reported dollar figures represent reimbursement amounts paid to providers and are not representative of final Medicaid costs after rebates. Any reported enrollment data presented are unofficial and are only for general information purposes for the DUR Board.

Please refer to the Mississippi Division of Medicaid website for the current official universal preferred drug list (PDL).

http://www.medicaid.ms.gov/providers/pharmacy/preferred-drug-list/

MISSISSIPPI DIVISION OF MEDICAID
OFFICE OF THE GOVERNOR
DRUG UTILIZATION REVIEW BOARD
AGENDA
January 21, 2016

DUR Board Meeting Minutes

MISSISSIPPI DIVISION OF MEDICAID
DRUG UTILIZATION REVIEW (DUR) BOARD
MINUTES OF THE November 5, 2015 MEETING

DUR Board Members:	Feb 2014	May 2014	Aug 2014	Nov 2014	Feb 2015	May 2015	Aug 2015	Nov 2015
Allison Bell, Pharm.D.	✓	✓	✓		✓	✓	✓	✓
James R. "Beau" Cox, Pharm.D.	✓		✓		✓	✓	✓	✓
Logan Davis, Pharm.D.	✓		✓	✓	✓	✓	✓	✓
Antoinette M. Hubble, M.D.	✓	✓	✓	✓	✓	✓	✓	✓
Cherise McIntosh, Pharm.D.	✓	✓	✓	✓	✓	✓		✓
Jason Parham, M.D.	✓	✓	✓	✓	✓	✓	✓	✓
Bobby Proctor, M.D.	✓		✓	✓		✓	✓	✓
Janet Ricks, D.O.								✓
Sue Simmons, M.D.	✓	✓	✓		✓	✓	✓	
Dennis Smith, R.Ph. (Chair)	✓	✓	✓	✓	✓	✓	✓	✓
Cynthia Undesser, M.D.	✓	✓	✓		✓	✓	✓	
Pearl Wales, Pharm.D.								✓
TOTAL PRESENT	**12**	**7**	**11**	**6**	**9**	**10**	**9**	**10**

Dr. McIntosh joined the meeting at 2:13 during old business discussion.

Also Present:

DOM Staff:
Judith Clark, R.Ph., Director, DOM Office of Pharmacy; Terri Kirby, R.Ph., DOM Clinical Pharmacist; Cindy Noble, Pharm.D., MPH, DOM DUR Coordinator;

MS-DUR Staff:
Ben Banahan, Ph.D., MS-DUR Project Director; Shannon Hardwick, R.Ph., MS-DUR Clinical Director

Xerox Staff:
Leslie Leon, Pharm.D.

Coordinated Care Organization Staff:
Conor Smith, R.Ph., Magnolia
Michael Todaro, Pharm D., Magnolia

Visitors:
Andrea McNeal, DOM Program Integrity; Beth Roberts, DOM Program Integrity; Tamiko Young, DOM Program Integrity; Carmen Robinson, DOM Program Integrity; Bernadette Parks, DOM Program Integrity; Sajani Bast, AstraZeneca; Jeff Knappen, Allergan; Rachel Thomas, Otsuka

Call to Order:
Mr. Dennis Smith, Chairman of the Board, called the meeting to order at 2:00 pm.

Introduction of New DUR Board Members

Ms. Judith Clark welcomed new members and conducted introductions.

Old Business:
The motion for approval of the minutes was made by Dr. Hubble and seconded by Dr. Proctor received unanimous approval.

Dr. Banahan provided feedback to the board about actions taken from previous board recommendations. During the August meeting, MS-DUR presented information on Synagis utilization during the 2014-15 season and indicated that MS-DUR was working on an outcomes based report. Due to the small sample size and limitations in identifying at risk children using claims data it was determined that an outcomes analysis could not be completed. In September 2015 the DUR Board recommended that the Pharmacy &Therapeutics (P&T) Committee change triazolam and methadone to non-preferred status on the MS DOM preferred drug list. The P&T Committee approved this recommendation and MS-DUR conducted an educational mailing to notify prescribers of the change. Dr. Banahan reviewed other educational mailings currently in progress that address high morphine equivalent doses and doctor shopping, adherence to chronic medications, metabolic monitoring related to antipsychotic use in children, and ADHD treatment follow-up care in children. The recent update to the Cough and Cold Quick List was mailed to high utilization prescribers of these products. Dr. Noble updated the board on the clinical edit and the manual prior authorization (PA) process being implemented when a third antipsychotic is prescribed.

Resource Utilization Review:
Dr. Banahan stated that the analysis of utilization among Fee-For-Service (FFS) and the two Coordinated Care Organizations (CCOs) noted no major exceptions. The Board was asked for recommendations regarding a value amount to use for high cost prescriptions in order to separate these high cost products from other products in the resource reports. After discussion, Mr. Smith recommended a cut off of $1500 per claim. Ms. Clark asked that MS-DUR begin with carving out hemophilia factor and to add the number of claims and number of unique beneficiaries in the top product reports.

Pharmacy Program Update:
Ms. Clark suggested that the DUR Board consider adopting a procedure which would allow for the co-chair to be mentored by the current DUR Board chair. This would allow for succession planning provided that the term limits of the co-chair allow this member's participation after the next election. Dr. McIntosh made a motion that Mr. Smith remain as chair and Dr. Wales be co-chair. The motion was seconded by Dr. Hubble and passed unanimously.

Ms. Clark reviewed major items related to pharmacy that will be included in the December Provider Bulletin. A major update in the Universal Preferred Drug List (UPDL) will become effective January 1, 2016. Additionally, Division of Medicaid (DOM) will add varicella vaccine to the adult vaccines covered through pharmacy services on January 1, 2016.

Feedback and Discussion from the Board

Mr. Smith asked that MS-DUR consider a review of respiratory care agents and impact due to guideline changes for short-acting and long-acting beta agonists that occurred in April 2015. Dr. Hubble reported it has been difficult getting Pulmicort for infants less than 12 months of age since it is not an FDA approved indication. She noted that it is the only agent with nebulizer. Ms. Clark asked the board about problems with opiate use and the need for DOM to reconsider current parameters and recommendations for "lock-in" program regarding beneficiaries utilizing multiple pharmacies and

prescribers for opiates. Drs. Proctor and Rick reported that pain management contracts require patients to use only one pharmacy except in emergency situations. It was reported that pain management clinics monitor the use of multiple pharmacies closely. Several members of the Board commented that five pharmacies was too many for patients to be allowed to use for opiates prior to being "locked-in". Members from the DUR Board expressed a strong belief that use of one pharmacy was sufficient for beneficiaries in lock-in for suspicious use of opiates, with the understanding that special circumstances will require the use of a second pharmacy occasionally.

New Business:

Jadenu / Exjade Utilization and Costs

Dr. Banahan provided an overview of the MS-DUR analysis of Jadenu and Exjade utilization and costs. Results indicated that utilization of deferasirox has increased significantly with the introduction of Jadenu but there was no indication of inappropriate use. The Board concurred with the recommendation that MS-DUR continue to monitor use of these products to see where utilization levels off but no action was needed at this time.

Daraprim Price Increase and Utilization

Dr. Banahan reported that when Turing Pharmaceuticals bought Daraprim from Impax Laboratories in August 2015, the company immediately raised the price of one pill from $13.50 to $750. As a result of this action, MS-DUR conducted an analysis of Daraprim utilization and the estimated impact of the price increase to DOM. Results indicated that current utilization is appropriate and although the price increase will result in a major increase in the amount DOM pays to pharmacies for Daraprim therapy, the net impact on DOM may be an actual reduction in net cost due to mandatory Federal rebate guidelines. The Board agreed that no actions were needed at this time.

Changes in Mental Health Medication Use Among Children Transitioning From Fee-for-Service (FFS) to Coordinated Care Organizations (CCOs)

Dr. Banahan informed the board that during the August 2015 P&T Committee meeting a committee member expressed concerns that children were not being allowed to remain on multiple stimulants when transitioning to coordinated care organizations (CCOs). Results of an analysis conducted by MS-DUR indicated that no systematic changes were occurring in the number of agents children were taking before and after transitioning to CCOs.

Exceptions Monitoring Criteria Recommendations

Dr. Banahan introduced the six new exceptions monitoring criteria that were being proposed. All criteria are based on recent warnings or updates from the Food and Drug Administration.

1. Concomitant administration of Stribild (elvitegravir, cobicistat, emtricitabine, tenofovir disoproxil fumarate) with anticonvulsant medications - carbamazepine, phenobarbital, and phenytoin.
2. Concomitant administration of Etopophos (etoposide phosphate) with antiepileptic medications.
3. Use of Daytrana (methylphenidate transdermal system) in patients with chemical leukoderma.
4. Co-administration of ACE inhibitors and mTOR inhibitors leading to increased risk of angioedema.
5. Concomitant use of PDE5 Inhibitors and mTOR inhibitors leading to increased risk of hypotension.
6. Proglycem (diazoxide) Capsules and Oral Suspension use in neonates and infants.

Dr. Hubble made a motion that the six new exceptions be approved as a group. The motion was seconded by Dr. Proctor and passed unanimously.

Next Meeting Information:

Ms. Clark explained that the 2016 schedule for DUR meetings is somewhat different than in the past years due to DOM's desire for the DUR meeting to be conducted prior to the P&T Committee. This would allow DUR Board recommendations to be shared with the P&T Committee during the same quarter. Mr. Smith announced that the next meeting date is January 21, 2016 at 2:00p.m. He thanked everyone for their attendance at the DUR Board meeting. Mr. Smith stated that there was good discussion surrounding the agenda and wished everyone a happy holiday. The meeting adjourned at 3:25 pm.

Submitted,
Evidence-Based DUR Initiative, MS-DUR

PUBLIC MEETING NOTICES

MISSISSIPPI DIVISION OF
MEDICAID

Drug Utilization Review
Board Meeting

November 5, 2015
2:00 P.M.
Woolfolk Building - Room 117

Resource Utilizaton Review

ENROLLMENT STATISTICS FOR LAST 6 MONTHS June 2015 through November 2015							
		Jun-16	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16
Total enrollment		763,199	762,787	759,118	753,834	748,451	742,896
Dual-eligibles		155,632	155,566	155,499	155,428	155,140	154,697
Pharmacy benefits		660,125	659,748	655,844	650,185	643,929	638,009
LTC		17,567	17,598	17,562	17,541	17,449	17,119
PLAN %	FFS	35.6%	23.6%	23.7%	23.5%	23.1%	22.3%
	MSCAN-UHC	31.8%	38.3%	38.3%	38.4%	38.6%	38.9%
	MSCAN-Magnolia	32.6%	38.2%	38.1%	38.1%	38.4%	38.8%

PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS June 2015 through November 2015							
		Jun-16	Jul-16	Aug-16	Sep-16	Oct-16	Nov-16
# Rx Fills	FFS	116,684	85,458	89,036	89,426	90,368	85,055
	MSCAN-UHC	161,386	179,503	200,856	204,298	212,113	209,843
	MSCAN-Mag	197,515	212,164	229,971	128,001	245,474	63
# Rx Fills / Bene	FFS	0.5	0.5	0.6	0.6	0.6	0.6
	MSCAN-UHC	0.8	0.7	0.8	0.8	0.9	0.8
	MSCAN-Mag	0.9	0.8	0.9	0.5	1.0	0.0
$ Paid Rx	FFS	$15,270,841	$12,719,320	$12,521,782	$13,318,346	$13,003,814	$12,910,686
	MSCAN-UHC	$14,471,676	$16,585,503	$17,900,328	$18,298,462	$18,444,524	$18,242,625
	MSCAN-Mag	$17,829,705	$19,252,552	$20,335,798	$10,487,502	$20,495,834	$6,637
$ /Rx Fill	FFS	$130.87	$148.84	$140.64	$148.93	$143.90	$151.79
	MSCAN-UHC	$89.67	$92.40	$89.12	$89.57	$86.96	$86.93
	MSCAN-Mag	$90.27	$90.74	$88.43	$81.93	$83.49	$105.35
$ /Bene	FFS	$64.98	$81.69	$80.56	$87.17	$87.42	$90.74
	MSCAN-UHC	$68.94	$65.64	$71.26	$73.29	$74.21	$73.50
	MSCAN-Mag	$82.85	$76.39	$81.38	$42.34	$82.89	$0.03

NOTE: Paid amounts represent amount reported on claims as paid to the pharmacy. These amounts do not reflect final actual costs after rebates, etc.

-- Indicates unreliable cells due to data reporting issues that need to be resolved.

Top 10 Drug Categories by Dollars Paid In Nov 2015 (FFS AND CCOs)

Category	Month Year	Rank Paid Amt	# RXs	$ Paid	# Benes
CENTRAL NERVOUS SYSTEM AGENTS	Nov 2015	1	14,119	$3095918	12,347
	Oct 2015	1	24,618	$5357388	21,327
	Sep 2015	1	20,671	$4500297	18,154
ANTIPSYCHOTICS	Nov 2015	2	6,672	$3023371	5,793
	Oct 2015	2	10,768	$4933844	9,547
	Sep 2015	2	8,815	$4009536	7,784
COAGULATION MODIFIERS	Nov 2015	3	79	$2609132	65
	Oct 2015	5	90	$2414810	77
	Sep 2015	3	85	$2960485	65
ANTIVIRAL AGENTS	Nov 2015	4	322	$1551354	303
	Oct 2015	3	712	$2927118	688
	Sep 2015	4	501	$2337235	485
RESPIRATORY AGENTS	Nov 2015	5	6,110	$1308373	6,022
	Oct 2015	4	11,401	$2435040	11,246
	Sep 2015	5	8,955	$1916063	8,875
ANTIDIABETIC AGENTS	Nov 2015	6	2,393	$1114748	1,802
	Oct 2015	6	4,534	$2192891	3,440
	Sep 2015	6	3,312	$1566047	2,563
GASTROINTESTINAL AGENTS	Nov 2015	7	4,986	$639,808	4,826
	Oct 2015	7	9,722	$1157013	9,400
	Sep 2015	8	7,252	$890,637	7,050
ANALGESICS	Nov 2015	8	14,529	$600,117	13,080
	Oct 2015	9	28,398	$1090614	25,228
	Sep 2015	9	22,375	$845,280	20,163
ADRENAL CORTICAL STEROIDS	Nov 2015	9	9,049	$597,382	8,511
	Oct 2015	10	15,929	$970,299	14,981
	Sep 2015	10	11,260	$738,426	10,713
BRONCHODILATORS	Nov 2015	10	9,657	$582,753	8,548
	Oct 2015	8	18,104	$1129458	15,821
	Sep 2015	7	13,122	$917,246	11,522

NOTE: Ranks are accurate but due to data reporting issues from CCO, total numbers for RXs , Paid and Benes for Sept and Oct cannot be compared to Oct

Top 10 Drug Categories by Number of Claims In Nov 2015 (FFS AND CCOs)

Category	Month Year	Rank Volume	# RXs	$ Paid	# Benes
ANALGESICS	Nov 2015	1	14,529	$600,117	13,080
	Oct 2015	1	28,398	$1090614	25,228
	Sep 2015	1	22,375	$845,280	20,163
CENTRAL NERVOUS SYSTEM AGENTS	Nov 2015	2	14,119	$3095918	12,347
	Oct 2015	2	24,618	$5357388	21,327
	Sep 2015	2	20,671	$4500297	18,154
RESPIRATORY AGENTS	Nov 2015	3	10,912	$231,957	10,490
	Oct 2015	3	21,261	$445,479	20,308
	Sep 2015	3	16,508	$347,151	15,923
PENICILLINS	Nov 2015	4	10,636	$111,577	10,411
	Oct 2015	4	18,821	$198,021	18,452
	Sep 2015	4	14,013	$145,459	13,804
BRONCHODILATORS	Nov 2015	5	9,657	$582,753	8,548
	Oct 2015	5	18,104	$1129458	15,821
	Sep 2015	5	13,122	$917,246	11,522
ADRENAL CORTICAL STEROIDS	Nov 2015	6	9,049	$597,382	8,511
	Oct 2015	6	15,929	$970,299	14,981
	Sep 2015	7	11,260	$738,426	10,713
MACROLIDE DERIVATIVES	Nov 2015	7	8,916	$319,119	8,713
	Oct 2015	8	15,350	$516,865	14,955
	Sep 2015	8	10,567	$374,294	10,373
ANALGESICS	Nov 2015	8	7,393	$120,235	7,162
	Oct 2015	7	15,422	$250,096	14,810
	Sep 2015	6	12,374	$197,088	12,044
ANTIPSYCHOTICS	Nov 2015	9	6,672	$3023371	5,793
	Oct 2015	11	10,768	$4933844	9,547
	Sep 2015	10	8,815	$4009536	7,784
RESPIRATORY AGENTS	Nov 2015	10	6,110	$1308373	6,022
	Oct 2015	9	11,401	$2435040	11,246
	Sep 2015	9	8,955	$1916063	8,875

NOTE: Ranks are accurate but due to data reporting issues from CCO, total numbers for RXs , Paid and Benes for Sept and Oct cannot be compared to Oct

Top 10 Drug Molecules by Change in Amount Paid From Sep 2015 TO Nov 2015 (FFS and UHC*)

Drug Molecule	Sep 2015 $ Paid	Oct 2015 $ Paid	Nov 2015 $ Paid	Sep 2015 # Claims	Oct 2015 # Claims	Nov 2015 # Claims	Sep 2015 # Benes	Oct 2015 # Benes	Nov 2015 # Benes
Palivizumab / Immune Globulins	$0	$107,790	$214,728	0	41	89	0	39	76
-------Synagis	$0	$109,264	$214,728	0	42	89	0	40	76
Cefdinir / Third Generation Cephalosporins	$176,935	$219,612	$242,334	2,176	2,721	2,974	2,156	2,683	2,932
-------Cefdinir	$258,581	$376,096	$242,334	3,228	4,720	2,974	3,194	4,639	2,932
Budesonide / Glucocorticoids	$440,034	$450,083	$503,814	980	1,061	1,145	963	1,044	1,122
-------Pulmicort Respules	$587,827	$764,764	$484,784	1,250	1,713	1,045	1,235	1,689	1,024
-------Pulmicort Flexhaler	$28,734	$37,022	$17,404	161	209	98	161	207	98
-------Budesonide	$6,573	$6,746	$1,627	11	12	2	11	12	2
-------Uceris	$1,550	$0	$0	1	0	0	1	0	0
Leuprolide / Antineoplastic Hormones	$35,013	$55,281	$95,941	11	16	25	11	16	25
-------Lupron Depot-Ped	$34,630	$67,199	$67,378	7	14	13	7	14	13
-------Lupron Depot	$17,516	$18,885	$25,197	8	8	10	8	8	10
-------Eligard	$0	$2,605	$2,866	0	1	1	0	1	1
-------Leuprolide Acetate	$0	$1,490	$500	0	1	1	0	1	1
Azithromycin / Macrolides	$201,254	$245,657	$258,743	6,652	7,866	8,374	6,550	7,727	8,203
-------Azithromycin	$225,984	$342,101	$206,384	6,988	10,494	6,048	6,897	10,259	5,941
-------Azithromycin 5 Day Dose Pack	$59,569	$83,166	$48,433	2,691	3,723	2,175	2,664	3,663	2,137
-------Azithromycin 3 Day Dose Pack	$4,680	$5,551	$3,927	188	218	151	184	213	149
Oseltamivir / Neuraminidase Inhibitors	$47,819	$72,121	$89,010	258	381	460	257	379	460

