



Pharmacy News & Views

February 2009

Maryland Department of Health and Mental Hygiene / Office of Systems, Operations and Pharmacy

National Provider Identifier (NPI) Information for Providers

Effective March 1, 2009 the pharmacy point-of-sale claims processor for the following Programs: Maryland Medicaid Fee-For-Service (MA), Kidney Disease Program (KDP), Maryland AIDS Drug Assistance Program (MADAP) and Breast & Cervical Cancer Diagnosis and Treatment Program (BCCDT) will **ONLY** accept the NPI number for the prescribing provider.

- Pharmacy claims for recipients that participate in the above programs, which are submitted without the **prescriber's** NPI, will be rejected.
- All prescribers must provide their NPI with each prescription.
- Prescribers who have yet to obtain an NPI can easily obtain one. Information on how to get an NPI can be found online at: <https://nppes.cms.hhs.gov/NPPES/Welcome.do>. A registry of assigned NPI numbers is also available at this website.
- When submitting claims electronically, pharmacists must enter the prescriber's NPI in field 411-DB (Prescriber ID) and 466-EZ (Prescriber ID Qualifier) in accordance with the Payer Specification Sheet found at <http://mdrxprograms.com/>.
- Pharmacies are expected to use diligence in obtaining a prescriber's NPI for all prescriptions billed to Maryland Pharmacy Programs. If a pharmacy has exhausted all efforts to obtain a prescriber's NPI, including searching the National Plan & Provider Enumeration System (<https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do>), only then may the pharmacy contact the Claims Processing Point of Sale (POS) Call Center at 800-932-3918 to obtain prior authorization.
- The pharmacy POS claims processor will validate the prescriber NPI for all pharmacy claims.
- Pharmacies will receive the following return message on claims submitted without an NPI number: "Missing/Invalid Prescriber ID"
- The pharmacy provider may then either:
 - Resubmit the claim with a valid NPI prescriber number or
 - Contact the claims processor (ACS) call center at 1-800-932-3918 and request assistance in determining the prescriber NPI number.

For controlled substances, the prescriber DEA number must still be noted on the prescription in order to comply with both federal and state regulations. However only the NPI number should be transmitted with the claim.

HealthChoice and Primary Adult Care (PAC) Medicaid Managed Care Organizations (MCOs) have already notified or will notify pharmacies directly of their NPI requirements.

Continuing Education

A free live continuing education seminar is being developed and is scheduled for Saturday May 16, 2009. The title is "Maximizing Pain Management While Minimizing Risk of Abuse." Both physician CME and pharmacy CE credits will be offered. The program will begin with a breakfast at 8:00 am and the seminar will run from 8:30 am to 1 pm. The program will be hosted by St. Agnes Hospital in Baltimore Maryland and will be held in their auditorium. The objectives of this seminar are to:

- Discuss strategies of pain management treatment and selection of agents to reduce the risk of misuse
- Review clinical considerations, such as drug interactions of analgesics, when selecting appropriate pain management therapy
- Distinguish pseudoaddiction from addiction
- Review the regulatory and legal considerations associated with prescribing and dispensing controlled substances
- Review the Maryland Medicaid Corrective Managed Care (Pharmacy Lock In) Program

The seminar is sponsored by the Department of Health and Mental Hygiene, Maryland Medicaid Pharmacy Program (MMPP). Registration information coming soon to the following website: www.marylandmedicaidpharmacyinformation.com

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Tamper-Resistant Prescriptions

Since October 1, 2008 all handwritten and computer-generated printed prescriptions for Fee-For-Service Medicaid patients must be fully tamper resistant in compliance with federal and state regulations. To simplify things, many prescribers are using the tamper-resistant features for all their prescriptions, not just for Medicaid.

