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

MISSISSIPPI DIVISION OF
MEDICAID

June 15, 2023 at 1:00pm

Woolfolk Building, Room 145

Jackson, MS

Prepared by:

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

Drug Utilization Review Board

Joseph Austin, MD
Vicksburg Women's Care
100 Maxwell Drive
Vicksburg, MS 39180
Term Expires: June 30, 2025

Lauren Bloodworth, PharmD
MS State Department of Health
3212 Hwy 51 S
Hernando, MS 38632
Term Expires: June 30, 2024

Terrence Brown, PharmD
BioScrip Infusion Services
187 Country Place Pkwy, Suite C
Pearl, MS 39208
Term Expires: June 20, 2023

Patrick Bynum, MD
MEA Vicksburg Ambulatory Care Clinic
4204 Clay Street
Vicksburg, MS 39183
Term Expires: June 30, 2025

Chrysanthia Davis, PharmD
Omnicare Pharmacy
100 Business Park Dr, Ste D
Ridgeland, MS 39157
Term Expires: June 30, 2025

Tanya Fitts, MD
Lafayette Pediatric Clinic
1300 Access Road, Suite 400
Oxford, MS 38655
Term Expires: June 30, 2024

Jahanzeb Khan, MD
University Hospital
2500 N. State Street
Jackson, MS 39216
Term Expires: June 30, 2024

Ray Montalvo, MD
KDMC Specialty Clinic
940 Brookway Boulevard
Brookhaven, MS 39601
Term Expires: June 30, 2023

Holly R. Moore, PharmD
Anderson Regional Medical Center
2124 14th Street
Meridian, MS 39301
Term Expires: June 30, 2023

Kristi Phelps, RPh
Burnham Drugs
12500 Hwy 57
Gautier, MS 39553
Term Expires: June 30, 2023

Joshua Pierce, PharmD
McGuffee Drugs
102 Main St.
Magee, MS 39111
Term Expires: June 30, 2024

Bobbie West, MD
MEA Medical Clinic
342 Gilchrist Drive
Pearl, MS 39208
Term Expires: June 30, 2025

2023 DUR Board Meeting Dates

March 2, 2023
June 15, 2023
September 7, 2023
December 7, 2023

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 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
June 15, 2023

Welcome

Old Business

Resource Utilization Review

Follow-up and Discussion from the Board

New Business

Pharmacy Program Update Terri Kirby, RPh

Next Meeting Information
Remaining 2023 DUR Board Meeting Dates:
September 7, 2023; December 7, 2023

DUR Board Meeting Minutes

MISSISSIPPI DIVISION OF MEDICAID
DRUG UTILIZATION REVIEW (DUR) BOARD
MINUTES OF THE MARCH 2, 2023 MEETING

DUR Board Roster: State Fiscal Year 2023 (July 1, 2022 – June 30, 2023)	Jun 2022	Sep 2022	Dec 2022	Mar 2023
Joseph Austin, MD	NA	✓	✓	
Lauren Bloodworth, PharmD				
Terrence Brown, PharmD	✓	✓	✓	✓
Patrick Bynum, MD	✓	✓	✓	
Chrysanthia Davis, PharmD	NA	✓	✓	✓
Tanya Fitts, MD	✓	✓		
Jahanzeb Khan, MD	NA	✓	✓	✓
Ray Montalvo, MD		✓		✓
Holly Moore, PharmD	✓	✓	✓	✓
Kristi Phelps, RPh	NA	✓	✓	✓
Joshua Pierce, PharmD	✓	✓	✓	
Bobbie West, MD	NA	✓		✓
TOTAL PRESENT**	**7**	**11**	**8**	**7**

** *Total Present may not be reflected by individual members marked as present above due to members who either resigned or whose terms expired being removed from the list.*

Also Present:

Division of Medicaid (DOM) Staff:
Dennis Smith, RPh, DUR Coordinator; Gail McCorkle, RPh, Clinical Pharmacist; Chris Yount, MA, PMP, Staff Officer – Pharmacy; Sue Reno, RN, Program Integrity;

University of Mississippi School of Pharmacy - MS-DUR Staff:
Eric Pittman, PharmD, MS-DUR Project Director; Kaustuv Bhattacharya, PhD, Research Assistant Professor; Claire Lin, Graduate Student;

Change Healthcare Staff:
Paige Clayton, PharmD, On-Site Clinical Pharmacist;

Coordinated Care Organization (CCO) Staff:
Jenni Grantham, PharmD, Director of Pharmacy, Magnolia Health; Heather Odem, PharmD, Director of Pharmacy - Mississippi, UnitedHealthcare Community & State; Trina Stewart, PharmD, Pharmacy Manager, Molina Healthcare;

Gainwell Staff:
Tricia Banks, PharmD, MS Clinical Pharmacist;

Alliant Health Staff:
Catherine Brett, MD, Quality Director, MS UM/QIO; Buddy Ogletree, PharmD, Pharmacist;

Visitors:
Shawn Headley, Gilead; Floyd Holmes, Lilly; John Lovegrove, Sunovion; Roberto Pedraza, Vertex; Michele Shirley, Indivior; Paul Whatley, Novo Nordisk; Gene Wingo, Biogen; Ryan Ball.

Call to Order/Welcome:
Dr. Brown called the meeting to order at 1:02 pm.

OLD BUSINESS:
Dr. Moore moved to approve the minutes from the December 2022 DUR Board Meeting, seconded by Dr. Davis, and unanimously approved by the DUR Board.

Resource Utilization Review:
Dr. Pittman presented the resource utilization report for December 2022. Dr. Pittman noted that MS-DUR continues to experience data transfer issues from Gainwell and is not receiving MCO encounter claims information. The included resource utilization reports contain claims information only for the fee-for-service program.

NEW BUSINESS:

Update on MS-DUR Educational Interventions:
Dr. Pittman provided an overview of all DUR mailings and educational notices that occurred between December 2022 – February 2023.

Special Analysis Projects:

Determining an MCI Cut Score for Predicting Severe Maternal Morbidity

Multiple factors have been shown to be associated with negative maternal outcomes. Specifically, from our studies in the Mississippi Medicaid population, we found that MCI, distance to delivery center, age, and race were all significantly associated with SMM events. This follow-up analysis determined that a pregnant beneficiary with a score of one or higher on the MCI was at a significantly greater risk of experiencing an SMM event.

The following recommendations were presented:

1. MS-DUR recommends DOM encourage providers utilize the MCI as a screening tool to help identify pregnant beneficiaries at risk of experiencing SMM events.
2. DOM is encouraged to explore opportunities to provide additional maternal care to those beneficiaries identified as being at an increased risk of experiencing SMM events.

Following discussion, Dr. Montalvo made a motion to accept the recommendations, seconded by Ms. Phelps, and unanimously approved by the Board.

Gene Therapy Agents and Identification of Potential Eligible Beneficiaries
Gene therapies offer much needed treatment options in the rare disease landscape where effective treatments have been limited in the past. In light of these groundbreaking treatment advances, payers are tasked with identifying appropriate individuals eligible of receiving these therapies. Although the number of individuals identified as being eligible to receive these therapies may be small, the cost of some of these gene therapies can be astronomical requiring payers to plan and appropriately allocate resources to cover these products.

This report for the DUR Board was for information and discussion purposes only. No action was sought as a result of this report.

FDA Drug Safety Updates:
Dr. Pittman noted there were no FDA drug safety communications between December 2022 – February 2023.

Pharmacy Program Update:
Mr. Smith provided a pharmacy program update highlighting two items:

- Stay Covered – Medicaid has begun the process of re-qualifying Medicaid members. Mr. Smith stressed the importance of having Medicaid members update their contact information as soon as possible. This is especially important as Congress passed the Consolidated Appropriations Act (CAA) in December 2022. Under the CAA, continuous coverage conditions will expire, and states will resume routine eligibility operations this spring.
- Late Breaking News – Mr. Smith encouraged all Medicaid providers to sign-up for email alerts that are distributed when DOM posts a Late Breaking News update.

Next Meeting Information:
The next Board meeting is scheduled for June 15, 2023.

Dr. Brown adjourned the meeting at 2:21 pm

Submitted,

Eric Pittman, PharmD
Evidence-Based DUR Initiative, MS-DUR

Meeting Location: Woolfolk Building, 501 North West Street, Conference Room 145, Jackson, MS 39201, unless otherwise noted by the corresponding date of the meeting listed below.

Contact Information: Office of Pharmacy:
Chris Yount, 601-359-5253: Christopher.yount@medicaid.ms.gov, or
Jessica Tyson, 601-359-5253; Jessica.Tyson@medicaid.ms.gov

Notice details:

State Agency: MS Division of Medicaid

Public Body: Drug Utilization Board (DUR) Meeting

Subject: Quarterly Meeting

Dates and Times:

2023 dates:

- March 2, 2023 (1-3pm; Room 117, Woolfolk Building)
- June 15, 2023 (1-3pm; Room 145)
- September 7, 2023 (1-3pm; Room 145)
- December 7, 2023 (1-3pm; Room 145)

Description: The Mississippi Division of Medicaid's Drug Utilization Review (DUR) Board is a quality assurance body which seeks to assure appropriate drug therapy to include optimal beneficiary outcomes and appropriate education for physicians, pharmacists, and the beneficiary. The Drug Utilization Review (DUR) Board is composed of twelve participating physicians and pharmacists who are active MS Medicaid providers and in good standing with their representative organizations.

The Board reviews utilization of drug therapy and evaluates the long-term success of the treatments.

The Drug Utilization Review (DUR) Board meets quarterly.

Meetings

Meetings will be held at 1:00 pm in Woolfolk Building Room 145 unless otherwise noted. 2023 dates are as follows:

- March 2, 2023 (Room 117, Woolfolk Building – no virtual options, live meeting);
- June 15, 2023 (Room 145,Woolfolk Building);
- Sept. 7, 2023 (Room 145, Woolfolk Building),
- Dec. 7, 2023 (Room 145, Woolfolk Building)

Important Updates: Beginning October 1, 2021, pharmaceutical and industry members, vendors, and general public must register to attend. Registration will open thirty (30) days prior to the meeting date. Registration will close at 12pm (noon) the day before the meeting. Due to the ongoing pandemic, *only one representative per company may register/attend*. Public speaking is not allowed at DUR meetings unless called on by the Board.

Parking: parking may be found on the perimeter of the Woolfolk Building, on the north side of the Woolfolk Building located at the old Wright and Ferguson building (yellow/brown building), and at the Division of Medicaid and First Baptist Church main parking lots at the corner of High Street and North President Street. *Guests may not park at the Woolfolk Building or in any parking space marked "Reserved".*

CLICK HERE to register online for the March 2, 2023 DUR Board meeting!

Note: as of 2/14/2023, registration limit (seating capacity for meeting room) has been reached.

NOTE: Registration is **required** for all pharmaceutical industry and advocacy representatives to be able to attend DUR Board meetings.

Note: as of 2/14/2023, registration limit (seating capacity for meeting room) has been reached.

Companies that have met the one (1) representative per company limit (as of 2/23/2023):

1. Alliant
2. Gainwell
3. Gilead
4. Indivior
5. Lilly
6. Magnolia
7. Molina
8. Novartis
9. Novo Nordisk
10. Provention Bio
11. Regeneron
12. Spark Therapeutics
13. Sunovion
14. UHC
15. Vertex
16. Viking Healthcare Solutions

Resource Utilizaton Review

TABLE 04A: ENROLLMENT STATISTICS FOR LAST 6 MONTHS
October 1, 2022 through March 31, 2023

			Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23
Total enrollment			884,185	888,022	892,217	895,552	898,321	901,512
Dual-eligibles			167,170	167,360	167,584	167,765	167,804	168,025
Pharmacy benefits			774,153	777,909	782,011	785,347	788,126	791,173
	LTC		15,471	15,435	15,481	15,526	15,565	15,620
	PLAN %	**FFS**	52.4%	52.2%	50.5%	50.3%	49.9%	49.8%
		MSCAN-UHC	18.4%	18.5%	19.1%	19.3%	19.4%	19.4%
		MSCAN-Magnolia	19.4%	19.4%	19.9%	19.9%	20.0%	20.0%
		MSCAN-Molina	9.8%	9.9%	10.5%	10.5%	10.7%	10.8%

TABLE 04B: PHARMACY UTILIZATION STATISTICS FOR LAST 6 MONTHS
October 1, 2022 through March 31, 2023

		Oct-22	Nov-22	Dec-22	Jan-23	Feb-23	Mar-23
# Rx Fills	**FFS**	205,746	218,117	182,209	193,368	179,750	200,533
	MSCAN-UHC	109,654	114,184	100,360	107,524	101,215	112,749
	MSCAN-Mag	217	216	210	159	138	182
	MSCAN-Mol	37,458	39,107	34,533	36,020	35,343	38,684
# Rx Fills / Bene	**FFS**	0.5	0.5	0.5	0.5	0.5	0.5
	MSCAN-UHC	0.8	0.8	0.7	0.7	0.7	0.7
	MSCAN-Mag	0.0	0.0	0.0	0.0	0.0	0.0
	MSCAN-Mol	0.5	0.5	0.4	0.4	0.4	0.5
$ Paid Rx	**FFS**	$23,132,347	$24,481,370	$23,187,584	$24,839,384	$24,367,004	$26,609,599
	MSCAN-UHC	$21,922,583	$22,702,724	$22,963,202	$27,675,602	$25,512,059	$29,972,708
	MSCAN-Mag	$14,630	$17,870	$15,054	$6,300	$5,430	$7,813
	MSCAN-Mol	$4,113,067	$4,188,019	$4,086,104	$4,367,074	$4,341,785	$5,047,010
$ /Rx Fill	**FFS**	$112.43	$112.24	$127.26	$128.46	$135.56	$132.69
	MSCAN-UHC	$199.93	$198.83	$228.81	$257.39	$252.06	$265.84
	MSCAN-Mag	$67.42	$82.73	$71.69	$39.62	$39.35	$42.93
	MSCAN-Mol	$109.80	$107.09	$118.32	$121.24	$122.85	$130.47
$ /Bene	**FFS**	$57.02	$60.29	$58.72	$62.88	$61.96	$67.54
	MSCAN-UHC	$153.90	$157.75	$153.74	$182.59	$166.86	$195.28
	MSCAN-Mag	$0.10	$0.12	$0.10	$0.04	$0.03	$0.05
	MSCAN-Mol	$54.21	$54.38	$49.76	$52.96	$51.49	$59.07

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

In April 2021, UHC changed their claims reporting procedure, and the estimates presented in these tables may be slightly higher than the amount actually paid by UHC

***Incomplete claim information for Magnolia for the reporting period*

TABLE C: TOP 10 DRUG CATEGORIES BY NUMBER OF CLAIMS IN MAR 2023 (FFS AND CCOs)

Category	Month Year	Rank Volume	# RXs	$ Paid	# Unique Benes
CNS stimulants	Mar 2023	1	19,547	$3,256,505	15,239
	Feb 2023	1	17,708	$2,900,194	14,056
	Jan 2023	1	18,656	$2,982,728	14,675
contraceptives	Mar 2023	2	13,264	$845,573	10,829
	Feb 2023	2	11,696	$681,710	9,843
	Jan 2023	2	12,733	$772,268	10,564
aminopenicillins	Mar 2023	3	11,724	$159,528	11,204
	Feb 2023	3	11,372	$153,776	10,867
	Jan 2023	3	10,775	$143,820	10,325
SSRI antidepressants	Mar 2023	4	11,024	$137,344	9,209
	Feb 2023	4	9,768	$117,479	8,403
	Jan 2023	4	10,257	$130,955	8,671
nonsteroidal anti-inflammatory agents	Mar 2023	5	9,861	$137,039	8,891
	Feb 2023	6	8,571	$119,954	7,847
	Jan 2023	5	9,612	$139,064	8,725
adrenergic bronchodilators	Mar 2023	6	9,423	$638,376	7,529
	Feb 2023	5	8,667	$545,600	7,097
	Jan 2023	6	9,361	$594,113	7,576
atypical antipsychotics	Mar 2023	7	9,320	$3,720,183	6,821
	Feb 2023	7	8,167	$3,257,038	6,318
	Jan 2023	7	8,797	$3,512,076	6,624
narcotic analgesic combinations	Mar 2023	8	9,229	$540,602	7,812
	Feb 2023	9	7,832	$444,336	6,828
	Jan 2023	9	8,579	$468,926	7,392
antihistamines	Mar 2023	9	7,607	$114,372	6,769
	Feb 2023	11	6,830	$102,958	6,119
	Jan 2023	11	6,710	$98,742	6,035
glucocorticoids	Mar 2023	10	7,138	$449,671	6,599
	Feb 2023	10	7,174	$310,165	6,723
	Jan 2023	10	7,370	$322,013	6,891

TABLE D: TOP 10 DRUG CATEGORIES BY DOLLARS PAID IN MAR 2023 (FFS AND CCOs)

Category	Month Year	Rank Paid Amt	# RXs	$ Paid	# Unique Benes
interleukin inhibitors	Mar 2023	1	1,067	$7,103,029	559
	Feb 2023	2	862	$5,598,038	483
	Jan 2023	2	933	$5,261,821	495
antirheumatics	Mar 2023	2	876	$6,246,232	505
	Feb 2023	1	776	$5,792,130	475
	Jan 2023	1	818	$6,273,733	494
atypical antipsychotics	Mar 2023	3	9,320	$3,720,183	6,821
	Feb 2023	3	8,167	$3,257,038	6,318
	Jan 2023	3	8,797	$3,512,076	6,624
CNS stimulants	Mar 2023	4	19,547	$3,256,505	15,239
	Feb 2023	4	17,708	$2,900,194	14,056
	Jan 2023	4	18,656	$2,982,728	14,675
antiviral combinations	Mar 2023	5	661	$2,877,300	507
	Feb 2023	5	628	$2,623,074	496
	Jan 2023	5	678	$2,914,720	508
CFTR combinations	Mar 2023	6	109	$2,557,088	59
	Feb 2023	6	105	$2,323,840	59
	Jan 2023	6	104	$2,373,254	62
GLP-1 receptor agonists	Mar 2023	7	2,165	$2,024,334	1,454
	Feb 2023	8	1,736	$1,514,173	1,212
	Jan 2023	8	1,807	$1,557,744	1,182
selective immunosuppressants	Mar 2023	8	348	$1,573,920	233
	Feb 2023	9	340	$1,416,158	223
	Jan 2023	9	348	$1,553,464	220
insulin	Mar 2023	9	3,980	$1,566,138	2,512
	Feb 2023	10	3,533	$1,371,900	2,353
	Jan 2023	11	3,866	$1,513,207	2,457
miscellaneous uncategorized agents	Mar 2023	10	136	$1,384,642	102
	Feb 2023	11	118	$1,362,656	91
	Jan 2023	7	120	$2,226,314	95

TABLE E: TOP 25 DRUG MOLECULES
BY NUMBER OF CLAIMS IN MAR 2023 (FFS and CCOs)

Drug Molecule Therapeutic Category	Feb 2023 # Claims	Mar 2023 # Claims	Mar 2023 $ Paid	Mar 2023 # Unique Benes
amoxicillin / aminopenicillins	11,338	11,688	$158,859	11,171
albuterol / adrenergic bronchodilators	8,143	8,692	$446,690	7,094
azithromycin / macrolides	7,737	6,842	$110,632	6,526
methylphenidate / CNS stimulants	5,433	6,060	$1,180,090	4,913
ondansetron / 5HT3 receptor antagonists	5,183	5,788	$81,460	5,424
acetaminophen-hydrocodone / narcotic analgesic combinations	4,553	5,418	$68,653	4,827
montelukast / leukotriene modifiers	4,112	5,292	$80,385	4,817
amphetamine-dextroamphetamine / CNS stimulants	4,869	5,226	$182,757	4,247
fluticasone nasal / nasal steroids	3,882	4,987	$75,325	4,689
gabapentin / gamma-aminobutyric acid analogs	4,133	4,665	$66,853	3,815
cetirizine / antihistamines	4,094	4,578	$66,027	4,121
ibuprofen / nonsteroidal anti-inflammatory agents	3,899	4,488	$52,593	4,202
amoxicillin-clavulanate / penicillins/beta-lactamase inhibitors	4,423	4,203	$91,664	3,948
sertraline / SSRI antidepressants	3,536	4,181	$50,871	3,469
clonidine / antiadrenergic agents, centrally acting	3,429	3,742	$45,854	3,219
amlodipine / calcium channel blocking agents	3,268	3,688	$43,276	3,089
triamcinolone topical / topical steroids	2,700	3,678	$57,690	3,184
cefdinir / third generation cephalosporins	3,515	3,600	$87,031	3,411
lisdexamfetamine / CNS stimulants	3,234	3,491	$1,254,030	2,856
dexmethylphenidate / CNS stimulants	2,953	3,418	$150,427	2,647
ethinyl estradiol-norgestimate / contraceptives	2,998	3,258	$51,998	2,773
prednisolone / glucocorticoids	3,333	3,175	$53,091	2,971
ergocalciferol / vitamins	2,570	2,980	$23,345	2,311
hydroxyzine / miscellaneous anxiolytics, sedatives and hypnotics	2,601	2,973	$44,502	2,633
fluconazole / azole antifungals	2,562	2,967	$34,881	2,678

TABLE F: TOP 25 DRUG MOLECULES
BY DOLLARS PAID IN MAR 2023 (FFS and CCOs)

Drug Molecule Therapeutic Category	Feb 2023 $ Paid	Mar 2023 $ Paid	Mar 2023 # Claims	Mar 2023 # Unique Benes
adalimumab / antirheumatics	$4,164,872	$4,572,261	480	265
dupilumab / interleukin inhibitors	$2,131,720	$2,699,172	764	404
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	$1,974,947	$2,326,582	98	53
paliperidone / atypical antipsychotics	$1,266,982	$1,566,803	529	378
ixekizumab / interleukin inhibitors	$1,096,904	$1,314,870	137	69
lisdexamfetamine / CNS stimulants	$1,157,825	$1,254,030	3,491	2,856
ustekinumab / interleukin inhibitors	$1,285,492	$1,242,898	60	35
bictegravir/emtricitabine/tenofovir / antiviral combinations	$1,181,754	$1,221,056	300	238
methylphenidate / CNS stimulants	$1,041,822	$1,180,090	6,060	4,913
aripiprazole / atypical antipsychotics	$878,672	$956,672	2,453	1,959
guselkumab / interleukin inhibitors	$181,094	$925,449	17	8
glycerol phenylbutyrate / urea cycle disorder agents	$778,036	$800,005	16	4
emicizumab / factor for bleeding disorders	$632,119	$749,271	31	26
fremanezumab / CGRP inhibitors	$41,223	$723,571	84	45
somatropin / growth hormones	$702,968	$704,844	147	95
liraglutide / GLP-1 receptor agonists	$624,631	$695,606	831	657
etanercept / antirheumatics	$650,386	$658,004	123	73
cannabidiol / miscellaneous anticonvulsants	$575,965	$625,131	191	112
insulin glargine / insulin	$541,818	$616,529	1,412	1,121
everolimus / selective immunosuppressants	$515,742	$600,115	36	22
empagliflozin / SGLT-2 inhibitors	$416,242	$513,928	629	527
semaglutide / GLP-1 receptor agonists	$353,800	$504,715	535	323
sofosbuvir-velpatasvir / antiviral combinations	$398,621	$495,828	50	21
dulaglutide / GLP-1 receptor agonists	$316,797	$473,647	556	433
dapagliflozin / SGLT-2 inhibitors	$366,022	$455,635	642	523

TABLE G: TOP 25 DRUG MOLECULES
BY CHANGE IN NUMBER OF CLAIMS FROM JAN 2023 TO MAR 2023 (FFS and CCOs)