*** NOTE: Magnolia claims are not included due to data reporting problems.**

Top 10 Drug Molecules by Change in Amount Paid From Sep 2015 TO Nov 2015 (FFS and UHC*)

Drug Molecule	Sep 2015 $ Paid	Oct 2015 $ Paid	Nov 2015 $ Paid	Sep 2015 # Claims	Oct 2015 # Claims	Nov 2015 # Claims	Sep 2015 # Benes	Oct 2015 # Benes	Nov 2015 # Benes
-------Tamiflu	$72,603	$128,608	$89,010	395	679	460	394	676	460
Amoxicillin-Clavulanate / Beta-Lactamase Inhibitors	$221,849	$243,612	$262,029	3,567	3,959	4,178	3,517	3,908	4,125
-------Amoxicillin-Clavulanate	$321,883	$434,292	$261,710	5,315	7,285	4,175	5,245	7,176	4,122
-------Amoxicillin-Clavulanate Er	$509	$2,255	$437	7	19	4	7	19	4
-------Augmentin	$1,179	$0	$0	1	0	0	1	0	0
Canakinumab / Interleukin Inhibitors	$0	$33,912	$34,112	0	1	2	0	1	2
-------Ilaris	$16,958	$50,870	$34,112	1	2	2	1	2	2
Dasabuvir/Ombitasvir/ Paritaprevir/Ritonavir / Antiviral Combinations	$0	$0	$29,329	0	0	1	0	0	1
-------Viekira Pak	$0	$0	$29,329	0	0	1	0	0	1
Albuterol / Adrenergic Bronchodilators	$414,719	$452,749	$441,967	8,383	9,370	9,360	7,356	8,306	8,319
-------Albuterol Sulfate	$163,557	$257,573	$145,933	4,961	7,706	4,420	4,842	7,445	4,292
-------Ventolin Hfa	$211,197	$277,706	$142,660	3,931	5,137	2,658	3,847	4,996	2,596
-------Proventil Hfa	$121,565	$149,760	$76,725	1,566	1,941	989	1,544	1,906	976
-------Proair Hfa	$120,580	$160,427	$76,598	2,004	2,689	1,285	1,985	2,631	1,262
-------Albuterol	$112	$158	$102	10	12	9	10	12	9
-------Albuterol Extended Release	$81	$323	$0	1	4	0	1	4	0

*** NOTE: Magnolia claims are not included due to data reporting problems.**

Top 10 Drug Molecules by Change in Amount Paid From Sep 2015 TO Nov 2015 With Factor Excluded (FFS and UHC*)

Drug Molecule	Sep 2015 $ Paid	Oct 2015 $ Paid	Nov 2015 $ Paid	Sep 2015 # Claims	Oct 2015 # Claims	Nov 2015 # Claims	Sep 2015 # Benes	Oct 2015 # Benes	Nov 2015 # Benes
Palivizumab / Immune Globulins	$0	$107,790	$214,728	0	41	89	0	39	76
-------Synagis	$0	$109,264	$214,728	0	42	89	0	40	76
Cefdinir / Third Generation Cephalosporins	$176,935	$219,612	$242,334	2,176	2,721	2,974	2,156	2,683	2,932
-------Cefdinir	$258,581	$376,096	$242,334	3,228	4,720	2,974	3,194	4,639	2,932
Budesonide / Glucocorticoids	$440,034	$450,083	$503,814	980	1,061	1,145	963	1,044	1,122
-------Pulmicort Respules	$587,827	$764,764	$484,784	1,250	1,713	1,045	1,235	1,689	1,024
-------Pulmicort Flexhaler	$28,734	$37,022	$17,404	161	209	98	161	207	98
-------Budesonide	$6,573	$6,746	$1,627	11	12	2	11	12	2
-------Uceris	$1,550	$0	$0	1	0	0	1	0	0
Leuprolide / Antineoplastic Hormones	$35,013	$55,281	$95,941	11	16	25	11	16	25
-------Lupron Depot-Ped	$34,630	$67,199	$67,378	7	14	13	7	14	13
-------Lupron Depot	$17,516	$18,885	$25,197	8	8	10	8	8	10
-------Eligard	$0	$2,605	$2,866	0	1	1	0	1	1
-------Leuprolide Acetate	$0	$1,490	$500	0	1	1	0	1	1
Azithromycin / Macrolides	$201,254	$245,657	$258,743	6,652	7,866	8,374	6,550	7,727	8,203
-------Azithromycin	$225,984	$342,101	$206,384	6,988	10,494	6,048	6,897	10,259	5,941
-------Azithromycin 5 Day Dose Pack	$59,569	$83,166	$48,433	2,691	3,723	2,175	2,664	3,663	2,137
-------Azithromycin 3 Day Dose Pack	$4,680	$5,551	$3,927	188	218	151	184	213	149
Oseltamivir / Neuraminidase Inhibitors	$47,819	$72,121	$89,010	258	381	460	257	379	460

*** NOTE: Magnolia claims are not included due to data reporting problems.**

Top 10 Drug Molecules by Change in Amount Paid From Sep 2015 TO Nov 2015 With Factor Excluded (FFS and UHC*)

Drug Molecule	Sep 2015 $ Paid	Oct 2015 $ Paid	Nov 2015 $ Paid	Sep 2015 # Claims	Oct 2015 # Claims	Nov 2015 # Claims	Sep 2015 # Benes	Oct 2015 # Benes	Nov 2015 # Benes
-------Tamiflu	$72,603	$128,608	$89,010	395	679	460	394	676	460
Amoxicillin-Clavulanate / Beta-Lactamase Inhibitors	$221,849	$243,612	$262,029	3,567	3,959	4,178	3,517	3,908	4,125
-------Amoxicillin-Clavulanate	$321,883	$434,292	$261,710	5,315	7,285	4,175	5,245	7,176	4,122
-------Amoxicillin-Clavulanate Er	$509	$2,255	$437	7	19	4	7	19	4
-------Augmentin	$1,179	$0	$0	1	0	0	1	0	0
Canakinumab / Interleukin Inhibitors	$0	$33,912	$34,112	0	1	2	0	1	2
-------Ilaris	$16,958	$50,870	$34,112	1	2	2	1	2	2
Dasabuvir/Ombitasvir/ Paritaprevir/Ritonavir / Antiviral Combinations	$0	$0	$29,329	0	0	1	0	0	1
-------Viekira Pak	$0	$0	$29,329	0	0	1	0	0	1
Albuterol / Adrenergic Bronchodilators	$414,719	$452,749	$441,967	8,383	9,370	9,360	7,356	8,306	8,319
-------Albuterol Sulfate	$163,557	$257,573	$145,933	4,961	7,706	4,420	4,842	7,445	4,292
-------Ventolin Hfa	$211,197	$277,706	$142,660	3,931	5,137	2,658	3,847	4,996	2,596
-------Proventil Hfa	$121,565	$149,760	$76,725	1,566	1,941	989	1,544	1,906	976
-------Proair Hfa	$120,580	$160,427	$76,598	2,004	2,689	1,285	1,985	2,631	1,262
-------Albuterol	$112	$158	$102	10	12	9	10	12	9
-------Albuterol Extended Release	$81	$323	$0	1	4	0	1	4	0

*** NOTE: Magnolia claims are not included due to data reporting problems.**

Top 10 Drug Molecules by Change in Number of Claims From Sep 2015 To Nov 2015 (FFS and UHC*)

Drug Molecule	Sep 2015 $ Paid	Oct 2015 $ Paid	Nov 2015 $ Paid	Sep 2015 # Claims	Oct 2015 # Claims	Nov 2015 # Claims	Sep 2015 # Benes	Oct 2015 # Benes	Nov 2015 # Benes
Azithromycin / Macrolides	$201,254	$245,657	$258,743	6,652	7,866	8,374	6,550	7,727	8,203
-------Azithromycin	$225,984	$342,101	$206,384	6,988	10,494	6,048	6,897	10,259	5,941
-------Azithromycin 5 Day Dose Pack	$59,569	$83,166	$48,433	2,691	3,723	2,175	2,664	3,663	2,137
-------Azithromycin 3 Day Dose Pack	$4,680	$5,551	$3,927	188	218	151	184	213	149
Amoxicillin / Aminopenicillins	$95,478	$106,020	$110,699	9,262	10,132	10,565	9,098	9,954	10,345
-------Amoxicillin	$143,474	$195,233	$110,573	13,938	18,708	10,566	13,730	18,344	10,346
-------Moxatag	$0	$0	$158	0	0	1	0	0	1
Prednisolone / Glucocorticoids	$50,243	$63,995	$65,287	3,380	4,293	4,499	3,317	4,195	4,389
-------Prednisolone Sodium Phosphate	$34,805	$51,412	$32,181	2,351	3,593	2,170	2,327	3,525	2,134
-------Prednisolone	$35,770	$54,352	$30,108	2,676	4,167	2,313	2,645	4,083	2,278
-------Prednisolone Sodium Phosphate Odt	$2,686	$5,419	$2,998	15	19	16	15	18	16
-------Veripred 20	$22	$513	$0	1	11	0	1	11	0
Albuterol / Adrenergic Bronchodilators	$414,719	$452,749	$441,967	8,383	9,370	9,360	7,356	8,306	8,319
-------Albuterol Sulfate	$163,557	$257,573	$145,933	4,961	7,706	4,420	4,842	7,445	4,292
-------Ventolin Hfa	$211,197	$277,706	$142,660	3,931	5,137	2,658	3,847	4,996	2,596
-------Proventil Hfa	$121,565	$149,760	$76,725	1,566	1,941	989	1,544	1,906	976
-------Proair Hfa	$120,580	$160,427	$76,598	2,004	2,689	1,285	1,985	2,631	1,262
-------Albuterol	$112	$158	$102	10	12	9	10	12	9

*** NOTE: Magnolia claims are not included due to data reporting problems.**

Top 10 Drug Molecules by Change in Number of Claims From Sep 2015 To Nov 2015 (FFS and UHC*)

Drug Molecule	Sep 2015 $ Paid	Oct 2015 $ Paid	Nov 2015 $ Paid	Sep 2015 # Claims	Oct 2015 # Claims	Nov 2015 # Claims	Sep 2015 # Benes	Oct 2015 # Benes	Nov 2015 # Benes
-------Albuterol Extended Release	$81	$323	$0	1	4	0	1	4	0
Cefdinir / Third Generation Cephalosporins	$176,935	$219,612	$242,334	2,176	2,721	2,974	2,156	2,683	2,932
-------Cefdinir	$258,581	$376,096	$242,334	3,228	4,720	2,974	3,194	4,639	2,932
Amoxicillin-Clavulanate / Beta-Lactamase Inhibitors	$221,849	$243,612	$262,029	3,567	3,959	4,178	3,517	3,908	4,125
-------Amoxicillin-Clavulanate	$321,883	$434,292	$261,710	5,315	7,285	4,175	5,245	7,176	4,122
-------Amoxicillin-Clavulanate Er	$509	$2,255	$437	7	19	4	7	19	4
-------Augmentin	$1,179	$0	$0	1	0	0	1	0	0
Codeine-Guaifenesin / Upper Respiratory Combinations	$8,377	$11,069	$13,022	575	760	890	570	754	880
-------Cheratussin Ac	$5,699	$9,343	$6,643	400	655	457	398	648	452
-------Codeine Phosphate-Guaifenesin	$4,974	$6,404	$4,951	337	423	329	332	417	325
-------Guaiatussin Ac	$1,174	$2,220	$1,286	84	158	93	83	157	93
-------Iophen-C Nr	$228	$279	$142	16	19	11	16	19	11
-------Virtussin Ac	$614	$1,404	$0	59	139	0	59	135	0
Permethrin Topical / Topical Anti-Infectives	$24,040	$45,742	$44,933	240	461	453	226	425	416
-------Permethrin	$29,079	$52,169	$44,933	294	530	453	278	490	416
Cetirizine / Antihistamines	$132,315	$140,802	$136,657	6,004	6,358	6,216	5,933	6,287	6,125
-------Cetirizine Hydrochloride	$201,665	$263,163	$136,609	9,119	11,900	6,212	9,044	11,732	6,121
-------All Day Allergy	$321	$435	$48	30	44	4	30	44	4

*** NOTE: Magnolia claims are not included due to data reporting problems.**

Top 10 Drug Molecules by Change in Number of Claims From Sep 2015 To Nov 2015 (FFS and UHC*)

Drug Molecule	Sep 2015 $ Paid	Oct 2015 $ Paid	Nov 2015 $ Paid	Sep 2015 # Claims	Oct 2015 # Claims	Nov 2015 # Claims	Sep 2015 # Benes	Oct 2015 # Benes	Nov 2015 # Benes
Prednisone / Glucocorticoids	$9,316	$9,372	$9,807	1,757	1,872	1,965	1,719	1,823	1,907
-------Prednisone	$13,488	$16,989	$9,807	2,608	3,448	1,965	2,562	3,356	1,907

*** NOTE: Magnolia claims are not included due to data reporting problems.**

Top 15 Drug Products by Change in Amount Paid Per Prescription Sep 2015 To Nov 2015 (FFS and UHC*)

Drug Product Therapeutic Category	Sep 2015 $ Paid	Oct 2015 $ Paid	Nov 2015 $ Paid	Sep 2015 # Claims	Oct 2015 # Claims	Nov 2015 # Claims	Sep 2015 Paid Per Rx	Oct 2015 Paid Per Rx	Nov 2015 Paid Per Rx
Feiba Nf - Powder For Injection / Factor For Bleeding Disorders	$1,358,177	$1,321,467	$1,263,701	9	7	7	$150,909	$188,781	$180,529
Kuvan 100 Mg Tablet, Dispersible / Miscellaneous Metabolic Agents	$4,156	$66,448	$25,955	1	4	1	$4,156	$16,612	$25,955
Actimmune 2000000 Intl Units/0.5 Ml Solution / Interferons	$42,005	$83,977	$41,973	2	3	1	$21,002	$27,992	$41,973
Alphanate - Powder For Injection / Factor For Bleeding Disorders	$67,507	$158,564	$98,026	2	3	2	$33,754	$52,855	$49,013
Neupogen 480 Mcg/1.6 Ml Solution / Colony Stimulating Factors	$5,146	$0	$18,522	1	0	1	$5,146	.	$18,522
Kalydeco 150 Mg Tablet / Cftr Potentiators	$75,916	$101,154	$25,238	4	5	1	$18,979	$20,231	$25,238
Enoxaparin Sodium 100 Mg/Ml Solution / Heparins	$350	$10,316	$2,972	1	4	1	$350	$2,579	$2,972
Orenitram 1 Mg Tablet, Extended Release / Agents For Pulmonary Hypertension	$4,943	$4,943	$7,414	1	1	1	$4,943	$4,943	$7,414
Imbruvica 140 Mg Capsule / Multikinase Inhibitors	$8,986	$43,120	$22,882	1	4	2	$8,986	$10,780	$11,441
Gleevec 100 Mg Tablet / Bcr-Abl Tyrosine Kinase Inhibitors	$33,812	$45,598	$39,658	8	7	6	$4,226	$6,514	$6,610
Revatio 10 Mg/Ml Suspension / Agents For Pulmonary Hypertension	$7,061	$10,581	$5,778	2	2	1	$3,531	$5,291	$5,778
Hizentra 20% Solution / Immune Globulins	$3,699	$1,537	$17,137	3	2	5	$1,233	$768	$3,427

*** NOTE: Magnolia claims are not included due to data reporting problems.**

Top 15 Drug Products by Change in Amount Paid Per Prescription Sep 2015 To Nov 2015 (FFS and UHC*)

Drug Product Therapeutic Category	Sep 2015 $ Paid	Oct 2015 $ Paid	Nov 2015 $ Paid	Sep 2015 # Claims	Oct 2015 # Claims	Nov 2015 # Claims	Sep 2015 Paid Per Rx	Oct 2015 Paid Per Rx	Nov 2015 Paid Per Rx
Zenpep 25,000 Units-136,000 Units-85,000 Units Delayed Release Capsule / Digestive Enzymes	$9,005	$4,471	$7,551	5	3	2	$1,801	$1,490	$3,776
Humira Pediatric 20 Mg/0.4 Ml Kit / Tnf Alfa Inhibitors	$10,953	$7,301	$7,301	2	1	1	$5,477	$7,301	$7,301
Nexavar 200 Mg Tablet / Vegf/Vegfr Inhibitors	$24,365	$20,887	$27,845	2	2	2	$12,182	$10,444	$13,923

*** NOTE: Magnolia claims are not included due to data reporting problems.**

Top 15 Drug Products by Change in Amount Paid Per Prescription Sep 2015 To Nov 2015 With Factor Excluded (FFS and UHC*)

Drug Product Therapeutic Category	Sep 2015 $ Paid	Oct 2015 $ Paid	Nov 2015 $ Paid	Sep 2015 # Claims	Oct 2015 # Claims	Nov 2015 # Claims	Sep 2015 Paid Per Rx	Oct 2015 Paid Per Rx	Nov 2015 Paid Per Rx
Kuvan 100 Mg Tablet, Dispersible / Miscellaneous Metabolic Agents	$4,156	$66,448	$25,955	1	4	1	$4,156	$16,612	$25,955
Actimmune 2000000 Intl Units/0.5 Ml Solution / Interferons	$42,005	$83,977	$41,973	2	3	1	$21,002	$27,992	$41,973
Neupogen 480 Mcg/1.6 Ml Solution / Colony Stimulating Factors	$5,146	$0	$18,522	1	0	1	$5,146	.	$18,522
Kalydeco 150 Mg Tablet / Cftr Potentiators	$75,916	$101,154	$25,238	4	5	1	$18,979	$20,231	$25,238
Enoxaparin Sodium 100 Mg/Ml Solution / Heparins	$350	$10,316	$2,972	1	4	1	$350	$2,579	$2,972
Orenitram 1 Mg Tablet, Extended Release / Agents For Pulmonary Hypertension	$4,943	$4,943	$7,414	1	1	1	$4,943	$4,943	$7,414
Imbruvica 140 Mg Capsule / Multikinase Inhibitors	$8,986	$43,120	$22,882	1	4	2	$8,986	$10,780	$11,441
Gleevec 100 Mg Tablet / Bcr-Abl Tyrosine Kinase Inhibitors	$33,812	$45,598	$39,658	8	7	6	$4,226	$6,514	$6,610
Revatio 10 Mg/Ml Suspension / Agents For Pulmonary Hypertension	$7,061	$10,581	$5,778	2	2	1	$3,531	$5,291	$5,778
Hizentra 20% Solution / Immune Globulins	$3,699	$1,537	$17,137	3	2	5	$1,233	$768	$3,427
Zenpep 25,000 Units-136,000 Units-85,000 Units Delayed Release Capsule / Digestive Enzymes	$9,005	$4,471	$7,551	5	3	2	$1,801	$1,490	$3,776
Humira Pediatric 20 Mg/0.4 Ml Kit / Tnf Alfa Inhibitors	$10,953	$7,301	$7,301	2	1	1	$5,477	$7,301	$7,301

*** NOTE: Magnolia claims are not included due to data reporting problems.**

Top 15 Drug Products by Change in Amount Paid Per Prescription Sep 2015 To Nov 2015 With Factor Excluded (FFS and UHC*)

Drug Product Therapeutic Category	Sep 2015 $ Paid	Oct 2015 $ Paid	Nov 2015 $ Paid	Sep 2015 # Claims	Oct 2015 # Claims	Nov 2015 # Claims	Sep 2015 Paid Per Rx	Oct 2015 Paid Per Rx	Nov 2015 Paid Per Rx
Nexavar 200 Mg Tablet / Vegf/Vegfr Inhibitors	$24,365	$20,887	$27,845	2	2	2	$12,182	$10,444	$13,923
Subsys 600 Mcg Spray / Narcotic Analgesics	$93,805	$62,536	$25,015	4	2	1	$23,451	$31,268	$25,015
Eryped 400 Ethylsuccinate 400 Mg/5 Ml Granule For Reconstitution / Macrolides	$3,329	$0	$3,209	2	0	1	$1,665	.	$3,209

*** NOTE: Magnolia claims are not included due to data reporting problems.**

New Business

Special Analysis Projects

UTILIZATION OF TRAMADOL IN CHILDREN AGE 17 AND YOUNGER

BACKGROUND

The U.S. Food and Drug Administration (FDA) released a safety notice on September 21, 2015 concerning the use of tramadol in children age 17 and younger. The issue, as summarized by the FDA, is outlined in the excerpt below.

