

Center for Medicaid and CHIP Services

September 12, 2013

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 165

For State Technical Contacts

COVERAGE OF BARBITURATES, BENZODIAZEPINES, AND ALL DRUGS USED FOR SMOKING CESSATION EFFECTIVE JANUARY 1, 2014

We are providing further guidance to that in State Release #162 regarding the coverage of barbiturates and benzodiazepines and changes states will need to make to their state plans effective January 1, 2014.

Changes Effective January 1, 2014

Effective January 1, 2014, section 2502 of the Affordable Care Act amends section 1927(d)(2) of the Social Security Act (the Act) by removing barbiturates, benzodiazepines, and agents used to promote smoking cessation from the list of drugs a state Medicaid program may exclude from coverage or otherwise restrict. It also added section 1927(d)(7) of the Act which explicitly prohibits states from excluding the following drugs, or their medical uses, from coverage: barbiturates, benzodiazepines, and agents when used to promote smoking cessation, including agents approved by the Food and Drug Administration under the over-the-counter (OTC) monograph process for purposes of promoting, and when used to promote, tobacco cessation .

Medicaid Beneficiaries (Other than Dual Eligible Beneficiaries)

For Medicaid beneficiaries (other than dual eligible beneficiaries), beginning January 1, 2014, benzodiazepines and barbiturates are no longer excluded from coverage or otherwise restricted under 1927(d)(2) of the Medicaid program. Additionally, drugs used to promote smoking cessation including OTC drugs, are no longer excluded from coverage or otherwise restricted under the Medicaid program.

Dual Eligible Beneficiaries

For Medicaid beneficiaries that also have Medicare (dual eligible beneficiaries), beginning January 1, 2014, benzodiazepines and barbiturates qualify as Part D drugs, and are no longer covered under Medicaid. Prescription smoking cessation drugs are already covered by Part D, but because Part D does not generally cover these non-prescription drugs, states are responsible for coverage of such non-prescription products for dual eligible beneficiaries.

State Plan Amendments

In light of the statute, states will need to remove from the state plan any indication that the following drugs are restricted or otherwise excluded: barbiturates, benzodiazepines and agents used to promote smoking cessation. To the extent that the state needs to change its state plan to be consistent with these Medicaid coverage requirements, the state will need to submit a state plan amendment (SPA) to be effective January 1, 2014.

CMS has addressed tobacco cessation coverage options for the coverage of counseling services and pharmacotherapy services in a State Directors Letter (#11-007) issued on June 24, 2011. We encourage states to refer to this letter for additional discussion on the Public Health Service Guideline which recommends a combination of counseling and medication as a more effective treatment for tobacco cessation than either medication or counseling alone.

In order to ensure timely processing of SPAs, we encourage states to submit a SPA as early as possible. In addition, the state may need to make necessary changes to its claims processing programs to allow the appropriate coverage of these drugs.

Please contact Joe Fine at 410-786-2128 if you have any questions.

PRODUCT DELETIONS

As previously notified, several labelers have informed us that the following NDCs are non-drug products and therefore, the NDCs do not meet the definition of a covered outpatient drug as set forth in Section 1927(k)(2) of the Social Security Act. As a result, the products are not eligible for inclusion in the Medicaid Drug Rebate Program or eligible for FFP as a covered outpatient drug.

Date of original notification: March 29, 2013

NDC	Product Name
00904-5983	AMMONIUM LACTATE 12% CREAM
00904-5984	AMMONIUM LACTATE 12% LOTION
00066-0105	SHEPARD'S SKIN CREAM
00066-0104	SHEPARD'S SKIN 16OZ. LOTION
00066-0108	SHEPARD'S 4 OZ CREAM
00066-0109	SHEPARD'S 4OZ
45802-0513	AMMONIUM LACTATE CREAM 12%
45802-0525	AMMONIUM LACTATE LOTION 12%
68712-0044	NUVAIL
00536-0160	VIT C 500MG SYRUP
00536-1938	CO ENZYME Q10 100MG
00536-2380	VIGORTOL NEW IMPROVED
00536-2450	ZINC SULFATE 220MG
00536-2770	CALCIONATE SYRUP
00536-2790	CEROVITE LIQUID
00536-3223	CITRUS CALCIUM 950
00536-3224	CITRUS CALCIUM 1500 + D