Drug Molecule	Jan 2023 # Claims	Feb 2023 # Claims	Mar 2023 # Claims	Mar 2023 $ Paid	Mar 2023 # Unique Benes
fluticasone nasal / nasal steroids	3,979	3,882	4,987	$75,325	4,689
amoxicillin / aminopenicillins	10,743	11,338	11,688	$158,859	11,171
montelukast / leukotriene modifiers	4,373	4,112	5,292	$80,385	4,817
cetirizine / antihistamines	3,770	4,094	4,578	$66,027	4,121
triamcinolone topical / topical steroids	3,171	2,700	3,678	$57,690	3,184
dexmethylphenidate / CNS stimulants	2,955	2,953	3,418	$150,427	2,647
ergocalciferol / vitamins	2,552	2,570	2,980	$23,345	2,311
methylphenidate / CNS stimulants	5,662	5,433	6,060	$1,180,090	4,913
sertraline / SSRI antidepressants	3,813	3,536	4,181	$50,871	3,469
acetaminophen-hydrocodone / narcotic analgesic combinations	5,072	4,553	5,418	$68,653	4,827
pantoprazole / proton pump inhibitors	2,340	2,317	2,681	$35,104	2,276
olopatadine ophthalmic / ophthalmic antihistamines and decongestants	235	240	564	$16,904	502
dulaglutide / GLP-1 receptor agonists	257	364	556	$473,647	433
ondansetron / 5HT3 receptor antagonists	5,507	5,183	5,788	$81,460	5,424
mupirocin topical / topical antibiotics	1,925	1,797	2,165	$31,976	2,033
buspirone / miscellaneous anxiolytics, sedatives and hypnotics	1,947	1,816	2,184	$25,907	1,874
hydrocortisone topical / topical steroids	1,051	990	1,271	$30,124	1,140
clonazepam / benzodiazepines	1,286	1,290	1,496	$18,816	1,267
guanfacine / antiadrenergic agents, centrally acting	2,407	2,335	2,616	$70,364	2,218
folic acid / vitamins	1,770	1,662	1,977	$14,559	1,358
ethinyl estradiol-norelgestromin / contraceptives	2,241	2,099	2,437	$318,098	1,702
epinephrine / adrenergic bronchodilators	445	430	639	$176,708	469
hydroxyzine / miscellaneous anxiolytics, sedatives and hypnotics	2,794	2,601	2,973	$44,502	2,633
mometasone topical / topical steroids	514	499	670	$12,632	593
cyclobenzaprine / skeletal muscle relaxants	1,656	1,427	1,812	$17,305	1,677

TABLE H: TOP 25 DRUG MOLECULES
BY CHANGE IN AMOUNT PAID FROM JAN 2023 TO MAR 2023 (FFS and CCOs)

Drug Molecule	Jan 2023 $ Paid	Feb 2023 $ Paid	Mar 2023 $ Paid	Mar 2023 # Claims	Mar 2023 # Unique Benes
guselkumab / interleukin inhibitors	$62,212	$181,094	$925,449	17	8
fremanezumab / CGRP inhibitors	$38,232	$41,223	$723,571	84	45
glycerol phenylbutyrate / urea cycle disorder agents	$400,954	$778,036	$800,005	16	4
elexacaftor/ivacaftor/tezacaftor / CFTR combinations	$2,021,254	$1,974,947	$2,326,582	98	53
dupilumab / interleukin inhibitors	$2,408,026	$2,131,720	$2,699,172	764	404
dulaglutide / GLP-1 receptor agonists	$227,179	$316,797	$473,647	556	433
paliperidone / atypical antipsychotics	$1,322,413	$1,266,982	$1,566,803	529	378
cladribine / antimetabolites	$0	$0	$217,648	3	1
valbenazine / VMAT2 inhibitors	$163,599	$239,435	$371,779	48	27
risankizumab / interleukin inhibitors	$160,868	$582,980	$366,515	19	12
bosutinib / BCR-ABL tyrosine kinase inhibitors	$37,483	$74,966	$224,899	12	5
immune globulin intravenous / immune globulins	$93,690	$147,508	$267,347	26	12
emicizumab / factor for bleeding disorders	$588,375	$632,119	$749,271	31	26
ixekizumab / interleukin inhibitors	$1,155,336	$1,096,904	$1,314,870	137	69
methylphenidate / CNS stimulants	$1,032,444	$1,041,822	$1,180,090	6,060	4,913
ustekinumab / interleukin inhibitors	$1,099,746	$1,285,492	$1,242,898	60	35
antihemophilic factor / factor for bleeding disorders	$252,576	$513,855	$389,227	14	8
deflazacort / glucocorticoids	$202,960	$196,388	$336,453	44	9
semaglutide / GLP-1 receptor agonists	$372,166	$353,800	$504,715	535	323
secukinumab / interleukin inhibitors	$221,943	$170,061	$350,801	31	11
bictegravir/emtricitabine/tenofovir / antiviral combinations	$1,098,449	$1,181,754	$1,221,056	300	238
berotralstat / hereditary angioedema agents	$121,067	$282,506	$242,121	6	2
everolimus / selective immunosuppressants	$483,371	$515,742	$600,115	36	22
eteplirsen / miscellaneous uncategorized agents	$249,628	$275,228	$364,836	4	2
selexipag / agents for pulmonary hypertension	$242,071	$77,682	$355,118	11	3

TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > $1
BY PERCENT CHANGE IN AMOUNT PAID PER UNIT JAN 2023 TO MAR 2023 (FFS and CCOs)

Drug Product Therapeutic Category	Mar 2023 # Claims	Mar 2023 $ Paid	Mar 2023 Avr. Paid Per Rx	Mar 2023 Avr. Units Per Rx	Jan 2023 Paid Per Unit	Feb 2023 Paid Per Unit	Mar 2023 Paid Per Unit	Percent Change
dexmethylphenidate 25 mg capsule, extended release / CNS stimulants (Y)	196	$15,893	$81.09	30	$2.04	$2.07	$2.35	15.1%
methylphenidate (30/70 release) 30 mg/24 hr capsule, extended release / CNS stimulants (Y)	111	$5,506	$49.60	30	$1.16	$1.15	$1.29	11.0%
dexmethylphenidate 30 mg capsule, extended release / CNS stimulants (Y)	289	$18,177	$62.89	30	$1.60	$1.22	$1.73	8.1%
Nurtec ODT (rimegepant) 75 mg tablet, disintegrating / CGRP inhibitors (Y)	150	$98,494	$656.63	10	$72.71	$75.08	$77.20	6.2%
scopolamine 1 mg/72 hr film, extended release / anticholinergics/antispasmodics	148	$11,976	$80.92	8	$8.27	$8.86	$8.64	4.5%
Xarelto (rivaroxaban) 20 mg tablet / factor Xa inhibitors (Y)	262	$121,092	$462.18	27	$15.86	$16.84	$16.45	3.7%
Entresto (sacubitril-valsartan) 49 mg-51 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (Y)	123	$73,937	$601.11	56	$10.18	$10.45	$10.48	3.0%
Vyvanse (lisdexamfetamine) 20 mg tablet, chewable / CNS stimulants (N)	102	$36,192	$354.83	30	$11.26	$11.39	$11.51	2.2%
Farxiga (dapagliflozin) 5 mg tablet / SGLT-2 inhibitors (Y)	119	$92,416	$776.60	43	$17.50	$17.82	$17.85	2.0%
QuilliChew ER (methylphenidate) 30 mg/24 hr tablet, chewable, extended release / CNS stimulants (Y)	646	$231,941	$359.04	31	$11.32	$11.48	$11.54	2.0%
Entresto (sacubitril-valsartan) 97 mg-103 mg tablet / angiotensin receptor blockers and neprilysin inhibitors (Y)	118	$72,494	$614.36	58	$10.21	$10.25	$10.39	1.8%
Eliquis (apixaban) 2.5 mg tablet / factor Xa inhibitors (Y)	126	$48,924	$388.28	44	$8.46	$8.70	$8.61	1.8%
Brilinta (ticagrelor) (ticagrelor) 90 mg tablet / platelet aggregation inhibitors (Y)	101	$37,676	$373.03	53	$6.67	$6.82	$6.78	1.5%

Products are only included if 100 or more fills in last month and average cost per unit in reference month was >= $1.

TABLE I: TOP 15 DRUG SOLID DOSAGE FORM HIGH VOLUME (100+ RX FILLS LAST MONTH) PRODUCTS WITH UNIT COST > $1
BY PERCENT CHANGE IN AMOUNT PAID PER UNIT JAN 2023 TO MAR 2023 (FFS and CCOs)

Drug Product Therapeutic Category	Mar 2023 # Claims	Mar 2023 $ Paid	Mar 2023 Avr. Paid Per Rx	Mar 2023 Avr. Units Per Rx	Jan 2023 Paid Per Unit	Feb 2023 Paid Per Unit	Mar 2023 Paid Per Unit	Percent Change
Linzess (linaclotide) 290 mcg capsule / guanylate cyclase-C agonists (Y)	108	$53,892	$499.00	30	$16.01	$16.39	$16.26	1.5%
Spiriva HandiHaler (tiotropium) 18 mcg capsule / anticholinergic bronchodilators (Y)	146	$72,402	$495.91	30	$16.13	$16.28	$16.37	1.5%

Products are only included if 100 or more fills in last month and average cost per unit in reference month was >= $1.

New Business

Special Analysis Projects

MISSISSIPPI DIVISION OF MEDICAID

MS-DUR INTERVENTION / EDUCATIONAL INITIATIVE UPDATE

March 2023 – May 2023

Ongoing Intervention(s):

PROVIDER SHOPPING FOR OPIOIDS (≥4 Prescribers AND ≥4 Pharmacies)				CONCOMITANT USE OF OPIOIDS AND ANTIPSYCHOTICS		
Month	Prescribers Mailed	Pharms Mailed	Benes Addressed	Month	Prescribers Mailed	Benes Addressed
22-Jun	4	4	8	22-Jun	39	43
22-Jul	3	2	5	22-Jul	46	55
22-Aug	3	2	5	22-Aug	48	58
22-Sep	2	1	3	22-Sep	49	56
22-Oct	3	2	5	22-Oct	34	39
22-Nov	2	2	4	22-Nov	41	43
22-Dec	3	3	6	22-Dec	27	28
23-Jan	1	1	2	23-Jan	19	19
23-Feb	4	4	8	23-Feb	14	17
23-Mar	4	2	6	23-Mar	16	16
23-Apr	2	2	4	23-Apr	9	10
23-May	6	7	13	23-May	37	40

Note: December 2022 - April 2023 mailings, data for all CCOs was not included due to issues receiving encounter claims.
May 2023 - encounter data for MAG incomplete.

{Date}

IMPORTANT INFORMATION REGARDING THE USE OF LOW-DOSE ASPIRIN TO PREVENT PREECLAMPSIA

Dear Dr. {Prescriber Name},

According to the March of Dimes Report Card, in 2021, Mississippi had the highest preterm birth rate in the U.S. (15.0%) and, subsequently, the highest infant mortality rate (5.4%).[1] Preeclampsia, a serious blood pressure disorder that can occur during pregnancy or soon after birth, has been linked to both maternal and infant morbidity and mortality.[2] Additionally, racial and ethnic disparities exist in the prevalence of preeclampsia with non-Hispanic Black women experiencing higher rates.[3]

The US Preventive Services Task Force (USPSTF) recommends the use of low-dose aspirin (81mg/day) as preventive medication for preeclampsia after 12 weeks of gestation in persons at high risk for preeclampsia. Pregnant persons with 2 or more moderate-risk factors may also benefit from low-dose aspirin.[2](Figure 1)

Figure 1. Risk Factors for Preeclampsia

Risk Level	Risk Factors	Recommendation
High	History of preeclampsia Multifetal gestation Chronic hypertension Pregestational type 1 or 2 diabetes Renal disease Autoimmune disease (systemic lupus erythematosus, antiphospholipid syndrome)	Recommend low-dose aspirin if the patient has one or more of these high-risk factors
Moderate	Nulliparity Obesity (body mass index > 30) Family history of preeclampsia (mother or sister) Sociodemographic characteristics (Black race, low socioeconomic status) Age ≥ 35 years Personal history factors (eg, low birthweight or small for gestational age, previous adverse pregnancy outcome, more than 10-year pregnancy interval) In vitro conception	Recommend low-dose aspirin if the patient has two or more moderate-risk factors Consider low-dose aspirin if the patient has one of these moderate-risk factors
Low	Previous uncomplicated full-term delivery	Do not recommend

[1] March of Dimes Report Card. Accessed May 8, 2023. https://www.marchofdimes.org/peristats/reports/united-states/report-card

[2] US Preventive Services Task Force. Aspirin Use to Prevent Preeclampsia and Related Morbidity and Mortality: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2021;326(12):1186-1191. doi:10.1001/jama.2021.14781

[3] Boakye E, Kwapong YA, Obisesan O, et al. Nativity-Related Disparities in Preeclampsia and Cardiovascular Disease Risk Among a Racially Diverse Cohort of US Women. *JAMA Network Open*. 2021;4(12):e2139564. doi:10.1001/jamanetworkopen.2021.39564

WHY YOU ARE RECEIVING THIS

Our records indicate that you provided care for one or more pregnant Medicaid beneficiaries during the past year. One of Medicaid's top priorities is improving maternal health and decreasing preterm births among covered individuals. We support the use of low-dose aspirin as preventive medication in at-risk pregnant individuals. To help facilitate those discussions with your patients, we have included a flyer that can be duplicated and utilized in your practice. A digital copy can also be found at _____.

We want to thank you for the care you provide to Medicaid beneficiaries. If we can be of any assistance, please do not hesitate to contact us.

Sincerely,

Terri R. Kirby, RPh, CPM
Director, Office of Pharmacy
Mississippi Division of Medicaid

Eric Pittman, PharmD
Project Director
MS-DUR

LOW-DOSE ASPIRIN CAN

PREVENT PREECLAMPSIA

WHAT IS PREECLAMPSIA?

Preeclampsia is a serious blood pressure disorder that can occur during pregnancy or soon after birth. It can cause preterm birth and other negative outcomes for infants and mothers.

WHAT CAN I DO?

The use of daily low-dose aspirin after 12 weeks of pregnancy in persons who are high-risk has been shown to help prevent preeclampsia.

AM I AT HIGH-RISK?

You may be considered high-risk if you:

- Have a history of preeclampsia
- Have a multifetal pregnancy
- Have chronic hypertension
- Have pregestational diabetes
- Have kidney disease
- Have certain autoimmune diseases

IF YOU HAVE QUESTIONS OR THINK YOU MAY BE ELIGIBLE TO TAKE LOW-DOSE ASPIRIN PREVENTION, PLEASE TALK TO YOUR HEALTHCARE PROVIDER.

MISSISSIPPI DIVISION OF MEDICAID

ADOLESCENT VACCINES

BACKGROUND

Vaccinations have been shown to provide protection against serious infectious diseases. Routine childhood vaccinations have dramatically reduced the impact of diseases such as polio, rubella, diphtheria, pertussis, mumps, and measles. Beginning in 1994, Mississippi has had one of the strongest childhood vaccination programs in the U.S. resulting in high vaccination rates.[1] One of the primary drivers of this strong vaccination program has been the state's vaccination requirements for school attendance.[1] Mississippi's vaccination program has led to 99% of school-aged children being appropriately protected when entering kindergarten.[1] Recently, a federal judge issued a ruling requiring Mississippi to allow religious exemptions for childhood vaccination requirements for school attendance. The impact this ruling will have on future childhood vaccination rates in Mississippi is unknown.

In addition to the routine immunization recommendations that begin at birth, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization (ACIP) also provides vaccine recommendations for adolescents ages 7-18 years.[2] (Figure 1) The following vaccinations are recommended for all adolescents in the United States: COVID-19; Influenza; Tetanus, diphtheria, and acellular pertussis (Tdap); Meningococcal; and Human papillomavirus (HPV). This report will focus on Tdap, Meningococcal, and HPV vaccinations.[3]

Tdap

The Tdap vaccine is a combination vaccine that protects against tetanus, diphtheria, and pertussis. Tetanus, an acute disease caused by a neurotoxin produced by *Clostridium tetani* bacteria, can cause lockjaw, serious muscle contractions, and even death.[4,5] Diphtheria is caused by *Corynebacterium diphtheria* and can cause respiratory, cardiac, and neurologic problems.[5,6] Pertussis is an acute respiratory disease caused by *Bordetella pertussis* which can produce a characteristic whooping cough.[5] Routine pediatric immunization against tetanus, diphtheria, and pertussis has been common in the United States for many years with high levels of coverage.[5] To maintain protection against tetanus, diphtheria, and pertussis, the CDC recommends a single booster dose of Tdap for persons aged 11-18 years, preferably during a preventive care visit between 11-12 years. Additionally, to ensure continued protection, a booster dose of Td or Tdap should be administered every 10 years.[7] In response to a recent national shortage of Td vaccines, the CDC issued guidance supporting the use of the Tdap vaccine as an acceptable alternative to the Td vaccine except in circumstances when there is a specific contraindication to pertussis vaccines. This recommendation includes circumstances when a tetanus booster is indicated for wound management.[8]

Coverage for the Tdap vaccine in the United States is generally high. All states in the U.S. require children to receive the Tdap vaccine for school attendance; however, age requirements and allowable exemptions vary by state.[9,10] According to the CDC, in 2021, 89.6% of adolescents aged

13-17 years had received at least one dose of Tdap.[11] In Mississippi, coverage rates for Tdap among adolescents aged 13-17 years is slightly lower than the national average at 89.1%.[12]

Meningococcal

Meningococcal disease, caused by the bacteria *Neisseria meningitidis*, is a severe, acute disease characterized by a sudden onset of symptoms and rapid progression of severity. Meningococcal disease is the leading cause of bacterial meningitis and sepsis in the U.S and can also lead to pneumonia and localized diseases such as septic arthritis.[13,14] Two types of meningococcal vaccines are available in the U.S.: Meningococcal conjugate (MenACWY) vaccines and Serogroup B meningococcal (MenB) vaccines. The CDC recommends routine vaccination with MenACWY vaccines with an initial dose for adolescents at 11-12 years and a booster dose recommended at age 16 years. The booster dose is intended to provide protection during the years when adolescents are at the highest risk for meningococcal disease. For those who receive their first dose of the MenACWY vaccine between the ages of 13 and 15 years, it is recommended to administer a booster dose between ages 16 and 18 years coinciding with the period of heightened risk. Adolescents who get their first MenACWY vaccine dose at or after the age of 16 years do not require a booster dose. Adolescents and teens may also receive a MenB vaccine between 16-23 years (preferably between ages 16-18 years) based on shared clinical decision making with a healthcare provider during the period of elevated risk. In addition to the routine vaccination recommendations, meningococcal vaccines are also recommended for others at increased risk for contracting meningococcal disease such as those who may be exposed to an outbreak through travel or crowded living conditions such as college dormitories, those with anatomic or functional asplenia, those with complement component deficiency, or those with complement inhibitor. Regular booster doses are necessary for those at increased risk. It is recommended to administer a booster dose of the MenB vaccine one year after completing the series and then every 2 to 3 years thereafter. If a year or more has passed since completing the primary MenB vaccine series for those at increased risk due to an outbreak, the CDC recommends a booster dose.[13,15–17]

The national MenACWY coverage rate for adolescents aged 13-17 years who had received at least one dose in 2021 was 89%, with Mississippi being below the national average at 60.2%.[11,12] According to 2021 data published by Immune.org, 35 states mandate at least one dose of MenACWY for secondary school with 19 states also having a booster dose requirement.[18] Twenty-four states have some type of MenACWY mandates for college attendance.[19] Mississippi currently has no MenACWY vaccine mandates for school attendance.[18,19] Coverage rates for MenB are much lower at 31.4% for the U.S. with multiple factors potentially contributing to this low rate.[11,20] The first MenB vaccine in the U.S. did not receive approval until 2014.[21] Additionally, there are currently no state-level requirements for MenB vaccination for college attendance. However, in spite of the lack of state-level requirements, several colleges and universities across the U.S. have policies requiring or recommending MenB vaccination for students.[22] No colleges or universities in Mississippi require MenB vaccination for students.

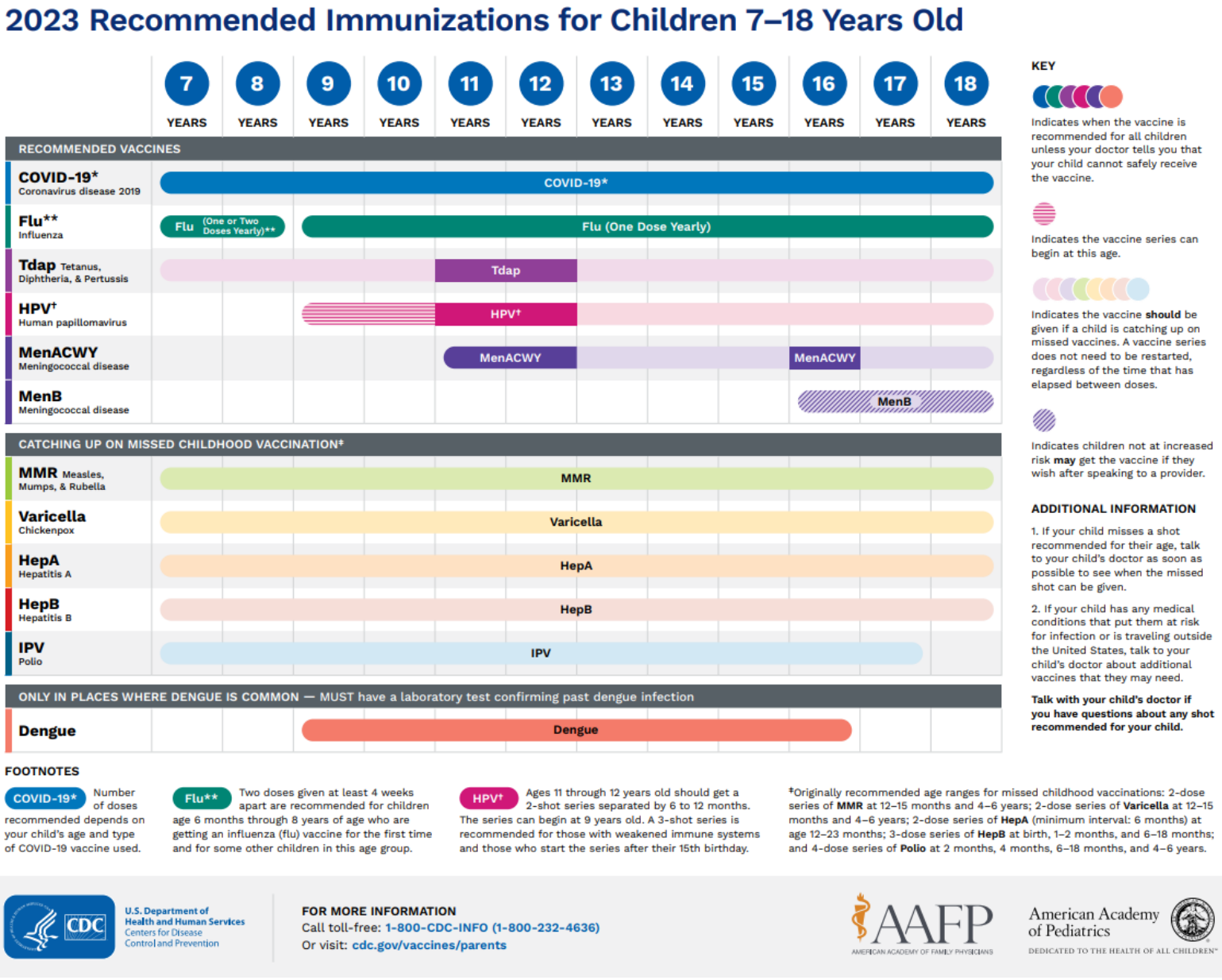
HPV

HPV is the most common sexually transmitted infection in the U.S and consists of various strains.[23] Infection with certain high-risk strains of HPV can cause genital warts and several types of cancer

(cervical, oropharyngeal, vulvar, vaginal, penile, and anal).[24,25] The HPV vaccine provides protection against strains of HPV that are most commonly associated with disease and has been found to be highly effective at preventing HPV-related cancers and genital warts.[26–28] The ACIP recommends beginning the routine HPV vaccination series at age 11-12 years (series can be initiated at age 9 years), and catch-up vaccination is recommended for all persons through age 26 years not adequately vaccinated.[29,30] The HPV vaccine may also be provided to adults aged 27-45 years in conjunction with shared clinical decision-making with their healthcare provider.[29]

Coverage rates for the HPV vaccine across the U.S. continue to improve with an estimated 76.9% of adolescents 13-17 years having received $\geq$ 1 dose of the HPV vaccine and 61.7% being up to date with HPV vaccination series in 2021.[11] Mississippi continues to trail the rest of the U.S. with only 56.2% of adolescents having received $\geq$ 1 dose and 32.7% being up to date.[31] Currently, only three states in the U.S. (Hawaii, Rhode Island, and Virginia) and the District of Columbia have HPV vaccination mandates for elementary or secondary schools.[32]

FIGURE 1: CDC Adolescent Vaccine Recommendations[2]