Most Maryland Medicaid recipients belong to one of the following Managed Care Organizations (MCOs): AMERIGROUP Community Care, Diamond Plan from Coventry Health Care, Jai Medical Systems, Inc., Maryland Physicians Care, MedStar Family Choice, Priority Partners and UnitedHealthcare. Prescriptions covered by these HealthChoice/Primary Adult Care (PAC) MCOs are not required to be written on tamper-resistant pads, **but prescriptions for their enrollees' antiretroviral and mental health drugs are, because they are paid for by the State of Maryland directly on a Fee-For-Service basis.**

For all medications paid for directly by the State of Maryland under Fee-For-Service, when a written prescription is presented that is not fully tamper-resistant, the pharmacy must contact the prescriber and confirm that it is a valid order. The date and name of the person who verifies the order must be noted on the non-compliant prescription.

Pharmacies can report to DHMH, prescribers who are not writing compliant prescriptions, by completing and sending in the form found on the website at http://www.dbmb.state.md.us/mma/mpap/pdf/2008/TRR_reporting_form_non-compliant_prescribers8-08.pdf.

The Maryland Medicaid Program is auditing pharmacies to insure compliance. Written prescriptions which were not compliant and were not validated by the pharmacy will be charged back to the pharmacy that filled them.

If the prescriber is unavailable to validate the prescription, Maryland Medicaid will pay for a 72-hour emergency supply. The pharmacist should use their professional judgment in determining whether the prescription is needed on an emergency basis and call 800-932-3918 to obtain authorization.

Limit of 12 Months to Submit Claims

The Maryland Medicaid Program has made changes to the regulation that specifies the time frame for submitting claims to the Fee-For-Service Program. Specifically, COMAR 10.09.36.06 has been changed to allow providers twelve (12) months to submit claims. The specific regulations can be found at:

<http://www.dsd.state.md.us/comar/10/10.09.36.06.btm>

Medroxyprogesterone Injection

Generic medroxyprogesterone injection suspension 150mg/ml is available as a single dose 1ml vial or as a single dose 1ml pre-filled syringe. Both dosage forms have the same Interchangeable Drug Cost (IDC) which is that of the single dose vial. The pre-filled syringe will be reimbursed at the cost of the single dose vial. Maryland Medicaid does not reimburse an additional amount for convenience packaging.

HealthChoice Formularies and Maryland Medicaid Preferred Drug List (PDL) Listed on Epocrates®

All HealthChoice MCO and Primary Adult Care (PAC) formularies, as well as the Maryland Medicaid PDL, are available on the Epocrates® system which is accessible from a desktop or laptop computer, smart phone or PDA device.

- Epocrates® will be updated monthly with MCO formulary changes and any Fee-For-Service PDL changes.
- The Epocrates® Online service is free to all physicians, other prescribers, pharmacists and healthcare providers.
- Coverage status of each drug is listed along with contact information and comments for each drug, including, if prior authorization is required or quantity limits are in place.
- The free system also provides drug label information and a drug-drug interaction checker.

To register for Epocrates®, visit www.epocrates.com. Click on "Epocrates Online" in the upper right corner of the page and follow the registration prompts.

Based on statistics supplied by Epocrates®, as of the end of the third quarter 2008, there were 6,682 current subscribers to Epocrates® who have selected to view on a regular basis either the Maryland Medicaid PDL or one of the HealthChoice/PAC formularies, as part of their subscription. The breakdown of subscribers is as follows:

- 2,765 Physicians
- 1,437 Medical Students
- 592 Registered Nurses.
- 428 Nurse Practitioners
- 326 Pharmacists
- 284 Physician Assistants

The remainder of subscribers represents a variety of other health care practitioners.

Possible New Generics for 2009

The table below lists several drugs that may become available as generics during 2009. As a general rule generic agents are usually preferred by the MMPP. However, in some cases, when only a single source generic is available, it may be more advantageous for the MMPP to make the brand agent preferred and the generic non-preferred. As these drugs become available generically, the MMPP will advise pharmacies if the brands are preferred or the generic equivalents will be preferred.