00536-3291	VIT C 500MG TABS CHEW
00536-3292	VIT C 500MG TABS
00536-3357	BEE-ZEE TABS
00536-3416	CALCIUM GLUCONATE 10GR
00536-3422	CALCIUM LACTATE 10GR TAB
00536-3424	CALCIUM 600-D SUPPLEMENT
00536-3426	CALCIUM 600 SUPPLEMENTS
00536-3442	CEROVITE TABS ADVANCED FORMULA
00536-3443	CEROVITE JR CHEWABLE TABS
00536-3445	CEROVITE SENIOR
00536-3448	CHEWABLE-VITE TABS NEW
00536-3449	CHEWABLE-VITE W/IRON TABS NEW
00536-3451	CHLOROPHYLL TABS C T
00536-3521	MAGNESIUM OXIDE 400MG
00536-3542	VIT B-12 100MCG TABS
00536-3546	DAILY-VITE TABS W/IRON NEW
00536-3547	DAILY-VITE TABS NEW
00536-3551	VIT B-12 500 MCG TABS
00536-3556	VIT B-12 1000MCG TABS
00536-3791	CALCI-MIX 100
00536-3792	CALCI-CHEW CHERRY 100
00536-3843	FOLIC ACID 800 MCG TABS
00536-3844	FOLIC ACID 400 MCG TABS
00536-3908	LIPOGEN SOFT GELATIN
00536-3984	INOSITOL 500MG TABS
00536-4044	MULTILEX TABS
00536-4046	MULTIVITAMINS TABS (8 VITAMINS)
00536-4060	MULTILEX-T/M W/MINERALS TABS
00536-4068	NIACINAMIDE 100MG TABS
00536-4069	NIACINAMIDE 500MG TABS
00536-4070	NIACIN 50MG TABS
00536-4074	NIACIN 250MG SR CAPS (NICOTINIC)
00536-4076	NIACIN 100MG TABS
00536-4077	NIACIN 500MG SR CAPS (NICOTINIC)
00536-4078	NIACIN 500MG TABS
00536-4087	LAC-DOSE CAPTAB
00536-4178	I-VITE PROTECT
00536-4304	POLY-VITAMIN CHEWABLE TABS NEW
00536-4406	VIT B- 6 25MG TABS PYRIDOX HCL
00536-4408	VIT B- 6 50MG TABS PYRIDOX HCL
00536-4409	VIT B- 6 100MG TABS PYRIDOX HCL
00536-4660	THEREMS FILM COATED TABLETS
00536-4661	THEREMS M FILM COATED TABLETS
00536-4667	THEREMS-H TABS
00536-4678	VIT B- 1 50MG TABS THIAMINE
00536-4680	VIT B- 1 100MG TABS THIAMINE
00536-4750	UNICOMPLEX-M TABS

00536-4753	VI-STRESS TABLETS NEW IMPROVED
00536-4763	VITABEE W/C CAPTABS
00536-4787	VIT B COMPLEX SGEL CAPS
00536-4793	VIT E 100 IU SGEL CAPS
00536-4798	VIT E 200 IU SGEL CAPS
00536-4799	VIT E 400 IU SGEL CAPS
00536-4801	VIT E 1000 IU SGEL CAPS
00536-4902	BETA CAROTENE 25000 1 U CAPS
00536-5090	I-VITE
00536-5440	VIT E 400 IU NAT SGEL CAPS
00536-5588	ANTIOXIDANT FORMULA
00536-5589	ANTIOXIDANT ULTRA FORMULA
00536-5890	FER SULFATE 324MG (5GR) FC RED TABS
00536-6384	COD LIVER OIL CAPS
00536-6412	MELATONIN 3MG
00536-6506	PAPAYA ENZYME TABS
00536-6659	BIOTIN 300 MCG TABS
00536-6668	CHROMIUM PICOLINATE 200MCG SOFTGEL
00536-6671	ZINC CHELATED 50MG TABS
00536-6680	MAGNESIUM 27 MG CHELATED TABS
00536-6717	PANTOTHENIC ACID 500MG TABS
00536-6731	L-LYSINE 500MG TABS
00536-6889	CALCIUM CHEWABLE 500MG TABS
00536-7030	NIACIN 500MG TR TABS
00536-7033	NIACIN 750MG TR TABS
00536-7038	NIACIN 1000MG TR TABS
00536-7049	L-TYROSINE 500MG CAPTABS
00536-7180	ACIDOPHILUS CAPTAB
00536-7181	ACIDOPHILUS EXTRA STRENGTH
00536-7183	ZINC & C LOZENGES
00536-7186	SEA-OMEGA 30
00536-7187	SEA-OMEGA 50
00536-7300	NEPHRO-VITE
00536-7410	L-CARNITINE
00536-7816	POLY-VITAMIN CHEWABLE W/IRON TABS
00536-8450	POLYVITAMIN DROPS
00536-8501	TRI-VITAMINS
00536-8530	POLYVITAMIN DROPS W/IRON
00536-8533	VITAMIN E OIL