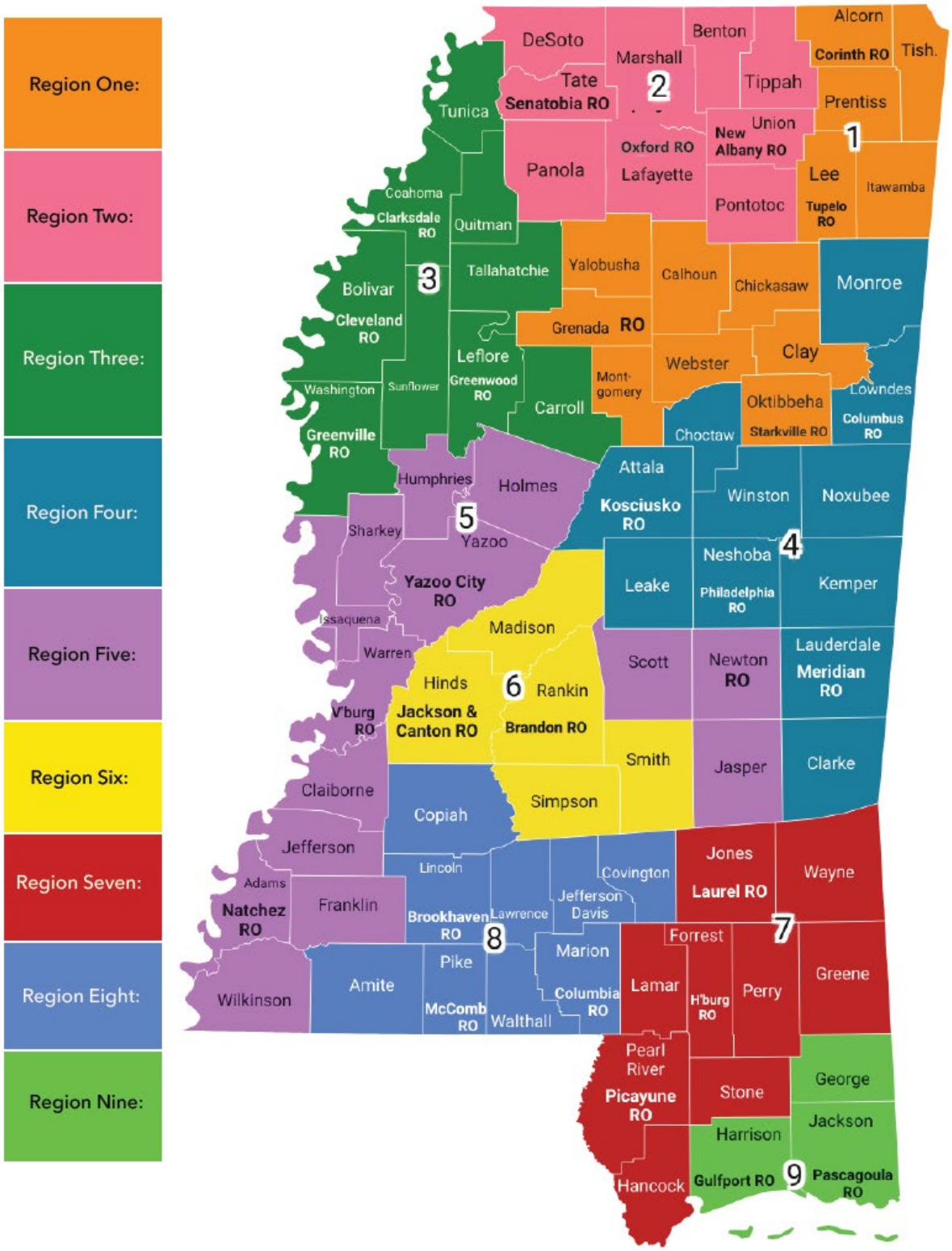


METHODS

A retrospective analysis was conducted using Mississippi Medicaid medical and pharmacy point-of-sale (POS) pharmacy claims for fee-for-service (FFS) and coordinated care organizations [CCOs: UnitedHealthcare (UHC), Magnolia Health (MAG) and Molina Healthcare (MOL)] claims from July 1st, 2020, to June 30th, 2022, to examine trends in utilization of CDC recommended adolescent vaccinations among Medicaid beneficiaries. Beneficiaries were included in the analysis if they had a medical or pharmacy claim for Tdap, Td, MenACWY, MenB, or HPV vaccines between July 1, 2020 and June 30, 2022. For each vaccination, claims were identified using National Drug Code (NDC) or procedure codes for both the vaccine and administration fees. Demographic and health plan enrollment characteristics of the beneficiaries were captured and trends in utilization of each vaccine were described based on age, sex, race, plan, category of eligibility, place of service, and region as defined in Figure 2.

Additionally for the HPV vaccine, a subset analysis was conducted examining HPV completion rates. Beneficiaries were included in this sub analysis if they were new initiators of the HPV vaccine between July 1, 2020 and June 30, 2021. An initiator was defined as anyone with an index HPV vaccination claim between July 1, 2020 and June 30, 2021 with no previous claim for an HPV vaccination one year prior to that first claim. The 12-month period following the index vaccination date was used to assess for series completion. Adolescents younger than age 15 years at index vaccination date should receive 2 doses within a year for completion and those aged 15 years and above at index date should 3 doses within a year for completion.

Figure 2. Regions in Mississippi



RESULTS

Tdap/Td Vaccines:

A total of 57,725 beneficiaries received Tdap/Td vaccines between July 1, 2020 and June 30, 2022. (Tables 1-4)

- Table 1:
  - Most beneficiaries were female (59.4%), ages 12-17 years (51.3%), and Black (57.5%).
  - MAG had the most beneficiaries (34.6%), followed by UHC (30.7%).
- Table 2:
  - Most beneficiaries were in the eligibility category 'Children 6-19 with income at or below 107% FPL' (56.7%), followed by those in the 'SSI Individual' category.
- Table 3:
  - Most vaccines were administered as part of an Office Visit (56.6%), followed distantly by Rural Health Clinic (14.9%) and State or Local Public Health Clinic (14.2%).
  - The region with the most Tdap/Td vaccinations was Region 6 (14.9%), which includes the Jackson/Metro area, while Region 8 (7.5%) had the least.
- Table 4:
  - Td vaccines made up only 5.3% of all the Tdap/Td vaccines administered. The vast majority of the Td vaccines were administered to beneficiaries ≥ 18 years, which aligns with booster recommendations.

TABLE 1. Characteristics of Beneficiaries Utilizing Tdap/Td Vaccine
Mississippi Medicaid
July 1, 2020 - June 30, 2022

Beneficiary Characteristics		TOTAL		Medicaid Program							
				FFS		UHC		MAG		MOL	
Total		57,725		14,588		17,774		19,954		5,409	
Gender	Female	34,306	59.4%	11,220	76.9%	9,320	52.4%	10,635	53.3%	3,131	57.9%
	Male	23,419	40.6%	3,368	23.1%	8,454	47.6%	9,319	46.7%	2,278	42.1%
Age	0-5	202	0.3%	41	0.3%	53	0.3%	63	0.3%	45	0.8%
	6-11	8,296	14.4%	808	5.5%	3,048	17.1%	3,670	18.4%	770	14.2%
	12-17	29,617	51.3%	3,129	21.4%	11,084	62.4%	12,287	61.6%	3,117	57.6%
	18+	19,610	34.0%	10,610	72.7%	3,589	20.2%	3,934	19.7%	1,477	27.3%
Race[a]	White	20,159	34.9%	6,069	41.6%	6,119	34.4%	6,108	30.6%	1,863	34.4%
	Black	33,201	57.5%	7,485	51.3%	10,143	57.1%	12,424	62.3%	3,149	58.2%
	Amer. Indian	178	0.3%	117	0.8%	15	0.1%	32	0.2%	14	0.3%
	Hispanic	1,880	3.3%	205	1.4%	801	4.5%	730	3.7%	144	2.7%
	Other	2,303	4.0%	709	4.9%	696	3.9%	660	3.3%	238	4.4%

Note: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina
a) beneficiaries missing race variable = 4. (N=57,721)

TABLE 2. Utilization of Tdap/Td Vaccines Among Beneficiaries by Categories of Eligibility

Mississippi Medicaid

July 1, 2020 - June 30, 2022

Beneficiary COE	Total[a]		Pharmacy		Medical							
					Total		Vaccine		Vaccine and Admin		Admin	
TOTAL	53,000		867		52,133		4,336		46,707		1,090	
SSI Individual via SDX	6,407	12.09%	244	28.14%	6,163	11.82%	582	13.42%	5,514	11.81%	67	6.15%
SSI Retro Eligibility	1	0.00%	0	0.00%	1	0.00%	0	0.00%	1	0.00%	0	0.00%
IV-E Foster Care/Adoption Assistance related	703	1.33%	5	0.58%	698	1.34%	23	0.53%	661	1.42%	14	1.28%
SSI in Institution Full Medicaid Benefits	54	0.10%	0	0.00%	54	0.10%	2	0.05%	51	0.11%	1	0.09%
Protected Foster Care	98	0.18%	1	0.12%	97	0.19%	4	0.09%	92	0.20%	1	0.09%
Nursing Home, under 300% FPL	7	0.01%	0	0.00%	7	0.01%	1	0.02%	6	0.01%	0	0.00%
NH, Eligible at Home	8	0.02%	0	0.00%	8	0.02%	0	0.00%	8	0.02%	0	0.00%
Disabled Child at Home	80	0.15%	1	0.12%	79	0.15%	2	0.05%	75	0.16%	2	0.18%
Working Disabled	20	0.04%	1	0.12%	19	0.04%	3	0.07%	16	0.03%	0	0.00%
CWS Foster Care/Adoption Assistance Child	394	0.74%	0	0.00%	394	0.76%	19	0.44%	365	0.78%	10	0.92%
Breast/Cervical	7	0.01%	0	0.00%	7	0.01%	1	0.02%	6	0.01%	0	0.00%
Family Planning	913	1.72%	28	3.23%	885	1.70%	211	4.87%	670	1.43%	4	0.37%
Qualified Medicare Beneficiary (QMB)	130	0.25%	0	0.00%	130	0.25%	23	0.53%	107	0.23%	0	0.00%
Healthier MS Waiver Only (No Medicare)	171	0.32%	11	1.27%	160	0.31%	20	0.46%	140	0.30%	0	0.00%
Specified Low-Income	47	0.09%	0	0.00%	47	0.09%	13	0.30%	34	0.07%	0	0.00%
Qualified Individual (QI-1)	23	0.04%	0	0.00%	23	0.04%	3	0.07%	20	0.04%	0	0.00%
HCBS Elderly/Disabled Waiver	25	0.05%	0	0.00%	25	0.05%	2	0.05%	23	0.05%	0	0.00%
HCBS ID/DD Waiver	1	0.00%	0	0.00%	1	0.00%	0	0.00%	1	0.00%	0	0.00%
HCBS Independent Living Waiver	1	0.00%	0	0.00%	1	0.00%	1	0.02%	0	0.00%	0	0.00%
TBI/SCI Waiver (Traumatic Brain Injury/Spinal Cord Injury)	2	0.00%	0	0.00%	2	0.00%	2	0.05%	0	0.00%	0	0.00%
Newborns age 0-1 with income at or below 194% FPL	68	0.13%	0	0.00%	68	0.13%	2	0.05%	66	0.14%	0	0.00%
Children 1-5 with income at or below 143% FPL	125	0.24%	0	0.00%	125	0.24%	11	0.25%	106	0.23%	8	0.73%
Children 6 - 19 with income at or below 107% FPL	30,038	56.68%	113	13.03%	29,925	57.40%	1,364	31.46%	27,712	59.33%	849	77.89%
Quasi-CHIP - children age 6-19 with income between 107% and 133% FPL who would have qualified for CHIP under per-ACA rules	4,660	8.79%	31	3.58%	4,629	8.88%	197	4.54%	4,310	9.23%	122	11.19%
Parents/Caretakers of children under the age 18 (EFFECTIVE: 1/1/2014)	4,409	8.32%	234	26.99%	4,175	8.01%	700	16.14%	3,467	7.42%	8	0.73%
Pregnant Women under 194%	4,604	8.69%	198	22.84%	4,406	8.45%	1,150	26.52%	3,252	6.96%	4	0.37%
Disabled Adult Child-DAC Full Medicaid Benefits	2	0.00%	0	0.00%	2	0.00%	0	0.00%	2	0.00%	0	0.00%
Widow(er) 50+yrs	2	0.00%	0	0.00%	2	0.00%	0	0.00%	2	0.00%	0	0.00%

Note: COE - Categories of Eligibility; FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina

a) beneficiaries missing COE = 4,725

TABLE 3. Trends in Utilization of Tdap/Td Vaccine Among Beneficiaries

Mississippi Medicaid

July 1, 2020 - June 30, 2022

Beneficiary COE		TOTAL		Pharmacy		Medical[d]							
						Total		Vaccine		Vaccine and Admin		Admin	
		57,725		1,029		56,696		5,111		50,358		1,227	
Gender	Female	34,306	59.4%	843	81.9%	33,463	59.0%	3,932	76.9%	28,924	57.4%	607	49.5%
	Male	23,419	40.6%	186	18.1%	23,233	41.0%	1,179	23.1%	21,434	42.6%	620	50.5%
Age	0-5	202	0.3%	0	0.0%	202	0.4%	16	0.3%	182	0.4%	4	0.3%
	6-11	8,296	14.4%	3	0.3%	8,293	14.6%	195	3.8%	7,990	15.9%	108	8.8%
	12-17	29,617	51.3%	133	12.9%	29,484	52.0%	1,261	24.7%	27,156	53.9%	1,067	87.0%
	18+	19,610	34.0%	893	86.8%	18,717	33.0%	3,639	71.2%	15,030	29.8%	48	3.9%
Race[a]	White	20,159	34.9%	489	47.5%	19,670	34.7%	1,942	38.0%	17,267	34.3%	461	37.6%
	Black	33,201	57.5%	453	44.0%	32,748	57.8%	2,858	55.9%	29,242	58.1%	648	52.8%
	Amer. Indian	178	0.3%	3	0.3%	175	0.3%	37	0.7%	137	0.3%	1	0.1%
	Hispanic	1,880	3.3%	12	1.2%	1,868	3.3%	74	1.4%	1,726	3.4%	68	5.5%
	Other	2,303	4.0%	72	7.0%	2,231	3.9%	200	3.9%	1,982	3.9%	49	4.0%
Plan	FFS	14,588	25.3%	475	46.2%	14,113	24.9%	2,463	48.2%	11,405	22.6%	245	20.0%
	UHC	17,774	30.8%	210	20.4%	17,564	31.0%	1,034	20.2%	15,873	31.5%	657	53.5%
	MAG	19,954	34.6%	294	28.6%	19,660	34.7%	1,234	24.1%	18,386	36.5%	40	3.3%
	MOL	5,409	9.4%	50	4.9%	5,359	9.5%	380	7.4%	4,694	9.3%	285	23.2%
Place of Service[b]	Pharmacy	1,030	2.1%	1029	100.0%	1	0.0%	1	0.0%	0	0.0%	0	0.0%
	Telehealth	9	0.0%	0	0.0%	9	0.0%	1	0.0%	8	0.0%	0	0.0%
	School	3	0.0%	0	0.0%	3	0.0%	0	0.0%	3	0.0%	0	0.0%
	Prison/Correctional Facility	1	0.0%	0	0.0%	1	0.0%	0	0.0%	1	0.0%	0	0.0%
	Office Visit	28,587	58.6%	0	0.0%	28,587	59.9%	2,655	62.9%	25,815	61.0%	117	9.8%
	Home	1	0.0%	0	0.0%	1	0.0%	0	0.0%	1	0.0%	0	0.0%
	Assisted Living Facility	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Group Home	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Mobile Unit	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Temporary Lodging	1	0.0%	0	0.0%	1	0.0%	0	0.0%	0	0.0%	0	0.0%
	Off Campus - Outpatient Hospital	103	0.2%	0	0.0%	103	0.2%	4	0.1%	99	0.2%	0	0.0%
	Urgent Care Facility	236	0.5%	0	0.0%	236	0.5%	15	0.4%	221	0.5%	0	0.0%
	Inpatient Hospital	4	0.0%	0	0.0%	4	0.0%	3	0.1%	1	0.0%	0	0.0%
	Outpatient Hospital	789	1.6%	0	0.0%	789	1.7%	13	0.3%	755	1.8%	21	1.8%
	Emergency Room – Hospital	1	0.0%	0	0.0%	1	0.0%	0	0.0%	1	0.0%	0	0.0%
	Federal Qualified Health Center	3,797	7.8%	0	0.0%	3,797	8.0%	404	9.6%	3,388	8.0%	5	0.4%
	State or Local Public Health Clinic	6,946	14.2%	0	0.0%	6,946	14.5%	10	0.2%	5,912	14.0%	1,024	85.5%
	Rural Health Clinic	7,276	14.9%	0	0.0%	7,276	15.2%	1,114	26.4%	6,132	14.5%	30	2.5%
	Independent Laboratory	1	0.0%	0	0.0%	1	0.0%	0	0.0%	1	0.0%	0	0.0%
	Other	1	0.0%	0	0.0%	1	0.0%	0	0.0%	1	0.0%	0	0.0%
Region[c]	1	6,737	11.8%	260	25.4%	6,477	11.6%	522	10.3%	5,719	11.5%	236	19.5%
	2	7,068	12.4%	130	12.7%	6,938	12.4%	511	10.0%	6,199	12.5%	228	18.9%
	3	5,361	9.4%	46	4.5%	5,315	9.5%	663	13.0%	4,550	9.2%	102	8.4%
	4	5,884	10.3%	94	9.2%	5,790	10.4%	459	9.0%	5,239	10.6%	92	7.6%
	5	5,225	9.2%	74	7.2%	5,151	9.2%	581	11.4%	4,486	9.0%	84	7.0%
	6	8,506	14.9%	141	13.8%	8,365	15.0%	658	12.9%	7,641	15.4%	66	5.5%
	7	7,651	13.4%	80	7.8%	7,571	13.5%	993	19.5%	6,390	12.9%	188	15.6%
	8	4,284	7.5%	66	6.4%	4,218	7.5%	371	7.3%	3,777	7.6%	70	5.8%
	9	6,233	10.9%	133	13.0%	6,100	10.9%	328	6.4%	5,630	11.3%	142	11.8%

Note: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina

a) beneficiaries missing race category = 4 (N=57,721)

b) beneficiaries missing place of service = 8,939 (N=48,786)

c) beneficiaries missing region = 776 (N=56,949)

d) Under medical events:

beneficiaries missing race category = 4. (N=56,692)

beneficiaries missing place of service = 8,939 (N=47,757)

beneficiaries missing region = 771 (N=55,925)

TABLE 4. Trends in Utilization of Tdap/TD Vaccines Among Beneficiaries by Vaccine Type
Mississippi Medicaid
July 1, 2020 - June 30, 2022

Beneficiary COE		Total		Vaccine Type*			
				TDAP		TD	
TOTAL		57,725		53,497		3,001	
Gender	Female	34,306	59.4%	32,017	59.8%	1,682	56.0%
	Male	23,419	40.6%	21,480	40.2%	1,319	44.0%
Age	0-5	202	0.3%	195	0.4%	3	0.1%
	6-11	8,296	14.4%	8,116	15.2%	72	2.4%
	12-17	29,617	51.3%	28,248	52.8%	302	10.1%
	18+	19,610	34.0%	16,938	31.7%	2,624	87.4%
Race[a]	White	20,159	34.9%	18,495	34.6%	1,203	40.1%
	Black	33,201	57.5%	31,025	58.0%	1,528	50.9%
	Amer. Indian	178	0.3%	164	0.3%	13	0.4%
	Hispanic	1,880	3.3%	1,784	3.3%	28	0.9%
	Other	2,303	4.0%	2,025	3.8%	229	7.6%
Plan	FFS	14,588	25.3%	13,280	24.8%	1,063	35.4%
	UHC	17,774	30.8%	16,286	30.4%	831	27.7%
	MAG	19,954	34.6%	19,068	35.6%	846	28.2%
	MOL	5,409	9.4%	4,863	9.1%	261	8.7%
Place of Service[b]	Pharmacy	1,030	2.1%	1	0.0%	0	0.0%
	Telehealth	9	0.0%	9	0.0%	0	0.0%
	School	3	0.0%	3	0.0%	0	0.0%
	Prison/Correctional Facility	1	0.0%	1	0.0%	0	0.0%
	Office Visit	28,587	58.6%	28,026	61.1%	444	61.7%
	Home	1	0.0%	1	0.0%	0	0.0%
	Assisted Living Facility	0	0.0%	0	0.0%	0	0.0%
	Group Home	0	0.0%	0	0.0%	0	0.0%
	Mobile Unit	0	0.0%	0	0.0%	0	0.0%
	Temporary Lodging	1	0.0%	1	0.0%	0	0.0%
	Off Campus - Outpatient Hospital	103	0.2%	103	0.2%	0	0.0%
	Urgent Care Facility	236	0.5%	124	0.3%	112	15.6%
	Inpatient Hospital	4	0.0%	4	0.0%	0	0.0%
	Outpatient Hospital	789	1.6%	768	1.7%	0	0.0%
	Emergency Room – Hospital	1	0.0%	1	0.0%	0	0.0%
	Federal Qualified Health Center	3,797	7.8%	3,753	8.2%	39	5.4%
	State or Local Public Health Clinic	6,946	14.2%	5,899	12.9%	23	3.2%
	Rural Health Clinic	7,276	14.9%	7,144	15.6%	102	14.2%
	Independent Laboratory	1	0.0%	1	0.0%	0	0.0%
	Other	1	0.0%	1	0.0%	0	0.0%
Region[c]	1	6,737	11.8%	6,312	12.0%	189	6.3%
	2	7,068	12.4%	6,654	12.6%	186	6.2%
	3	5,361	9.4%	5,111	9.7%	148	5.0%
	4	5,884	10.3%	5,564	10.5%	228	7.6%
	5	5,225	9.2%	4793	9.1%	348	11.6%
	6	8,506	14.9%	7,628	14.5%	812	27.2%
	7	7,651	13.4%	6,967	13.2%	496	16.6%
	8	4,284	7.5%	3,998	7.6%	216	7.2%
	9	6,233	10.9%	5,725	10.9%	366	12.2%

Note:
*1227 events with only admin code - unable to determine vaccine type (N= 56,498)
a) beneficiaries missing race category = 4 (N=57,721)
b) beneficiaries missing place of service = 8,939 (N=48,786)
c) beneficiaries missing region = 776 (N=56,949)

Meningococcal Vaccines:

A total of 42,515 beneficiaries received a meningococcal vaccine between July 1, 2020 and June 30, 2021.

(Tables 5-8)

- Table 5:
  - Most beneficiaries were female (50.8%), ages 12-17 (74.9%), and Black (64.6%).
  - MAG had most of the beneficiaries (40.7%), followed by UHC (36.3%).
- Table 6:
  - The vast majority of meningococcal vaccines were administered to beneficiaries in the 'Children 6-19 with income at or below 107% FPL' eligibility category (75.9%).
- Table 7:
  - Most vaccines were administered as part of an Office Visit (58.6%), followed by Rural Health Clinic (15.9%), Federal Qualified Health Center (11.6%), and State or Local Public Health Clinic (10.1%).
  - Region 6 (18.9%) and Region 2 (15.8%) had the most meningococcal vaccinations while Region 8 (7.8%) had the least.
- Table 8:
  - MenACWY accounted for 84.1% of all meningococcal vaccines administered while MenB accounted for 15.9%.