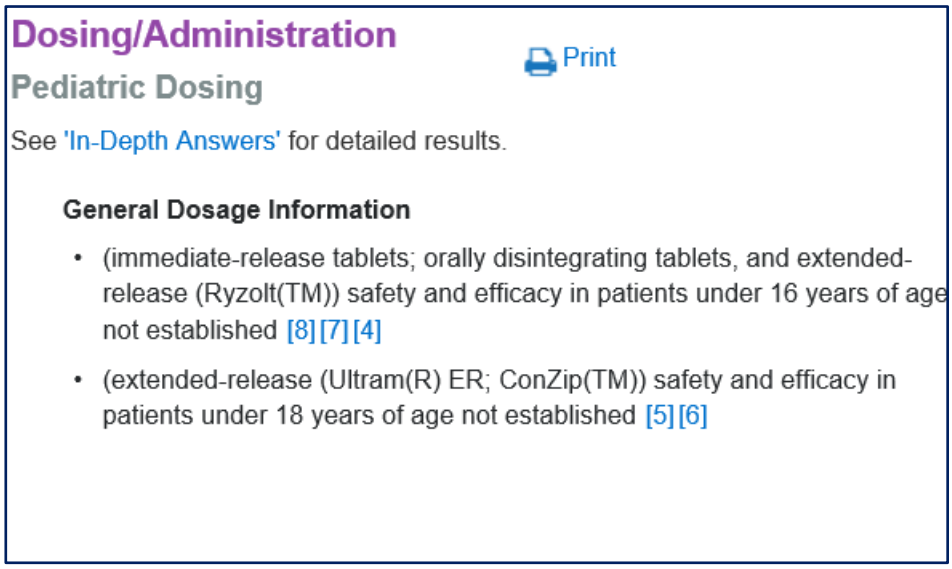
> **ISSUE**: FDA is investigating the use of the pain medicine tramadol in children aged 17 years and younger, because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in children treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete.
>
> Tramadol is not FDA-approved for use in children; however, data show it is being used "off-label" in the pediatric population. Health care professionals should be aware of this and consider prescribing alternative FDA-approved pain medicines for children.

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm

Tramadol is not FDA-approved for use in children age 17 and younger. Although the FDA safety notice refers to children age 17 and younger, indicated age limits vary by formulation and are not consistently listed by the FDA and various compendia.

Micromedex® (see box below) reports the following age limits:

- 16 and above - tramadol immediate-release tablets, orally disintegrating tablets, and extended release (Ryzolt™)
- 18 and above - tramadol extended-release (Ultram® ER, ConZip®)



Dosing/Administration

Print

Pediatric Dosing

See 'In-Depth Answers' for detailed results.

General Dosage Information

- (immediate-release tablets; orally disintegrating tablets, and extended-release (Ryzolt(TM)) safety and efficacy in patients under 16 years of age not established [8] [7] [4]
- (extended-release (Ultram(R) ER; ConZip(TM)) safety and efficacy in patients under 18 years of age not established [5] [6]

Clinical Pharmacology (see box below) reports the following age limits:

- 16 and above - tramadol extended-release tablets (Ryzolt™)
- 17 and above - tramadol immediate-release tablets, orally disintegrating tablets, and extended-release tablets (Ryzolt™)

The Clinical Pharmacology listing mentions Ryzolt™ in each reference to extended-release tablets but does not clearly indicate where Ultram® ER or ConZip® are included.

Maximum Dosage Limits
•Adults
400 mg/day PO for immediate-release and orally disintegrating tablets; 300 mg/day PO for extended-release formulations.
•Geriatric
65—75 years: 400 mg/day PO for immediate-release and orally disintegrating tablets; 300 mg/day PO for extended-release formulations.
> 75 years: 300 mg/day PO.
•Adolescents
>= 17 years: 400 mg/day PO for immediate-release and orally disintegrating tablets; 300 mg/day PO for dual-matrix extended-release tablets (Ryzolt). Safety and efficacy of other formulations have not been established.
16 years: 300 mg/day PO for dual-matrix extended-release tablets (Ryzolt). Safety and efficacy of other formulations have not been established.
< 16 years: Safety and efficacy have not been established.
•Children
Safety and efficacy have not been established.
•Infants
Safety and efficacy have not been established.
•Neonates
Safety and efficacy have not been established.

The prescribing information for Ultram® ER states in the dosage and administration section that it is for use in adults (18 years of age and older). The prescribing information for ConZip® also states that safety and efficacy in patients under 18 years of age have not been established and use in the pediatric population is not recommended.

In response to the FDA safety notice, MS-DUR has conducted an analysis of tramadol utilization in children. Utilization was examined by age and formulation in order to evaluate use at all of the potential age limits.

METHODS

A retrospective analysis was conducted using pharmacy claims data from July 2014 – November 2015 from fee-for-service (FFS) and coordinated care organizations (CCOs). All claims were extracted for NDCs related to all tramadol formulations. Age and pharmacy program enrollment was determined for beneficiaries at the time each prescription was filled. Prescriptions were classified as being filled for children below the indicated age if age at time of fill was less than 18 years for Ultram® ER and ConZip® prescriptions and less than 16 years for all other tramadol formulations.

RESULTS

Table 1 shows the number of tramadol prescriptions by formulation and age for each pharmacy program. Generic tramadol and generic acetaminophen/tramadol are the preferred products on the Preferred Drug List (PDL) with branded immediate-release products and all extended-release products being non-preferred. All utilization was for generic products. Tramadol products are included in the product list for the FFS SmartPA Short-acting Narcotics rule but there are no age or product specific edits in place. These data indicate that the CCOs also do not have age edit in place for use of tramadol.

TABLE 1: Tramadol Use by Pharmacy Program
(July 2014 - November 2015)

FFS				
Age	Acetaminophen / Tramadol	Tramadol	Tramadol ER	Total
5 or less	0	3	0	3
6 - 11	7	77	0	77
12 - 15	92	747	0	747
16	30	442	0	442
17	48	608	0	608
18 or more	581	7,690	0	7,690
United Health Care				
Age	Acetaminophen / Tramadol	Tramadol	Tramadol ER	Total
5 or less	0	3	0	3
6 - 11	0	40	0	40
12 - 15	22	250	0	250
16	15	131	1	132
17	14	192	0	192
18 or more	729	21,143	6	21,149
Magnolia				
Age	Acetaminophen / Tramadol	Tramadol	Tramadol ER	Total
5 or less	0	2	0	2
6 - 11	3	12	0	12
12 - 15	12	205	0	205
16	7	128	0	128
17	19	180	0	180
18 or more	1,755	24,557	15	24,572

NOTE: All tramadol use was for generic products.

The provider types writing Tramadol prescriptions for children below the age for use indicated in Micromedex® are listed in Table 2. The provider types accounting for the largest numbers of prescriptions were Family Practice (MD and NP), Emergency Medicine, Dentists and Orthopedists. Based on the provider types writing these prescriptions, use appears to be primarily pain management for conditions other than surgery to remove tonsils and/or adenoids.

TABLE 2: Tramadol Prescribing for Children Below Indicated Age* by Provider Type					
		Number of Beneficiaries		Number of Claims	
Provider Type	Number of Prescribers	Total	Average / Prescriber	Total	Average / Beneficiary
DDO-Dentist	57	138	2.4	153	1.1
DDO-Pediatrics	2	2	1.0	2	1.0
EMS	1	2	2.0	2	1.0
HOSP	1	2	2.0	2	1.0
MD-Anesth	4	5	1.3	5	1.0
MD-EM	81	212	2.6	216	1.0
MD-FP	93	217	2.3	272	1.3
MD-GP	6	8	1.3	8	1.0
MD-Gastro	1	1	1.0	1	1.0
MD-Hospit	1	7	7.0	7	1.0
MD-IM	18	30	1.7	32	1.1
MD-Neur	6	7	1.2	18	2.6
MD-OB/GYN	16	18	1.1	27	1.5
MD-Ortho	36	87	2.4	104	1.2
MD-Other	8	13	1.6	24	1.8
MD-Ped	12	22	1.8	36	1.6
MD-Psych	2	2	1.0	2	1.0
MD-Rheumj	2	3	1.5	5	1.7
MD-Sports	2	9	4.5	10	1.1
MD-Surg	8	8	1.0	10	1.3
MD-Urol	5	6	1.2	6	1.0
NP	27	55	2.0	57	1.0
NP-FM	85	202	2.4	216	1.1
NP-PCP	2	5	2.5	5	1.0
NP-Ped	2	2	1.0	2	1.0
Nurse	3	4	1.3	4	1.0
PA	14	30	2.1	33	1.1
PA/APN	1	1	1.0	1	1.0
Podiatrist	4	25	6.3	27	1.1
Prov-Other	23	30	1.3	38	1.3

** age < 18 for Ultram ER and ConZip; age < 16 for all other formulations.*

CONCLUSIONS AND RECOMMENDATIONS

As reported by the FDA, immediate release tramadol, which is the preferred product on the PDL, is being prescribed for use in Mississippi Medicaid beneficiaries who are under the age of 18. The FDA has identified safety concerns about tramadol use in an age 17 and under population.

The recommended age limit for immediate-release tramadol is unclear:

- FDA safety notice implies age 18 and above for use
- Micromedex® states age 16 and above
- Clinical Pharmacology states age 17 and above

MS-DUR presents the following recommendations for consideration by the DUR Board.

1. The DUR Board recommends that DOM add the following age limits to the Universal Preferred Drug List (UPDL).
    a. Minimum age limit: 18 years – Ultram® ER, ConZip®
    b. Minimum age limit: 17 years – all other generic and brand formulations of tramadol

2. The DUR Board recommends that DOM add these age limits to the SmartPA Short-acting Narcotics rule used for the FFS program.

3. The DUR Board recommends that DOM share these limitations on the use of tramadol with the coordinated care programs to assure constancy in the pharmacy program.

ANTIPSYCHOTIC QUALITY MEASURES: METABOLIC MONITORING IN CHILDREN TAKING ANTIPSYCHOTICS

BACKGROUND

Increasing concerns regarding obesity and diabetes emergence in children and adolescents[1] are heightened for youth prescribed antipsychotic medications due to adverse metabolic and other physical effects.[2] A multi-year study of youth enrolled in three health maintenance organizations found that exposure to antipsychotics (AP) was associated with a four-fold increased risk of diabetes in the following year, compared to children not prescribed psychotropic medication[3].

The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) established the Pediatric Quality Measures Program (PQMP), an initiative funded by the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) to support the development of new measures in child health care. The National Collaborative for Innovation in Quality Measurement (NCINQ) is the group responsible for developing and proposing measures for inclusion in the Child Core Set used in Medicaid programs. The Healthcare Effectiveness Data and Information Set (HEDIS) is a tool used by more than 90 percent of America's health plans to measure performance on important dimensions of care and service. Both of these sources recommend use of quality measures addressing metabolic monitoring in children taking antipsychotics.

HEDIS Measure: Metabolic Screening for Children and Adolescents On Antipsychotics. The percentage of children and adolescents 0-17 of age who had two or more antipsychotic prescriptions and had metabolic screening (during the observation period).

NCINQ Proposed Measure for inclusion in Child Core Set: Metabolic Screening for Children and Adolescents on Antipsychotics. The percentage of children 0 to 20 years of age taking any antipsychotic medication who had metabolic screening documented during the measurement year.

At the November 2014 DUR Board Meeting, MS-DUR presented an analysis that showed that during the period July 2013 to June 2014 only 13% of children and adolescents enrolled in Mississippi Medicaid taking antipsychotic medications had claims documenting blood glucose and cholesterol tests had been performed during the observation year.

[1] Eisenmann JC. Secular trends in variables associated with the metabolic syndrome of North American children and adolescents: a review and synthesis. Am J Hum Biol. 2003 Nov-Dec;15(6):786-94. Review. PubMed PMID: 14595870.
[2] Pringsheim T, Lam D, Ching H, Patten S. Metabolic and neurological complications of second-generation antipsychotic use in children: a systematic review and meta-analysis of randomized controlled trials. Drug Saf. 2011 Aug 1;34(8):651-68. doi: 10.2165/11592020-000000000-00000. Review. PubMed PMID: 21751826.
[3] Andrade S, Lo J, Roblin D, Fouyazi H, Connor D, Penfold R, Chandra M, Reed G, Gurwitz J. (2011) antipsychotic medication use antipsychotic medication use among children and risk of diabetes mellitus. Pediatrics, 128, 1135-1141.

Unfortunately, since there was no quorum at the November 2014 DUR board meeting, there was no vote and recommendations were tabled until the February 2015 meeting. During the February 2015 meeting, the DUR Board recommended that MS-DUR initiate an educational intervention to notify prescribers of the need for metabolic monitoring, evaluate the impact of the intervention, and report back to the Board for consideration of further actions that might be needed to address this issue.

EDUCATIONAL INTERVENTION

The educational intervention was conducted from February 2015 through September 2015. The intervention each month consisted of the following actions:

- We identified all beneficiaries under the age of 21 who had a prescription filled for an antipsychotic and determined if they had medical claims for metabolic monitoring within one year prior to the prescription fill.

- Providers were ranked based on the number of their patients who had filled antipsychotic prescriptions during the previous month and had not had medical claims documenting appropriate metabolic monitoring during the previous year.

- The providers with the largest number of patients not receiving monitoring were mailed a letter informing them of the importance of metabolic monitoring and reporting their rates for the prior month and the overall rate for all providers in the state during that month.

- Up to 100 providers were contacted monthly. No provider was contacted more often than once every three months.

Each month, providers were ranked based on their rate of compliance with metabolic monitoring for beneficiaries filling prescriptions that month. The top 100 providers were sent the educational mailing notifying them about the importance of metabolic monitoring and their performance on the quality measure during the previous month. A total of 179 different providers were contacted as part of the intervention. 70% of these providers were contacted more than once. The prescribers contacted during the intervention accounted for more than 80% of the children filling prescriptions for antipsychotics during this time period.

EVALUATION

Analyses were conducted to evaluate the pre- vs post-intervention period behavior among providers contacted during the intervention. In order to compare pre- and post-educational intervention periods and to measure lab monitoring in a manner similar to what could be detected through prospective DUR, modifications were made in the technical specifications for the quality measures. The quality measure is defined as the percentage of beneficiaries taking an

antipsychotic at any time during the observation period who have claims for metabolic monitoring anytime during the same observation period. For purposes of the evaluation, the measure was converted into a prospective DUR edit in which each prescription fill was checked to determine if claim(s) for metabolic monitoring were found within a one-year look back period. This criteria was applied to all antipsychotic prescriptions filled for children during the pre and post observation periods. The pre observation period was April – November, 2014 and the post observation period was April – November, 2015. The same months were used for each period to control for any seasonal variations that might occur. For each observation period, beneficiaries with at least one prescription meeting metabolic monitoring criterion were classified as having met the criteria. When calculating physician rates, children were attributed to the prescriber of the last antipsychotic prescription filled during the observation period. Performance rates for prescribers were calculated for each observation period as the percentage of children attributed to the provider who met the metabolic monitoring criteria. This modification in the measurement resulted in higher percentages for obtaining metabolic monitoring than did the technical specifications used in the quality measure. This occurs because there was a full year look-back for every prescription filled because the look-back period included months prior to the beginning of the observation period.

Beneficiaries were included in the analysis if they met all of the following inclusion criteria:

- Age < 21 years at time of prescription fill; and
- Enrolled in Medicaid at least 3 months during observation period; and
- Not dual-enrolled or a resident in a long-term-care facility; and
- Had > 3 prescription fills for antipsychotics.

The percent of beneficiaries classified as meeting the metabolic monitoring requirement during each observation period are reported in Table 1, which describes whether they had a visit with the provider prescribing their antipsychotic prescription during the observation period. Overall, the percentage of children taking antipsychotics who had metabolic monitoring did not change significantly between the 2014 and 2015 observation periods. It was assumed that prescribers would most likely wait until the next patient visit to perform metabolic monitoring after receiving the educational letter, therefore, we examined changes in the rates for metabolic monitoring for children having office visits and those not having office visits during the two observation periods. Among children having office visits, a slight increase (+2.9%) in the rate for lipid monitoring was observed.

TABLE 1: Percentage of Children Who Are Taking Antipsychotics That Had Metabolic Monitoring Within One Year of a Prescription Fill by Whether The Child Had a Visit With The AP Prescriber During Observation Period
(Prescription fills between April - November 2014 and April - November 2015; FFS and CCOs)

NOTE: Includes all beneficiaries with 3+ prescription fills during each period		# Children on APs	Glucose monitoring[a]	Lipid monitoring[a]	Both lab tests[a]
ALL Children Taking Antipsychotics	2014	5,071	54.2%	32.4%	31.4%
	2015	4,851	49.5%	32.4%	30.6%
	Change 2014 - 2015		-4.7%	0.0%	-0.8%
Children WITH Visit During Observation Period	2014	2,887	57.1%	34.1%	32.9%
	2015	2,540	54.3%	37.0%	34.4%
	Change 2014 - 2015		-2.8%	2.9%	1.5%
Children WITHOUT Visit During Observation Period	2014	2,184	50.5%	30.0%	29.4%
	2015	2,311	44.2%	27.3%	26.4%
	Change 2014 - 2015		-6.3%	-2.7%	-3.0%

[a] *Monitoring was considered to have occurred if a medical claim containing a procedure code included in the measure technical specifications was found within one year prior to the prescription fill.*

The rates for children receiving metabolic monitoring by whether the prescribing provider was contacted in the educational initiative or not are shown in Table 2. The educational initiative increased the rate of monitoring among children on antipsychotics prescribed by providers contacted during the intervention by only 1.4%. A decrease was seen in the percentage of children having glucose monitoring. Among prescribers who were not contacted as part of the educational initiative, the percentage of children being prescribed APs that had glucose monitoring went down -7.0% and the percentage having lipid monitoring went down -5.5%. It appears that the initiative had a small beneficial effect among the providers contacted.