Date of original notification: August 2, 2013

50383-0120	GERI-TONIC
50383-0167	VITAMIN C SYRUP
50383-0625	POLYVITAMINS DROPS
50383-0632	POLYVITAMIN DROPS WITH IRON
50383-0683	THERA-PLUS

Date of original notification: August 12, 2013

50383-0635 TRI-VITAMIN DROPS

Please note that while the products listed above are not eligible for coverage or FFP under the Medicaid Drug Rebate Program, they may be eligible for Medicaid coverage or FFP as part of home health services, EPSDT services as defined in section 1905(r)(5) of the Social Security Act, or elsewhere to the extent that such coverage is consistent with the approved state plan.

NEW/REINSTATED REBATE AGREEMENTS

Labeler Name: TALON THERAPEUTICS, INC.
Optional Effective Date: 09/03/2013
Mandatory Effective Date: 01/01/2014
Labeler Code: 20536

Labeler Name: COVIS PHARMACEUTICALS INC.
Optional Effective Date: 07/09/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 24987

Labeler Name: RENAISSANCE PHARMA, INC.
Optional Effective Date: 07/12/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 40085

Labeler Name: MICRO LABS LIMITED
Optional Effective Date: 04/29/2013
Mandatory Effective Date: 07/01/2013
Labeler Code: 42571

Labeler Name: PARAGON BIOTECK, INC.
Optional Effective Date: 07/16/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 42702

Labeler Name: THERAVANCE, INC
Optional Effective Date: 07/29/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 52118

Labeler Name: SILVERGATE PHARMACEUTICALS, INC.
Optional Effective Date: 08/28/2013
Mandatory Effective Date: 01/01/2014
Labeler Code: 52652

Labeler Name: TRUPHARMA, LLC
Optional Effective Date: 07/29/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 52817

Labeler Name: AMNEAL-AGILA, LLC
Optional Effective Date: 05/21/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 53150

Labeler Name: XENOPORT, INC
Optional Effective Date: 06/06/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 53451

Labeler Name: OREXO US, INC.
Optional Effective Date: 07/24/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 54123

Labeler Name: LINEAGE THERAPEUTICS INC.
Optional Effective Date: 05/21/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 54505

Labeler Name: DUCHESNAY USA, INC.
Optional Effective Date: 04/12/2013
Mandatory Effective Date: 07/01/2013
Labeler Code: 55494

Labeler Name: CITRON PHARMA, LLC
Optional Effective Date: 06/26/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 57237

Labeler Name: GALENA BIOPHARMA, INC.
Optional Effective Date: 09/03/2013
Mandatory Effective Date: 01/01/2014
Labeler Code: 57881

Labeler Name: PHARMACIST PHARMACEUTICAL LLC
Optional Effective Date: 05/24/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 63704

Labeler Name: MEDEFIL, INC
Optional Effective Date: 05/09/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 64253

Labeler Name: STRIDES ARCOLAB LIMITED
Optional Effective Date: 07/23/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 64380

Labeler Name: BIOGEN IDEC INC.
Optional Effective Date: 04/29/2013
Mandatory Effective Date: 07/01/2013
Labeler Code: 64406

Labeler Name: PALMETTO PHARMACEUTICALS, INC
Optional Effective Date: 07/02/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 68134

Labeler Name: AVION PHARMACEUTICALS
Optional Effective Date: 07/01/2013
Mandatory Effective Date: 10/01/2013
Labeler Code: 75854

Labeler Name: ACTON PHARMACEUTICALS
Optional Effective Date: 08/27/2013
Mandatory Effective Date: 01/01/2014
Labeler Code: 75989

Labeler Name: BD RX, INC
Optional Effective Date: 04/18/2013
Mandatory Effective Date: 07/01/2013
Labeler Code: 76045

TERMINATED LABELERS

<u>Labeler Code</u>	<u>Labeler Name</u>	<u>Effective Date</u>
00072	WESTWOOD-SQUIBB PHARMACEUTICALS	07/01/2013
00126	COLGATE ORAL PHARMACEUTICALS, INC.	07/01/2013
00276	MISEMER PHARMACEUTICAL, INC.	07/01/2013
51879	TEC LABORATORIES, INC.	01/01/2014
61787	HEALTH CARE PRODUCTS HI-TECH PHARMACAL CO	10/01/2013
66977	MPM MEDICAL, INC.	07/01/2013

Please direct your drug rebate data questions to MDROperations@cms.hhs.gov and your drug policy questions to RxDrugPolicy@cms.hhs.gov.

/s/

Barbara Coulter Edwards
Director
Disabled & Elderly Health Programs Group