TABLE 5. Characteristics of Beneficiaries Utilizing Meningococcal Vaccines
Mississippi Medicaid
July 1, 2020 - June 30, 2022

Beneficiary Characteristics		TOTAL		Medicaid Program							
				FFS		UHC		MAG		MOL	
Total		42,515		4,666		15,453		17,300		5,096	
Gender	Female	21,613	50.8%	2,313	49.6%	7,788	50.4%	8,866	51.2%	2,646	51.9%
	Male	20,902	49.2%	2,353	50.4%	7,665	49.6%	8,434	48.8%	2,450	48.1%
Age	0-5	315	0.7%	151	3.2%	55	0.4%	54	0.3%	55	1.1%
	6-11	6,675	15.7%	598	12.8%	2,416	15.6%	2,923	16.9%	738	14.5%
	12-17	31,849	74.9%	3,320	71.2%	11,633	75.3%	12,940	74.8%	3,956	77.6%
	18+	3,676	8.6%	597	12.8%	1,349	8.7%	1,383	8.0%	347	6.8%
Race[a]	White	11,225	26.4%	1,363	29.2%	4,233	27.4%	4,237	24.5%	1,392	27.3%
	Black	27,473	64.6%	2,753	59.0%	9,664	62.5%	11,772	68.0%	3,284	64.4%
	Amer. Indian	155	0.4%	84	1.8%	21	0.1%	32	0.2%	18	0.4%
	Hispanic	2,130	5.0%	141	3.0%	971	6.3%	829	4.8%	189	3.7%
	Other	1,529	3.6%	322	6.9%	564	3.6%	430	2.5%	213	4.2%

Note: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina
a) beneficiaries missing race variable = 3 (N=42,512)

TABLE 6. Utilization of Meningococcal Vaccines Among Beneficiaries by Categories of Eligibility

Mississippi Medicaid

July 1, 2020 - June 30, 2022

Beneficiary COE	TOTAL[a]		Pharmacy		Medical								Vaccine Type[b]			
					Total		Vaccine		Vaccine and Admin		Admin		MenACWY		MenB	
TOTAL	40,652		43		40,609		1,370		38,975		264		33,889		6,499	
SSI Individual via SDX	3,306	8.1%	9	20.9%	3,297	8.1%	159	11.6%	3,114	8.0%	24	9.1%	2,633	7.8%	649	10.0%
IV-E Foster Care/Adoption Assistance related	715	1.8%	0	0.0%	715	1.8%	22	1.6%	686	1.8%	7	2.7%	611	1.8%	97	1.5%
SSI in Institution Full Medicaid Benefits	16	0.0%	0	0.0%	16	0.0%	0	0.0%	16	0.0%	0	0.0%	15	0.0%	1	0.0%
NH, Eligible at Home	1	0.0%	0	0.0%	1	0.0%	0	0.0%	1	0.0%	0	0.0%	1	0.0%	0	0.0%
Disabled Child at Home	90	0.2%	0	0.0%	90	0.2%	3	0.2%	84	0.2%	3	1.1%	73	0.2%	14	0.2%
Working Disabled	2	0.0%	0	0.0%	2	0.0%	1	0.1%	1	0.0%	0	0.0%	1	0.0%	1	0.0%
CWS Foster Care/Adoption Assistance Child	460	1.1%	0	0.0%	460	1.1%	10	0.7%	445	1.1%	5	1.9%	379	1.1%	76	1.2%
Family Planning	16	0.0%	0	0.0%	16	0.0%	1	0.1%	13	0.0%	2	0.8%	11	0.0%	3	0.0%
Qualified Medicare Beneficiary (QMB)	2	0.0%	0	0.0%	2	0.0%	1	0.1%	1	0.0%	0	0.0%	2	0.0%	0	0.0%
Healthier MS Waiver Only (No Medicare)	7	0.0%	1	2.3%	6	0.0%	0	0.0%	5	0.0%	1	0.4%	6	0.0%	0	0.0%
HCBS ID/DD Waiver	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
HCBS Independent Living Waiver	1	0.0%	0	0.0%	1	0.0%	0	0.0%	1	0.0%	0	0.0%	0	0.0%	1	0.0%
Newborns age 0-1 with income at or below 194% FPL	67	0.2%	0	0.0%	67	0.2%	4	0.3%	60	0.2%	3	1.1%	64	0.2%	0	0.0%
Children 1-5 with income at or below 143% FPL	92	0.2%	0	0.0%	92	0.2%	7	0.5%	83	0.2%	2	0.8%	86	0.3%	4	0.1%
Children 6 - 19 with income at or below 107% FPL	30,835	75.9%	24	55.8%	30,811	75.9%	992	72.4%	29,639	76.0%	180	68.2%	25,877	76.4%	4,778	73.5%
Quasi-CHIP - children age 6-19 with income between 107% and 133% FPL who would have qualified for CHIP under per-ACA rules	5,005	12.3%	4	9.3%	5,001	12.3%	170	12.4%	4,796	12.3%	35	13.3%	4,105	12.1%	865	13.3%
Parents/Caretakers of children under the age 18 (EFFECTIVE: 1/1/2014)	23	0.1%	3	7.0%	20	0.0%	0	0.0%	19	0.0%	1	0.4%	14	0.0%	8	0.1%
Pregnant Women under 194%	14	0.0%	2	4.7%	12	0.0%	0	0.0%	11	0.0%	1	0.4%	11	0.0%	2	0.0%

Note: COE - Categories of Eligibility; FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina

a) beneficiaries missing COE = 1,863

b) 264 events with only admin code - unable to determine vaccine type (N=40,388)

TABLE 7. Trends in Utilization of Meningococcal Vaccines among Beneficiaries
Mississippi Medicaid
July 1, 2020 - June 30, 2022

Beneficiary COE		TOTAL		Pharmacy		Medical[d]							
						Total		Vaccine		Vaccine and Admin		Admin	
TOTAL		42,515		46		42,469		1,433		40,684		352	
Gender	Female	21,613	50.8%	30	65.2%	21,583	50.8%	733	51.2%	20,673	50.8%	177	50.3%
	Male	20,902	49.2%	16	34.8%	20,886	49.2%	700	48.8%	20,011	49.2%	175	49.7%
Age	0-5	315	0.7%	0	0.0%	315	0.7%	19	1.3%	225	0.6%	71	20.2%
	6-11	6,675	15.7%	0	0.0%	6,675	15.7%	140	9.8%	6,490	16.0%	45	12.8%
	12-17	31,849	74.9%	3	6.5%	31,846	75.0%	1,119	78.1%	30,530	75.0%	197	56.0%
	18+	3,676	8.6%	43	93.5%	3,633	8.6%	155	10.8%	3,439	8.5%	39	11.1%
Race[a]	White	11,225	26.4%	11	23.9%	11,214	26.4%	303	21.1%	10,796	26.5%	115	32.7%
	Black	27,473	64.6%	27	58.7%	27,446	64.6%	989	69.0%	26,245	64.5%	212	60.2%
	Amer. Indian	155	0.4%	0	0.0%	155	0.4%	43	3.0%	112	0.3%	0	0.0%
	Hispanic	2,130	5.0%	3	6.5%	2,127	5.0%	55	3.8%	2,065	5.1%	7	2.0%
	Other	1,529	3.6%	5	10.9%	1,524	3.6%	43	3.0%	1,463	3.6%	18	5.1%
Plan	FFS	4,666	11.0%	13	28.3%	4,653	11.0%	186	13.0%	4,330	10.6%	137	38.9%
	UHC	15,453	36.3%	9	19.6%	15,444	36.4%	496	34.6%	14,775	36.3%	173	49.1%
	MAG	17,300	40.7%	22	47.8%	17,278	40.7%	571	39.8%	16,699	41.0%	8	2.3%
	MOL	5,096	12.0%	2	4.3%	5,094	12.0%	180	12.6%	4,880	12.0%	34	9.7%
Place of Service[b]	Pharmacy	46	0.1%	46	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
	Telehealth	10	0.0%	0	0.0%	10	0.0%	2	0.1%	8	0.0%	0	0.0%
	School	3	0.0%	0	0.0%	3	0.0%	0	0.0%	3	0.0%	0	0.0%
	Prison/Correctional Facility	1	0.0%	0	0.0%	1	0.0%	0	0.0%	1	0.0%	0	0.0%
	Office Visit	24,695	58.6%	0	0.0%	24,695	58.7%	191	14.1%	24,332	60.3%	172	49.7%
	Home	1	0.0%	0	0.0%	1	0.0%	0	0.0%	1	0.0%	0	0.0%
	Off Campus - Outpatient Hospital	136	0.3%	0	0.0%	136	0.3%	11	0.8%	125	0.3%	0	0.0%
	Inpatient Hospital	3	0.0%	0	0.0%	3	0.0%	0	0.0%	3	0.0%	0	0.0%
	Outpatient Hospital	1,383	3.3%	0	0.0%	1,383	3.3%	48	3.5%	1,322	3.3%	13	3.8%
	Federal Qualified Health Center	4,903	11.6%	0	0.0%	4,903	11.7%	317	23.4%	4,582	11.4%	4	1.2%
	State or Local Public Health Clinic	4,248	10.1%	0	0.0%	4,248	10.1%	8	0.6%	4,103	10.2%	137	39.6%
	Rural Health Clinic	6,689	15.9%	0	0.0%	6,689	15.9%	780	57.5%	5,889	14.6%	20	5.8%
Region[c]	1	2,406	5.8%	2	4.3%	2,404	5.8%	169	11.9%	2,208	5.5%	27	7.9%
	2	6,606	15.8%	7	15.2%	6,599	15.8%	172	12.1%	6,390	16.0%	37	10.8%
	3	3,424	8.2%	5	10.9%	3,419	8.2%	77	5.4%	3,325	8.3%	17	5.0%
	4	4,115	9.9%	4	8.7%	4,111	9.9%	276	19.5%	3,811	9.5%	24	7.0%
	5	4,518	10.8%	3	6.5%	4,515	10.8%	416	29.3%	4,083	10.2%	16	4.7%
	6	7,888	18.9%	11	23.9%	7877	18.9%	157	11.1%	7,646	19.2%	74	21.6%
	7	4,382	10.5%	4	8.7%	4,378	10.5%	32	2.3%	4,317	10.8%	29	8.5%
	8	3,264	7.8%	2	4.3%	3,262	7.8%	69	4.9%	3,178	8.0%	15	4.4%
	9	5,125	12.3%	8	17.4%	5,117	12.3%	50	3.5%	4,963	12.4%	104	30.3%

Note: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina
a) beneficiaries missing race category = 3 (N=42,512)
b) beneficiaries missing place of service = 397 (N=42,118)
c) beneficiaries missing region = 787 (N=41,728)
d) Under medical events:
beneficiaries missing race category = 3 (N=42,466)
beneficiaries missing place of service = 397 (N=42,072)
beneficiaries missing region = 787 (N=41,682)

TABLE 8. Trends in Utilization of Meningococcal Vaccines Among Beneficiaries by Vaccine Type
Mississippi Medicaid
July 1, 2020 - June 30, 2022

Beneficiary COE		Total		Vaccine Type*			
				MenACWY		MenB	
TOTAL		42,515		35,468		6,695	
Gender	Female	21,613	50.8%	18,044	50.9%	3,392	50.7%
	Male	20,902	49.2%	17,424	49.1%	3,303	49.3%
Age	0-5	315	0.7%	237	0.7%	7	0.1%
	6-11	6,675	15.7%	6,563	18.5%	67	1.0%
	12-17	31,849	74.9%	27,008	76.1%	4,644	69.4%
	18+	3,676	8.6%	1,660	4.7%	1,977	29.5%
Race[a]	White	11,225	26.4%	9,787	27.6%	1,323	19.8%
	Black	27,473	64.6%	22,552	63.6%	4,709	70.3%
	Amer. Indian	155	0.4%	132	0.4%	23	0.3%
	Hispanic	2,130	5.0%	1,744	4.9%	379	5.7%
	Other	1,529	3.6%	1,250	3.5%	261	3.9%
Plan	FFS	4,666	11.0%	3,801	10.7%	728	10.9%
	UHC	15,453	36.3%	12,796	36.1%	2,484	37.1%
	MAG	17,300	40.7%	14,458	40.8%	2,834	42.3%
	MOL	5,096	12.0%	4,413	12.4%	649	9.7%
Place of Service[b]	Pharmacy	46	0.1%	37	0.1%	9	0.1%
	Telehealth	10	0.0%	10	0.0%	0	0.0%
	School	3	0.0%	3	0.0%	0	0.0%
	Prison/Correctional Facility	1	0.0%	1	0.0%	0	0.0%
	Office Visit	24,695	58.6%	20,288	57.6%	4,235	64.7%
	Home	1	0.0%	1	0.0%	0	0.0%
	Off Campus - Outpatient Hospital	136	0.3%	95	0.3%	41	0.6%
	Inpatient Hospital	3	0.0%	1	0.0%	2	0.0%
	Outpatient Hospital	1,383	3.3%	1,111	3.2%	259	4.0%
	Federal Qualified Health Center	4,903	11.6%	3,454	9.8%	1,445	22.1%
	State or Local Public Health Clinic	4,248	10.1%	4,111	11.7%	0	0.0%
	Rural Health Clinic	6,689	15.9%	6,119	17.4%	550	8.4%
Region[c]	1	2,406	5.8%	2,264	6.5%	115	1.7%
	2	6,606	15.8%	5,189	14.9%	1,380	21.0%
	3	3,424	8.2%	3,201	9.2%	206	3.1%
	4	4,115	9.9%	3,524	10.1%	567	8.6%
	5	4,518	10.8%	3,892	11.2%	610	9.3%
	6	7,888	18.9%	5671	16.3%	2,143	32.6%
	7	4,382	10.5%	3,789	10.9%	564	8.6%
	8	3,264	7.8%	2,682	7.7%	567	8.6%
	9	5,125	12.3%	4,595	13.2%	426	6.5%

Note:
*352 events with only admin code - unable to determine vaccine type (N= 42,163)
a) beneficiaries missing race category = 3 (N=42,512)
b) beneficiaries missing place of service = 397 (N=42,118)
c) beneficiaries missing region = 787 (N=41,728)

HPV Vaccine:

A total of 47,395 beneficiaries received HPV vaccines between July 1, 2020 and June 30, 2022. (Tables 9-12)

- Table 9:
  - Most beneficiaries that received the HPV vaccine were female (51.6%), ages 12-17 years (80.1%), and Black (64.0%).
  - MAG had the most beneficiaries (41%), followed by UHC (35.7%).
- Table 10:
  - The vast majority of HPV vaccines were administered to beneficiaries in the 'Children 6-19 with income at or below 107% FPL' eligibility category (76.3%).
- Table 11:
  - Most vaccines were administered as part of an Office Visit (58.9%), followed by Rural Health Clinic (16.7%), State or Local Public Health Clinic (11.4%), and Federal Qualified Health Center (10.0%).
  - Region 6 (17.0%) had the most vaccinations, followed by Region 2 (14.5%), while Region 1 (7.1%) and Region 8 (7.1%) had the least.
- Table 12:
  - A total of 25,359 beneficiaries initiated the HPV vaccine between July 1, 2020 and June 30, 2021 and had 12 months follow-up after the initial dose.
  - Of those that initiated the HPV vaccine, 41.6% completed the series within 12 months which is higher than the 32.7% completion rate reported by the CDC for Mississippi.[11] This completion rate is also higher than the completion rate reported in the December 2019 DUR Board Report.[33]
  - HPV completion rates were highest for beneficiaries less than 15 years of age (47.9%), Hispanic (48.8%), and enrolled in MAG (43.8%) and UHC (43.0%).
  - There was very little difference in the completion rate for females (42.0%) versus males (41.1%).

TABLE 9. Characteristics of Beneficiaries Utilizing HPV Vaccine
Mississippi Medicaid
July 1, 2020 - June 30, 2022

Beneficiary Characteristics		TOTAL		Medicaid Program							
				FFS		UHC		MAG		MOL	
Total		47,395		5,146		16,908		19,421		5,920	
Gender	Female	24,460	51.6%	2,807	54.5%	8,598	50.9%	9,927	51.1%	3,128	52.8%
	Male	22,935	48.4%	2,339	45.5%	8,310	49.1%	9,494	48.9%	2,792	47.2%
Age	0-5	35	0.1%	15	0.3%	9	0.1%	2	0.0%	9	0.2%
	6-11	7,402	15.6%	629	12.2%	2,671	15.8%	3,220	16.6%	882	14.9%
	12-17	37,944	80.1%	3,903	75.8%	13,635	80.6%	15,595	80.3%	4,811	81.3%
	18+	2,014	4.2%	599	11.6%	593	3.5%	604	3.1%	218	3.7%
Race[a]	White	12,678	26.7%	1,577	30.6%	4,663	27.6%	4,804	24.7%	1,634	27.6%
	Black	30,350	64.0%	2,985	58.0%	10,473	61.9%	13,137	67.6%	3,755	63.4%
	Amer. Indian	211	0.4%	116	2.3%	22	0.1%	50	0.3%	23	0.4%
	Hispanic	2,491	5.3%	163	3.2%	1,137	6.7%	955	4.9%	236	4.0%
	Other	1,663	3.5%	303	5.9%	613	3.6%	475	2.4%	272	4.6%

Note: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina
a) beneficiaries missing race variable = 2 (N=47,393)

TABLE 10. Utilization of HPV Vaccine Among Beneficiaries by Categories of Eligibility

Mississippi Medicaid

July 1, 2020 - June 30, 2022

Beneficiary COE	TOTAL[a]		Pharmacy		Medical							
					Total		Vaccine		Vaccine and Admin		Admin	
TOTAL	45,436		73		45,363		1,545		43,259		559	
SSI Individual via SDX	3,248	7.1%	14	19.2%	3,234	7.1%	105	6.8%	3,093	7.1%	36	6.4%
IV-E Foster Care/Adoption Assistance related	790	1.7%	0	0.0%	790	1.7%	26	1.7%	760	1.8%	4	0.7%
SSI in Institution Full Medicaid Benefits	23	0.1%	0	0.0%	23	0.1%	0	0.0%	23	0.1%	0	0.0%
Protected Foster Care	5	0.0%	0	0.0%	5	0.0%	0	0.0%	5	0.0%	0	0.0%
Disabled Child at Home	75	0.2%	0	0.0%	75	0.2%	0	0.0%	74	0.2%	1	0.2%
CWS Foster Care/Adoption Assistance Child	555	1.2%	0	0.0%	555	1.2%	20	1.3%	528	1.2%	7	1.3%
Breast/Cervical	2	0.0%	0	0.0%	2	0.0%	0	0.0%	2	0.0%	0	0.0%
Family Planning	169	0.4%	2	2.7%	167	0.4%	23	1.5%	143	0.3%	1	0.2%
Healthier MS Waiver Only (No Medicare)	5	0.0%	0	0.0%	5	0.0%	0	0.0%	5	0.0%	0	0.0%
HCBS ID/DD Waiver	1	0.0%	0	0.0%	1	0.0%	0	0.0%	1	0.0%	0	0.0%
Newborns age 0-1 with income at or below 194% FPL	8	0.0%	0	0.0%	8	0.0%	0	0.0%	5	0.0%	3	0.5%
Children 1-5 with income at or below 143% FPL	21	0.0%	0	0.0%	21	0.0%	1	0.1%	17	0.0%	3	0.5%
Children 6 - 19 with income at or below 107% FPL	34,670	76.3%	17	23.3%	34,653	76.4%	1,118	72.4%	33,087	76.5%	448	80.1%
Quasi-CHIP - children age 6-19 with income between 107% and 133% FPL who would have qualified for CHIP under per-ACA rules	5,453	12.0%	0	0.0%	5,453	12.0%	184	11.9%	5,214	12.1%	55	9.8%
Parents/Caretakers of children under the age 18 (EFFECTIVE: 1/1/2014)	265	0.6%	31	42.5%	234	0.5%	49	3.2%	184	0.4%	1	0.2%
Pregnant Women under 194%	146	0.3%	9	12.3%	137	0.3%	19	1.2%	118	0.3%	0	0.0%

Note: COE - Categories of Eligibility; FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina

a) beneficiaries missing COE = 1,959

TABLE 11. Trends in Utilization of HPV Vaccine Among Beneficiaries

Mississippi Medicaid

July 1, 2020 - June 30, 2022

Beneficiary COE		TOTAL		Pharmacy		Medical[d]							
						Total		Vaccine		Vaccine and Admin		Admin	
		47,395		80		47,315		1,602		45,089		624	
Gender	Female	24,460	51.6%	72	90.0%	24,388	51.54%	893	55.74%	23,170	51.39%	325	52.08%
	Male	22,935	48.4%	8	10.0%	22,927	48.46%	709	44.26%	21,919	48.61%	299	47.92%
Age	0-5	35	0.1%	0	0.0%	35	0.07%	1	0.06%	26	0.06%	8	1.28%
	6-11	7,402	15.6%	0	0.0%	7,402	15.64%	121	7.55%	7,261	16.10%	20	3.21%
	12-17	37,944	80.1%	12	15.0%	37,932	80.17%	1,311	81.84%	36,050	79.95%	571	91.51%
	18+	2,014	4.2%	68	85.0%	1,946	4.11%	169	10.55%	1,752	3.89%	25	4.01%
Race[a]	White	12,678	26.8%	24	30.0%	12,654	26.75%	380	23.72%	12,058	26.74%	216	34.62%
	Black	30,350	64.0%	50	62.5%	30,300	64.04%	1,027	64.11%	28,921	64.14%	352	56.41%
	Amer. Indian	211	0.4%	0	0.0%	211	0.45%	72	4.49%	137	0.30%	2	0.32%
	Hispanic	2,491	5.3%	0	0.0%	2,491	5.26%	74	4.62%	2,386	5.29%	31	4.97%
	Other	1,663	3.5%	6	7.5%	1,657	3.50%	49	3.06%	1,585	3.52%	23	3.69%
Plan	FFS	5,146	10.9%	22	27.5%	5,124	10.83%	241	15.04%	4,767	10.57%	116	18.59%
	UHC	16,908	35.7%	37	46.3%	16,871	35.66%	524	32.71%	16,000	35.49%	347	55.61%
	MAG	19,421	41.0%	13	16.3%	19,408	41.02%	632	39.45%	18,746	41.58%	30	4.81%
	MOL	5,920	12.5%	8	10.0%	5,912	12.49%	205	12.80%	5,576	12.37%	131	20.99%
Place of Service[b]	Pharmacy	80	0.2%	80	100.0%	0	0.00%	0	0.00%	0	0.00%	0	0.00%
	Telehealth	10	0.0%	0	0.0%	10	0.02%	1	0.06%	9	0.02%	0	0.00%
	School	3	0.0%	0	0.0%	3	0.01%	0	0.00%	3	0.01%	0	0.00%
	Prison/Correctional Facility	1	0.0%	0	0.0%	1	0.00%	0	0.00%	1	0.00%	0	0.00%
	Office Visit	27,822	58.9%	0	0.0%	27,822	59.05%	324	20.74%	27,485	61.31%	13	2.09%
	Home	1	0.0%	0	0.0%	1	0.00%	0	0.00%	1	0.00%	0	0.00%
	Temporary Lodging	1	0.0%	0	0.0%	1	0.00%	0	0.00%	1	0.00%	0	0.00%
	Off Campus - Outpatient Hospital	175	0.4%	0	0.0%	175	0.37%	11	0.70%	164	0.37%	0	0.00%
	Outpatient Hospital	1,118	2.4%	0	0.0%	1,118	2.37%	24	1.54%	1,093	2.44%	1	0.16%
	Federal Qualified Health Center	4,740	10.0%	0	0.0%	4,740	10.06%	353	22.60%	4,283	9.55%	4	0.64%
	State or Local Public Health Clinic	5,375	11.4%	0	0.0%	5,375	11.41%	6	0.38%	4,782	10.67%	587	94.22%
	Rural Health Clinic	7,872	16.7%	0	0.0%	7,872	16.71%	843	53.97%	7,011	15.64%	18	2.89%
Region[c]	1	3,305	7.1%	7	8.8%	3,298	7.10%	227	14.40%	2,888	6.52%	183	29.71%
	2	6,764	14.5%	16	20.0%	6,748	14.52%	246	15.61%	6,419	14.50%	83	13.47%
	3	4,338	9.3%	6	7.5%	4,332	9.32%	87	5.52%	4,163	9.40%	82	13.31%
	4	4,624	9.9%	7	8.8%	4,617	9.94%	352	22.34%	4,176	9.43%	89	14.45%
	5	5,004	10.8%	7	8.8%	4,997	10.75%	359	22.78%	4,611	10.42%	27	4.38%
	6	7,907	17.0%	11	13.8%	7,896	16.99%	147	9.33%	7,719	17.44%	30	4.87%
	7	5,396	11.6%	4	5.0%	5,392	11.60%	60	3.81%	5,256	11.87%	76	12.34%
	8	3,312	7.1%	1	1.3%	3,311	7.13%	55	3.49%	3,221	7.28%	35	5.68%
	9	5,894	12.7%	21	26.3%	5,873	12.64%	43	2.73%	5,819	13.14%	11	1.79%

Note: FFS - Fee-for-Service; UHC - UnitedHealthcare; MAG - Magnolia; MOL - Molina

a) beneficiaries missing race category = 2 (N=47,393)

b) beneficiaries missing place of service = 197 (N=47,198)

c) beneficiaries missing region = 851 (N=46,544)

d) Under medical events:

beneficiaries missing race category = 2 (N=47,313)

beneficiaries missing place of service = 197 (N=47,118)

beneficiaries missing region = 851 (N=46,464)

TABLE 4. HPV Vaccine Series Completion Rates Among Initiators
Mississippi Medicaid
July 1, 2020 - June 30, 2021

Beneficiary Characteristics		Initiators		Dose Completion			
				Incomplete		Complete	
Total		**25,359**		**14,817**	**58.4%**	**10,542**	**41.6%**
Gender	**Female**	13,049	51.5%	7,566	58.0%	5,483	42.0%
	Male	12,310	48.5%	7,251	58.9%	5,059	41.1%
Age	**0-14**	21,276	83.9%	11,094	52.1%	10,182	47.9%
	15 +	4,083	16.1%	3,723	91.2%	360	8.8%
Race	**White**	6,817	26.9%	3,913	57.4%	2,904	42.6%
	Black	16,116	63.6%	9,570	59.4%	6,546	40.6%
	Amer. Indian	139	0.5%	90	64.7%	49	35.3%
	Hispanic	1,393	5.5%	713	51.2%	680	48.8%
	Other	894	3.5%	531	59.4%	363	40.6%
Plan	**FFS**	2,143	8.5%	1,461	68.2%	682	31.8%
	UHC	9,325	36.8%	5,319	57.0%	4,006	43.0%
	MAG	10,711	42.2%	6,024	56.2%	4,687	43.8%
	MOL	3180	12.5%	2013	63.3%	1167	36.7%

Note: This table depicts a subset of total HPV events and represents beneficiaries that initiated the HPV vaccine series during the study period and had 12 months follow-up.