TABLE 2: Percentage of Children Taking Antipsychotics Having Metabolic Monitoring Within One Year of a Prescription Fill by Whether The Prescriber Was Contacted During Educational Initiative[a]
(Prescription fills between April - November 2014 and April - November 2015; FFS and CCOs)

NOTE: Includes all beneficiaries with 3+ prescription fills during each period		# Children on APs	Glucose monitoring[b]	Lipid monitoring[b]	Both lab tests[b]
Children With Prescribers CONTACTED in 2015	2014	2,925	52.0%	31.4%	30.6%
	2015	3,811	48.5%	32.8%	31.2%
	Change 2014 - 2015		-3.5%	1.4%	0.6%
Children With Prescribers NOT CONTACTED in 2015	2014	780	60.1%	36.5%	35.6%
	2015	1,040	53.1%	31.0%	28.4%
	Change 2014 - 2015		-7.0%	-5.5%	-7.2%

[a] *Educational intervention letters were mailed from February 2015 - September 2015. 2014 data are reported as baseline information for the contacted providers.*

[b] *Monitoring was considered to have occurred if a medical claim containing a procedure code included in the measure technical specifications was found within one year of the prescription fill.*

As previously noted, providers are not likely to schedule lab tests until the next patient visit. Table 3 compares provider rates for monitoring by whether the prescriber was contacted as part of the educational initiative and whether the beneficiary had an office visit during the observation period. Comparing the two observation periods in this breakdown provides a method of examining whether provider behaviors actually changed with respect to ordering lab tests during office visits. Performance on monitoring actually decreased among providers not contacted through the educational initiative. Among providers who were contacted the rate of monitoring for lipids increased by 5.2% and the rate for glucose monitoring decreased by 2.4% for beneficiaries who had office visits during the observation periods.

TABLE 3: Prescriber Performance Rates For Metabolic Monitoring by Whether The Prescriber Was Contacted During Educational Initiative[a] and Whether Child Visited Prescriber During Observation Period
(Prescription fills between April - November 2014 and April - November 2015; FFS and CCOs)

NOTE: Includes all prescribers with ratings in both years based on 2+ beneficiaries			Average # Children / Prescriber	% With Glucose Monitoring[b]	% With Lipid Monitoring[b]	% With Both Lab Tests[b]
Prescribers NOT CONTACTED in 2015 (n = 119)	Children WITH VISIT During Observation Period	2014	10.5	52.3%	24.4%	23.9%
		2015	7.9	46.8%	19.3%	18.7%
		Change 2014 - 2015		-5.5%	-5.1%	-5.2%
Prescribers CONTACTED in 2015 (n = 111)	Children WITH VISIT During Observation Period	2014	20.8	53.5%	32.2%	29.6%
		2015	19.8	51.1%	37.4%	34.4%
		Change 2014 - 2015		-2.4%	5.2%	4.8%
	Children WITHOUT VISIT During Observation Period	2014	14.3	44.6%	25.7%	24.0%
		2015	16.6	35.8%	21.0%	19.0%
		Change 2014 - 2015		-8.8%	-4.7%	-5.0%

[a] *Educational intervention letters were mailed from February 2015 - September 2015. 2014 data are reported as baseline information for the contacted providers.*

[b] *Monitoring was considered to have occurred if a medical claim containing a procedure code included in the measure technical specifications was found within one year of the prescription fill.*

Providers were targeted for contact during the educational initiative based on the number of children they had prescribed APs and their rate of metabolic monitoring. Priority was given to contacting providers with high numbers of children without monitoring. As such, few of the providers with only one or two patients were contacted. As shown in Table 4, providers with only a few children on APs had the lowest rates for metabolic monitoring. These providers do not account for a very large percentage of the children on APs, but do continue to present a problem with respect to metabolic monitoring.

TABLE 4: Prescriber Performance Rates For Metabolic Monitoring by Number of Children Prescribed Antipsychotics During 2015 Observation Period
(Prescription fills between April - November 2015; FFS and CCOs)

		Number of Prescribers	Total Number Children on APs	% Children With Glucose Monitoring[a]	% Children With Lipid Monitoring[a]	% Children With Both Lab Tests[a]
Number of Children Prescribed APs in 2015	1 - 2	473	571	46.7%	14.6%	13.8%
	3 - 5	106	399	42.1%	19.8%	18.9%
	6 - 10	47	341	42.8%	27.4%	23.5%
	11 - 20	50	717	62.3%	41.4%	39.7%
	21+	95	5,786	56.0%	43.5%	40.4%

[a] *Monitoring was considered to have occurred if a medical claim containing a procedure code included in the measure technical specifications was found within one year prior to the prescription fill.*

CONCLUSION

The educational intervention conducted in 2015 appears to have had a small positive effect on metabolic monitoring rates. However, the program did not increase rates as much as would be desired, even among the providers who were contacted. Additional educational actions and/or clinical edits or procedures are needed to adequately address metabolic monitoring in children taking antipsychotics. However, when beneficiaries saw prescribers at their offices, rates for metabolic monitoring were higher. The number of children taking antipsychotics and not having office visits during the 8-month observation periods is a concern and may indicate that increased supervision of beneficiaries taking antipsychotics is needed.

Next Steps:

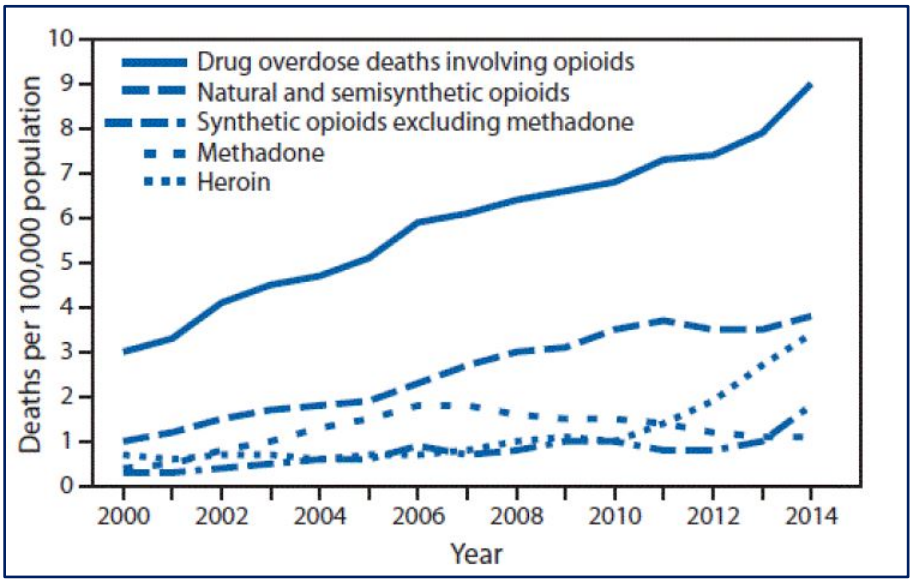
In the next few months, DOM and MS-DUR will be participating in a committee of 10 state Medicaid programs selected by the American Drug Utilization Review Society (ADURS) that will meet with representatives from CMS to discuss programs for monitoring antipsychotic use among children. MS-DUR will present findings from this meeting to the DURB at the April 2016 meeting.

At this time, MS-DUR seeks input from the DUR Board regarding what might be more effective methods for communicating the importance of metabolic monitoring to providers. A copy of an educational piece used by the California Medicaid is included as Appendix A.

OPIOID OVERUSE AND ABUSE: HIGH MORPHINE EQUIVALENT DAILY DOSING (MEDD) AND DOCTOR SHOPPING EDUCATIONAL INITIATIVES

BACKGROUND

Reports from the Center for Disease Control and Prevention (CDC), the Drug Abuse Warning Network and the National Poison Data System have illustrated that over the last two decades the country has seen a disturbing increase in opioid misuse and abuse.[1,2,3,4] The sale of prescription opioid drugs have increased four-fold between 1999-2010.[2] As shown in the figure below, overdose deaths involving opioid medications have increased steadily for more than a decade and now exceed deaths involving heroin and cocaine combined.[5]



The Office of Inspector General (OIG) of the Department of Health and Human Services recommends that states implement steps addressing opioid misuse and diversion. Highlighted in the box below, the OIG's 2016 Work Plan will focus on state actions taken through drug utilization

[1] Centers for Disease Control and Prevention. CDC's top ten: 5 health achievements in 2013 and 5 health threats in 2014 (December 17, 2013). http://blogs. cdc.gov/cdcworksforyou24-7/2013/12/cdc%e2%80%99s-top-ten-5-health-achievements-in-2013-and-5-health-threats-in-2014/ (accessed 2014 Feb 10).

[2] Centers for Disease Control and Prevention. Overdose deaths involving prescription opioids among Medicaid enrollees - Washington, 2004–2007. MMWR. 2009; 58:1171-5.

[3] Budnitz DS, Pollock DA, Weidenbach KN et al. National surveillance of emergency department visits for outpatient adverse drug events. JAMA. 2006; 296:1858-66.

[4] Hall AJ, Logan JE, Toblin RL et al. Patterns of abuse among unintentional pharmaceutical overdose fatalities. JAMA. 2008; 300:2613-20.

[5] Centers for Disease Control and Prevention. Increase in drug and opioid deaths – United States, 2000 - 2014. MMWR. 2016; 64:1378-82.

review (DUR) programs to address opioid misuse and abuse in state Medicaid.[6] Efforts are directed to protect "an expanding Medicaid program from fraud, waste, and abuse."

> ➢ **REVISED** States' actions based on Medicaid drug utilization reviews
>
> We will review the education and enforcement actions that States have taken on the basis of information generated by their drug utilization review (DUR) programs related to inappropriate dispensing and potential abuse of prescription drugs, including opiates. We also will review State oversight of and coordination with MCOs' DUR programs and any resulting actions related to inappropriate dispensing of opiates.

The Drug Enforcement Agency (DEA) has also expressed concerns about opioid abuse and has become more aggressive in their enforcement of the Controlled Substances Act. Traditionally, the DEA focused on abuses amongst independent pharmacies, but have recently increased their scrutiny and enforcement to large pharmacy chains, long term care providers, and drug wholesalers.[7]

In December 2015, the Center for Medicare and Medicaid Services (CMS) sent information to state agencies (Appendix B) announcing updates in the Adult and Child Core Set quality measures. In response to concerns about opioid abuse and overdose, CMS announced the inclusion of the Pharmacy Quality Alliance (PQA) quality measures focused on opioid prescriptions from multiple providers and high dose opioid use (see Table 1).

TABLE 1: Opioid Quality Measures Added to the CMS Adult Core Measurement Sets for 2016

Measure Sponsor: Measure Name	Measure Description
PQA: Use of Opioids from Multiple Providers or at High Dosage in Persons Without Cancer: Opioid High Dosage	The proportion (XX out of 1,000) of individuals without cancer receiving a daily dosage of opioids greater than 120mg morphine equivalent dose (MED) for 90 consecutive days or longer.
PQA: Use of Opioids from Multiple Providers or at High Dosage in Persons Without Cancer: Multiple prescribers and multiple pharmacies	The proportion (XX out of 1,000) of individuals without cancer receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.
PQA: Use of Opioids from Multiple Providers or at High Dosage in Persons Without Cancer: Multiple-provider, high dosage	The proportion (XX out of 1,000) of individuals without cancer receiving prescriptions for opioids greater than 120mg morphine equivalent dose (MED) for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

[6] OIG Work Plan 2016, p 31. http://oig.hhs.gov/reports-and-publications/archives/workplan/2016/oig-work-plan-2016.pdf

[7] Keast SL, Nesser N, Farmer K (2015) Strategies aimed at controlling misuse and abuse of opioid prescription medications in a state Medicaid program: a policymaker's perspective, The American Journal of Drug and Alcohol Abuse, 41:1, 1-6, DOI: 10.3109/00952990.2014.988339. Available at: http://dx.doi.org/10.3109/00952990.2014.988339

During the February 2014 DUR Board Meeting the board recommended and approved an educational intervention program to be implemented by MS-DUR based on the quality measures that were being developed by PQA. For the previous 18 months, MS-DUR conducted an analysis of the monthly mailings notifying providers about beneficiaries receiving prescriptions from four or more unique prescribers. The previous educational activity was directed at notifying prescribers when suspected doctor/pharmacy shopping was occurring. This intervention primary addressed possible abuse and safety problems that could occur from lack of coordination among prescribers. When the intervention was implemented, the maximum morphine equivalent daily dose (MEDD) component was not included due to uncertainty within the PQA workgroup about the specific criteria for maximum daily doses.

The Mississippi Prescription Drug Monitoring Program (MPMP) was established to help providers, professional boards, and drug enforcement agencies track prescriptions for opioids and other controlled substances. The Board of Medical Licensure required all physicians to be enrolled in the MPMP by December 2013. Last year, the Board of Pharmacy required all pharmacists to be enrolled by December 2015. Providers can use the MPMP to identify potentially inappropriate use by patients when they are considering writing a prescription or when they are requested to fill a prescription for an opiate. Although physicians and pharmacists are required to register, utilization review of Medicaid claims still indicates not all providers are using the MPMP system to detect potential overdose or abuse.

As PQA has finalized their opiate related quality measures and CMS has added the measures to the Adult Core Set, MS-DUR proposes a revised educational intervention to address concerns about safety and the potentials for abuse.

The Opioid High Dosage measure addresses higher than recommended daily doses of opioids for an extended period of time. The outlier to the first measure in Table 1 would occur when a beneficiary without cancer received a daily dosage of opioids greater than 120mg MEDD for 90 consecutive days or longer. Long-term use of opioids at high doses can contribute to the likelihood of overdose, a major safety concern and extended use at high doses can increase the risk of addiction and subsequent abuse.

The Multiple Prescriber and Multiple Pharmacy measure address the concept of “doctor shopping.” The outlier to the second measure in Table 1 would occur when a beneficiary without cancer received prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies. Obtaining prescriptions for opiates from multiple prescribers and utilizing multiple pharmacies is an indicator of potential abuse, especially when the geographical locations of the prescribers and/or pharmacies does not reflect a reasonable utilization pattern. Even when abuse is not occurring, use of multiple prescribers represents a potential safety problem due to the potential for uncoordinated care and an increased risk of overdose.

The combined measure using high dosage and multiple providers is a strong indicator of potential abuse and/or a significant safety problem. The outlier to the third measure in Table 1 would occur when a beneficiary without cancer received a daily dosage of opioids greater than 120mg MEDD

for 90 consecutive days or longer AND the beneficiary received prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.

Exceptions occurring to any of these quality measure concepts are a serious concern. Providers need to be informed when exceptions to these quality measures occur in order to alert them to potential coordination of care issues resulting from multiple providers being involved and increased safety concerns due to high dosages and the potential for addiction/abuse. An important part of the educational intervention needs to be encouraging appropriate use of the MPMP database.

RECOMMENDATIONS:

In order to more completely address the new Adult Core measures, MS-DUR proposes the following recommendations for the DUR Board:

1. MS-DUR initiates an educational intervention based on the Opioid High Dosage measure. Each month beneficiaries filling an opioid prescription during the previous month will be identified if they exceed the criteria in the first measure during a six-month look back period. ALL prescribers and pharmacies involved in the prescriptions contributing to the exception will be notified.

2. MS-DUR initiates an education intervention based on the Multiple Prescriber and Multiple Pharmacy measure. Each month beneficiaries filling an opioid prescription during the previous month will be identified if they exceed the criteria in the second measure during a six-month look back period. ALL prescribers and pharmacies involved in the prescriptions contributing to the exception will be notified.

3. MS-DUR will conduct a quarterly analysis based on the combined Opioid High Dosage and Multiple Prescriber/Pharmacy measure. Beneficiaries will be identified who exceed the criteria in the third measure and a report will be provided to Medicaid Program Integrity for further investigation and evaluation for DOM consideration for lock-in.

CDC GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN AND DUR ACTIONS: BACKGOUND FOR INITIAL DISCUSSION

BACKGROUND

As described in the background section of the previous report on the High Morphine Equivalent Dosing (Med) and Doctor Shopping Educational Initiatives, the Office of Inspector General of the Department of Health and Human Services (OIG) has strongly recommended that steps must be taken to address opioid misuse and diversion. The OIG 2016 Work Plan will focus on state actions taken through drug utilization review (DUR) programs to address opioid misuse and abuse in state Medicaid.[1] Efforts are directed to protect "an expanding Medicaid program from fraud, waste, and abuse."

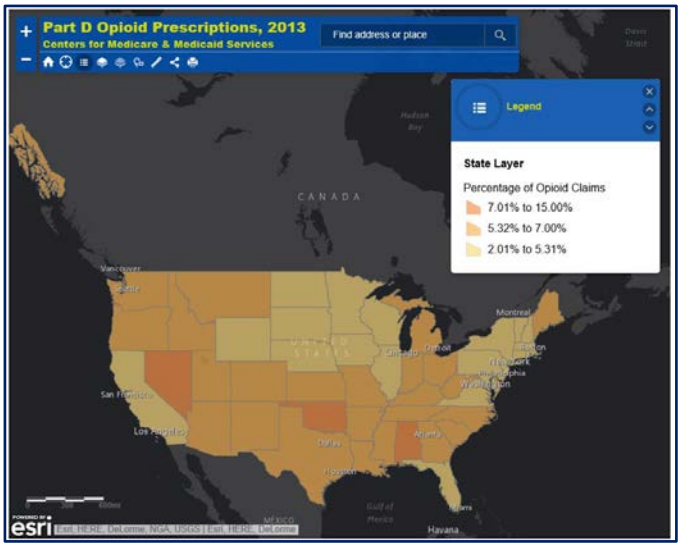
> ➢ **REVISED** States' actions based on Medicaid drug utilization reviews
>
> We will review the education and enforcement actions that States have taken on the basis of information generated by their drug utilization review (DUR) programs related to inappropriate dispensing and potential abuse of prescription drugs, including opiates. We also will review State oversight of and coordination with MCOs' DUR programs and any resulting actions related to inappropriate dispensing of opiates.

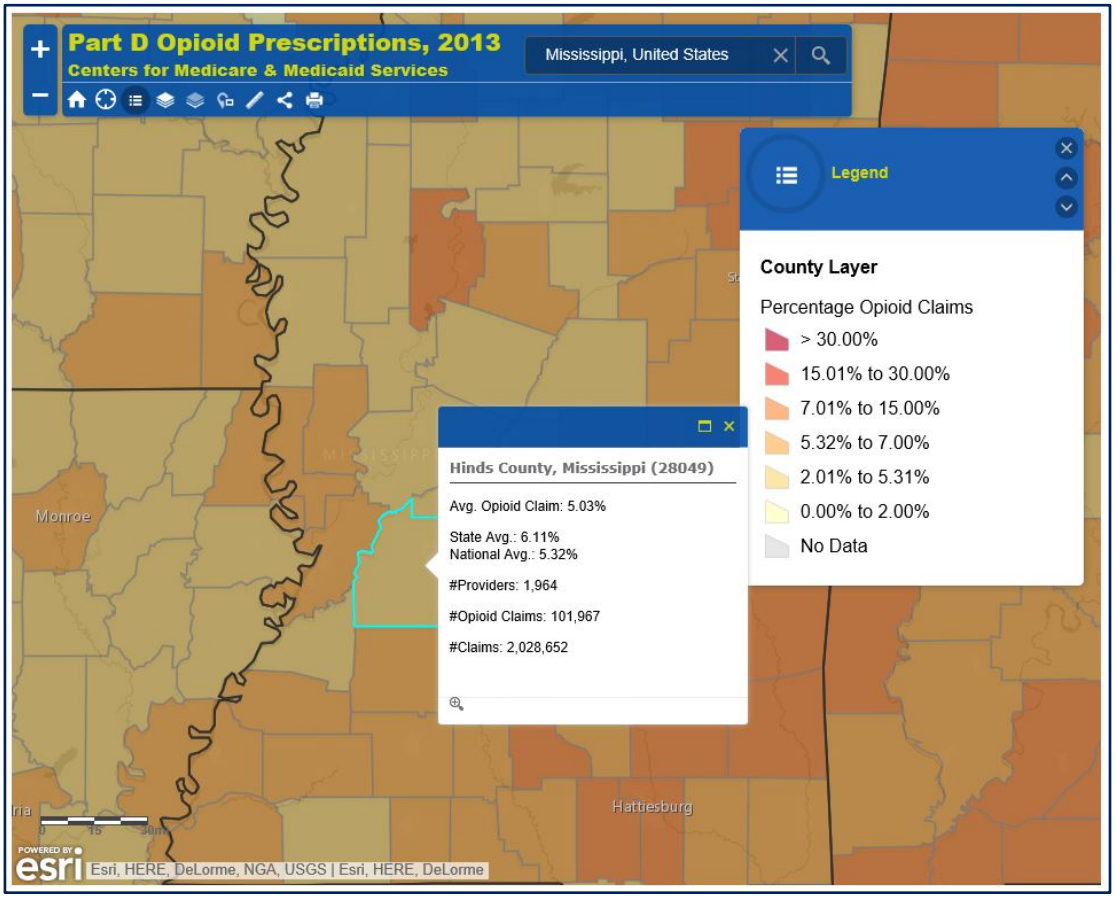
Various efforts have been underway in Mississippi to address the opioid abuse problem. The Mississippi Prescription Drug Monitoring Program (MPMP) was established to help providers, professional boards and drug enforcement agencies track prescriptions for opioids and other controlled substances. The Board of Medical Licensure required all physicians to be enrolled in the MPMP by December 2013. The Board of Pharmacy required all pharmacists to be enrolled by December 2015. Providers can use the MPMP to identify potentially inappropriate use by patients when they are considering writing a prescription or when they are requested to fill a prescription for an opiate. Mississippi Medicaid uses the MPMP to evaluate potential drug abuse cases, to make decisions about prior authorization (PA) approvals and to make decisions about assigning beneficiaries to the lock-in program. The lock-in program limits which and how many providers and pharmacies a beneficiary can use.