YEAR	PERIOD	BRAND NAME	GENERIC NAME
2009	1Q (Mar)	Ambien® CR	zolpidem controlled-release
2009	2Q (Apr)	Topamax®	topiramate
2009	2Q (Apr)	Casodex®	bicalutamide
2009	3Q (Aug)	Glyset®	miglitol
2009	4Q (Oct)	Prandin®	repaglinide
2009	4Q (Oct)	Fosamax Plus D®	alendronate/cholecalciferol
2009	4Q (Nov)	Cellcept®	mycophenolate mofetil
2009	4Q (Nov)	Prevacid®	lansoprazole
2009	4Q (Nov)	Aceon®	perindopril
2009	4Q (Nov)	Sarafem® tablets	fluoxetine tablets
2009	4Q (Dec)	Acular®	ketorolac
2009	4Q (Dec)	Valtrex®	valacyclovir

Source: Medco Health Solutions. Estimated Dates of Possible First Time Generic/Rx-to-OTC Market Entry. Medco Health Solutions website. Available at: http://www.medcohealth.com/art/corporate/anticipatedfirsttime_generics.pdf - Accessed February 17, 2009.

Estimated dates for new generics are subject to change due to a number of factors including patent litigation or patent extensions and drug availability in the market place.

Preferred Drug List

The Maryland Medicaid Pharmacy and Therapeutics (P&T) Committee met on February 5, 2009 to discuss the PDL. A total of 30 drug classes were reviewed along with 7 individual drugs. Changes made to the PDL will be implemented as of April 1, 2009. The entire updated PDL will be printed in the next issue of this newsletter. The PDL can also be viewed on line at <http://www.dbmb.state.md.us/mma/mpap/prefdruglist.html>

Clinical



Corner

Clinical Corner is a new feature of the MMPP Newsletter. This section will feature a brief discussion concerning issues relating to a specific drug or class of drugs. This issue features information on the use of botulinum toxin for the treatment of dystonia.

The use of botulinum toxin type A or type B requires prior authorization. **Type A and type B botulinum toxin are not interchangeable.** Units and dosing for each agent are unique. The drugs are currently FDA approved for the following:

- Types A and B - treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia.
- Type A - treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.
- Type A – treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.

Requests for off-label uses will be considered on a case by case basis. Only those off-label uses which have been documented in and supported by official compendia, such as the American Hospital Formulary Service (AHFS) and MICROMEDEX DRUGDEX, will be considered. **Cosmetic use of botulinum toxin will not be approved.**

The number of vials approved for use will be a sufficient quantity needed for one treatment session. Large quantities of vials to be used for multiple treatment sessions will not be approved. Prior authorization must be completed every three (3) months for ongoing treatment.

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New Drugs Approved in 2008

The following are new drugs approved in 2008. Those drugs noted with an asterisk and bolded are included in drug classification that are part of the mental health carve out and should be billed Fee-For-Service.

New Molecular Entities	
Drug Name	Indication
difluprednate (Durezol®)	Treatment of post operative ocular inflammation
eltrombopag (Promacta®)	Treatment of chronic immune thrombocytopenia
fesoterodine fumarate (Toviaz®)	Treatment of the symptoms related to overactive bladder
<i>lacosamide (Vimpat®)*</i>	<i>Treatment of partial-onset seizures</i>
methylnaltrexone bromide (Relistor®)	Treatment of opioid induced constipation
<i>rifunamide (Banzel®)*</i>	<i>Treatment of seizures associated with Lennox-Gastaut Syndrome</i>
silodosin (Rapaflo®)	Treatment of benign prostatic hypertrophy
tapentadol (this drug does not have a trade name at this time)	Treatment of moderate to severe pain
tetrabenazine (Xenazine®)	Treatment of chorea associated with Huntington's disease
New Dosage Forms	
Drug Name	Indication
<i>bupropion (Alplenzin®)*</i>	<i>hydrobromide salt of bupropion for treatment of depression</i>
granisetron (Sancuso®)	Transdermal for of granisetron for chemotherapy induced nausea and vomiting
Sumatriptan/naproxen (Treximet®)	Combination of sumatriptan and naproxen for migraines
tramadol (Ryzolt®)	Extended release formulation of tramadol for moderate to severe pain
<i>valproic acid (Stavzor®)*</i>	<i>Extended release valproic acid for bipolar depression, seizures and migraine prophylaxis</i>
<i>zolpidem (Zolpimist®)*</i>	<i>Inhalation spray of zolpidem for insomnia</i>