CONCLUSIONS

Mississippi has traditionally performed well when it comes to childhood vaccination rates, particularly regarding vaccinations required for school attendance. With vaccinations that are not required for school attendance, Mississippi often lags behind other states. Efforts are ongoing to improve vaccination rates. This report examined trends in Tdap, meningococcal, and HPV vaccinations among Medicaid beneficiaries. Opportunities exist for the further advancement of vaccination rates in our state.

RECOMMENDATIONS

1. DOM is encouraged to consider using this study as evidence to explore possible efforts or policy changes to promote increasing rates for the meningococcal, Tdap, and HPV vaccines.

REFERENCES

1. What Parents Should Know About Childhood Immunizations - Mississippi State Department of Health. Accessed June 9, 2023. http://www.msdh.state.ms.us/msdhsite/_static/14,15556,71.html

2. Vaccine Schedule for Children, 7 to 18 Years Old | CDC. Published February 9, 2023. Accessed May 25, 2023. https://www.cdc.gov/vaccines/schedules/easy-to-read/adolescent-easyread.html

3. Judge: Mississippi Must Give Religious Exemption on Vaccines. Accessed June 9, 2023. https://www.usnews.com/news/health-news/articles/2023-04-18/judge-mississippi-must-give-religious-exemption-on-vaccines

4. Pinkbook: Tetanus | CDC. Published October 19, 2022. Accessed April 19, 2023. https://www.cdc.gov/vaccines/pubs/pinkbook/tetanus.html

5. Broder KR, Cortese MM, Iskander JK, et al. Preventing tetanus, diphtheria, and pertussis among adolescents: use of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccines recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep Morb Mortal Wkly Rep Recomm Rep*. 2006;55(RR-3):1-34.

6. Pinkbook: Diphtheria | CDC. Published October 19, 2022. Accessed April 19, 2023. https://www.cdc.gov/vaccines/pubs/pinkbook/dip.html

7. Havers FP, Moro PL, Hunter P, Hariri S, Bernstein H. Use of Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccines: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2019. *MMWR Morb Mortal Wkly Rep*. 2020;69(3):77-83. doi:10.15585/mmwr.mm6903a5

8. Diphtheria, Tetanus, and Pertussis Vaccine Recommendations | CDC. Published April 26, 2023. Accessed June 9, 2023. https://www.cdc.gov/vaccines/vpd/dtap-tdap-td/hcp/recommendations.html

9. Tdap Vaccine Mandates for Elementary and Secondary Schools. Accessed May 24, 2023. https://www.immunize.org/laws/tdap.asp

10. State School Immunization Requirements and Vaccine Exemption Laws. Published online February 2022. https://www.cdc.gov/phlp/docs/school-vaccinations.pdf

11. Pingali C, Yankey D, Elam-Evans LD, et al. National Vaccination Coverage Among Adolescents Aged 13–17 Years — National Immunization Survey-Teen, United States, 2021. *MMWR Morb Mortal Wkly Rep*. 2022;71(35):1101-1108. doi:10.15585/mmwr.mm7135a1

12. TeenVaxView | Adolescent Vaccine Coverage Interactive Data | NIS | CDC. Published November 14, 2022. Accessed April 20, 2023. https://www.cdc.gov/vaccines/imz-managers/coverage/teenvaxview/data-reports/index.html

13. Pinkbook: Meningococcal Disease | CDC. Published September 21, 2022. Accessed April 20, 2023. https://www.cdc.gov/vaccines/pubs/pinkbook/mening.html

14. Facts on Adolescent Vaccines. National Foundation for Infectious Diseases. Published September 22, 2019. Accessed May 25, 2023. https://www.nfid.org/immunization/what-vaccines-does-my-family-need/facts-on-adolescent-vaccines/

15. Vaccines for Meningococcal | CDC. Published March 28, 2023. Accessed April 20, 2023. https://www.cdc.gov/vaccines/vpd/mening/index.html

16. Folaranmi T, Rubin L, Martin SW, Patel M, MacNeil JR, Centers for Disease Control (CDC). Use of Serogroup B Meningococcal Vaccines in Persons Aged ≥10 Years at Increased Risk for Serogroup B Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices, 2015. *MMWR Morb Mortal Wkly Rep*. 2015;64(22):608-612.

17. Meningococcal Vaccine Recommendations | CDC. Published June 6, 2022. Accessed April 20, 2023. https://www.cdc.gov/vaccines/vpd/mening/hcp/recommendations.html

18. State Mandates on Immunization and Vaccine-Preventable Diseases: MenACWY Vaccine. Accessed May 25, 2023. https://www.immunize.org/laws/menin_sec.asp

19. MenACWY Vaccine Mandates for Colleges and Universities. Accessed May 29, 2023. https://www.immunize.org/laws/menin.asp

20. Alderfer J, Srivastava A, Isturiz R, et al. Concomitant administration of meningococcal vaccines with other vaccines in adolescents and adults: a review of available evidence. *Hum Vaccines Immunother*. 2019;15(9):2205-2216. doi:10.1080/21645515.2019.1581542

21. First vaccine approved by FDA to prevent serogroup B Meningococcal disease. FDA. Published November 3, 2018. Accessed June 5, 2023. https://www.fda.gov/news-events/press-announcements/first-vaccine-approved-fda-prevent-serogroup-b-meningococcal-disease

22. Meningococcal B Vaccine (MenB) Information. Accessed June 5, 2023. https://www.immunize.org/meningococcal-b/

23. Satterwhite CL, Torrone E, Meites E, et al. Sexually Transmitted Infections Among US Women and Men: Prevalence and Incidence Estimates, 2008. *Sex Transm Dis*. 2013;40(3):187-193. doi:10.1097/OLQ.0b013e318286bb53

24. Cancers Associated with Human Papillomavirus (HPV) | CDC. Published October 4, 2022. Accessed June 5, 2023. https://www.cdc.gov/cancer/hpv/basic_info/cancers.htm

25. Viens LJ, Henley SJ, Watson M, et al. Human Papillomavirus–Associated Cancers — United States, 2008–2012. *MMWR Morb Mortal Wkly Rep*. 2016;65(26):661-666. doi:10.15585/mmwr.mm6526a1

26. Drolet M, Perez N, Jit M, Brisson M. Human papillomavirus vaccine effectiveness by number of doses: Systematic review of data from national immunization programs. *Vaccine*. 2018;36(32 Pt A):4806-4815. doi:10.1016/j.vaccine.2018.01.057

27. Markowitz LE, Dunne EF, Saraiya M, et al. Human papillomavirus vaccination: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep Morb Mortal Wkly Rep Recomm Rep*. 2014;63(RR-05):1-30.

28. Joura EA, Giuliano AR, Iversen OE, et al. A 9-Valent HPV Vaccine against Infection and Intraepithelial Neoplasia in Women. *N Engl J Med*. 2015;372(8):711-723. doi:10.1056/NEJMoa1405044

29. Pinkbook | HPV | Epidemiology of Vaccine Preventable Diseases | CDC. Published September 21, 2022. Accessed April 19, 2023. https://www.cdc.gov/vaccines/pubs/pinkbook/hpv.html

30. Immunization Schedules for 18 & Younger. Centers for Disease Control and Prevention. Published April 27, 2023. Accessed June 5, 2023. https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

31. Supplementary Table 2. National Vaccination Coverage Among Adolescents Aged 13–17 Years — National Immunization Survey-Teen, United States, 2021. Accessed June 5, 2023. https://stacks.cdc.gov/view/cdc/120476

32. HPV Vaccine Mandates for Elementary and Secondary Schools. Accessed June 5, 2023. https://www.immunize.org/laws/hpv.asp

33. Drug Utilization Review Board Archive - Mississippi Division of Medicaid. Published April 15, 2014. Accessed June 8, 2023. https://medicaid.ms.gov/drug-utilization-review-board-archive/

Place Holder -

GLP-1 Topics

FDA DRUG SAFETY COMMUNICATIONS

March 2023 – May 2023

- 5/11/2023 - FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions. (see additional information)
- 4/13/2023 - FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use. (see additional information)

FDA Drug Safety Communication

FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions

Serious risks with misuse, abuse, addiction, and sharing these drugs

05-11-2023 FDA Drug Safety Communication

What safety concern is FDA announcing?

To address continuing concerns of misuse, abuse, addiction, and overdose of prescription stimulants, the U.S. Food and Drug Administration (FDA) is requiring updates to the *Boxed Warning* and other information to ensure the prescribing information is made consistent across the entire class of these medicines. The current prescribing information for some prescription stimulants does not provide up to date warnings about the harms of misuse and abuse, and particularly that most individuals who misuse prescription stimulants get their drugs from other family members or peers. Further, individuals who are prescribed stimulants are often faced with requests to share their medication. Sharing these medicines with others can lead to development of substance use disorder and addiction in those with whom these drugs are shared.

Prescription stimulants can be an important treatment option for disorders for which they are indicated. However, even when prescribed to treat an indicated disorder, their use can lead to misuse or abuse. Misuse and abuse, also called nonmedical use, can include taking your own medicine differently than prescribed or using someone else's medicine. For this reason, sharing prescription stimulants with those for whom they are not prescribed is an important concern and a major contributor to nonmedical use and addiction. Misuse and abuse of prescription stimulants can result in overdose and death, and this risk is increased with higher doses or unapproved methods of taking the medicine such as snorting or injecting.

What is FDA doing?

We are requiring the *Boxed Warning*, FDA's most prominent warning, to be updated and we are adding other information to the prescribing information for all prescription stimulants. We are adding information that patients should never share their prescription stimulants with anyone, and the *Boxed Warning* information will describe the risks of misuse, abuse, addiction, and overdose consistently across all medicines in the class. The *Boxed Warning* also will advise heath care professionals to monitor patients closely for signs and symptoms of misuse, abuse, and addiction.

Information on these risks is being required in several sections of the prescribing information, including the *Warnings and Precautions*, *Drug Abuse and Dependence*, *Overdosage*, and *Patient Counseling* sections. We are also requiring updates to the existing patient Medication Guides to help educate patients and caregivers about these risks.

What is a prescription stimulant and how can it help me?

Prescription stimulants are used to treat attention deficit/hyperactivity disorder (ADHD), binge-eating disorder, and uncontrollable episodes of deep sleep called narcolepsy. Prescription stimulants may help decrease impulsivity and hyperactivity, and increase attention in patients with ADHD; help reduce the number of excessive overeating episodes in patients with binge-eating disorder; and help promote wakefulness in patients with narcolepsy. These medicines have benefits when used appropriately, but

they also have serious risks, including the risk of misuse and abuse, addiction, overdose, and death. Examples of common prescription stimulants include Adderall (amphetamine/dextroamphetamine), Concerta (methylphenidate), Dexedrine (dextroamphetamine), and Ritalin (methylphenidate).

What should health care professionals do?
Assess patient risk of misuse, abuse, and addiction before prescribing stimulant medicines. Counsel patients not to share their prescribed stimulant with anyone else. Educate patients and their families on these serious risks, proper storage of the medicine, and proper disposal of any unused medicine. Throughout treatment, regularly assess and monitor them for signs and symptoms of nonmedical use, addiction, and potential diversion, which may be evidenced by more frequent renewal requests than warranted by the prescribed dosage.

What should patients and caregivers do?
Always take your prescription stimulant exactly as prescribed by your health care professional. Do not take more of the medicine or take it more often than prescribed. Never provide any of your prescription stimulant medicine to anyone else as it can have serious risks for those for whom it was not prescribed. Store your prescription stimulant medicines securely, out of sight and reach of children and in a location not accessible by others, including visitors to the home. Immediately dispose of unused or expired prescription stimulants properly or take them to a drug take-back site, location, or program. Talk to your health care professional if your use of prescription stimulants has resulted in problems with your health, relationships, responsibilities, or the law, or if you are struggling with misusing these or other medicines. Go to an emergency room or call 911 if you experience symptoms of stimulant overdose, including new tremors or change in existing tremors, seizures, restless or aggressive behavior, overactive reflexes, fast breathing, fast or irregular pulse rate, confusion, stomach cramps, or more serious symptoms such as heart attack or stroke. Talk to your health care professional if you have questions or concerns about risks of taking prescription stimulants.

What did FDA find?
We reviewed the medical literature published from January 2006 to May 2020 on misuse and abuse, also called nonmedical use, of prescription stimulants and associated adverse events. Overall, the most common source of prescription stimulants for nonmedical use in the general population came from friends or family members, with estimates generally ranging from 56 percent to 80 percent, usually provided for free. Nonmedical use from their own prescription accounted for approximately 10 percent to 20 percent of people who report having used stimulants nonmedically in the past year. Less commonly reported sources included drug dealers or strangers accounting for 4 percent to 7 percent of people who report having used stimulants nonmedically in the past year, and the internet accounting for 1 percent to 2 percent.

Our review found that nonmedical use has remained relatively stable over the past two decades, despite the increasing number of prescription stimulants dispensed. However, the past-year prevalence of nonmedical use of these medicines varies across specific subpopulations and is highest in the following groups: young adults ages 18 to 25 (estimates ranged from 4.1 percent to 7.5 percent), college students (4.3 percent), and adolescents and young adults diagnosed with ADHD (estimates ranged from 14 percent to 32 percent). According to the available data, people who use prescription stimulants for nonmedical reasons have a higher risk of developing a substance use disorder than those who do not. The most serious harms were more commonly observed with nonmedical use by a non-oral route such

as snorting or injecting.

What is my risk?
All medicines have side effects even when used correctly as prescribed. It is important to know that people respond differently to all medicines depending on their health, the diseases they have, genetic factors, other medicines they are taking, and many other factors. As a result, we cannot determine how likely it is that someone will experience these side effects when taking prescription stimulants. However, it is harmful to take prescription stimulants or other medicines in ways other than exactly as prescribed by your health care professional. Talk to your health care professional if you have questions or concerns about the risks of taking prescription stimulant medicines.

How do I report side effects from prescription stimulants?
To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving prescription stimulants or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

How can I get new safety information on medicines I'm prescribing or taking?
You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Table of Prescription Stimulant Label changes
The following tables provide comparisons of the more significant updates FDA is requiring to ensure that the prescribing information concerning the serious risks of misuse, abuse, addiction, and sharing of these medications with those for whom they are not prescribed is consistent across the entire class of prescription stimulant medicines. These updates will align labels with recent labeling language, address diversion and stigmatization, and incorporate recent safety changes.
The "Former" column contains current language, with removals shown by red-lined text. The "New" column shows updated language in **bold in the "New" column** and will be added to the Boxed Warning (Table 1), Warnings and Precautions (Table 2), Drug Abuse and Dependence (Table 3), Overdosage (Table 4), and Patient Counseling Information (Table 5).

*NOTE: There are different versions of the example language across the stimulant class. Other minor updates were incorporated within this action but are not listed below and will be available once the label updates for each product are approved by FDA.

Table 1. Boxed Warning	
Former*	**New**
~~POTENTIAL for~~ ABUSE ~~AND DEPENDENCE~~ ~~CNS stimulants, including~~ [DRUG-X]~~, other amphetamine-containing products, and methylphenidate,~~ have high potential for abuse ~~and dependence~~. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy [see WARNING AND PRECAUTIONS (5.1) and DRUG ABUSE AND DEPENDENCE (9.2, 9.3)].	WARNING: ABUSE**, MISUSE, AND ADDICTION** DRUG-X has a high potential for abuse **and misuse,** which can lead to the development of a substance use disorder, including addiction. **Misuse and abuse of CNS stimulants, including DRUG-X, can result in overdose and death [see Overdosage (10)], and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.** **Before prescribing DRUG-X,** assess each patient's

	risk for abuse**, misuse, and addiction. Educate patients and their families about these risks, proper storage of the drug, and proper disposal of any unused drug. Throughout DRUG-X treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently monitor for signs and symptoms of abuse, misuse, and addiction [see Warnings and Precautions (5.1) and Drug Abuse and Dependence (9.2)].**
Table 2. Warnings and Precautions	
Former*	**New**
~~**Potential for Abuse and Dependence**~~ ~~CNS stimulants, including DRUG-X, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy [see Boxed Warning, Drug Abuse and Dependence (9.2, 9.3)].~~	**Abuse, Misuse, and Addiction** DRUG-X has a high potential for abuse **and misuse. The use of DRUG-X exposes individuals to the risks of abuse and misuse, which can lead to the development of a substance use disorder, including addiction. DRUG-X can be diverted for non-medical use into illicit channels or distribution [see Drug Abuse and Dependence (9.2)]. Misuse and abuse of CNS stimulants, including DRUG-X, can result in overdose and death [see Overdosage (10)], and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.** **Before prescribing DRUG-X,** assess each patient's risk for abuse**, misuse, and addiction. Educate patients and their families about these risks and proper disposal of any unused drug. Advise patients to store DRUG-X in a safe place, preferably locked, and instruct patients to not give DRUG-X to anyone else. Throughout DRUG-X treatment, reassess each patient's risk of abuse, misuse, and addiction and frequently** monitor for signs **and symptoms of** abuse**, misuse, and addiction.**
Table 3. Drug Abuse and Dependence	
Former*	**New**
~~CNS stimulants, including~~ DRUG-X~~, other amphetamines, and methylphenidate-containing products~~ have a high potential for abuse. Abuse is the intentional non-therapeutic use of a drug, even once, to achieve a desired psychological or physiological effect. Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use (e.g., continuing drug use despite harmful consequences, giving a higher priority to drug use than other activities and obligations), and possible tolerance or physical dependence. ~~Both abuse and misuse may lead to addiction, and some individuals may develop addiction even when taking [DRUG-X] as prescribed.~~	DRUG-X has a high potential for abuse **and misuse which can lead to the development of a substance use disorder, including addiction [see Warnings and Precautions (5.1)]. DRUG-X can be diverted for non-medical use into illicit channels or distribution.** Abuse is the intentional non-therapeutic use of a drug, even once, to achieve a desired psychological or physiological effect. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed. Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that may include a strong desire to take the drug, difficulties in controlling drug use (e.g.,

~~Signs and symptoms of CNS stimulant abuse may include increased heart rate, respiratory rate, blood pressure, and/or sweating, dilated pupils, hyperactivity, restlessness, insomnia, decreased appetite, loss of coordination, tremors, flushed skin, vomiting, and/or abdominal pain. Anxiety, psychosis, hostility, aggression, and suicidal or homicidal ideation have also been observed. Individuals who abuse CNS stimulants may chew, snort, inject, or use other unapproved routes of administration, which can result in overdose and death [see OVERDOSAGE (10)].~~ ~~To reduce the abuse of [DRUG-X], assess the risk of abuse prior to prescribing. After prescribing, keep careful prescription records, educate patients and their families about abuse and on proper storage and disposal of CNS stimulants, monitor for signs of abuse while on therapy, and re-evaluate the need for [DRUG-X] use.~~	continuing drug use despite harmful consequences, giving a higher priority to drug use than other activities and obligations), and possible tolerance or physical dependence. **Misuse and abuse of [insert active ingredient] may cause increased** heart rate, respiratory rate, or blood pressure; sweating; dilated pupils; hyperactivity; restlessness; insomnia; decreased appetite; loss of coordination; tremors; flushed skin; vomiting; and/or abdominal pain. Anxiety, psychosis, hostility, aggression, and suicidal or homicidal ideation have also **been observed with CNS stimulants abuse and/or misuse. Misuse and abuse of CNS stimulants, including DRUG-X, can result in overdose and death [see Overdosage (10)], and this risk is increased with higher doses or unapproved methods of administration, such as snorting or injection.**
Physical Dependence [DRUG-X] may produce physical dependence ~~from continued therapy~~. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug. Withdrawal symptoms after abrupt cessation ~~following prolonged high-dosage administration of~~ CNS stimulants include dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.	**Physical Dependence** DRUG-X may produce physical dependence. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug. Withdrawal **signs and symptoms after abrupt discontinuation or dose reduction following prolonged use of CNS stimulants including DRUG-X include** dysphoric mood; depression; fatigue; vivid, unpleasant dreams; insomnia or hypersomnia; increased appetite; and psychomotor retardation or agitation.
Tolerance [DRUG-X] may produce tolerance ~~from continued therapy~~. Tolerance is a physiological state characterized by a reduced response to a drug after repeated administration (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose).	**Tolerance** DRUG-X may produce tolerance. Tolerance is a physiological state characterized by a reduced response to a drug after repeated administration (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose).

Table 4. Overdosage

Former*	**New** (reordered information)
~~Manifestations of amphetamine overdose include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states, hyperpyrexia, and rhabdomyolysis. Fatigue and depression usually follow the central nervous system stimulation. Serotonin syndrome has been reported with amphetamine use.~~	**Clinical Effects of Overdose** **Overdose of CNS stimulants is characterized by the following sympathomimetic effects:** **•Cardiovascular effects including tachyarrhythmias, and hypertension or hypotension. Vasospasm, myocardial infarction, or aortic dissection may precipitate sudden cardiac**

~~Cardiovascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning is usually preceded by convulsions and coma.~~ ~~Remove all transdermal systems immediately and cleanse the area(s) to remove any remaining adhesive. The continuing absorption of dextroamphetamine from the skin, even after removal of the transdermal system, should be considered when treating patients with overdose.~~ Dextroamphetamine is not dialyzable. (*moved to Overdose Management*)	**death. Takotsubo cardiomyopathy may develop.** **•CNS effects including psychomotor agitation, confusion, and hallucinations. Serotonin syndrome, seizures, cerebral vascular accidents, and coma may occur.** **•Life-threatening hyperthermia (temperatures greater than 104°F) and rhabdomyolysis may develop.**
Management of Overdose Consult with ~~a Certified~~ Poison ~~Control Center~~ (1-800-222-1222) ~~for up-to-date guidance and advice on the management of overdosage with methylphenidate~~. ~~Provide supportive care, including close medical supervision and monitoring.~~ Treatment should consist of those general measures employed in the management of overdosage with any drug. Consider the possibility of multiple drug ~~overdosages~~. ~~Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. Use supportive and symptomatic measures. Individual patient response to amphetamines varies widely. Toxic symptoms may occur idiosyncratically at low doses~~.	**Overdose Management** Treatment **for CNS stimulant overdose** should consist of those general measures employed in the management of overdose with any drug. Consider the possibility of multiple drug **ingestion. [[for amphetamines state: D-amphetamine is not dialyzable] [for methylphenidate state: Because methylphenidate has a large volume of distribution and is rapidly metabolized, dialysis is not useful]]**. Consider contacting the Poison **Help line** (1-800-222-1222) **or a medical toxicologist for additional overdose management recommendations**.
~~**Disposal**~~ ~~Comply with local laws and regulations on drug disposal of CNS stimulants. Dispose of remaining, unused, or expired [DRUG-X] by a medicine take-back program or at authorized collector registered with the Drug Enforcement Administration. If no take-back program or authorized collector is available, each unused system should be removed from its individual pouch, separated from the protective liner, folded in half, and disposed of in the same manner as used systems.~~	**(Disposal text removed)**

Table 5. Patient Counseling Information

Former*	**New** (added misuse and diversion information)
Advise the patient to read the FDA-approved patient labeling (Medication Guide). ~~**Controlled Substance Status/High Potential for Abuse and Dependence**~~ ~~Advise patients that [DRUG-X] are controlled substances, and they can be abused and lead to dependence.~~ Instruct patients that they should not give [DRUG-X] to anyone else. Advise patients to store	Advise the patient to read the FDA-approved patient labeling (Medication Guide). Abuse**, Misuse, and Addiction** Educate patients and their families about the risks of abuse, misuse, and addiction **of DRUG-X, which can lead to overdose and death,** and proper disposal of any unused drug [see Warnings and Precautions (5.1), Drug Abuse and Dependence (9.2)**, and Overdosage**

[DRUG-X] in a safe place, preferably locked~~, to prevent abuse. Advise patients to comply with laws and regulations on drug disposal. Advise patients to dispose of remaining, unused, or expired [DRUG-X] by a medicine take-back program if available [see Boxed Warning, Warnings and Precautions (5.1), Drug Abuse and Dependence (9.1, 9.2, 9.3), How Supplied/Storage and Handling (16)].~~	**(10)**]. Advise patients to store DRUG-X in a safe place, preferably locked, **and instruct patients to not give DRUG-X to anyone else**.