Recently, the Centers for Medicare and Medicaid Services (CMS) announced a new tool that allows providers and others to track the number of opioid prescription claims in their communities, counties and states. The tool – The Opioid Heat Map – shows local level data of de-identified Medicare Part D opioid prescription claims, comparing the local area to data across the country

[1] OIG Work Plan 2016, p 31. http://oig.hhs.gov/reports-and-publications/archives/workplan/2016/oig-work-plan-2016.pdf

(https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/OpioidMap.html). The data currently used in this mapping tool is from 2013 Medicare Part D prescription drug claims. The tool was developed in response to the increasing amount of deaths each year related to drug overdose for both opioid-based pain relievers and from illicit drugs like heroin. CMS noted that in 2013, overdose from prescription opioid pain relievers claimed more than 16,000 lives, with more than 145,000 people dying from these overdoses in the last decade. Two images from the mapping tool show the ratings by state and the statistics for Hinds County with the state and national averages.





The Centers for Disease Control and Prevention (CDC) released draft Guidelines for Prescribing Opioids for Chronic Pain for public comment, which is due by January 13. The draft guideline summarizes scientific knowledge about the effectiveness and risks of long-term opioid therapy and provides recommendations for when to initiate or continue opioids for chronic pain; opioid selection, dosage, duration, follow-up, and discontinuation; and assessing risk and addressing harms of opioid use. The draft Guideline identifies important gaps in the literature where further research is needed.

It is intended to be used by primary care providers who are treating patients with chronic pain (i.e., pain lasting longer than 3 months or past the time of normal tissue healing) in outpatient settings. The draft Guideline is intended to apply to patients aged 18 years of age or older with chronic pain outside of palliative and end-of-life care. The Guideline is not intended to apply to patients in treatment for active cancer. The Guideline is not a federal regulation; adherence to the Guideline will be voluntary. The complete guideline and background materials are available and comments can be provided at:

http://www.regulations.gov/#!documentDetail;D=CDC-2015-0112-0001

The following is an excerpt from the CDC document.

> Opioids are commonly prescribed for pain. An estimated 20% of patients presenting to physician offices with non-cancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receive an opioid prescription.[2] In 2012, health care providers wrote 259 million prescriptions for opioid pain medication, enough for every adult in the United States to have a bottle of pills.[3] Opioid prescriptions per capita increased 7.3% from 2007 to 2012, with opioid prescribing rates increasing more for family practice, general practice, and internal medicine compared with other specialties.[4] Rates of opioid prescribing vary greatly across states in ways that cannot be explained by the underlying health status of the population, highlighting the lack of consensus among providers on how to use opioid pain medication.[3]
>
> Prevention, assessment, and treatment of chronic pain are challenges for health providers and systems. Pain might go unrecognized, and patients can be at risk for inadequate pain treatment, particularly racial and ethnic minorities, women, the elderly, persons with cognitive impairment, and those with cancer and at the end of life.[5] Patients should receive appropriate pain treatment based on a careful consideration of the benefits and risks of treatment options. Chronic pain can be the result of an underlying medical disease or condition, injury, medical treatment, inflammation, or an unknown cause[5]. Estimates of the prevalence of chronic pain vary, but it is clear that the number of persons experiencing chronic pain in the United States is

[2] Daubresse M, Chang HY, Yu Y, et al. Ambulatory diagnosis and treatment of nonmalignant pain in the United States, 2000–2010. Med Care 2013;51:870–8.

[3] Paulozzi LJ, Mack KA, Hockenberry JM. Vital signs: variation among states in prescribing of opioid pain relievers and benzodiazepines—United States, 2012. MMWR Morb Mortal Wkly Rep 2014;63:563–8.

[4] Levy B, Paulozzi L, Mack KA, Jones CM. Trends in opioid analgesic-prescribing rates by specialty, U.S., 2007–2012. Am J Prev Med 2015;49:409–13.

[5] Institute of Medicine. Relieving pain in America: a blueprint for transforming prevention, care, education, and research. Washington, DC: The National Academies Press; 2011.

substantial. The 1999–2002 National Health and Nutrition Examination Survey estimated a prevalence of current widespread or localized pain lasting at least 3 months of 14.6%. [6] The overall prevalence of common, predominantly musculoskeletal pain conditions that can be chronic (e.g., arthritis, rheumatism, chronic back or neck problems, and frequent severe headaches) was estimated at 43% among adults in the United States [7] based on a survey conducted during 2001–2003. Most recently, analysis of data from the 2012 National Health Interview Study revealed an estimated prevalence of daily pain of 11.2%.[8] It is hard to estimate the number of persons who could potentially benefit from opioid pain medication long term. Although evidence supports short-term efficacy of opioids for reducing pain and improving function in non-cancer nociceptive and neuropathic pain in trials lasting <16 weeks,[9] few studies to assess the long-term benefits of opioids for chronic pain (pain lasting >3 months) with outcomes examined at least 1 year later have been conducted.[10] On the basis of data available from health systems, researchers estimate that 9.6 to 11.5 million adults, or approximately 3%–4% of the adult U.S. population, were prescribed long-term opioid therapy in 2005.[11]

In the past decade, while the death rate for the top leading causes of death such as heart disease and cancer has decreased substantially, the death rate associated with opioid pain medication has increased substantially.[12] Since 1999, more than 140,000 persons have died from overdose related to opioid pain medication in the United States.[13]

More than 16,000 deaths occurred in 2013, four times the number of overdose deaths related to these drugs in 1999. [14] Sales of opioid pain medication have increased in parallel with opioid-related overdose deaths.[15] The Drug Abuse Warning Network estimated that >420,000 emergency department visits were related to the misuse or abuse of narcotic pain relievers in 2011, the most recent year for which data are available.[16]

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Opioid use disorder is a problematic pattern of opioid use leading to clinically significant impairment or distress. In 2013, an estimated 1.9 million persons abused or were dependent on prescription opioid pain medication (based on DSM-IV criteria).[17] Having a history of a prescription for an opioid pain medication increases the risk for overdose and opioid use disorder,[18, 19, 20] highlighting the value of guidance on safer prescribing practices for providers.

The CDC guidelines have sparked considerable controversy[21] with regard to the secrecy surrounding the development process and concerns about overly restricting patients' access to needed medications. Major recommendations included in the proposed guidelines is provided in Appendix B.

Regardless of changes that might result from comments received, the final guidelines will probably be very similar to the proposed guidelines and should have significant impact on criteria that will be used by drug utilization review (DUR) programs. A 2015 article reviewing actions taken by Oklahoma Medicaid's DUR during the last few years to control opiate use is included in Appendix C.[22] Actions taken by Oklahoma Medicaid include:

- quantity limits,
- pharmacy lock-in program,
- prior authorization program,
- step-therapy programs,
- prospective drug utilization review,
- limit on number of prescriptions,
- preferred brand authorization,
- age restrictions, and
- prescriber contract requirement.

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ACTION REQUESTED:

MS-DUR is providing you this information in preparation of a full review of all Division of Medicaid DUR activities and efforts related to prescribing of opioids, which will take place at the April 2016 meeting. We ask that you review the information included and at the link provided and be prepared to provide feedback and comments as input to guide us in preparing for the April meeting.

CMS MEDICAID PROGRAM INTEGRITY EDUCATION

The CMS Center for Program Integrity provides educational resources to educate providers, beneficiaries and other stakeholders in promoting best practices and awareness of Medicaid fraud, waste and abuse. Medicaid Provider Integrity Education (MPIE) materials are applicable to providers, beneficiaries, and State managed care plans. MPIE materials include topic-based information in an easy to read format that aid in furthering education efforts of providers, beneficiaries and other Medicaid stakeholders. The information provided is intended to further the education efforts of Medicaid Program Integrity Education, assist providers with being in compliance with their billing and assist in the fight against fraud, waste and abuse. Please visit Medicaid Program Integrity Education - Centers for Medicare & Medicaid Services to access educational booklets, fact sheets and provider checklist resources and tools which promote efforts to prevent Medicaid fraud, waste and improper payments.

https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/edmic-landing.html

Audit Toolkit	Basic Data Mining Toolkit ****NEW****
Beneficiary Card Sharing Toolkit	Documentation Matters Toolkit ****UPDATED material****
Drug Diversion Toolkit	Electronic Health Records
Fraud, Waste & Abuse (Healthcare Fraud & Program Integrity)	Home and Community-Based Services (HCBS) ****NEW****
Hospice Care Toolkit	Managed Care Compliance Toolkit
Medicaid Compliance for the Dental Professional	Non Emergency Medical Transportation
Nursing Home Toolkit ****UPDATED material****	Off Label Pharmaceutical Marketing
Partners In Integrity Toolkit	Personal Care Services
Pharmacy Audit and Dispensing Toolkit ****NEW****	Pharmacy Education Toolkit ****UPDATED material****
Safeguarding Your Medical Identity	

Program Integrity: Drug Diversion Toolkit

The Drug Diversion materials review various aspects of drug diversion, including the types of drug diversion, the targeted medications for drug diversion, drug diversion behaviors, preventive actions, and the consequences for providers and patients involved in drug diversion activities.

****NEW****

* Buprenorphine - A Primer for Prescribers and Pharmacists (*booklet*)

Controlled Substance Integrity - Documentation for Drop-Off to Pickup (*booklet*)

Patient Counseling - A Pharmacist's Responsibility to Ensure Compliancy (*booklet*)

Prescription Drug Trafficking - Recognizing Suspicious Prescriptions (*booklet*)

Prescription Opioids - An Overview for Prescribers and Pharmacists (*booklet*)

Prescription Drug Diversion - Use of Legal Drugs for Illegal Purposes Module 1 (*presentation*)

Prescription Drug Diversion - Use of Legal Drugs for Illegal Purposes Module 1 (*presentation handout - updated 3/23/15*)

Prescription Drug Diversion - Use of Legal Drugs for Illegal Purposes Module 2 (*presentation*)

Prescription Drug Diversion - Use of Legal Drugs for Illegal Purposes Module 2 (*presentation handout - updated 3/23/15*)

The Role of a Prescription Drug Monitoring Program in Reducing Prescription Drug Diversion, Misuse, and Abuse (*fact sheet*)

Prescription Drug Diversion Resource Guide

Do You Know Where the Drugs Are Going? (*presentation - updated 4/29/15*)

Do You Know Where the Drugs Are Going? (*presentation handout - updated 3/31/15*)

What Is a Prescriber's Role in Preventing the Diversion of Prescription Drugs? (*booklet - updated 3/31/15*)

The Mississippi Division of Medicaid and MS-DUR strongly encourage all providers to take advantage of the educational materials available at this site.

Appendix

APPENDIX A

Table 1 was updated on August 13, 2015

March 31, 2015

Improving the Quality of Care: Antipsychotic Use in Children and Adolescents

Key Points:

- Prescribing of antipsychotic medications to children and adolescents is increasing, despite a lack of safety data and a high risk of neurologic, psychiatric, and metabolic adverse effects.
- Antipsychotic medications should be prescribed for a specific clinical indication only when the scientific evidence supports the likelihood that benefits will exceed harms. For children and adolescents, use of antipsychotic medication for United States Food and Drug Administration (FDA)-approved indications generally implies more certainty that benefits will exceed risks, compared to off-label use. Prescribing beyond FDA-approved indications must be approached cautiously.
- No antipsychotics are FDA-approved for patients under three years of age. Only two older, first-generation antipsychotics are FDA-approved for patients under five years of age. FDA-approved indications for children under 10 years of age are very limited, especially among newer, second-generation antipsychotics.
- As of October 1, 2014, any use of antipsychotics for Medi-Cal beneficiaries 0 – 17 years of age requires an approved *Treatment Authorization Request* (TAR).
- Concurrent use of more than one antipsychotic medication is not recommended. Among all children and adolescents in the Medi-Cal fee-for-service population with at least 90 consecutive days of antipsychotic medication treatment, almost 6 percent were taking two or more antipsychotic medications concurrently for at least 90 consecutive days.
- Serious adverse effects are common with antipsychotic medication use, particularly weight gain, dyslipidemia, diabetes, and cardiovascular disease. While both baseline and periodic metabolic monitoring is recommended, only 37 percent of children and adolescents in the Medi-Cal fee-for-service population had appropriate metabolic testing during a one-year time period.
- Psychosocial care, which includes behavioral interventions, psychological therapies, and skills training, among others, remains the recommended first-line treatment option for children and adolescents for nonpsychotic conditions such as attention deficit disorder and disruptive behaviors. Antipsychotic medications, when prescribed, should be part of a comprehensive, multi-modal plan for coordinated treatment that includes psychosocial care.
- The safest use of antipsychotic medications in children and adolescents requires close, in-person clinical monitoring by prescribers for both clinical response and adverse neurologic, psychiatric, and metabolic effects.

Background

Prescribing of antipsychotic medications to children and adolescents has increased rapidly in recent decades, driven by new prescriptions and by longer duration of use.[1] The frequency of prescribing antipsychotics to children and adolescents increased almost fivefold from 1996 – 2002, from 8.6 per 1,000 to 39.4 per 1,000.[2] A national study found that prescribing of atypical antipsychotics increased 62 percent from 2002 – 2007 among children and adolescents enrolled in Medicaid.[3]

Although some clinical evidence supports the efficacy of antipsychotics in patients under 18 years of age for certain narrowly defined conditions, according to a 2011 report by the Agency for Healthcare Research and Quality (AHRQ), children taking antipsychotic medications receive an

atypical antipsychotic 90 percent of the time, and in the majority of patients the use is for an off-label indication, including attention deficit/hyperactivity disorder (ADHD) and aggressive behavior.[4] One study found that in the Medicaid population, more than 3/4 of children and adolescents were taking antipsychotics for an indication that is not FDA approved.[5] For reference, current FDA-approved indications for selected antipsychotic medications are listed in Table 1.

Table 1. Antipsychotic Medications: FDA-approved Indications for Children and Adolescents

	Age (years)							
	<1	**1 – 2**	**3 – 4**	**5**	**6 – 9**	**10 – 11**	**12**	**13 – 17**
Second-Generation (Atypical) Antipsychotics								
aripiprazole*	NONE				**I,T**	**I,M,T**		**I,M,S,T**
asenapine*	NONE					**M**		
clozapine*	NONE							
iloperidone*	NONE							
lurasidone*	NONE							
olanzapine*	NONE					**D,M**		**D,M,S**
paliperidone	NONE						**S**	
quetiapine*	NONE					**M**		**M,S**
risperidone*	NONE			**I**		**I,M**		**I,M,S**
ziprasidone*	NONE							
First-Generation (Typical) Antipsychotics								
chlorpromazine*	NONE	**B**						NONE
fluphenazine*	NONE							
haloperidol*	NONE	**H,P,S,T**						
loxapine*	NONE							
molindone*	NONE						**S**	
perphenazine*	NONE						**S**	
pimozide	NONE						**T**	
thioridazine*	NONE			**S**				
thiothixene*	NONE						**S**	
trifluoperazine*	NONE				**S**			

* As of the date of publication of this article, these drugs appear on the Medi-Cal List of Contract Drugs, although some medications have restrictions on manufacturer codes. For current information, use the online Medi-Cal Formulary search tool available at http://www.dhcs.ca.gov/services/Pages/FormularyFile.aspx.

Key:

B	Severe behavioral problems marked by combativeness and/or explosive hyperexcitable behavior and short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders
D	Acute depressive episodes associated with Bipolar I Disorder (along with fluoxetine)
H	Hyperactivity
I	Irritability associated with autism disorder
M	Manic or mixed episodes associated with Bipolar I Disorder
P	Psychosis
S	Schizophrenia
T	Tourette's Syndrome

While antipsychotic medications can be of significant benefit, these drugs also have serious common side effects, including weight gain, hyperprolactinemia, and metabolic disturbance,

which may result in children and adolescents developing into adults who struggle with obesity, diabetes, and dyslipidemias.[6] In addition, serious neurologic side effects, such as tardive dyskinesia, are associated with both first- and second-generation antipsychotic medications.[7] Even when used for approved indications, antipsychotic medications can complicate treatment by creating or unmasking additional psychiatric symptoms, including sedation, agitation, anxiety, and suicidal thinking and behavior.[7] Therefore, antipsychotics should be prescribed for a specific clinical indication only when the scientific evidence supports the likelihood that benefits will exceed harms, and the risk of treatment should be considered and periodically re-evaluated for each individual patient. Considering that atypical antipsychotics already have the greatest mean prescription cost of any psychotropic medication and are the most costly drug class within the Medicaid program, the additional costs associated with potential long-term treatment of chronic diseases makes it even more important for providers to carefully balance the economic and medical consequences with the potential benefits of treatment.[5,8]

In addition, a recent systematic review found that among children and adolescents prescribed any antipsychotic, 10 percent were taking multiple concurrent antipsychotics.[9] One study of a large state Medicaid fee-for-service program found that approximately seven percent of children 6 – 17 years of age taking any antipsychotic were prescribed two or more antipsychotics for longer than 60 days.[10] These rates are of particular concern given that none of the American Academy of Child & Adolescent Psychiatry (AACAP) practice parameters recommend concurrent use of multiple antipsychotic medications, due to a lack of high-quality studies on the side effects and clinical efficacy of multiple concurrent antipsychotics.[11,12]

Measuring Quality Care: Safe and Judicious Use of Antipsychotics in Children and Adolescents

For 2015, the National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS®) added the following three new measures focused on the safe and judicious use of antipsychotic medications in children and adolescents:[13]

1. Metabolic Monitoring for Children and Adolescents on Antipsychotics (APM), which assesses the percentage of children and adolescents who have ongoing use of antipsychotic medications and metabolic testing during the measurement year. AACAP practice parameters for the use of atypical antipsychotic medications in children and adolescents state:

   - "The acute and long-term safety of these medications in children and adolescents has not been fully evaluated and therefore careful and frequent monitoring of side effects should be performed…Ideally, monitoring of BMI, blood pressure, fasting blood glucose and fasting lipid profiles should follow, whenever feasible, the recommendations found in the consensus statement put forth by the American Diabetes Association and the American Psychiatric Association." (Recommendation 10, Clinical Guideline).[11]

Table 2. American Diabetes Association Screening Guidelines for Patients on Second-Generation Antipsychotics[14]

	Baseline	4 weeks	8 weeks	12 weeks	Annually
Personal & family history	X				X
Weight (BMI)	X	X	X	X	
Waist circumference	X				X
Blood pressure	X			X	X
Fasting plasma glucose	X			X	X
Fasting lipid profile	X			X	

   - "Careful attention should be given to the increased risk of developing diabetes with the use of atypical antipsychotic agents (AAA), and blood glucose levels and other parameters should be obtained at baseline and monitored at regular intervals." (Recommendation 12, Clinical Standard).[11]

- "In those patients with significant weight changes and/or a family history indicating high risk, lipid profiles should be obtained at baseline and monitored at regular intervals." (Recommendation 13, Clinical Guideline).[11]

2. Use of Multiple Concurrent Antipsychotics in Children and Adolescents (APC), which assesses the percentage of children and adolescents who were taking two or more concurrent antipsychotics for at least 90 days during the measurement year. AACAP practice parameters for the use of atypical antipsychotic medications in children and adolescents state:

   - "The simultaneous use of multiple AAA has not been studied rigorously and generally should be avoided." (Recommendation 8, Not Endorsed).[11]

3. Use of First-line Psychosocial Care for Children and Adolescents on Antipsychotics (APP), which assesses the percentage of children and adolescents who had a new prescription for an antipsychotic medication without a primary indication for it and had documentation of psychosocial care as first-line treatment. AACAP practice parameters for the use of atypical antipsychotic medications in children and adolescents state:

   - "Prior to the initiation of and during treatment with an AAA, the general guidelines that pertain to the prescription of psychotropic medications should be followed." (Recommendation 1, Clinical Standard).[11]
   - "When selecting any AAA for use in a child or adolescent, the clinician should follow the most current available evidence in the scientific literature." (Recommendation 2, Clinical Standard).