* Part of the mental health carve out and should be billed Fee-For-Service

New Generics Approved in 2008

Recently the Food and Drug Administration (FDA) reported what it refers to as the “Generic Drug Roundup” for the previous year. This is a listing of recent generic approvals for a few drugs which have had significant utilization based on sales of the brand name agent. For the list reported in February 2009, the new generics noted by the FDA are included on the table below. This table is provided in an effort to show the preferred status of these new generics on the Maryland Medicaid PDL. In some cases, due to higher rebates provided for brand name products, the overall cost of the brand name drug is less than the cost of the generic. Therefore, some branded agents may be preferred over generics. The entire PDL can be accessed on line at: <http://www.dbmb.state.md.us/mma/mpap/prefdruglist.html>

Generics Approved in 2008	Preferred Status
risperidone (Risperdal®)	Generic preferred, brand non-preferred
divalproex (Depakote®)	Brand and generic preferred
ropinirole (Requip®)	Generic preferred, brand non-preferred
dorzolamide/timolol maleate (CoSopt®)	Brand and generic preferred
galantamine (Razadyne®)	Brand and generic non-preferred

**effective April 1, 2009*

Brand Agents with Non-preferred Generics

In addition to the drugs noted above, there are several brand agents included on the PDL that are preferred over the generics based on higher rebates provided for these specific brand name products. These are included on the table below.

Brand Agents with Non-preferred Generics	PDL Status
duragesic (Fentanyl®)	Brand preferred, generic non-preferred
levetiracetam (Keppra®)*	Brand preferred, generic non-preferred
lamotrigine (Lamictal®)*	Brand preferred, generic non-preferred
oxcarbazepine (Trileptal®)	Brand preferred, generic non-preferred
calcium acetate (PhosLo®)*	Brand preferred, generic non-preferred
finasteride (Proscar®)*	Brand preferred, generic non-preferred

**effective April 1, 2009*

FDA Discussing Risk Evaluation and Mitigation Strategy (REMS) for Certain Opioid Drugs

The Food and Drug Administration (FDA) has contacted manufacturers of both brand and generic versions of certain opioid drug products including; fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. The FDA has indicated that these drugs will be required to have a Risk Evaluation and Mitigation Strategy (REMS) developed for their use to ensure that the benefits of the drugs continue to outweigh the risks.

The FDA believes that establishing a REMS for opioids will reduce these risks of using these agents, while still ensuring that patients with legitimate need for these drugs will continue to have appropriate access. The first step in the process involves FDA meeting with manufacturers. Public meetings are planned for late spring or early summer to allow for broader input and participation. These new REMS will undoubtedly affect both prescribing and dispensing in the future and the impact on the Maryland Medicaid Pharmacy Program is not known at this time. As more information is available it will be reported in this newsletter or in the form of an Advisory or Transmittal.

Pharmacy Briefs

Maryland Medicaid Pharmacy Program Website

The MMPP website can be found at <http://www.dbmb.state.md.us/mma/mpap/>. The MMPP has also developed another website which contains other information regarding the Pharmacy Program, including past issues of the Pharmacy Newsletter, links to Advisories, Transmittals, the PDL, MCO Formularies listings on Epocrates and information regarding continuing education programs. The website can be viewed at www.marylandmedicaidpharmacyinformation.com.

DHMH E-mail “Advisory”

The MMPP utilizes an e-mail notification service called an “Advisory” to give the pharmacy community important timely information. If you are currently not receiving e-mail Advisories through a pharmacy organization you belong to, please contact the MMPP representative at 410-767-1455.

Clinical Corner (continued from Page 3)

The drug may be billed through pharmacy services or through physician services. However, prescribers cannot bill the drug under physician services if medication has already been billed and approved under pharmacy services.

The prior authorization form is available at this link: <http://www.dbmb.state.md.us/mma/mpap/forms.htm>

The form should be completed and signed by the prescriber and faxed to the MMPP at 410-333-5398 for review and approval. Specific dosages must be provided, such as number of units per injection site. Requests with dosages or directions of “as directed” will not be approved.

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