NOTE: FDA defines *misuse* as the intentional use, for therapeutic purposes, of a drug in a manner other than as prescribed or by an individual for whom it was not prescribed. FDA defines *abuse* as the intentional, nontherapeutic use of a drug for its desirable psychological or physiological effects. The term *abuse* is used in this document to describe a specific behavior that confers a risk of adverse health outcomes; it is not intended to imply moral judgment. FDA is committed to reducing stigma, expanding therapeutic options, and ensuring access to evidence-based treatment for individuals with substance use disorders.

Facts about Prescription Stimulants

- Prescription stimulants can help patients: with ADHD stay focused longer, listen better, and fidget less; with a binge-eating disorder, reduce the number of excessive overeating episodes; and with narcolepsy, stay awake during the day.
- Prescription stimulants also carry serious risks, including misuse and abuse, substance abuse disorder and addiction, overdose, and death.
- There are two main categories of prescription stimulants: immediate-release and extended-release. Immediate-release stimulants are usually taken two or three times a day, and extended-release stimulants are taken once a day.
- Prescription stimulants are available in many different formulations, including tablets, capsules, and liquid form.
- Common side effects of prescription stimulants include loss of appetite, trouble sleeping, headache, stomachache, irritability, fast heart rate, and high blood pressure.
- Store your prescription stimulants securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home. Do not share these medicines with anyone else, and immediately dispose of unused or expired prescription stimulants properly or take them to a drug take-back site, location, or program.

Additional Information for Health Care Professionals

- To address continuing concerns of misuse, abuse, and addiction of prescription stimulants, FDA is requiring updates to the *Boxed Warning* and other information to ensure the prescribing information is made consistent across the entire class of these medicines. The current prescribing information in some prescription stimulants does not provide up to date warnings about the harms of misuse and abuse, and particularly that most individuals who misuse prescription stimulants get their drugs from other family members or peers. Further, individuals who are prescribed stimulants are often faced with requests to share their medication. Sharing these medicines with others can lead to development of substance use disorder and addiction in those with whom these drugs are shared.

- Counsel patients not to give any of their medicine to anyone else and monitor for signs and symptoms of diversion such as requesting refills more frequently than needed. As many as half of youth with valid prescriptions for these medicines are approached by peers and other individuals in the person's peer group to sell or give away their medicine.
- Throughout treatment with prescription stimulants, regularly assess and monitor for signs and symptoms of nonmedical use and addiction.
- Keep careful records of prescribing information, including quantity, frequency, and renewal requests, as required by state and federal laws.
- Educate patients and caregivers on the importance of proper storage and disposal of prescription stimulants.
- Advise patients and caregivers that taking a prescription stimulant other than how it is prescribed, or together with alcohol or other controlled substances, could increase the risk of overdose and death.
- Inform patients and caregivers how to recognize the signs and symptoms of an overdose.
- Counsel patients that nonmedical use of prescription stimulants can cause anxiety, nervousness, loss of appetite, and sleep deprivation—all of which can interfere with studying and performance on exams.
- Encourage patients to read the Medication Guide they receive with their filled prescription(s). This important information will be included, as well as additional information about the medicine.
- To help FDA track safety issues with medicines, report adverse events involving prescription stimulants or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

Additional Information for Patients, Caregivers, and Others

- To address continuing concerns of misuse, abuse, and addiction of prescription stimulants, FDA is requiring updates to the *Boxed Warning* and other information to ensure the prescribing information is made consistent across the entire class of these medicines.
- The current prescribing information in some prescription stimulants does not provide up to date warnings about the harms of misuse and abuse, and particularly that most individuals who misuse prescription stimulants get their drugs from other family members or peers. Individuals prescribed stimulants also are often faced with requests to share their medication. Sharing these medicines can lead to the development of substance use disorder and addiction in those with whom these drugs are shared.
- Even when prescription stimulants are taken as prescribed by a health care professional, they can lead to misuse and abuse, also called nonmedical use, and addiction, which can lead to overdose and death.
- The risk of overdose and death is increased with higher doses or when a pill is manipulated (e.g., crushed or made into a liquid form) and snorted or injected.
- Take prescription stimulants exactly as your health care professional prescribes.
- Do not take larger doses than prescribed.
- Do not take them more frequently than prescribed.

- Using prescription stimulants, which are controlled substances, without a doctor's prescription or misusing someone else's prescription is dangerous and is against the law.
- Do not purchase prescription stimulants from dealers or illegal online sellers. Taking prescription stimulants not prescribed to you may be harmful, and illegal sellers may provide falsified products that appear to be legitimate prescription products but contain dangerous illicit drugs like fentanyl or methamphetamine, which can have fatal consequences.
- Do not take prescription stimulants with alcohol or other controlled substances like opioids, if they are not prescribed for you, as this can have serious and possible deadly consequences.
- Seek medical attention immediately by going to an emergency room or calling 911 if you experience serious side effects or symptoms of stimulant overdose, which can lead to a heart attack, stroke, or seizures. Symptoms may include:
    - Fast heart rate
    - Fast breathing
    - Increased blood pressure
    - Dilated pupils
    - Restlessness
    - Tremors
    - Overactive reflexes
    - Loss of coordination
    - Muscle pain
    - Stomach cramps
    - Nausea and vomiting
    - Aggressive behavior
    - Panic
    - Confusion
    - Hallucinations
- Talk to your health care professional if you have questions or concerns about the risks of taking prescription stimulants.
- Many who take unprescribed prescription stimulants experience anxiety, nervousness, loss of appetite, and sleep deprivation—all of which can interfere with studying and performance on exams.
- Store your prescription stimulants securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home. Do not share these medicines with anyone else, and immediately dispose of unused or expired prescription stimulants properly or take them to a drug take-back site, location, or program.
- Read the patient Medication Guide that comes with your filled prescription(s). This important information will be included, and there may be additional information about your medicine. The Medication Guide explains the important things you need to know about the medicine. These include the side effects, what the medicine is used for, how to take and store it properly, and other things to watch out for when you are taking the medicine.
- To help FDA track safety issues with medicines, report side effects from prescription stimulants or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

Background Summary

We reviewed the medical literature published from January 2006 to May 2020 on adverse events associated with misuse and abuse, also known as nonmedical use, of prescription stimulants. Our review found the most common source of prescription stimulants for nonmedical use was from family members and friends, and those in an individual's peer group. These shared medications are usually provided for free[1,2] and are not from users' own prescriptions, with estimates generally ranging from 56 percent to 80 percent.[3-8] In general, people use these medicines nonmedically thinking they will enhance work or academic performance,[1,2,7,9] and less commonly for recreational or social reasons.[1,2,7,9]

Our review found that nonmedical use has remained relatively stable over the past two decades[9,10] despite the increasing number of prescription stimulants dispensed. Overall, the dispensing for Schedule II stimulants increased over the last three decades, almost doubling in the past 10 years from approximately 12.5 million prescriptions in the first quarter of 2011 to 20 million in the first quarter of 2022.[11] The prevalence of nonmedical use of prescription stimulants varies across specific subpopulations and is highest in young adults (past-year prevalence estimates ranged from 4.1 percent to 7.5 percent),[12,13] people in college (nationally representative estimate of past-year prevalence 4.3 percent),[14] and people diagnosed with ADHD (past-year prevalence ranged from 14 percent to 32 percent).[15-18] Nonmedical use of prescription stimulants is most common in young adults ages 18 to 25,[12,13] and often begins in early adulthood.[19-22] In general, people who use prescription stimulants nonmedically do so infrequently, with approximately 50 percent to 75 percent reporting nonmedical use less than or equal to once a month,[19,23] although some college students reported doing so more frequently.[19,23]

People who use prescription stimulants nonmedically may have a higher risk of developing a substance use disorder[24,25,26] than those who do not. Use of other substances in the past year is common among those who use prescription stimulants nonmedically.[7,23,27,28] Common substances include alcohol, marijuana, cocaine, and opioids.[7,23,27,28] Data suggest that college students who nonmedically use prescription stimulants may not perceive polysubstance use as a risky behavior.[29]

Among those presenting with an acute adverse event related to their nonmedical use of prescription stimulants, the most severe harms are more commonly observed when the nonmedical use was by a non-oral route, as observed in data from U.S. poison centers. Among poison center cases with documentation of nonmedical use of a schedule-II prescription stimulant[30] from 2001 to 2018, approximately 70 percent of cases that mentioned an injection route had a related medical outcome with clinical effects that were moderate (i.e., prolonged or systemic in nature and usually requiring treatment)[31] or major (i.e., life-threatening or resulting in significant residual disability).[32] Approximately 65 percent of nasal/inhalation and approximately 56 percent of oral route cases had a related medical outcome with a moderate or major effect.

Deaths involving stimulants continue to increase and often involve multiple substances, such as opioids.[33] Deaths involving illicit stimulants or opioids outnumber deaths involving prescription stimulants.[34] People seeking to illegally obtain prescription stimulants from others have been exposed to greater risks in recent years because of the increasing presence of illicit sellers offering falsified prescription stimulant products that contain harmful substances such as methamphetamine or fentanyl.[35-38]

References

1. Arria AM, Caldeira KM O'Grady KE, Vincent KB, Johnson EP, Wish ED. 2008b. Nonmedical use of prescription stimulants among college students: Associations with attention-deficit-hyperactivity disorder and polydrug use. Pharmacotherapy 28:156-169.
2. Advokat CD, Guidry D, Martino L. 2008. Licit and illicit use of medications for attention-deficit hyperactivity disorder in undergraduate college students. J Am Coll Health 56:601-606.
3. Chen LY, Strain EC, Crum RM, Storr CL, Mojtabai R. 2014. Sources of nonmedically used prescription stimulants: Differences in onset, recency and severity of misuse in population-based study. Drug Alcohol Depen 145:106-112.
4. Chen LY, Crum RM, Strain EC, Alexander GC, Kaufmann C, Mojtabai R. 2016. Prescriptions, nonmedical use, and emergency department visits involving prescription stimulants. J Clin Psychiatry 77:e297-304.
5. Compton WM, Han B, Blanco C, Johnson K, Jones CM. 2018. Prevalence and correlates of prescription stimulant use, misuse, use disorders, and motivations for misuse among adults in the United States. Am J Psychiatry 175:741-755.
6. Han B, Jones CM, Blanco C, Compton WM. 2017. National trends in and correlates of nonmedical use of prescription stimulants, nonmedical use frequency, and use disorders. J Clin Psychiatry 78:e1250-e1258.
7. Novak SP, Kroutil LA, Williams RL, Van Brunt DL. 2007. The nonmedical use of prescription ADHD medications: Results from a national internet panel. Subst Abuse Treat Prev Policy 2:32.
8. Saloner B, Bachhuber M, Barry CL. 2017. Physicians as a source of medications for nonmedical use: Comparison of opioid analgesic, stimulant, and sedative use in a national sample. Psychiatr Serv 68:56-62.
9. SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, Quarters 1 and 4, 2020. NSDUH Detailed Tables: Table 1.22B. ONLINE. Available at: https://www.samhsa.gov/data/report/2020-nsduh-detailed-tables [accessed 11/15/22].
10. Han B, Jones CM, Blanco C, Compton WM. 2017. National trends in and correlates of nonmedical use of prescription stimulants, nonmedical use frequency, and use disorders. J Clin Psychiatry 78:e1250-e1258.
11. Source: FDA internal analysis using data from IQVIA, US Launch. Jan 1992 through March 2022. Data extracted June 17, 2022.
12. Ford JA, Pomykacz C. 2016. Non-medical use of prescription stimulants: A comparison of college students and their same-age peers who do not attend college. J Psychoactive Drugs 48:253-260.
13. McCabe SE, Wilens TE, Boyd CJ, Chua KP, Voepel-Lewis T, Schepis TS. 2019c. Age-specific risk of substance use disorders associated with controlled medication use and misuse subtypes in the United States. Addict Behav 90:285-293.
14. McCabe SE, Teter CJ, Boyd CJ, Wilens TE, Schepis TS. 2018. Sources of prescription medication misuse among young adults in the United States: The role of educational status. J Clin Psychiatry 79.
15. Egan TE, Dawson AE, Wymbs BT. 2017. Substance use in undergraduate students with histories of attention-deficit/hyperactivity disorder (ADHD): The role of impulsivity. Subst Use Misuse 52:1375-1386.
16. Holt LJ, Marut PN, Schepis TS. 2018. Pursued for their prescription: Exposure to compliance-gaining strategies predicts stimulant diversion in emerging adults. Psychol Addict Behav 32:122-131.

17. Holt LJ, McCarthy MD. 2020. Predictors of prescription stimulant misuse in U.S. College graduates. Subst Use Misuse 55:644-657.
18. Bright GM. 2008. Abuse of medications employed for the treatment of ADHD: Results from a large-scale community survey. Medscape J Med 10:111.
19. Arria AM, Caldeira KM, Allen HK, Bugbee BA, Vincent KB, O'Grady KE. 2017. Prevalence and incidence of drug use among college students: An 8-year longitudinal analysis. Am J Drug Alcohol Abuse 43:711-718
20. Bavarian N, McMullen J, Flay BR, Kodama C, Martin M, Saltz RF. 2017. A mixed-methods approach examining illicit prescription stimulant use: Findings from a northern California university. J Prim Prev 38:363-383.
21. Kirkpatrick ZA, Boyd CJ. 2018. Stimulant use among undergraduate nursing students. J Addict Nurs 29:84-89
22. Luthar et al. 2018 Luthar SS, Small PJ, Ciciolla L. 2018. Adolescents from upper middle class communities: Substance misuse and addiction across early adulthood. Dev Psychopathol 30:315-335.
23. Ross MM, Arria AM, Brown JP, Mullins CD, Schiffman J, Simoni-Wastila L, et al. 2018. College students' perceived benefit-to-risk tradeoffs for nonmedical use of prescription stimulants: Implications for intervention designs. Addict Behav 79:45-51.
24. O'Brien MS, Anthony JC. 2009. Extra-medical stimulant dependence among recent initiates. Drug Alcohol Depend 104:147-155.
25. McCabe SE, Veliz P, Boyd CJ. 2016c. Early exposure to stimulant medications and substance-related problems: The role of medical and nonmedical contexts. Drug Alcohol Depend 163:55-63.
26. McCabe SE, Veliz P, Wilens TE, Schulenberg JE. 2017. Adolescents' prescription stimulant use and adult functional outcomes: A national prospective study. J Am Acad Child Adolesc Psychiatry 56:226-233c224.
27. McCabe SE, Teter CJ, Boyd CJ. 2006. Medical use, illicit use and diversion of prescription stimulant medication. J Psychoactive Drugs 38:43-56.
28. Sepulveda DR, Thomas LM, McCabe SE, Cranford JA, Boyd CJ, Teter CJ. 2011. Misuse of prescribed stimulant medication for ADHD and associated patterns of substance use: Preliminary analysis among college students. J Pharm Pract 24:551-560.
29. Parks KA, Levonyan-Radloff K, Przybyla SM, Darrow S, Muraven M, Hequembourg A. 2017. University student perceptions about the motives for and consequences of nonmedical use of prescription drugs (NMUPD). J Am Coll Health 65:457-465.
30. In America's Poison Centers database, National Poison Data System, route is provided at the level of the case rather than for each involved substance. Therefore, in the assessment of routes of prescription stimulant nonmedical use, the cases were limited to those that only mentioned involvement of a prescription stimulant. Cases were further limited to those with medical outcomes that were considered related to the exposure.
31. America's Poison Centers definition of Moderate Effect: The patient exhibited symptoms as a result of the exposure which are more pronounced, more prolonged or more of a systemic nature than minor symptoms. Usually, some form of treatment is or would have been indicated. Symptoms were not life-threatening, and the patient has returned to a pre-exposure state of well-being with no residual disability or disfigurement.

32. America's Poison Centers definition of Major Effect: The patient has exhibited symptoms as a result of the exposure which were life-threatening or resulted in significant residual disability or disfigurement.
33. Hoots B, Vivolo-Kantor A, Seth P. 2020. The rise in non-fatal and fatal overdoses involving stimulants with and without opioids in the United States. Addiction 115:946-958.
34. Hedegaard H, Bastian BA, Trinidad JP, Spencer M, Warner M. 2018. Drugs most frequently involved in drug overdose deaths: United States, 2011-2016. Natl Vital Stat Rep 67:1-14.
35. Powell T. Ohio State University Warns of Fake Adderall Pills After Two Students Died in One Week. CBS News. ONLINE. Available at: https://www.cbsnews.com/news/ohio-state-university-students-dead-fake-adderall-pills/ [Accessed 11/17/2022].
36. United States Attorney's Office, District of Massachusetts. Twenty-Three Individuals Charged with Trafficking Counterfeit Prescription Pills. ONLINE. Available at: https://www.justice.gov/usao-ma/pr/23-individuals-charged-trafficking-counterfeit-prescription-pills [Accessed 11/17/2022].
37. United States Attorney's Office, Western District of Michigan. West Michigan Man Sentenced to 23 Years in Prison for Illegally Possessing Firearms and Intending to Sell Fake Adderall Pills. ONLINE. Available at: https://www.justice.gov/Usao-wdmi/pr/2022_0628_Wilson [Accessed 11/17/2022].
38. United States Drug Enforcement Administration. Public Safety Alert: Sharp Increases in Fake Prescription Pills Containing Fentanyl and Meth. ONLINE. Available at: https://www.dea.gov/alert/sharp-increase-fake-prescription-pills-containing-fentanyl-and-meth [Accessed 11/18/2022].

Related Information

- Controlled Substances Program: Future public conference planning to discuss topics related to ADHD stimulants
- Information about Medications Used to Treat Attention-Deficit/Hyperactivity Disorder (ADHD)
- Prescription Stimulants DrugFacts
- 5 Myths About Stimulant Abuse
- Prescription Stimulant Misuse and Prevention Among Youth and Young Adults
- Drug Diversion
- Disposal of Unused Medicines: What You Should Know
- Lock it Up: Medicine Safety in Your Home
- The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective
- Think It Through: Managing the Benefits and Risks of Medicines

FDA Drug Safety Communication

FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use

Includes updates to help reduce unnecessary prescribing

04-13-2023 FDA Drug Safety Communication

What safety concern is FDA announcing?

As part of its ongoing efforts to address the nation's opioid crisis, the U.S. Food and Drug Administration (FDA) is making several updates to the prescribing information of opioid pain medicines to provide additional guidance on the use of these powerful medicines. Opioid pain medicines are an important treatment option when used as prescribed; however, they also have serious risks, including misuse and abuse, addiction, overdose, and death.

Although there has been a substantial overall decrease in the number of dispensed prescriptions for opioid pain medicines, overdose deaths involving prescription opioids have remained steady. Data also suggest that:

- many acute pain conditions treated in the outpatient setting require no more than a few days of an opioid pain medicine, although the dose and duration of treatment needed to adequately manage pain will vary based on the underlying cause and individual patient factors.
- patients who use opioid pain medicines after surgery often have unused tablets, which may pose a risk of accidental use, misuse and abuse, addiction, and overdose, including by children and teenagers.
- extended-release/long-acting (ER/LA) opioid pain medicines have unique risks and should be used only for those with severe and persistent pain.

Based on our review of available data, FDA has also determined that a new warning is needed about opioid-induced hyperalgesia (OIH), which is when an opioid that is prescribed and taken for pain relief causes an increase in pain (called hyperalgesia) or an increased sensitivity to pain (called allodynia). Although OIH can occur at any opioid dosage, it may occur more often with higher doses and longer-term use. This condition can be difficult to recognize and may result in increased opioid dosages that could worsen symptoms and increase the risk of respiratory depression.

What is FDA doing?

We are requiring several updates to the prescribing information for both immediate-release (IR) and extended release/long acting (ER/LA) opioid pain medicines (See Table of Key Opioid Label Updates). This includes stating for all opioid pain that the risk of overdose increases as the dose increases. The updates to IR opioids state these products should not be used for an extended period unless the pain remains severe enough to require them and alternative treatments continue to be inadequate, and that many acute pain conditions treated in the outpatient setting require no more than a few days of an opioid pain medicine. This may include pain occurring with a number of surgical conditions or musculoskeletal injuries. We are also updating the approved use for ER/LA opioid pain medicines to recommend they be reserved for severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine and for which alternative treatment options are inadequate.

In addition, we are adding a new warning about opioid-induced hyperalgesia (OIH) for both IR and ER/LA opioid pain medicines. This includes information describing the symptoms that differentiate OIH from opioid tolerance and withdrawal.

Information in the *Boxed Warning,* FDA's most prominent warning, for all IR and ER/LA opioid pain medicines will be updated and reordered to elevate the importance of warnings concerning life-threatening respiratory depression, and risks associated with using opioid pain medicines in conjunction with benzodiazepines or other medicines that depress the central nervous system (CNS). Other changes are also being required to several sections of the prescribing information, including to the *Indications and Usage*, *Dosage and Administration*, and *Warnings and Precautions* sections (See Table of Key Opioid Label Updates). We are also requiring updates to the existing patient Medication Guides to help educate patients and caregivers about these risks.

These changes to the prescribing information are designed to inform about appropriate prescribing of opioid pain medicines while also recognizing that they remain an important treatment option in appropriate situations and that undertreatment of pain (including abrupt discontinuations and forced tapering) carries its own risks, including other morbidities and even the risk of illicit substance use for self-treatment. These changes are designed to provide essential information that prescribers need to prescribe opioid pain medicines appropriately, but the prescribing information itself cannot substitute for individual clinical judgment and talking to patients about their pain control.

What is an opioid and how can it help me?
Opioid pain medicines are a class of powerful pain medicines prescribed to treat pain that does not respond well to other treatments or non-opioid pain medicines. They activate an area of nerve cells in the brain and body that block pain signals. These medicines have benefits when used appropriately, but they also have serious risks, including misuse and abuse, addiction, overdose, and death. Examples of common opioid pain medicines include codeine, hydrocodone, hydromorphone, morphine, oxycodone, oxymorphone, fentanyl, buprenorphine, and tramadol.

What should health care professionals do?
In assessing the severity of pain, discuss with the patient the impact of the pain on their ability to function and their quality of life. Assessment of pain should consider both the cause of pain and individual patient factors.

If the patient's pain is severe enough to require an opioid pain medicine and alternative treatment options are insufficient, prescribe the lowest effective dose of an IR opioid for the shortest duration of time to reduce the risks associated with these products. Reserve increasing to higher doses only when lower doses are inadequate and the benefits of using a higher dose outweigh the substantial risks. Many acute pain conditions, such as pain occurring with a number of surgical procedures or musculoskeletal injuries, require no more than a few days of an IR opioid pain medicine.

Reserve ER/LA opioid pain medicines only for severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine and for which alternative treatment options are inadequate. For patients currently on an ER/LA opioid who have pain severe enough to require an opioid but are not assessed as having severe and persistent pain, ensure that a multimodal approach to pain management is available, including mental health support. Discuss options for optimizing their

treatment, which might include moving to an IR opioid or other alternative pain treatment, with the potential to appropriately and carefully taper the opioid but avoiding any abrupt discontinuation. Regularly reevaluate and discuss with your patients the optimum management of pain that appropriately balances the known benefits and risks, and frequently assess for development of addiction, misuse, or abuse. Inform patients of the added risks of using opioid pain medicines with benzodiazepines and other CNS depressants, and educate them on the signs and symptoms of respiratory depression.

For all patients prescribed opioid pain medicines, discuss the availability of naloxone, and consider prescribing it to those at increased risk of overdose. This may include patients who are also using benzodiazepines or other medicines that depress the central nervous system, with a history of opioid use disorder (OUD), or have experienced a previous opioid overdose. Health care professionals should also consider prescribing naloxone if the patient has household members, including children, or other close contacts at risk for accidental ingestion or opioid overdose. In March 2023, FDA approved an inhaled nasal spray version of naloxone to be sold over-the-counter without a prescription.

Be aware that the symptoms of OIH, a condition where opioids cause an increase in pain (called hyperalgesia) or an increased sensitivity to pain (called allodynia), are distinct from opioid tolerance and withdrawal and can be difficult to recognize (see Additional Information for Health Care Professionals). If a patient is suspected to be experiencing OIH, carefully consider an appropriate decrease in dose of the current opioid pain medicine or safely switching them to a different opioid product, if tolerated. Advise patients about the risk of OIH and tell them to never increase the opioid dosage without first consulting a health care professional, because this could worsen the pain and increase the risk of respiratory depression.