Medi-Cal Policy Aligns with Clinical Guidelines

- Medi-Cal has always required an approved TAR for the use of antipsychotics for non-FDA approved indications, and for any use in children less than 6 years of age. Of note, it was found that requiring an approved TAR for non-FDA approved indications was often difficult to enforce.
- Since May 1, 2012, antipsychotic use for Medi-Cal beneficiaries 6 – 17 years of age has been restricted to the use of one antipsychotic, except during titration period and, within this age group, concurrent use of two or more antipsychotics has required an approved TAR.
- As of October 1, 2014, **any** use of antipsychotics for Medi-Cal beneficiaries 0 – 17 years of age requires an approved TAR. For additional information about this policy, a Frequently Asked Questions (FAQ) document is available on the California Department of Health Care Services Pharmacy Benefits Division website at http://www.dhcs.ca.gov/services/Pages/PharmacyBenefits2.aspx.

Antipsychotic Use Among Children and Adolescents in the Medi-Cal Fee-for-Service Population

A retrospective cohort study was conducted to evaluate two of the HEDIS performance measures for antipsychotic medication use among children and adolescents (APM and APC) in the Medi-Cal fee-for-service population, using medical and pharmacy claims data. Study population selection criteria were adapted from HEDIS performance indicators and included all Medi-Cal beneficiaries who met the following inclusion criteria:

- Continuously eligible beneficiary enrolled in the Medi-Cal fee-for-service program for the duration of the measurement year (October 1, 2013, through September 30, 2014)
- 1 – 17 years of age as of September 30, 2014
- At least one paid pharmacy claim for an antipsychotic medication during the measurement year

Descriptive statistics were used to summarize beneficiary characteristics and HEDIS rates. Data were stratified into three age groups, per HEDIS specifications.

Results
A total of 6,688 Medi-Cal fee-for-service beneficiaries met the inclusion criteria, and within this group there were a total of 58,598 paid claims for antipsychotic medications. Demographic characteristics of the beneficiaries are listed in Table 3 including gender and race/ethnicity.

Table 3. Demographic Characteristics of the Medi-Cal Fee-for-Service Study Population

	1 – 5 years	6 – 11 years	12 – 17 years
Overall Population (n = 6,688)	82 (1%)	2,038 (30%)	4,568 (68%)
Gender			
Male (n = 4,349; 65%)	61 (74%)	1,409 (69%)	2,879 (63%)
Female (n = 2,339; 35%)	21 (26%)	629 (31%)	1,689 (37%)
Race/Ethnicity			
White/Caucasian, non-Hispanic (n = 3,173; 47%)	29 (35%)	924 (45%)	2,220 (49%)
All other races/ethnicities (n = 3,515; 53%)	53 (65%)	1,114 (55%)	2,348 (51%)

The study population was almost 2/3 male (n = 4,439; 65%) and almost half of these beneficiaries identified as white/Caucasian race, non-Hispanic ethnicity (n = 3,173; 47%).

Overall rates for APM (Table 4) and APC (Table 5), as well as rates stratified by the three age groups are listed below. Of note, for the APM calculation, a total of 675 beneficiaries were excluded as they only had one paid claim for an antipsychotic medication during the measurement year (leaving a denominator of 6,013 beneficiaries) and, for the APC calculation, a total of 1,313 beneficiaries were excluded as they had less than 90 days of continuous antipsychotic medication treatment during the measurement year (leaving a denominator of 5,375 beneficiaries).

Table 4. Metabolic Monitoring in Children and Adolescents with ≥2 Paid Claims for Antipsychotic Medications During the Measurement Year (October 1, 2013, through September 30, 2014)

Age Group	**Numerator** Children and adolescents with ≥1 test for **both** blood glucose/HbA1C and LDL-C/cholesterol	**Denominator** Children and adolescents with ≥2 paid claims for antipsychotic medications	Percentage of children and adolescents with ≥2 paid claims for antipsychotic medications and metabolic testing
1 – 5 years	18	68	26.5%
6 – 11 years	575	1,838	31.3%
12 – 17 years	1,653	4,107	40.2%
TOTAL	**2,246**	**6,013**	**37.4%**

Although the 37.4 percent figure calculated using HEDIS measure parameters gives the rate at which both tests were completed (blood glucose or HbA1C and LDL-C or cholesterol), individual testing rates were also calculated for the study population. The rate of glucose or Hb1AC monitoring (n = 3,151; 52.4%), was much greater than LDL-C or cholesterol monitoring

(n = 2,279; 37.9%), suggesting there is an opportunity for outreach to providers, who could raise the metabolic monitoring rate calculated in the HEDIS measure by ordering both tests at the same time.

Of note, the HEDIS documentation for this measure included an analysis using the 2008 Medicaid Analytic eXtract (MAX) data files. These data showed an average metabolic monitoring rate across data collected from 11 states of 18.5 percent (range: 4.8 percent – 36.2 percent), more than half the rate found in the Medi-Cal fee-for-service population.[13]

Table 5. Children and Adolescents on Multiple Concurrent Antipsychotic Medications During the Measurement Year (October 1, 2013, through September 30, 2014)

Age Group	**Numerator** Children and adolescents on ≥2 concurrent antipsychotic medications ≥90 consecutive days	**Denominator** Children and adolescents with ≥90 consecutive days of antipsychotic medication treatment	Percentage of children and adolescents on ≥2 concurrent antipsychotic medications
1 – 5 years	0	53	0.0%
6 – 11 years	61	1,665	3.7%
12 – 17 years	245	3,657	6.7%
TOTAL	**306**	**5375**	**5.7%**

This calculated rate of 5.7 percent of Medi-Cal fee-for-service beneficiaries on multiple concurrent antipsychotic medications is close to the published rates for this measure found in the HEDIS documentation, which used the 2008 MAX data files and found average rate of 6.0 percent across 11 states (range: 2.8 percent – 9.4 percent).[13]

Within the 306 beneficiaries identified on greater than two concurrent antipsychotic medications for at least 90 consecutive days, concurrent use of aripiprazole, risperidone, and/or quetiapine accounted for 65.4 percent of concurrent antipsychotic medication use, including concurrent use of risperidone-aripiprazole (n = 70), quetiapine-aripiprazole (n = 68), quetiapine-risperidone (n = 62).

Clinical Recommendations

- Psychosocial care, which includes behavioral interventions, psychological therapies, and skills training, among others, is the recommended first-line treatment option for children and adolescents diagnosed with nonpsychotic conditions such as attention-deficit disorder and disruptive behaviors.
- Prior to the initiation of treatment with antipsychotic medication, obtain a personal and family history of diabetes and hyperlipidemia, seizures and cardiac abnormalities, as well as any family history of previous response or adverse events associated with antipsychotic medication.
- When prescribed, antipsychotic medications should be part of a comprehensive, multi-modal plan for coordinated treatment that includes psychosocial care.
- Antipsychotic dosing should follow the “start low and go slow” approach and seek to find the lowest effective dose. Determination of an appropriate target dose should follow both the current scientific literature and the clinical response of the patient, while also monitoring the patient for side effects and tolerability. Multiple clinical guidelines suggest that higher than approved dosages of antipsychotic medications should be avoided.[14]
- Periodically review the ongoing need for continued therapy with antipsychotic medications.

- Monitor BMI, blood pressure, fasting blood glucose, and fasting lipid profiles according to the recommendations found in the consensus statement put forth by the American Diabetes Association and the American Psychiatric Association.
- Periodically review AACAP practice parameters for updated information on the AACAP website at http://www.aacap.org/AACAP/Resources_for_Primary_Care/Practice_Parameters_and_Resource_Centers/Practice_Parameters.aspx.
- Review additional prescriber resources developed by the Ohio Psychotropic Medication Quality Improvement Collaborative, including a psychotropic medication contraindications and interactions table, atypical antipsychotics adverse effects table, and a screening and monitoring tool available at their website at http://www.ohiomindsmatter.org/Prescribers_Psychotropic.html.

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CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

CMCS Informational Bulletin

DATE: December 11, 2015

FROM: Vikki Wachino
Director
Center for Medicaid and CHIP Services

SUBJECT: 2016 Updates to the Child and Adult Core Health Care Quality Measurement Sets

This informational bulletin describes the 2016 updates to the core set of children's health care quality measures for Medicaid and the Children's Health Insurance Program (CHIP) (Child Core Set) and the core set of health care quality measures for adults enrolled in Medicaid (Adult Core Set).

Background

The Center for Medicaid and CHIP Services (CMCS) has worked with stakeholders to identify two core sets of health care quality measures that can be used to assess the quality of health care provided to children and adults enrolled in Medicaid and CHIP (see http://www.medicaid.gov/medicaid-chip-program-information/by-topics/quality-of-care/quality-of-care-—-performance-measurement.html). The core sets are tools states can use to monitor and improve the quality of health care provided to Medicaid and CHIP enrollees. The goals of this effort are to:

- Encourage national reporting by states on a uniform set of measures; and
- Support states in using these measures to drive quality improvement.

Part of implementing an effective "quality measures reporting program" is to periodically reassess the measures that comprise it since many factors, such as changes in clinical guidelines and experiences with reporting and performance rates, may warrant modifying the measure set. In addition, CMCS continues to prioritize working with federal partners to promote quality measurement alignment across programs (e.g., Meaningful Use, Hospital Inpatient Quality Reporting Program, Physician Quality Reporting System) recognizing that this reduces burden on states reporting data to multiple programs and helps to drive quality improvement across payers and programs.

For the 2016 updates to the Child and Adult Core Sets, CMCS, once again, worked with the National Quality Forum's (NQF) Measure Applications Partnership (MAP),[1] a public-private partnership that reviews measures for potential use in federal public reporting, to review and identify ways to improve the core sets. Collaborating with NQF's MAP process for core set updates promotes measure alignment across CMS since NQF also reviews measures for other CMS reporting programs.

[1] http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx

CMCS is encouraged by state reporting on the core measures. For the Child Core Set, fifty states and the District of Columbia voluntarily reported, for federal fiscal year (FFY) 2014, a median of 16 measures. For the Adult Core Set, 34 states reported a median of 17 measures in FFY 2014. Additional information on state reporting and performance on each core set can be found in the forthcoming respective *2015 Annual Report on the Quality of Care for Children in Medicaid and CHIP* and *the 2015 Annual Report on the Quality of Care for Adults Enrolled in Medicaid* . CMCS looks forward to working with states on the core measures reporting for FFY 2015.

2016 Child Core Set

Since the release of the initial Child Core Set in 2011, CMCS has collaborated with state Medicaid and CHIP agencies to voluntarily collect, report, and use the measures to drive quality improvements. Section 1139A of the Social Security Act, as amended by Section 401(a) of the Children's Health Insurance Reauthorization Act (CHIPRA) of 2009, provides that, beginning annually in January 2013, the Secretary shall publish recommended changes to the core measures.[2]

For the 2016 Child Core Set update, CMCS will add two measures:

- Use of Multiple Concurrent Antipsychotics in Children and Adolescents[3]
- Audio logical Evaluation no later than 3 months of age[4]

The addition of these two measures allows CMCS to expand the measurement of quality of care for two populations – children prescribed psychotropic drugs and children at-risk of hearing problems. CMCS also is engaged in a pilot of a reporting process for the child version of the hospital Consumer Assessment of Healthcare Providers and Systems survey (Child HCAHPS)[5] in order to determine whether or not to include HCAHPS in a future Child Core Set. This measure was recommended by the 2014 MAP to help address gaps noted in the measure set in three areas: inpatient care; patient experience; and care coordination. Additional information about the 2015 Child Core Set MAP review process and their recommendations to CMCS can be found at: http://medicaid.gov/medicaid-chip-program-information/by-topics/quality-of-care/chipra-initial-core-set-of-childrens-health-care-quality-measures.html.

2016 Adult Core Set

In January 2012, CMCS released its initial Adult Core Set. Section 1139B of the Social Security Act, as amended by Section 2701 of the Affordable Care Act, notes that the Secretary shall issue updates to the Adult Core Set beginning in January 2014 and annually thereafter.[6, 7]

[2] The first update was issued via a State Health Official Letter "2013 Children's Core Set of Health Care Quality Measures," SHO #13-002. http://www.medicaid.gov/Federal-Policy-Guidance/downloads/SHO-13-002.pdf . The 2014 update was issued via a CMCS Informational Bulletin "2014 Updates to the Child and Adult Core Health Care Quality Measurement Sets." http://medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-12-19-13.pdf as was the "2015 Updates to the Child and Adult Health Care Quality Measurements Sets." http://www.medicaid.gov/federal-policy-guidance/downloads/cib-12-30-2014.pdf

[3] Measure steward: AHRQ-CMS CHIPRA National Collaborative for Innovation in Quality Measurement (NCINQ), Not NQF Endorsed

[4] Measure steward: Centers for Disease Control and Prevention, NQF #1360

[5] Measure steward: Center for Quality Improvement and Patient Safety-Agency for Healthcare Research and Quality, NQF#2548

[6] The first update was issued via a CMCS Informational Bulletin "2014 Updates to the Child and Adult Core Health Care Quality Measurement Sets." http://medicaid.gov/Federal-Policy-Guidance/Downloads/CIB-12-19-13.pdf

For the 2016 Adult Core Set update, CMCS will add two measures:

- Use of Opioids from Multiple Providers at High Dosage in Persons Without Cancer: Opioid High Dosage[8]
- Diabetes Screening for People With Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications[9]

The addition of these two measures allows CMCS and states to expand the measurement of quality of care in Medicaid for two population groups – adults with substance use disorders and/or mental health disorders. Additional information about the 2015 Adult Core Set MAP review process and their recommendations to CMCS can be found at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/Adult-Health-Care-Quality-Measures.html

Next Steps

The 2016 updates to the Core Sets will take effect in the FFY 2016 reporting cycle, which will begin no later than December 2016. To support states in making these changes, CMCS will release updated technical specifications for both Core Sets in spring 2016 and make them available at: http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Quality-of-Care/Quality-of-Care.html. States with questions or that need further assistance with reporting and quality improvement regarding the Child and Adult Core Sets can submit questions or requests to: MACQualityTA@cms.hhs.gov.

If you have questions about this bulletin, please contact Marsha Lillie-Blanton, Children and Adults Health Programs Group, at marsha.lillie-blanton@cms.hhs.gov.

[7] The second update was issued via a CMCS Informational Bulletin "2015 Updates to the Child and Adult Core Health Care Quality Measurement Sets."http://www.medicaid.gov/federal-policy-guidance/downloads/cib-12-30-2014.pdf

[8] Measure steward: Pharmacy Quality Alliance, Not NQF Endorsed

[9] Measure steward: NCQA, NQF #1932

APPENDIX C

September 30, 2015

Clinical Review: Morphine Equivalent Daily Dose to Prevent Opioid Overuse

Learning Objectives:

- Define morphine equivalent daily dose (MEDD) and how it is being used to indicate potential dose-related risk for prescription opioid overdose.
- Describe high-risk prescribing of prescription opioids within the Medi-Cal fee-for-service program.
- Summarize best practices for responsible opioid prescribing.

Key Points:

- While there is no completely safe dose of opioids, MEDD can be used as an indicator of potential dose-related risk for adverse drug reactions, including overdose.
- While there are differing opinions as to the maximum MEDD threshold that should trigger additional action by clinicians, the Medical Board of California (MBC) recommends proceeding cautiously once the MEDD reaches 80 mg.
- In the Medi-Cal fee-for-service population, the vast majority (87%) of paid claims for opioids were well under the 80 mg MEDD threshold recommended by the MBC for a yellow flag warning.
- Online MEDD calculators are available to help clinicians determine morphine milligram equivalency. These calculators are not intended for dosage conversion from one product to another, but can be used to assess the comparative potency of opioids using a morphine equivalency standard.
- All providers who prescribe opioids need to enroll in and access California's prescription drug monitoring program, available on the Controlled Substance Utilization Review and Evaluation System (CURES) Web page of the Office of the Attorney General website. In order to be most effective, MEDD calculations need to include all opioid prescriptions written for a patient, including those written by other providers.

Background

Each day in the United States, 46 people die from an overdose of prescription opioid or narcotic pain relievers.[1] The Centers for Disease Control and Prevention (CDC) describes the following groups as particularly vulnerable to prescription opioid overdose: 1) people who obtain multiple controlled substance prescriptions from multiple providers; 2) those who take high daily dosages of prescription painkillers and those who misuse multiple abuse-prone prescription drugs, especially other CNS depressants, such as benzodiazepines, carisoprodol, or other sedatives; 3) low-income people and those living in rural areas; and 4) people with mental illness and/or those with a history of substance abuse.[2]

Morphine Equivalent Daily Dose (MEDD)

Recent studies demonstrate that a patient's cumulative MEDD is an indicator of potential dose-related risk for adverse drug reactions to opioids, including overdose.[3,4] The terminology for daily morphine equivalency may vary depending on the resource used, and may be described as MEDD, morphine equivalent dose (MED), or morphine milligram equivalents (MME). **Daily morphine milligram equivalents are used to assess comparative potency, but not to convert a particular opioid dosage from one product to another**. The calculation to determine morphine milligram equivalents includes drug strength, quantity, days' supply and a defined conversion factor unique to each drug. By converting the dose of an opioid to a morphine

equivalent dose, a clinician can determine whether a cumulative daily dose of opioids approaches an amount associated with increased risk.