What should patients and parents/caregivers do?

Always take your opioid medicines exactly as prescribed. Do not take more of the medicine or take it more often than prescribed without first talking to your health care professional. Talk with them if your pain increases, you feel more sensitive to pain, or if you have new pain, especially from touch or other things that are not usually painful such as combing your hair.

Store your opioid pain medicines securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home. Do not share these medicines with anyone else, and immediately dispose of unused or expired opioids or take them to a drug take-back site, location, or program. If provided, use the prepaid mail-back envelopes included with the prescription.

Seek emergency medical help or call 911 immediately if you or someone you are caring for experiences symptoms of respiratory problems, which can be life-threatening. Signs and symptoms include serious slowed, shallow, or difficult breathing, severe sleepiness, or not being able to respond or wake up.

Talk to your health care professionals about the benefits of naloxone, which can reverse and opioid overdose, and how to obtain it. Your health care professional can give you a prescription for naloxone. Additionally, in most states and the District of Columbia you can obtain naloxone from a pharmacy under a standing order that takes the place of an individual prescription. Some states also allow you to obtain naloxone without a prescription from a community-based program

or pharmacy. Check with your state Health Department for more information. In March 2023, FDA approved an inhaled nasal spray version of naloxone to be sold over-the-counter without a prescription while multiple forms of naloxone remain available as prescription only.

What did FDA find?

Despite substantial declines in the rates for opioid pain medicine dispensing,[1] prescription opioid medicine-involved overdose deaths have remained relatively steady over time, with 16,706 deaths in 2021.[2] However, these statistics likely underestimate the role of prescription opioids in contributing to overall opioid-related overdose deaths. Data suggest some patients who are prescribed opioid pain medicines may progress to nonmedical use of opioids and other controlled substances, contributing to the number of opioid-related overdoses.[3] The impact of the opioid crisis extends beyond deaths and includes health consequences and harm to families.[4,5]

Evidence suggests that patients getting opioid pain medicines for acute pain are often prescribed a larger quantity than needed,[6] resulting in unused tablets. When not properly disposed of, these unused opioid tablets provide opportunities for nonmedical use, accidental exposure, and overdose.[7] Data also strongly suggest that the risk of overdose increases as the prescribed dosage of opioid pain medicines increases,[8] and this risk can occur at any point during treatment.

Opioid pain medicines also have been associated with other complications such as OIH. We identified 46 cases describing hyperalgesia and allodynia when opioid pain medicines were being used to treat pain, including eight with short-term use and 38 with longer-term use. These cases include only those submitted to the FDA Adverse Event Reporting System or those found in the medical literature,[9] so there may be cases about which we are unaware (see Background and Data Summary). The cases involved a range of opioid pain medicines, including morphine, hydromorphone, and fentanyl/fentanyl analogs most commonly. Other possible causes of the increased pain were excluded, such as worsening of disease. Cancer was the most reported underlying condition being treated. Patients reported improvement in pain after stopping opioid pain medicines. Though the mechanism of OIH is not fully understood, multiple biochemical pathways have been suggested.

What is my risk?

Like all medicines, opioid pain medicines can have side effects, even when used correctly as prescribed. It is important to know that people respond differently to medicines depending on their health, the diseases they have, genetic factors, other medicines they are taking, and many other factors. As a result, we cannot determine how likely it is that someone will experience these side effects when taking opioid pain medicines. Talk to your health care professional if you have questions or concerns about the risks of taking opioid pain medicines.

How do I report side effects from opioid pain medicines?

To help FDA track safety issues with medicines, we urge patients and health care professionals to report side effects involving opioid pain medicines or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

How can I get new safety information on medicines I'm prescribing or taking?

You can sign up for email alerts about Drug Safety Communications on medicines or medical specialties of interest to you.

Table of Key Opioid Label Updates

The following tables provide a comparison of the more significant label updates included in this action intended to provide additional guidance on prescribing opioid analgesics. These updates apply to opioid analgesics intended for use in the outpatient setting, although many also apply to opioid analgesics used in the inpatient setting. The below list is not exhaustive. These are representative examples of "former" and "new" labels. Other minor updates were incorporated within this action but are not listed below and will be available once the label updates for each product are approved by the FDA. Updated language is shown **in bold** and will be added to the Boxed Warning (Table 1), Indications and Usage (Tables 2 and 3), Dosage and Administration (Tables 4-7), Warnings and Precautions (Table 8), and Medication Guide (Table 9 - 11) sections of the opioid analgesic labels.

Table 1: Boxed Warning
(Applies to both Immediate-Release and Extended-Release/Long-Acting Opioid Analgesics)

Former Order and Language	New Order and Updated (shortened) Language
Addiction, Abuse, and Misuse [TRADENAME] exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing [TRADENAME] and monitor all patients regularly for the development of these behaviors and conditions *[see Warnings and Precautions (5.X)]*. **Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)** To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the Food and Drug Administration (FDA) has required a REMS for these products *[see Warnings and Precautions (5.X)]*. Under the requirements of the REMS, drug companies with approved opioid analgesic products must make REMS-compliant education programs available to healthcare providers. Healthcare providers are strongly encouraged to • complete a REMS-compliant education program, • counsel patients and/or their caregivers, with every prescription, on safe use, serious risks, storage, and disposal of these products, • emphasize to patients and their caregivers the importance of reading the Medication Guide every time it is provided by their pharmacist, and • consider other tools to improve patient, household, and community safety. **Life-Threatening Respiratory Depression** Serious, life-threatening, or fatal respiratory depression may occur with use of [TRADENAME].	**Addiction, Abuse, and Misuse** **Because the use of** [TRADENAME] exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death, assess each patient's risk prior to prescribing and **reassess** all patients regularly for the development of these behaviors and conditions *[see Warnings and Precautions (5.X)]*. **Life-Threatening Respiratory Depression** Serious, life-threatening, or fatal respiratory depression may occur with use of [TRADENAME], especially during initiation or following a dose increase. **To reduce the risk of respiratory depression, proper dosing and titration of** [TRADENAME] **are essential** *[see Warnings and Precautions (5.X)]*. **Accidental Ingestion** (no change) Accidental ingestion of even one dose of [TRADENAME], especially by children, can result in a fatal overdose of [active moiety] *[see Warnings and Precautions (5.X)]*. **Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants** Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of [TRADENAME] and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate *[*see *Warnings and Precautions (5.X), Drug Interactions (7)]*.

Monitor for respiratory depression, especially during initiation of [TRADENAME] or following a dose increase *[see Warnings and Precautions (5.X)]*. **Accidental Ingestion** Accidental ingestion of even one dose of [TRADENAME], especially by children, can result in a fatal overdose of [active moiety] *[see Warnings and Precautions (5.X)]*. **Neonatal Opioid Withdrawal Syndrome** Prolonged use of [TRADENAME] during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available *[see Warnings and Precautions (5.X)]*. **Risks From Concomitant Use With Benzodiazepines Or Other CNS Depressants** Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death *[*see *Warnings and Precautions (5.X), Drug Interactions (7)]*. • Reserve concomitant prescribing of [TRADENAME] and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate. • Limit dosages and durations to the minimum required. • Follow patients for signs and symptoms of respiratory depression and sedation.	**Neonatal Opioid Withdrawal Syndrome (NOWS)** **If opioid use is required for an extended period of time in a pregnant woman,** advise the patient of the risk of NOWS, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery *[see Warnings and Precautions (5.X)]*. **Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)** (also shortened) Healthcare providers are strongly encouraged to complete a REMS-compliant education program and to counsel patients and caregivers on serious risks, safe use, and the importance of reading the Medication Guide with each prescription *[see Warnings and Precautions (5.X)]*.

Table 2: Indications and Usage *(Applies to Immediate-Release Opioid Analgesics)*	
Former	New
Limitations of Use: Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses *[see Warnings and Precautions (5.X)]*, reserve [TRADENAME] for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products): • Have not been tolerated, or are not expected to be tolerated, • Have not provided adequate analgesia, or are not expected to provide adequate analgesia, or are not expected to provide adequate analgesia	**Limitations of Use:** Because of the risks of addiction, abuse, and misuse with opioids, **which can occur at any dosages or duration** *[see Warnings and Precautions (5.X)]*, reserve [TRADENAME] for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products): • Have not been tolerated, or are not expected to be tolerated, • Have not provided adequate analgesia, or are not expected to provide adequate analgesia [TRADENAME] **should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.**

Table 3: Indications and Usage *(Applies to Extended-Release/Long-Acting Opioid Analgesics)*	
Former	New
[TRADENAME] is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatments are inadequate. **Limitations of Use:** • Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations *[see Warnings and Precautions (5.X)]*, reserve [TRADENAME] for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. • [TRADENAME] is not indicated as an as-needed (prn) analgesic.	[TRADENAME] is indicated for the management of **severe and persistent** pain **that requires an extended treatment period with a daily opioid analgesic** and for which alternative treatment options are inadequate. **Limitations of Use:** • Because of the risks of addiction, abuse, and misuse with opioids, **which can occur at any dosage or duration**, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, *[see Warnings and Precautions (5.X)]*, reserve [TRADENAME] for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. • [TRADENAME] is not indicated as an as-needed (prn) analgesic.

Table 4: Dosage and Administration Important Dosage and Administration Instructions *(Applies to Immediate-Release Opioid Analgesics)*	
Former	New
Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals *[see Warnings and Precautions (5)]*. Initiate the dosing regimen for each patient individually, taking into account the patient's severity of pain, patient response, prior analgesic treatment experience, and risk factors for addiction, abuse, and misuse *[see Warnings and Precautions (5.X)]*. Monitor patients closely for respiratory depression, especially within the first 24-72 hours of initiating therapy and following dosage increases with [TRADENAME] and adjust the dosage accordingly *[see Warnings and Precautions (5.X)]*.	[TRADENAME] **should be prescribed only by healthcare professionals who are knowledgeable about the use of opioids and how to mitigate the associated risks.** Use the lowest effective dosage for the shortest duration **of time** consistent with individual patient treatment goals *[see Warnings and Precautions (5)]*. **Because the risk of overdose increases as opioid doses increase, reserve titration to higher doses of** [TRADENAME] **for patients in whom lower doses are insufficiently effective and in whom the expected benefits of using a higher dose opioid clearly outweigh the substantial risks.** **Many acute pain conditions (e.g., the pain that occurs with a number of surgical procedures or acute musculoskeletal injuries) require no more than a few days of an opioid analgesic. Clinical guidelines on opioid prescribing for some acute pain conditions are available.** **There is variability in the opioid analgesic dose and duration needed to adequately manage pain due both to the cause of pain and to individual patient factors.** Initiate the dosing regimen for each patient individually, taking into account the patient's **underlying cause and** severity of pain, prior analgesic treatment **and response**, and risk factors for addiction, abuse, and misuse *[see Warnings and Precautions (5.X)]*. **Respiratory depression can occur at any time during opioid therapy, especially when** initiating and following dosage increases with [TRADENAME]. **Consider this risk when selecting an initial dose and when making dose adjustments** *[see Warnings and Precautions (5)]*.

Table 5: Dosage and Administration Initial Dosage *(Applies to Immediate-Release Opioid Analgesics)*	
Former	New
Use of [TRADENAME] as the First Opioid Analgesic Initiate treatment with [TRADENAME] in a dosing range of X mg to X mg every Y to Y hours as	Use of [TRADENAME] as the First Opioid Analgesic Initiate treatment with [TRADENAME] in a dosing range of X mg to X mg every Y to Y hours as

needed for pain.	needed for pain, **at the lowest dose necessary to achieve adequate analgesia. Titrate the dose based upon the individual patient's response to their initial dose of** [TRADENAME].

Table 6: Dosage and Administration **Important Dosage and Administration Instructions** *(Applies to Extended-Release/Long-Acting Opioid Analgesics)*	
Former	New
[TRADENAME] should be prescribed only by healthcare professionals who are knowledgeable in the use of potent opioids for the management of chronic pain. … (product-specific information)… Use the lowest effective dosage for the shortest duration consistent with individual patient treatment goals *[see Warnings and Precautions (5)]*. Initiate the dosing regimen for each patient individually, taking into account the patient's severity of pain, patient response, prior analgesic treatment experience, and risk factors for addiction, abuse, and misuse *[see Warnings and Precautions (5.X)]*. Monitor patients closely for respiratory depression, especially within the first 24-72 hours of initiating therapy and following dosage increases with [TRADENAME] and adjust the dosage accordingly *[see Warnings and Precautions (5.X)]*.	[TRADENAME] should be prescribed only by healthcare professionals who are knowledgeable **about the use of extended-release/long-acting opioids and how to mitigate the associated risks.** … (product-specific information)… Use the lowest effective dosage for the shortest duration **of time** consistent with individual patient treatment goals *[see Warnings and Precautions (5)]*. **Because the risk of overdose increases as opioid doses increase, reserve titration to higher doses of** [TRADENAME] **for patients in whom lower doses are insufficiently effective and in whom the expected benefits of using a higher dose opioid clearly outweigh the substantial risks.** Initiate the dosing regimen for each patient individually, taking into account the patient's **underlying cause and** severity of pain, prior analgesic treatment **and response**, and risk factors for addiction, abuse, and misuse *[see Warnings and Precautions (5.X)]*. **Respiratory depression can occur at any time during opioid therapy, especially when** initiating and following dosage increases with [TRADENAME]. **Consider this risk when selecting an initial dose and when making dose adjustments** *[see Warnings and Precautions (5)]*.

Table 7: Dosage and Administration **Initial Dosage** *(Applies to Extended-Release/Long-Acting Opioid Analgesics)*	
Former	New
Conversion from Other Opioids to [TRADENAME] Discontinue all other around-the-clock opioid drugs when [TRADENAME] therapy is initiated.	Conversion from Other Opioids to [TRADENAME] When [TRADENAME] therapy is initiated, discontinue all opioid **analgesics other than those used on an as needed basis for breakthrough pain when appropriate.**

Table 8: Warnings and Precautions *(Applies to <u>both</u> Immediate-Release and Extended-Release/Long-Acting Opioid Analgesics)*	
Former	New
(n/a)	**<u>5.X Opioid-Induced Hyperalgesia and Allodynia</u>** **Opioid-Induced Hyperalgesia (OIH) occurs when an opioid analgesic paradoxically causes an increase in pain, or an increase in sensitivity to pain. This condition differs from tolerance, which is the need for increasing doses of opioids to maintain a defined effect *[see Dependence (9.3)].* Symptoms of OIH include (but may not be limited to) increased levels of pain upon opioid dosage increase, decreased levels of pain upon opioid dosage decrease, or pain from ordinarily non-painful stimuli (allodynia). These symptoms may suggest OIH only if there is no evidence of underlying disease progression, opioid tolerance, opioid withdrawal, or addictive behavior.** **Cases of OIH have been reported, both with short-term and longer-term use of opioid analgesics. Though the mechanism of OIH is not fully understood, multiple biochemical pathways have been implicated. Medical literature suggests a strong biologic plausibility between opioid analgesics and OIH and allodynia. If a patient is suspected to be experiencing OIH, carefully consider appropriately decreasing the dose of the current opioid analgesic, or opioid rotation (safety switching the patient to a different opioid moiety) *[see Dosage and Administration (2.X); Warnings and Precautions (5.X)]*.**

Table 9: Medication Guide *(Applies to Extended-Release/Long-Acting Opioid Analgesics)*	
Former	New
[TRADENAME] is: • A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily, around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them. • A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death. • Not for use to treat pain that is not around-the-clock	**[TRADENAME] is:** • A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage **severe and persistent** pain **that requires an extended treatment period with a daily opioid medicine**, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them. • A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death. • Not **to be taken on an "as needed" basis.**

Table 10: Medication Guide *(Applies to both Immediate-Release and Extended-Release/Long-Acting Opioid Analgesics)*	
Former	New
Tell your healthcare provider if you: • **are pregnant or planning to become pregnant.** Prolonged use of [TRADENAME] during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.	**Tell your healthcare provider if you:** • **are pregnant or planning to become pregnant. Use of** [TRADENAME] **for an extended period of time** during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated. • **notice your pain getting worse. If your pain gets worse after you take** [TRADENAME]**, do not take more of** [TRADENAME] **without first talking to your doctor. Talk to your doctor if the pain you have increases, if you feel more sensitive to pain, or if you have new pain after taking** [TRADENAME].

Table 11: Medication Guide *(Applies to Immediate-Release Opioid Analgesics)*	
Former	New
When taking [TRADENAME]: • Do not change your dose. Take [TRADENAME]exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed. • Take your prescribed dose every 4 to 6 hours. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time. • Call your healthcare provider if the dose you are taking does not control your pain. • If you have been taking [TRADENAME] regularly, do not stop taking [TRADENAME] without talking to your healthcare provider. • Dispose of expired, unwanted, or unused [TRADENAME] by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.	**When taking [TRADENAME]:** • Do not change your dose. Take [TRADENAME]exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed. • **For acute (short-term) pain, you may only need to take** [TRADENAME] **for a few days. You may have some** [TRADENAME] **left over that you did not use. See disposal information at the bottom of this section for directions on how to safely dispose of** [TRADENAME]**.** • Take your prescribed dose every 4 to 6 hours. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time. • Call your healthcare provider if the dose you are taking does not control your pain. • If you have been taking [TRADENAME] regularly, do not stop taking [TRADENAME] without talking to your healthcare provider. • Dispose of expired, unwanted, or unused [TRADENAME] by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

NOTE: FDA defines *misuse* as the intentional use, for therapeutic purposes, of a drug in a manner other than as prescribed or by an individual for whom it was not prescribed. FDA defines *abuse* as the intentional, nontherapeutic use of a drug for its desirable psychological or physiological effects. The term *abuse* is used in this document to describe a specific behavior that confers a risk of adverse health outcomes; it is not intended to imply moral judgment. FDA is committed to reducing stigma, expanding therapeutic options, and ensuring access to evidence-based treatment for individuals with substance use disorders.

Facts about Opioid Pain medicines

- Opioid pain medicines are powerful prescription medicines that can help manage pain when other treatments and medicines are not able to provide enough relief. However, opioid pain medicines also carry serious risks, including misuse and abuse, addiction, overdose, and death.

- There are two main categories of prescription opioid pain medicines. Immediate-release (IR) products are usually intended for use every 4-6 hours as needed for acute pain. Extended-release/long-acting (ER/LA) opioid pain medicines are intended to be taken only once or twice a day for severe and persistent pain that requires an extended treatment period and for which alternative treatment options are inadequate, depending on the individual product and patient.
- Opioid pain medicines are available in many different forms, including tablets, capsules, lozenges, sublingual tablets, transdermal patches, nasal sprays, and injections.
- Common side effects of opioid pain medicines include drowsiness, dizziness, nausea, vomiting, constipation, physical dependence, and slowed or difficult breathing.
- The risk of opioid addiction, misuse, or abuse is increased in patients with a personal or family history of substance use disorder or mental illness.
- Naloxone is an opioid reversal medicine used to treat an opioid overdose or possible overdose and can help prevent death. Naloxone is widely available according to individual state's requirements or guidelines. Consider co-prescribing naloxone with all opioid prescriptions for those at increased risk of opioid overdose. In March 2023, FDA approved the inhaled nasal spray version of naloxone to be sold over-the-counter without a prescription.

Additional Information for Health Care Professionals

- As part of its ongoing efforts to address the nation's opioid crisis, FDA is making several updates to the opioid analgesics' prescribing information to provide additional guidance on prescribing these powerful medicines. Although there has been a substantial overall decrease in the number of dispensed prescriptions for opioid analgesics, prescription opioid-related overdoses have not similarly decreased. Data suggest that:
    - many acute pain conditions treated in the outpatient setting, such as pain occurring with a number of surgical procedures or musculoskeletal injuries, require no more than a few days of an opioid pain medicine, although dose and duration of treatment needed to adequately manage pain will vary based on the underlying cause and individual patient factors.
    - outpatient opioid pain medicine use after surgery often results in unused tablets, and when not properly disposed of these unused medicines provide opportunities for nonmedical use, accidental exposure, and overdose.
    - extended-release/long-acting (ER/LA) opioid pain medicines have unique risks due to their properties and should be reserved for those with severe and persistent pain that requires an extended treatment period with a daily opioid pain medicine and for which alternative treatment options are inadequate.
- We are also adding a new warning about opioid-induced hyperalgesia (OIH), a condition where opioids cause an increase in pain (called hyperalgesia) or an increased sensitivity to pain (called allodynia). This condition, which can occur at any dosage but may occur more often with higher doses and longer-term use, can be difficult to recognize and may result in increasing the opioid pain medicine dosage, which could worsen the OIH and increase the risk of respiratory depression. If a patient is suspected to be experiencing OIH, carefully consider appropriately decreasing the dose of the current opioid or safely switching to a different opioid product, if tolerated. Symptoms of OIH can include:
    - increased pain intensity despite increasing opioid pain medicine doses
    - decreased pain intensity in response to a decrease in opioid pain medicine doses
    - hypersensitivity to non-painful stimuli (in the absence of opioid tolerance or withdrawal)

- Prescribe the lowest effective dose for the shortest duration for all opioid pain medicines consistent with a patient's individual treatment goals. Because the risk of overdose increases as opioid pain medicine doses increase, reserve titrating to higher doses for patients who have an inadequate response to lower doses and when the benefits of a higher dose clearly outweigh the substantial risks.
- Periodically reassess the continued need for opioid pain medicine use regardless of the dose and for signs of addiction, misuse, or abuse.
- Educate patients and caregivers that taking an opioid pain medicine other than how it is prescribed or with alcohol or benzodiazepines and other CNS depressants could increase the risk of overdose, and how to recognize the signs and symptoms of respiratory depression.
- Naloxone is used to treat an opioid emergency, such as an overdose or possible overdose. Consider co-prescribing naloxone with all opioid prescriptions for those at risk of opioid overdose or talk to patients about options for obtaining naloxone according to their state requirements or guidelines. Prescription and non-prescription forms of naloxone are FDA approved.
- Encourage patients to read the patient Medication Guide they receive with their filled prescription(s). Important, new information will be included. The Medication Guide explains the important things they need to know about the medicine. These include the side effects, what the medicine is used for, how to take and store it properly, and other things to watch out for when you are taking the medicine.
- To help FDA track safety issues with medicines, report adverse events involving opioid pain medicines or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

Additional Information for Patients and Caregivers

- As part of its ongoing efforts to address the nation's opioid crisis, FDA is making several updates to the prescribing information of opioids used for pain to provide additional guidance to health care professionals prescribing these powerful medicines, which have serious risks, including misuse and abuse, addiction, overdose, and death.
- FDA is also adding a new warning about opioid-induced hyperalgesia (OIH), which is when an opioid that is prescribed and taken for pain relief causes an increase in pain (called hyperalgesia) or an increased sensitivity to pain (called allodynia).
    - OIH is a condition that can occur at any dosage of an opioid, but it may occur more often with higher doses and longer-term use
    - Talk to your health care professional if your pain increases, if you feel more sensitive to pain, or if you have new pain after taking your opioid pain medicine
- We are also updating the patient Medication Guide with this information. Read the Medication Guide and other information that comes with your filled prescription(s). Important, new information will be included. The Medication Guide explains the important things you need to know about the medicine. These include the side effects, what the medicine is used for, how to take and store it properly, and other things to watch out for when you are taking the medicine.
- Always take opioid pain medicines as prescribed. Do not take more doses or take them more often than prescribed.

- For many acute pain conditions such as pain occurring with a number of surgical procedures or musculoskeletal injuries, you may only need to take your opioid pain medicine for a few days. You may have some medicine left over that you did not use. Never give anyone else your opioid pain medicine. They could die from taking it. Selling or giving away your opioid pain medicine is against the law. Immediately dispose of unused or expired opioids or take them to a drug take-back site, location, or program. See disposal information in the Medication Guide on how to safely dispose of your opioid pain medicine. If provided, use the prepaid mail-back envelopes included with the prescription.
- Store your opioid pain medicines securely, out of sight and reach of children, and in a location not accessible by others, including visitors. Every year thousands of children are hospitalized, and some die, after taking medicine not meant for them. Millions of people misuse prescription opioid pain medicines each year, and thousands die from overdoses involving prescription opioids.
- Signs of an opioid overdose include breathing problems, severe sleepiness, or not being able to respond or wake up. Seek medical attention immediately if you or someone you are caring for experiences these life-threatening symptoms.
- Naloxone is used to treat an opioid emergency, such as an overdose or possible overdose. Talk to your health care professional about how to use the naloxone product and options for obtaining naloxone according to your state's requirements or guidelines. In March 2023, FDA approved an inhaled nasal spray version of naloxone to be sold over-the-counter without a prescription while multiple forms of naloxone remain available as prescription only.
- To help FDA track safety issues with medicines, report side effects from opioid pain medicines or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.
- You can sign up for email alerts about Drug Safety Communications on medicines and medical specialties of interest to you.

Background and Data Summary

Opioid-involved overdose deaths have risen steadily over the past 15 years, with a dramatic increase between 2017 (47,600 deaths) and 2021 (80,411 deaths).[2] Although most opioid-involved deaths are due to illicit fentanyl and fentanyl analogs,[2] several statistics help frame the context in which FDA is taking action to update the prescribing information for opioid pain medicines. Despite substantial declines in the rates of opioid pain medicine dispensing, falling from 81.3 prescriptions per 100 persons in 2012 to 43.3 prescriptions per 100 persons in 2020,[1] prescription opioid-involved overdose deaths have remained relatively steady over time, with 16,706 deaths in 2021.[2] These mortality statistics likely underestimate the role of prescription opioid pain medicines in contributing to overall opioid-related overdose deaths.

Data suggest that some patients prescribed opioid pain medicines may transition to nonmedical use of opioids and other controlled substances. In one study conducted between 2019 and 2021, researchers led in-depth interviews with 148 participants from three different states who reported using heroin, illicit fentanyl, or prescription opioid pain medicines nonmedically.[3] Of those participants, 90 percent reported their initial exposure involved prescription opioid pain medicines, nearly half (48%) of whom

obtained them through a prescription. Many reported using opioids nonmedically for many years. Some study participants reported that their use of illicit opioids may have been influenced by policies and prescribing practices that unintentionally limited access to prescription opioids in inappropriate ways, e.g., rapid discontinuation of prescribed opioids.

The impact of the opioid crisis extends beyond mortality and includes associated morbidity and societal costs. Among Americans 12 and older, 5.6 million (2%) reported in 2021 having an opioid use disorder (OUD) in the past year.[7] Health consequences of non-fatal, opioid-involved overdoses may include acute complications, such as opioid-induced respiratory depression, and more serious, chronic complications, such as brain injury.[4] The impacts on children and their families include an increased risk of mental health problems, drug use, development of substance use disorder, accidental opioid poisoning, and loss of a parent to an opioid overdose.[5]

Evidence suggests opioid pain medicines continue to be overprescribed for many patients with some acute pain conditions. A systematic review of studies published through 2019 examined patient-reported outpatient opioid pain medicine use after surgery, finding that among studies that reported on excess tablets, 25 percent to 98 percent of total tablets prescribed were reported as excess, with most studies reporting between 50 percent and 70 percent excess tablets.[6] Studies show that many patients report having leftover opioids after surgery.[11,12, 13,] For many acute and chronic pain conditions, other non-opioid treatments, including both non-pharmacologic and pharmacologic, have been found to be effective. For a number of conditions, non-opioid medicines may be just as effective as opioid pain medicines. [14,15]

Opioid-induced Hyperalgesia (OIH)

Opioid pain medicines have been associated with opioid-induced hyperalgesia (OIH), a condition where opioids cause an increase in pain (called hyperalgesia) or an increased sensitivity to pain (called allodynia). Increases in pain typically occur following a dose increase and resolve quickly following proper diagnosis and management of the condition.

We identified 46 patients describing hyperalgesia and allodynia when opioid pain medicines were being using to treat pain, including eight with short-term and 38 with longer-term use. These cases include only those submitted to the FDA Adverse Event Reporting System or those found in the medical literature,[9] so there may be cases about which we are unaware. The cases involved a range of opioid pain medicines, including most commonly morphine, hydromorphone, and fentanyl/fentanyl analogs. Cancer was the most reported underlying condition being treated. Other possible causes were excluded such as worsening of disease. Patients reported improvement in pain after stopping opioid pain medicines. Though the mechanism of OIH is not fully understood, multiple biochemical pathways have been suggested.

References

1. Centers for Disease Control and Prevention, National Center for Injury Prevention and Control, November 10, 2021, U.S. Opioid Dispensing Rate Maps, https://www.cdc.gov/drugoverdose/rxrate-maps/index.html.
2. National Institute on Drug Abuse, February 9, 2023, Drug Overdose Death Rates, https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates.

3. Dickson-Gomez J, S Krechel, A Spector, M Weeks, J Ohlrich, HD Green Montaque, J Li, July 21, 2022, The effects of opioid policy changes on transitions from prescription opioids to heroin, fentanyl and injection drug use: a qualitative analysis, Subst Abuse Treat Prev Policy, 17(1):55, doi: 10.1186/s13011-022-00480-4.
4. Office of the Assistant Secretary for Planning and Evaluation, 2019, Non-Fatal Opioid Overdose and Associated Health Outcomes: Final Summary Report, https://aspe.hhs.gov/reports/non-fatal-opioid-overdose-associated-health-outcomes-final-summary-report-0.
5. Winstanley E, A Stover, September 2019, The Impact of the Opioid Epidemic on Children and Adolescents, Clin Ther, 41(9):1655–1662, epub ahead of print July 11, 2019, doi: 10.1016/j.clinthera.2019.06.003.
6. Mallama CA, C Greene, AA Alexandridis, JK McAninch, G Dal Pan, T Meyer, January 3, 2022, Patient-Reported Opioid Pain medicine Use After Discharge from Surgical Procedures: A Systematic Review, Pain Med, 23(1):29–44. doi: 10.1093/pm/pnab244. PMID: 34347101.
7. Substance Abuse and Mental Health Services Administration, 2022, Key substance use and mental health indicators in the United States: Results from the 2021 National Survey on Drug Use and Health (HHS Publication No. PEP22-07-01-005, NSDUH Series H-57), Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration, https://www.samhsa.gov/data/report/2021-nsduh-annual-national-report
8. Coyle, D. T., Pratt, C. Y., Ocran-Appiah, J., Secora, A., Kornegay, C., & Staffa, J. (2018). Opioid pain medicine dose and the risk of misuse, overdose, and death: A narrative review. *Pharmacoepidemiol Drug Saf, 27*(5), 464-472. doi:10.1002/pds.4366.
9. Guichard, L., Hirve, A., Demiri, M., & Martinez, V. (2021). Opioid-induced Hyperalgesia in Patients with Chronic Pain: A Systematic Review of Published Cases. Clin J Pain, 38(1), 49-57. doi:10.1097/ajp.0000000000000994.
10. Mattson, C.L., et al., *Drug Overdose Deaths in 28 States and the District of Columbia: 2020 data from the State Unintentional Drug Overdose Reporting System (SUDORS)*. SUDORS Data Brief, No 1, Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2022. Figure 3. Accessed Jan 23, 2023, available from: https://www.cdc.gov/drugoverdose/databriefs/sudors-1.html.
11. Thiels CA, DS Ubl, KJ Yost, SC Dowdy, TM Mabry, HM Gazelka, RR Cima, EB Habermann, September 2018, Results of a Prospective, Multicenter Initiative Aimed at Developing Opioid-prescribing Guidelines After Surgery, Ann Surg, 268(3):457–468. doi: 10.1097/SLA.0000000000002919. PMID: 30004924.
12. Howard R, B Fry, V Gunaseelan, J Lee, J Waljee, C Brummett, D Campbell Jr, E Seese, M Englesbe, J Vu, 2019, Association of Opioid Prescribing With Opioid Consumption After Surgery in Michigan, JAMA Surg, 154(1):e184234, epub ahead of print January 16, 2019, doi: 10.1001/jamasurg.2018.4234.
13. The NO PAin Investigators, 2022, Effect of a Postoperative Multimodal Opioid-Sparing Protocol vs Standard Opioid Prescribing on Postoperative Opioid Consumption After Knee or Shoulder Arthroscopy: A Randomized Clinical Trial, JAMA, 328(13):1326–1335, doi: 10.1001/jama.2022.16844.
14. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC guideline for prescribing opioids for chronic pain—United States, 2022. MMWR Recomm Rep. 2022; 71:1-95.
15. Krebs EE, A Gravely, S Nugent, AC Jensen, B DeRonne, ES Goldsmith, K Kroenke, MJ Bair, S Noorbaloochi, 2018, Effect of Opioid vs Nonopioid Medications on Pain-Related Function in

Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain: The SPACE Randomized Clinical Trial, JAMA, 319(9):872–882, doi: 10.1001/jama.2018.0899.

Related Information

- FDA Overdose Prevention Framework
- Opioid Medications
- Opioid Overdose
- Misuse of Prescription Pain Relievers
- Information about Naloxone
- State Health Departments
- Naloxone Access by State
- Disposal of Unused Medicines: What You Should Know
- Lock it Up: Medicine Safety in Your Home
- The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective
- Think It Through: Managing the Benefits and Risks of Medicines

APPENDIX

Division of Medicaid
Drug Utilization Review Board
By-Laws

Article I. Purpose

The Drug Utilization Review Board (DUR) is a requirement of the Social Security Act, Section 1927. The purpose of the DUR Board is to provide clinical guidance to the Division of Medicaid (DOM) regarding the utilization of pharmaceutical products within the Mississippi Medicaid program. The DUR Board makes recommendations to DOM to promote patient safety and cost effective care in the Mississippi Medicaid program. The DUR Board shall advise DOM with respect to the content of medical criteria and standards for utilization management strategies including prospective drug prior authorization (PA), concurrent patient management, retrospective drug utilization review, and educational intervention programs. DOM retains the authority to accept or reject the recommendations by the DUR Board.

Article II. Membership

Section 1 – Board Composition

A. The DUR Board will consist of not less than twelve (12) voting members.
B. The DUR Board voting members will be comprised of at least one-third (1/3), but no more than fifty-one percent (51%), licensed and actively practicing physicians and at least one-third (1/3) licensed and actively practicing pharmacists. Voting members may consist of health care professionals with knowledge/expertise in one or more of the following:
   1) Prescribing of drugs,
   2) Dispensing and monitoring of drugs,
   3) Drug use review, evaluation, and intervention,
   4) Medical quality assurance.
C. Non-voting board members consist of the Division of Medicaid (DOM) Executive Director, Office of Pharmacy pharmacists, DUR Coordinator, the DUR contractor and Medical Director.

Section 2 – Appointment selection methodology

A. DOM's Office of Pharmacy in consultation with officially recognized state professional healthcare associations recommends potential, qualified new candidates for appointment or reappointment of existing board members to DOM's Executive Director.
B. Nominations are considered internally and appointments are given final approval by the DOM Executive Director.
C. Board members are appointed by the Governor of the State of Mississippi, or Governor's designee, pursuant to state law.

Section 3 - Term of Office

A. All members are appointed for three year terms following a staggered appointment fulfillment as follows: one-third of DUR Board members shall be appointed each term. All subsequent appointments shall be for terms of three years from the expiration date of the previous term.
B. Members may serve up to three consecutive three-year terms (for a total of nine consecutive years).
C. Members may serve for either an extended term or a fourth consecutive term at the discretion of the Executive Director and by recommendation of both the DUR Coordinator and Division of Medicaid Office of Pharmacy in the event that no qualified, willing candidate is found in sufficient time. Members, including those filling vacated positions, may be re-appointed by the Executive Director for a subsequent term.
D. In the event of an unexpected or expected vacancy, the DUR Coordinator and Office of Pharmacy may recommend a qualified replacement candidate to DOM's Executive Director for emergency approval.
E. The Executive Director shall fill any vacancy before the end of the term, and the person appointed to fill the vacancy shall serve for the remainder of the unexpired term. Members, including those filling vacated positions, may be re-appointed by the Executive Director for a subsequent term.

Section 4 - Attendance

A. Members are required to attend at least fifty percent of the meetings per year. Failure to attend meetings without an explanation of extenuating circumstances will result in the termination of the member's appointment.
B. Members are asked to give advance notice regarding any planned absences so that a quorum may be determined prior to meetings.

Section 5 - Resignation

A member of the DUR Board may resign by giving a 30 day written advance notice to the DUR Board Chair and DUR Coordinator.

Section 6 - Removal

A member of the DUR Board may be removed by either the DUR Board Chair or majority vote of the DUR Board for good cause. Good cause may be defined as one or more of the following conditions:

A. Lack of attendance –failure to attend at least 50% of the scheduled DUR meetings shall constitute a resignation by said DUR Board member,
B. Identified misconduct or wrongdoing during any DUR Board term, or

C. Not disclosing a conflict of interest either upon initial disclosure or throughout the rest of the term.

Section 7 - Board Officers

At the first meeting of the state fiscal year, which constitutes July 1 through June 30, board members shall select two members to serve as Chair and Chair-Elect of the board, respectively. The Chair and Chair-Elect shall both serve one year terms. At the end of the serving year, the Chair-Elect assumes the role of Chair, and a new Chair-Elect will be chosen.

If the persons serving as Chair and Chair-Elect have either previously served as Chair or Chair-Elect, that person may be reelected to either posting.

The Chair-Elect will serve as Chair in absentia of the Chair or by the Chair's request.

Section 8 – Reimbursement

The Division of Medicaid will reimburse DUR Board members for travel related expenses.

Article III. Meetings

Section 1 – Frequency

The DUR Board shall meet at least quarterly, and may meet at other times as necessary for the purpose of conducting business that may be required. The DUR Board Chair, a majority of the members of the board, or the Division of Medicaid Office of Pharmacy and DUR Coordinator, shall maintain the authority of calling DUR meetings.

Section 2 – Regular Meetings

The DUR Board will hold regular quarterly meetings in the city of Jackson, Mississippi. Meetings will occur at the predesignated time and place. Dates for the upcoming year's quarterly meetings will be posted before the first quarterly meeting of the upcoming year.

Section 3 – Special Meetings

The DUR Board may meet at other times other than regular quarterly meetings as deemed necessary and appropriate. The DUR Coordinator and Office of Pharmacy must notify DUR Board members of any special meeting at least two weeks, i.e., ten (10) days, prior to the requested meeting date. Special meetings may be requested by the following officials:

A. Division of Medicaid Executive Director,
B. DUR Coordinator and Office of Pharmacy,
C. DUR Board Chair, or
D. Majority of DUR Board members via communication to DUR Coordinator and/or DUR Board Chair.

Section 4 – Meeting Notice

DUR Board members will be notified of the location for the meeting a minimum of ten (10) days in advance. Notification may include one or a combination of the following methods: e-mail, fax, or other written communication. DUR Board members are required to keep on file with
DOM Office of Pharmacy his or her address, primary phone number, alternate phone number (i.e., cell), fax number, and email address to which notices and DUR related communications may be submitted.

Meetings may be cancelled due to lack of quorum, severe inclement weather, or other reasons as determined by the DUR Coordinator and Office of Pharmacy. In the event of a cancellation, the DUR Coordinator and DOM Pharmacy staff will communicate with DUR Board members regarding the meeting cancellation as soon as circumstances permit. Notifications shall also be posted with DFA and on DOM's website to ensure that the public is notified of any meeting cancellation.

DUR Board Meetings shall be open to the public and conducted in accordance with state law, specifically the Open Meetings Act. Notice of any meetings held shall be provided at least five (5) days in advance of the date scheduled for the meeting. The notice shall include the date, time, place and purpose for the meeting and shall identify the location of the meeting to the general public.

Section 5 – Meeting Sign-In

All meeting attendees will be required to sign-in at the meeting entrance for DUR meetings. Sign-in sheets will be logged, scanned and transferred to electronic medium for official records. All attendees shall include participant's name and entity represented (as applicable).

Section 6 – Quorum

A simple majority of voting board members shall constitute a quorum and must be present for the transaction of any business of the board. For a fully-appointed 12-person DUR Board as required by state law, seven voting board members constitutes a quorum. If a quorum is not present, the Chair, Chair-Elect or DUR Coordinator maintains the responsibility to conclude meeting proceedings. Meeting minutes shall reflect that a quorum was not present.

Section 7 – Voting

The voting process shall be conducted by the Chair or the Chair-Elect in absentia of the Chair.

All board recommendations shall begin with a motion by a voting board member. The motion may then be seconded by a voting board member. If a recommendation does not receive a second motion, the motion shall not pass. If a recommendation receives a second motion, then the board shall vote on the motion. A motion shall be considered as passed if the motion carries a majority of votes if a quorum of the board is present.

In the event that a motion receives a tie vote in the presence of a quorum, the motion shall not pass. The motion can be brought up for further discussion after which a subsequent motion may be made to vote on the issue again during the same meeting, or a motion can be made to table the issue and discussion until the next quarterly DUR Board meeting.

A vote abstention occurs when a voting member is present for the meeting and the action but has chosen not to vote on the current motion. An abstention is a vote with the majority on the measure. A recusal, on the other hand, is necessitated when a voting member has a conflict of interest or potential pecuniary benefit resulting from a particular measure. In order to properly and completely recuse oneself from a matter, the DUR Board member must leave the room or area where discussions, considerations, or other actions take place

before the matter comes up for discussion. The member must remain absent from the meeting until the vote is concluded. The minutes will state the recusing member left the room before the matter came before the DUR Board and did not return until after the vote.

Section 8 – Minutes

A public body speaks only through its minutes. State law, specifically the Open Meetings Act, requires minutes be kept of all meetings of a public body, whether in open or executive session, showing the following:

A. Members present or absent,
B. Date, time and place of meeting,
C. Accurate recording of any final actions taken,
D. Record, by individual member, of how s/he voted on any final action, and
E. Any other information that the public body requests is reflected in the minutes.

The minutes shall be finalized no later than thirty (30) days after the adjournment of the DUR Board meeting and shall be made available for public inspection. DOM Office of Pharmacy posts all DUR Board Minutes on the DUR webpage.

Section 9 – Speakers & Special Topics

DUR Board members may request various healthcare, industry, or specialized professionals to present at DUR meetings regarding a posted topic on an upcoming DUR agenda.

A. The DUR Board may allow up to 20 minutes for topic presentation by an invited speaker.
B. DUR Board Members may ask a member of the audience to provide information on a topic being discussed by the Board. Invited participants may be asked to disclose any potential conflicts of interests if applicable. (See Article IV, Section 1).
C. Members of the audience may not speak unless so designated at the appropriate time by a DUR Board member.
D. DUR Board Members, both voting and non-voting, maintain speaking privileges at DUR meetings.
E. Contracted employees of DOM and employees of other DOM vendors are considered members of the audience.

Section 10 – Executive Session

During special circumstances, the DUR Board may go into executive session at the conclusion of normal meeting proceedings; however, all DUR Board meetings must commence as an open meeting. In order for executive session to be called, the following procedure must be followed in accordance with the Open Meetings Act:

A. A member may <u>move to close</u> the meeting to determine whether board needs to go into executive session; vote in open meeting with vote recorded in minutes, majority rules.
B. Closed meeting: vote taken on whether to <u>declare</u> executive session, requires 3/5 of all members present.
C. Board comes back into open session and states statutory reason for executive session. The reason for the executive session shall be recorded in the meeting minutes.
D. Board members then will go into executive session where action may be taken on stated subject matter only.

E. Minutes must be kept in accordance with the Open Meetings Act.

Section 11 – Conduct of Participants

Pursuant to state law, specifically the Open Meetings Act, the DUR Board may make and enforce reasonable rules and regulations for the conduct of persons attending the DUR meetings. The following is a non-exhaustive list of rules for DUR Board meetings:

A. Attendees should please remain silent and allow for the efficient transaction of business.
B. Cell phones should be placed on silent or vibrate.
C. Laptop computers are discouraged from being utilized during meetings as frequent typing may distract board members.
D. Food and drink are not allowed in the meeting room.
E. Security is provided by the state. Guests not following proper decorum may be asked to leave by security.

Article IV. Public Participation

Section 1 - Disclosure of Persons Appearing Before DUR Board

The DUR Board may ask individuals appearing before the board to disclose either in writing or verbally their relationship, as applicable, including but not limited to pharmaceutical companies or special interest groups. Any such disclosures should be recorded as a matter of public record in the documented meeting minutes.

Article V. Conflicts of Interest

DUR Board members are expected to maintain the highest professional, ethical standards. A conflict of interest may exist when a DUR Board member maintains a financial/pecuniary, personal, or professional interest that may compete or interfere with the DUR Board member's ability to act in a fair, impartial manner while acting in the best interests of the Division of Medicaid and the beneficiaries that it serves.

As such, DUR Board members are required to complete and submit annually a Conflict of Interest disclosure statement with the DOM Office of Pharmacy and DUR Coordinator. Statements shall be maintained by the Office of Pharmacy. Members have an ongoing responsibility to update and revise said statements, disclosing any new conflicts of interest to the DUR Coordinator and DOM Office of Pharmacy.

It is the sole responsibility and requirement of each board member to review the agenda of each forthcoming board meeting to determine any if any potential conflicts of interest exist. If so, an aforementioned Disclosure statement must be updated indicating the conflict of interest. The board member should notify the Chair or Chair-Elect of the conflict of interest prior to the meeting.

A DUR Board member shall recuse himself/herself from any vote, action, or discussion pertaining to any product or product class if there is documentation stating an actual or perceived conflict of interest. Please refer to the procedure outlined in Article III, Section 7.

Article VI. Confidentiality

DUR Board members are required to safeguard all confidential and proprietary information, including but not limited to pricing information, which is disclosed by the Mississippi Division of Medicaid for purposes of conducting DUR Board activities. Any provider or patient specific information discussed by the DUR Board shall also be kept strictly confidential in accordance with state and federal law.

Article VII. Amendments

Proposed Amendments of By-Laws

A. Proposed amendments must be submitted to the DUR Coordinator at least thirty (30) days prior to the next scheduled DUR meeting and the proposed amendments will be disseminated to the DUR Board en masse for consideration at said DUR Board meeting.
B. Proposed amendments will be distributed to board members no less than five (5) business days prior to next DUR Board meeting.
C. Proposed amendments will be initiated by the Chair, or the Chair-Elect in absentia of the Chair, prior to Next Meeting Information announcements.
D. Proposed amendments will be voted upon at the next scheduled DUR Board meeting. If majority of DUR Board votes to ratify amendment, the amendment will take effect immediately at the conclusion of the meeting.

MS-DUR BOARD
COMMON ABBREVIATIONS

AWP	Any Willing Provider, Average Wholesale Price
BENE	Beneficiary
CAH	Critical Access Hospital
CCO	Coordinated Care Organization
CDC	Centers for Disease Control
CHIP	Children's Health Insurance Program
CMS	Center for Medicare and Medicaid Services
COB	Coordination of Benefits
CPC	Complex Pharmaceutical Care
DME	Durable Medical Equipment
DOC	Department of Corrections
DOM	Division of Medicaid
DUR	Drug Utilization Review
EOB	Explanation of Benefits
EPSDT	Early and Periodic Screening, Diagnosis and Treatment
FA	Fiscal Agent
FFS	Fee For Service
FPW	Family Planning Waiver
FQHC	Federally Qualified Health Clinic
FY	Fiscal Year
HB	House Bill
HCPCS/ HEIDIS	Health Plan Employer Data and Information Set
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability
IDD	Intellectual and Developmental Disabilities
LTC	Long Term Care
MAG	Magnolia Health
MEDD	Morphine Equivalent Daily Dose
MOL	Molina Healthcare
MPR	Medication Possession Ratio
MSCAN	Mississippi Coordinated Access Network
MSDH	Mississippi State Department of Health
NADAC	National Average Drug Acquisition Cost
NDC	National Drug Code
P&T	Pharmacy and Therapeutics
PA	Prior Authorization
PBM	Pharmacy Benefit Manager
PDC	Proportion of Days Covered
PDL	Preferred Drug List
PI	Program Integrity
PIP	Performance Improvement Program
POS	Point of Sale, Place of Service, Point of Service
Pro-DUR	Prospective Drug Use Review
OTC	Over the Counter
QI	Quality Indicator
QIO	Quality Improvement Organization
QM	Quality Management
RA	Remittance Advise
REOMB	Recipient's Explanation of Medicaid Benefits
Retro-DUR	Retrospective Drug Utilization Review
RFI	Request for Information
RFP	Request for Proposal
RHC	Rural Health Clinic
SB	Senate Bill
SCHIP	State Child Health Insurance Program
SMART PA	Conduent's Pharmacy Application (SmartPA) is a proprietary electronic prior authorization system used for Medicaid fee for service claims
SPA	State Plan Amendment
UHC	United Healthcare
UM/QIO	Utilization Management and Quality Improvement Organization
UPDL	Universal Preferred Drug List
UR	Utilization Review
VFC	Vaccines for Children
WAC	Wholesale Acquisition Cost
WIC	Women, Infants, Children
340B	Federal Drug Discount Program