Online calculators are available to estimate MEDD. **It should be noted again that these calculators are not intended for dosage conversion from one product to another, but only to assess the comparative potency of opioids**. Furthermore, calculated morphine equivalency may vary between tools for certain drugs, depending on the algorithm used. Commonly used websites that offer MEDD calculators include the following:

- Washington State Agency Medical Directors' Group
- Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC)
- The New York City Department of Health and Mental Hygiene

Equianalgesic dose ratios are only approximations and do not account for genetic factors, incomplete cross-tolerance between various opioids, and variable pharmacokinetics that may affect relative potency. If used to estimate a conversion, it is recommended that after calculating the appropriate conversion dose, the prescribed dose be reduced by 25 – 50% to assure patient safety.[4]

Compared with patients receiving an MEDD of 1 – 20 mg, who had a 0.2% annual overdose rate, patients receiving an MEDD of 100 mg or more had almost nine times as much risk of overdose and a 1.8% annual overdose rate as compared to the lowest doses.[3] The CDC review of opioid prescribing and overdose found that among patients who are prescribed opioids, an estimated 80% are prescribed low doses (<100 mg MEDD) by a single provider, and these patients account for an estimated 20% of all prescription drug overdoses. Another 10% of patients are prescribed high doses (≥100 mg MEDD) of opioids by single prescribers and account for an estimated 40% of prescription opioid overdoses. The remaining 10% of patients seek care from multiple doctors, are prescribed high daily doses, and account for another 40% of opioid overdoses.[5]

While there are differing opinions among experts and organizations as to the maximum MEDD threshold that should trigger additional action by clinicians (Table 1), the MBC recommends proceeding cautiously (a yellow flag warning) once the MEDD reaches 80 mg.[6] There is no completely safe opioid dose.

Table 1. Selected Organizations' MEDD Thresholds and Recommended Actions

Year	Organization	MEDD Threshold (mg/day)	Recommended Action at MEDD Threshold
2010	American Academy of Pain Medicine[7]	>200	Increase frequency and intensity of monitoring
2010	Utah State Clinical Guidelines[8]	>120 – 200	Increase clinical vigilance
2010	Veterans Affairs/Department of Defense[9]	>200	Refer or consult
2010, 2015	Washington State Agency Medical Directors' Group[4]	>120	Consult from pain management expert
2011	Canadian Guidelines[10]	>200	Reassess or monitor
2011, 2014	American College of Occupational and Environmental Medicine[11]	≥50	Follow up frequently; document improved function
2011	New York City Department of Health and Mental Hygiene[12]	>100	Reassess pain status or consider other approaches
2012	American Society of Interventional Pain Physicians[13]	>91	Consider pain management consultation
2012	Centers for Medicare and Medicaid Services[14]	>120	Consider case management
2014	Medical Board of California[6]	≥80	Proceed cautiously and consider referral to specialist when higher doses are contemplated
2015	California Division of Workers' Compensation[15]	≥80	Increase clinical monitoring, consider specialty referral, attempt to wean to lower dose.

In addition, as of federal fiscal year 2013 (FFY 2013), nine state Medicaid programs reported having an established policy with a recommended maximum MEDD (Table 2).[16]

Table 2. State Medicaid Drug Use Review (DUR) Programs with Established Recommendations for Maximum MEDD

State	MEDD Threshold (mg/day)	Additional Information
Delaware	120	All long-acting opioids require prior authorization. The total dose for all narcotic therapy must be <120 mg MEDD.
Kansas	200	
Massachusetts	360	Individual dose limits for each opioid were determined based on utilization trends.
Maine	30	Prior authorization is required for any dose over 30mg; maximum allowable dose 300 mg
Michigan	30	
North Carolina	750	Maximum allowable dose
Oregon	120	
Washington	120	Based on Agency Medical Directors Association Interagency Guidelines
Wyoming	120	

Both Massachusetts and Washington have described in detail the impact of implementing an established policy and predetermined maximum MEDD threshold for triggering a detailed patient review.[17,18] Massachusetts defined a specific maximum MEDD for oxycodone, fentanyl, morphine,

and methadone (they selected two standard deviations outside the mean dose noted in their drug utilization review). In addition to requiring prior authorization for the specified dose, a multidisciplinary team including a physician, pharmacist, and behavioral specialist reviewed high-dose utilization profiles every two weeks. The team participated in phone interventions for clarification of prior authorization requests, treatment care plans, or specific restrictions. Over a three-year period (2002 – 2005), the number of unique utilizers decreased by 17.8% ($p < 0.0001$) and the number of claims by 4.1% ($p < 0.0001$).[17] Claims for oxycodone decreased by 34.9% and claims for fentanyl decreased by 25%.[17]

In 2007, the Washington State Agency Medical Directors' Group, which represents all public payers in Washington, developed a collaborative interagency guideline on opioid dosing (updated in June 2015).[4] The guideline recommends that at an MEDD of 120 mg providers must obtain consultation from a pain medicine expert for patients whose pain and function have not substantially improved as a result of opioid treatment. An evaluation of the impact of the guideline was conducted through 2010, and showed the number of prescriptions for Schedule II opioids plateaued during 2006 – 2008, then declined sharply in 2009 and 2010.[7] The total number of paid prescriptions for Schedule III opioids had peaked in 1999 (93,550), then declined through 2008 (79,882), 2009 (63,808) and 2010 (52,499).[7] The average MEDD among beneficiaries declined from a peak of 144.7 in 2002 to 105 in 2010.[18]

MEDD in the Medi-Cal Fee-For-Service Population

A retrospective cohort study was conducted to calculate the MEDD for all paid pharmacy claims for prescription opioid medications in the Medi-Cal fee-for-service population (dates of service between July 1, 2014, and June 30, 2015). The National Drug Code (NDC), days supply, and drug quantity fields were extracted from Medi-Cal pharmacy claims data and matched (via NDC) to the drug strength and MME conversion factor using the Morphine Equivalent Calculator Tool developed by the PDMP TTAC at Brandeis University, in collaboration with the CDC.

The following equation was used to calculate MEDD:

$$\frac{\text{(Drug Strength)} \times \text{(Drug Quantity)} \times \text{(MME Conversion Factor)}}{\text{(Days Supply)}}$$

All instructions for MEDD calculation were followed using the technical assistance guide provided by the PDMP TTAC.[19]

An additional analysis was performed on a subset of Medi-Cal fee-for-service beneficiaries who were continuously eligible in the Medi-Cal fee-for-service program between January 1, 2015, and June 30, 2015, and who had at least one paid claim for a prescription opioid medication between April 1, 2015, and June 30, 2015 (the measurement period). Medical and pharmacy claims data were reviewed for all beneficiaries in the study population with a calculated cumulative morphine equivalent dose >120 mg for at least one day during the measurement period. Data fields specifying diagnostic codes and place of service were extracted from medical claims data and were used to identify those beneficiaries in the study population who had a primary or secondary diagnosis of cancer and/or who were receiving hospice care.

Descriptive statistics were used to summarize MEDD values and claims data. Data analyses were performed using IBM® SPSS®, version 23.0 (Chicago, IL).

Results

Between July 1, 2014, and June 30, 2105, a total of 529,681 paid pharmacy claims for prescription opioid medications were filled by a total of 262,017 Medi-Cal fee-for-service beneficiaries. The summary of paid claims exceeding MEDD thresholds of 80 mg, 100 mg, and 120 mg for all paid claims is shown in Table 3. Also shown in Table 3 is the distribution among a subset of paid claims with a days supply >14 days, as over half (56%) of all paid claims for opioids between July 1, 2014, and June 30, 2015, were for a days supply ≤7 days.

Table 3. Total Paid Claims Exceeding Recommended MEDD Thresholds in the Medi-Cal Fee-For-Service Population (Dates of Service Between July 1, 2014, and June 30, 2015)

	Recommended MEDD Thresholds		
	>80 mg/day	**>100 mg/day**	**>120 mg/day**
Total paid claims (n = 529,681)	71,236 (13.4%)	58,741 (11.1%)	47,769 (9.0%)
Total paid claims >14 days supply (n = 237,106)	62,596 (26.4%)	54,060 (22.8%)	43,865 (18.5%)

The vast majority of paid claims for opioids were well under the 80 mg/day threshold recommended by the MBC for a yellow flag warning (87% of all paid claims and 74% of paid claims >14 days supply). However, during one year there were 47,769 paid claims identified that exceeded 120 mg MEDD.

As the CDC identified people who obtain multiple controlled substance prescriptions from multiple providers as one of the high-risk groups for opioid overdose, a summary of the total number of prescribers and pharmacies is shown in Table 4 for all Medi-Cal fee-for-service beneficiaries who had a paid claim for an opioid during that same year.

Table 4. Crosstabulation of Total Prescribers and Total Pharmacies for Opioid Paid Claims in the Medi-Cal Fee-For-Service Population (Dates of Service Between July 1, 2014, and June 30, 2015)

Total Utilizing Beneficiaries (n = 262,017)		**Total Pharmacies**					
		1	**2**	**3**	**4**	**5 – 9**	**10+**
Total Prescribers	1	208,071	8,131	886	129	24	0
	2	18,113	13,079	1,434	269	66	0
	3	2,952	3,104	1,467	288	113	0
	4	648	790	533	249	102	1
	5-9	300	403	365	241	208	7
	10+	2	5	3	5	22	7

The majority of these beneficiaries (n = 208,071; 79%) had only one paid claim for a prescription opioid medication during this one-year period. However, a total of 3,611 beneficiaries (1%) had paid claims for opioids from three or more prescribers and filled these claims at three or more pharmacies.

A total of 22,505 beneficiaries were included in an analysis of cumulative MEDD. Each of these beneficiaries was continuously eligible in the Medi-Cal fee-for-service program between January 1, 2015, and June 30, 2015, and had at least one paid claim for a prescription opioid medication between April 1, 2015, and June 30, 2015. This 90-day window was selected in order to identify the distribution of beneficiaries who exceeded a cumulative total of >120 mg MEDD for at least one of those days, and to identify beneficiaries who exceeded >120 mg MEDD for the entire 90 days, which would make this group at high-risk for overdose due to sustained high-dose opioid use over time.

As shown in Table 5, a total of 3,904 beneficiaries (17%) were identified in this group with at least one day out of 90 that exceeded >120 mg cumulative MEDD. Results are stratified by those who had a primary or secondary diagnosis of cancer and/or who were receiving hospice care, and those who did not have a primary or secondary diagnosis of cancer and no indication of hospice care in the medical claims data.

Table 5. Summary of Medi-Cal Fee-For-Service Beneficiaries Days >120 mg Cumulative MEDD (Dates of Service Between April 1, 2015, and June 30, 2015)

Days with MEDD >120 mg	Cancer/Hospice (n = 1,306)	Non-cancer/ Non-hospice (n = 21,199)	Total (n = 22,505)
0	1,078 (83%)	17,523 (83%)	18,601 (83%)
≥1	228 (17%)	3,676 (17%)	3,904 (17%)
≥2	225 (17%)	3,648 (17%)	3,873 (17%)
≥3	223 (17%)	3,593 (17%)	3,816 (17%)
≥10	217 (17%)	3,467 (16%)	3,684 (16%)
≥30	178 (14%)	2,778 (13%)	2,956 (13%)
≥60	120 (9%)	1,900 (9%)	2,020 (9%)
≥90	65 (5%)	963 (5%)	1,028 (5%)

Of the 1,028 beneficiaries that exceeded >120 mg cumulative MEDD for all 90 days, almost half (n = 410; 40%) had only one prescriber and one pharmacy for all opioid claims, while 49 beneficiaries (5%) had paid claims for opioids from three or more prescribers and filled these claims at three or more pharmacies. There was no statistically significant difference between the number of days that exceeded >120 mg cumulative MEDD when stratified by cancer/hospice status.

Conclusion/Discussion

While there is no completely safe dose of opioids, the ability to calculate morphine equivalent dose adds an additional assessment tool to combat potential opioid overdose and/or overuse. Federal and state agencies should provide guidelines and instructions for calculation of MEDD and promote case management and, as needed, referrals to appropriate pain specialists as higher doses of opioids are considered. Finally, all providers who prescribe opioids need to enroll in and access California's prescription drug monitoring program, CURES. In order to be most effective, MEDD calculations need to include all opioid prescriptions written for a patient, including those written by other providers.

Clinical Recommendations

- Review materials and resources for preventing prescription drug abuse available through the California State Board of Pharmacy, Medical Board of California, and the California Department of Public Health.
- Weigh the benefits and risks of opioid therapy, especially for opioid therapy when alternative treatments are ineffective.
- Discuss with patients the risks and benefits of pain treatment options, including those that do not involve prescription painkillers.
- Follow best practices for responsible opioid prescribing, including:
  - Consult CURES initially and at every subsequent visit
  - Conduct a physical exam, urine drug test, and document pain history prior to prescribing opioids
  - Screen for substance abuse, mental health problems, and other physical conditions that are contraindicated for opioid use
  - Advise against concomitant use of alcohol, sedatives, and hypnotics
  - Implement pain treatment agreements

  - Prescribe the lowest effective dose of short-acting opioid producing analgesia and improved function (no more than 80 mg MEDD) in a limited supply with no refills
  - Regularly evaluate the role of opioid therapy beyond 3 months for non-cancer chronic pain
    - ❖ Use tapering (not abrupt cessation) to discontinue or reduce dose of opioids
  - Track and document levels of pain and function at every visit
  - Exercise vigilance at high doses
    - ❖ Consider prescribing naloxone as a rescue medication in the event of a potentially life-threatening overdose and instruct caregivers on proper use and administration. For detailed information on dosing and administration of naloxone, please go to the Prescribe to Prevent website

- Enroll in and access CURES reports to establish whether or not an individual is receiving controlled substances from multiple prescribers. The CURES report should be requested frequently for patients who are being treated for pain and/or addiction.

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APPENDIX D

CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016

Listed below are the 12 major recommendations in the proposed guidelines. Detailed information, the clinical background and rationale for each recommendation can be found in the full report.

http://www.regulations.gov/#!documentDetail;D=CDC-2015-0112-0002

Determining When to Initiate or Continue Opioids for Chronic Pain

1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks to the patient (recommendation category: A, evidence type 3).

2. Before starting opioid therapy for chronic pain, providers should establish treatment goals with all patients, including realistic goals for pain and function. Providers should not initiate opioid therapy without consideration of how therapy will be discontinued if unsuccessful. Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety (recommendation category: A, evidence type: 4).

3. Before starting and periodically during opioid therapy, providers should discuss with patients known risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy (recommendation category: A, evidence type: 3).

Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation

4. When starting opioid therapy for chronic pain, providers should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids (recommendation category: A, evidence type: 4).

5. When opioids are started, providers should prescribe the lowest effective dosage. Providers should use caution when prescribing opioids at any dosage, should implement additional precautions when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should generally avoid increasing dosage to ≥90 MME/day (recommendation category: A, evidence type: 3).

6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, providers should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three or fewer days usually will be sufficient for most nontraumatic pain not related to major surgery (recommendation category: A, evidence type: 4).

7. Providers should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Providers should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, providers should work with patients to reduce opioid dosage and to discontinue opioids (recommendation category: A, evidence type: 4).

Assessing Risk and Addressing Harms of Opioid Use

8. Before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid-related harms. Providers should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, or higher opioid dosages (≥50 MME), are present (recommendation category: A, evidence type: 4).

9. Providers should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving high opioid dosages or dangerous combinations that put him or her at high risk for overdose. Providers should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months (recommendation category: A, evidence type: 4).

10. When prescribing opioids for chronic pain, providers should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs (recommendation category: B, evidence type: 4).

11. Providers should avoid prescribing opioid pain medication for patients receiving benzodiazepines whenever possible (recommendation category: A, evidence type: 3).

12. Providers should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder (recommendation category: A, evidence type: 3).

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APPENDIX E

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PERSPECTIVE

Strategies aimed at controlling misuse and abuse of opioid prescription medications in a state Medicaid program: a policymaker's perspective

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Abstract

Society in America, like many others, continues to wrestle with the problem of misuse and abuse of prescription opioids. The implications of this struggle are widespread and involve many individuals and institutions including healthcare policymakers. State Medicaid pharmacy programs, in particular, undergo significant scrutiny of their programs to curtail this problem. While recent efforts have been made by government agencies to both quantify and offer methods for curbing this issue, it still falls to each state's policymakers to protect its resources and the population it serves from the consequences of misuse and abuse. This paper details the history of one state Medicaid's management of this issue at the pharmacy benefit level. Examples of various methods employed and the results are outlined and commentary is provided for each method. Regardless of the methods used to address this issue, the problem must still be a priority at all levels, not just for payers.

Keywords

Health spending, healthcare policy, Medicaid, opioid abuse, prescription diversion, public health, state issues, substance abuse

History

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Introduction

The Centers for Medicare and Medicaid Services (CMS) stated in January 2012 that state Medicaid programs are seeing increases in drug diversion (defined as:''diversion of licit drugs for illicit purposes'') (1). Diversion is a form of prescription drug abuse. Use of prescription drugs for reasons other than originally intended or by persons other than for whom prescribed can be considered misuse and abuse. This struggle with misuse and abuse of prescription opioids is not new. The problem is societal in nature, with implications for all entities from individuals to governments. The source and payment of prescription products abused makes prescription opioid misuse and abuse unique compared to other types of illicit drug use (2). Though theft is one way for prescription drugs to end up ''on the street'', diversion through normal distribution channels also occurs. When such diversion occurs, payment for the prescription products is often through legitimate third party payers such as commercial or government-sponsored insurance, like Medicaid or Medicare (1). In a study by McAdam-Marx et al., costs for Medicaid patients with abuse/dependence-related diagnoses were higher than costs for patients without a related diagnosis. The authors suggest interventions targeted at preventing abuse and managing comorbidities in these patients can reduce costs and potential abuse (3).

Suggested methods for intervention were proposed by Katz et al. based on a meeting sponsored by Tufts Health Care Institute Program on Opioid Risk Management. Proposed methods included pharmacy and prescriber controls, promotion of abuse-deterrent opioid products, monitoring of prescription claims, data sharing among insurance providers, and promoting strategies at the provider level to reduce risk of abuse (2).

Over the past 10 years, Oklahoma Medicaid (MOK) has considered misuse and abuse of prescription narcotics a priority area of concern. At least nine unique prescription policies for opioid products were recommended by the Drug Utilization Review (DUR) Board and implemented by the Oklahoma Health Care Authority (OHCA)with the goal of decreasing misuse and abuse of opioids. The objective of this paper was to discuss the historical steps which MOK has taken to limit potential misuse and abuse of opioids.

Review of Oklahoma Medicaid policies

The policies that the DUR Board developed for OHCA's SoonerCare pharmacy benefit program are listed in Table 1 and discussed further below. Each policy has an alphabetical identifier which correlates with the graph in Figure 1. This figure demonstrates the trend in opioid prescription claims over time. The vertical lines on Figure 1 indicate the points of policy implementation.

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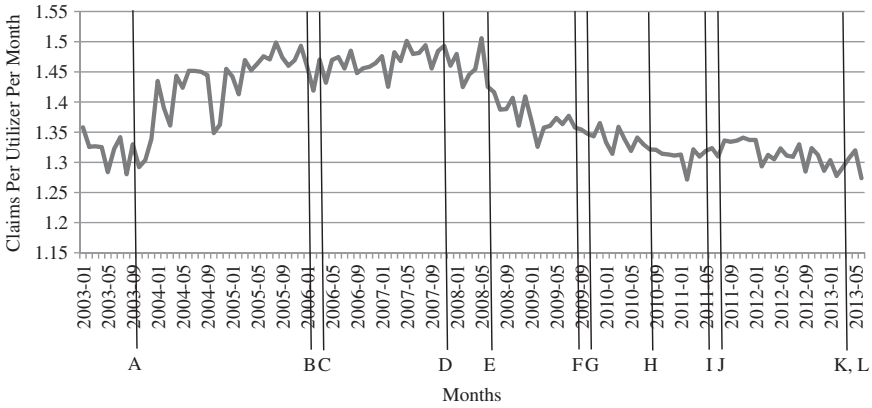
Table 1. List of Oklahoma SoonerCare policy implementations and dates.

Identifier*	Date	Policy category	Products or action
A	October 2003	Quantity limits	Fentanyl, hydromorphone, methadone, merperidine, and oxycodone (additional quantity limits added over time)
B	January 2006	Pharmacy Lock-In program	Intensification of previous 'Lock-In' management
C	April 2006	Prior authorization	Applied to tramadol products
D	November 2007	ProDUR	Restriction of hydrocodone to 1 claim per day supply
E	July 2008	Step therapy program	Step therapy (3 tiers and oncology-only tier)
F	August 2009	ProDUR	Hydrocodone ingredient duplication
G	October 2009	Quantity limit	Applied to all narcotic/acetaminophen combination products
H	August 2010	Prescription limit	Hydrocodone limited to 13 prescriptions per 360 day period
I	May 2011	Prior authorization	Applied to buprenorphine
J	July 2011	Prescriber restrictions	Removal of non-contracted prescribers
K	March 2013	Prior authorization	Branded oxymorphone extended-release preferred over new generic product
L	March 2013	Age restrictions	Applied to liquid and solid opioid dosage forms

*Each letter corresponds to the date of initial implementation on Figure 1.

Figure 1. Opioid prescription claims per utilizer per month. Each letter corresponds to a policy listed in Table 1.



Quantity limits

Total quantity allowed on a single prescription claim is a standard control measure used by pharmacy benefit managers to reduce over-utilization across therapeutic categories in their programs. The limit is typically set based on maximum daily dosage or duration approved by the Food and Drug Administration (FDA). The first opioid products given quantity limits by MOK were butorphanol nasal spray, fentanyl transdermal and oral products, hydromorphone, methadone, meperidine, and oxycodone immediate and controlled-release products in October 2003 (Table 1, Identifier A). Quantity limits were applied to other products in subsequent years until all opioid products were included (Table 1, Identifier G).

Pharmacy Lock-In program

Lock-In programs, common to all Medicaid and some commercial insurance plans, typically function by creating a prescription gatekeeper for beneficiaries who are deemed to have potential for misuse of their prescription benefits based on their prescription and medical services utilization history. Most programs include at minimum a restriction to a single pharmacy for these beneficiaries and may include a single physician source that also controls access to other health care services. A few states restrict members to a specific hospital for emergency services. While the research regarding the effectiveness of these programs is limited, the states which studied their effect found reductions in opioid utilization (4–6).

MOK transferred the responsibility for the program to their DUR vendor in January 2006 (Table 1, Identifier B). An evaluation of the program found mean monthly opioid prescriptions were reduced after a beneficiary was locked-in to a single pharmacy, with no apparent effect on non-opioid related medications (7). The results of the analysis indicated the average per member per month (PMPM) number of opioid prescription claims decreased by 0.09 ($p < 0.0001$) while there was no statistically significant change in the PMPM for the number of medications considered by the MOK DUR Board as maintenance for chronic disease states (Figure 1, Identifier B). However, this study was unable to determine if the Lock-In program changed actual behavior outside of the patients' Medicaid prescription usage because the program administrators were not authorized to review the Oklahoma Prescription Drug Monitoring Program (PDMP) data, a barrier which remains. Even though dispensers of controlled substances are required to report details of the transaction to the PDMP within 5 minutes, it does not change prescribing when a practitioner is not routinely checking the PDMP (8,9).

Prior authorization programs

Several prior authorizations (PA) of single opioid prescription products were implemented (Table 1, Identifiers C, I, and K). The PA process for MOK typically consists of manual requests initiated by the physician or pharmacy for the

prescribed product after the prescription claim is denied at point-of-sale (POS). Individual products included were tramadol extended-release (C), buprenorphine (I), and generic oxymorphone extended-release (K).

Step therapy programs

Step therapy programs are PA programs which MOK utilizes for entire classes of medications. These programs require the use of products designated as first step before use of second or third step products. An example is requiring use of immediate-release generic opioid medications in opioid-naïve patients before moving to extended-release products. Step therapy programs can use manual or automated (computer generated) approvals for products placed on ''higher'' steps. Step therapy was implemented on the entire class of opioid prescription products in July 2008 (Table 1, Identifier E). The intent of this step therapy was increased use of short-term immediate release products for acute pain situations and breakthrough therapy for chronic pain situations and reserving long-acting opioids for opioid tolerant patients. Preferred long-acting generic products were established as the second step before patients were allowed to move to the third step of non-preferred long-acting brand products. Preferred and non-preferred short-acting categories were also established. This policy resulted in a reduction in utilization of second and third step products (10); however, research was not performed to measure other possible outcomes such as an increase in overall short-acting use over preferred long-acting products.

Prospective drug utilization review

MOK first used Prospective DUR POS programming in 2007 to limit prescriptions for hydrocodone to one claim per day supply, thus allowing a patient to have only one prescription for a hydrocodone containing product at a time (Table 1, Identifier D). In 2009, MOK implemented a second Prospective DUR ingredient duplication which examines prescription claims as they are submitted for hydrocodone-containing products and reviews each patient's medication profile to determine if hydrocodone products from previous prescription claims are still available to the patient (Table 1, Identifier F). If a duplication of hydrocodone is found, then the new claim rejects at POS and an override is required for claim payment. This POS programming resulted in approximately 70 000 denied claims in the first year (11). However, it is unknown if pharmacies dispensed these products to the patients as cash transactions.

Limit on number of prescriptions

An additional POS programming method was implemented based on the number of hydrocodone prescriptions filled during a 360-day period (Table 1, Identifier H). This programming limits patients to 13 prescriptions per year unless authorization is granted and resulted in just over 28 000 denied prescription claims for hydrocodone the first reporting year after implementation (12). Again, it is not known whether patients received the prescriptions on a cash basis from the dispensing pharmacies.

Preferred brand prior authorization

Recently a preferred brand PA was initiated for the new abuse-deterrent formulation of oxymorphone extended-release (Table 1, Identifier K). Abuse-deterrent products are formulated to decrease the likelihood of abuse by targeting known or potential routes for each specific product. This PA restricts lower-cost generic versions of the original brand product and allows only use of the new abuse-deterrent brand. There has not been sufficient time to determine if this policy will result in decreased misuse of oxymorphone in the MOK population.

Age restrictions

A final POS programming method was implemented on opioid products based on the patient's age (Table 1, Identifier L). These age restrictions were placed on products containing hydrocodone and allow the liquid formulations for use by children and the solid oral products for use by adolescents and adults. The objective of this policy was to limit the more costly liquid formulations to the most appropriate age group. Exceptions are allowed for members with physical disabilities who require non-solid dosage forms.

Prescriber contract requirement

Previously, prescriptions written by any licensed prescriber could be covered by the MOK pharmacy benefit. However, as part of compliance with the Affordable Care Act (ACA), in 2011, MOK restricted payment of pharmacy claims to those written by prescribers contracted to serve MOK members(Table 1, Identifier J). The rationale for the contract requirement was based on patterns noticed by states and CMS of narcotic utilization by members with prescriptions written by non-contracted prescribers. If the prescriber was not contracted and thus not being paid by the Medicaid agencies for office visits, they must have been charging patients directly for services. Additionally, prescribers were under no obligation to comply with agency policy or submit patient records upon request.

Discussion

Oklahoma was in the highest category of state prescription drug overdose age-adjusted death rates in 2008 (15.8 per 100 000 compared to the national average of 11.9 per 100 000) (13). Faced with the significant issue of opioid abuse in the state, policymakers through MOK have attempted to curb misuse by implementing various policies over time within the pharmacy benefit. The number of different policies enacted by MOK reflects efforts to curtail misuse and abuse without interference where high utilization of opioid products may be medically appropriate. Although it is not within the scope of this report to determine if these efforts had an overall effect on the state, it is interesting to highlight some changes in mortality rates in Oklahoma. According to a report in 2013 by the Oklahoma Department of Health, unintentional poisoning mortality rates for Oklahoma increased significantly over the US average from 1999–2010. Oklahoma also saw an increase in the number of prescribed opioids during this time period and prescription opioids remained the most common product listed in unintentional poisoning deaths.

And although mortality rates increased for all ages over the entire time period reported, it can be noted that there was an increase from 16.0 in 2007 to 17.7 in 2009 but a subsequent decrease in the rate to 17.2 by 2011. Likewise, there was a decrease in the number of deaths attributed to prescription drugs from 2009–2011 (14). Unfortunately while heroin appears to be an increasing issue of concern nationally (15), Oklahoma currently is not able to clearly distinguish heroin deaths from other morphine-related deaths and it is unclear whether heroin use is replacing prescription opioid use in Oklahoma as it is in other areas of the US.

MOK, in conjunction with its DUR Board, believes that misuse and abuse of these substances is an important societal issue and should be confronted at all intersections of the lives of these individuals, not just at an insurer level. Reaching patients before misuse and abuse occurs is vital. However, MOK has implemented and continues to implement policies which are intended to limit potential misuse and abuse while providing good stewardship of resources and maintaining positive health outcomes.

Programmatic implications of policy changes

For MOK, basic restrictions such as quantity limits, number of prescriptions, and limits based on age, may be most effective in terms of reducing numbers of paid prescription claims for products. While these restrictions are not difficult to implement, maintain, and operate, they do result in additional questions to call centers and higher PA or claim override volumes. These restrictions also place a higher burden on physicians and pharmacies if they wish to move forward with payment of the prescription claim by MOK. An additional limitation of these programs occurs when the dispensing pharmacy simply instructs the patient that the prescription is not covered by MOK and does not attempt to receive reimbursement by MOK for potentially legitimate claims. The result is patients not receiving necessary prescriptions or patients paying out-of-pocket for appropriate opioid prescriptions. PAs and step therapy programs are more complicated to implement and maintain, with step therapy being the most difficult to continually monitor. They also generate higher numbers of phone calls and PA requests. For instance, when the step therapy program was implemented, the number of prior authorizations for opioid products increased from approximately 100 requests monthly to 400 requests monthly. The current average number of requests for this category for all reasons is 650 per month. Based on a recent analysis of OHCA's prior authorization program, the cost for each PA in Oklahoma is $12.50 (lower than the national benchmark) (16). If implemented today, the step therapy program would have cost the state an additional $3750 per month. A simple PA on a single product such as buprenorphine typically requires a manual review and approval for all initial prescription requests. Products which are placed in step therapy typically have automated pathways which are processed at POS by the claims processing software. Of these two methods, the manual PA process typically results in the highest reduction in approved prescription claims due to the review by clinical pharmacists. Automated approvals are limited to more explicit criteria and do not allow for clinical judgment.

Outcome evidence from policy implementation

Some first efforts at curbing misuse in the Medicaid system were the Lock-In programs. As early as 1977, Singleton published a review of the effects of state Lock-In programs, reporting that the Missouri Medicaid Lock-In program may have reduced the 1976 state Medicaid budget by 1.7% (or $1.8 million) (5). The Hawaii Medicaid Lock-In program estimated a total of $909 992 in saving for 1983 (4). And a review by Blake in 1999 of the Louisiana Medicaid Lock-In program showed reductions in multiple pharmacies, poly-pharmacy, opioid analgesics and overall pharmacy expenditures (6).

Lock-In programs have appeared once again on the national radar. In August 2012, the Center for Disease Control and Prevention (CDC) convened an expert panel to discuss ''Medicaid Patient Review and Restriction (PRR)'' (or Lock-In) programs. The final report issued after this panel meeting concluded that PRRs are important programs to reduce accidental deaths, particularly for Medicaid patients (17). In December 2012, researchers at the University of California, Davis prepared a report for the CDC which evaluated the cost and health impacts of PRR programs. A tool was developed that simulated patterns of opioid use and evaluated the results of different restriction policies on health outcomes and costs. The goal is to allow state policy makers to improve their decision making using evidence-based information and allow specific state reviews of current or proposed PRR programs (19).

Finally, the preferred brand PA is a new area for consideration. Medicaid programs may achieve lower net costs for brand name drugs than generics when one of the following situations occurs:

(1) Brand product has a high federally mandated rebate which renders the net cost below that of the generic; or
(2) Brand product has a sufficient supplemental rebate from the drug manufacturer paid directly to the state which renders the net product cost below that of the generic.

These situations typically occur when only one manufacturer's generic is available on the market; however these situations might also arise when multiple manufacturers' products are available. However in the case of the preferred brand for oxymorphone extended-release, the policy implementation is based on the expectation that the new abuse-deterrent formulation will decrease misuse and abuse of the product. The result of this new ''experimental'' policy requires further review.

As previously mentioned under Lock-In programs, MOK under current state law does not have the legal authority to examine and review the PDMP data. Only providers of care (prescribers and pharmacies) and law enforcement officials have access to PDMP data. This creates a significant hindrance in attempts to evaluate programmatic initiatives to impact abuse and misuse outside of MOK financial responsibility for these prescriptions. From a public health perspective, the goal of program initiatives is to improve the health of plan members by decreasing or eliminating opioid abuse, not to just avoid financial responsibility for abuse. Access to the PDMP would allow MOK and other payers to coordinate monitoring and treatment activities with

prescribers and pharmacies even when patients elected to pay cash and avoid plan oversight.

Figure 1 displays the opioid prescription claims per utilizer per month (PUPM) from January 2003 through June 2013. PUPM is a measure based on the number of enrollees who utilize the benefit; this number is a subset of the entire enrolled population. Several events affected the total population of MOK during the time period, including carve-in of a managed care program (January 2004) and carve-out of dually eligible Medicare beneficiaries as a result of Medicare Part D (January 2006). However, by reviewing the claim PUPM for opioids, the effect of the changes in the overall utilizer base is reduced. Upon review, the most noticeable change in the trend is the drop in claims PUPM after the step therapy program was initiated in July 2008.

While not all of the policies MOK implemented over the years were evaluated either for safety and effectiveness or for cost savings, several were. The Prospective DUR duplication of hydrocodone-containing products was estimated to have an annualized cost avoidance of $325 755 (2010 US$) (11). The hydrocodone annual prescription limit was estimated to have an annualized cost avoidance of $83 823 (2011 US$) (12). Overall, the Lock-In program was estimated to have an annual cost reduction of $606 (2006 US$) per locked-in member per month (7). Finally, the restriction of prescribers to those contracted with OHCA, resulted in a decrease of 6% in overall opioid prescription claims (19).

Efforts at limiting misuse and abuse of opioid prescriptions are necessary regardless of payer type. Not only do misuse and abuse of opioid prescriptions contribute to rising healthcare costs, but unchecked misuse and abuse will ultimately lead to addiction for the patient, and/or to fraud on the part of the patient and possibly the provider. Currently MOK is planning to review more of its policies for opioid prescription misuse and abuse. It is hoped that the policy preferring the abuse-deterrent formulation will result in a slower uptake of the generic product by those seeking to misuse it. Although the step therapy program shifted market share from the highest tier to the lower tiers, concern remains over whether this program may have increased use of short-acting opioid products.

According to CMS, opioid abuse and diversion is a leading problem faced by all state Medicaid programs (1). In a study done in Kentucky by Manchikanti et al. on 400 patients treated at a pain management clinic, when compared to commercial insurance, Medicare only, and Medicare and Medicaid (dually eligible), those in the Medicaid-only group had the highest percentage of patients with illicit drug use (39%). Additionally, the Medicaid-only group had the highest combined rate of both illicit drug use and inappropriate use of prescription drugs (60%) (20). CMS partners with the Drug Enforcement Agency (DEA) and state agencies to promote appropriate use of opioid prescriptions. A law enacted in October 2008 established a ''tamper-resistant'' prescription paper policy for all non-electronic prescriptions written for Medicaid outpatient drugs. Further, the ACA includes additional measures which can be used to combat abuse. These new measures are: ''establish enhanced oversight for new providers, establish periods of enrollment moratoria or other limits on providers identified as being high risk for fraud and abuse, establish enhanced provider screening, and require states to suspend payment when there is a credible allegation of fraud which may include evidence of overprescribing by doctors, overutilization by recipients, or questionable medical necessity'' (1). CMS also promotes measures which states can incorporate to detect abuse: using retrospective DUR processes to identify potential patterns of abuse, improving prospective DUR screenings at POS for high opioid doses or potential overuse, reviewing prescriptions written at pain management clinics, searching for fraud across programs, forming collaborative workgroups with other state agencies and neighboring states, using PDMPs, developing new or enhanced Medicaid patient Lock-In programs, promoting the national ''Take-Back'' campaign, and encouraging both providers and patients to take appropriate steps to safeguard their identities (1).

Recommendations

Any payer contemplating actions similar to MOK should carefully consider the potential for increased work load to their current staff and the overall healthcare system when planning their policies. In general, each of the policies implemented by MOK achieved the desired result in the short term. It is the experience of these policymakers that as one product or sub-category is identified and acted upon, another quickly takes its place. Therefore it is not enough to simply implement a policy and consider this complicated problem solved. Simultaneous implementation of multiple policies may have a higher initial effect on opioid utilization; however, as with most policies, these effects may be greatest in the shortterm. And while policies may seem to meet short-term goals, review of the outcomes for unintended clinical consequences should also occur (21).

The current epidemic should be addressed on the patient level in areas unrelated to prescription utilization. Payers should ensure that addiction treatment and counseling services are readily available and affordable. Nationally, programs should continue encouraging people to seek help or encouraging family members to seek help for loved ones. Most people do not plan to become physically and psychologically addicted to prescription pain medications and should not face stigma when seeking treatment.

Payers should address the provider side of this epidemic. Analysis of physician prescribing patterns is necessary to control misuse and abuse of opioid prescription drugs. When prescribing patterns are reviewed in combination with a thorough physician peer quality panel assessment, a higher impact on prescribing may be possible. State boards of medical licensure must become more active in monitoring narcotic prescribing patterns and in providing assistance as well as disciplinary measures when needed. Information provided by payers should be used by physicians to review and revise their prescribing habits, and not assumed to be punitive or invasive. Only by working together can we prevent serious problems before they arise.

Regardless of the nature of policies for deterring misuse and abuse of opioid prescription drugs, it is imperative that these efforts continue and results from these policies be shared across payer types. To that end, the CDC and the National Institutes of Health – National Institute on Drug

Abuse (NIH-NIDA) are currently funding research to determine the impact of policies such as those outlined above on inappropriate prescribing of opioids (22).

Conclusions

Despite multiple efforts currently in effect for the pharmacy benefit, misuse and abuse of prescription opioids continues. As health plans, regulatory agencies, and law enforcement officials introduce more complex countermeasures, a thorough review of new policies should be performed to determine their effectiveness so others may adopt successful policies and avoid poor or overly expensive options. With new abuse-deterrent formulations for long-acting products coming to market, real-world evaluations are needed to determine whether these products effectively reduce misuse, or simply divert users to other drugs of abuse. Only by continued combined effort to treat not only abuse, but also to intervene before more devastating consequences occur, can we begin to conquer this serious social problem which touches us all.

Declaration of interest

The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this paper.

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