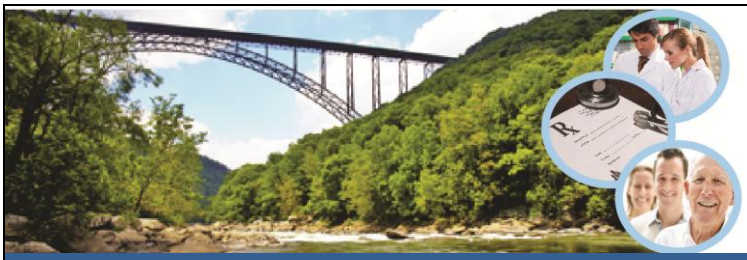

West Virginia Medicaid
Pharmacy Solutions

March 2015 Volume 4, Number 1

West Virginia Medicaid Pharmacy Department

http://www.dhhr.wv.gov/bms/Pharmacy

Provider Services

888-483-0793
888-483-0801 (Pharmacy)
304-348-3360
Monday – Friday
8:00 am until 5:00 pm

Pharmacy Help Desk& Pharmacy Prior Authorization (Rational Drug Therapy Program)

800-847-3859 (Phone)
800-531-7787 (Fax)
Monday – Saturday
8:30 am until 9:00 pm
Sunday 12:00 pm until 6:00 pm

Member Services

888-483-0797
304-348-3365
Monday – Friday
8:00 am until 5:00 pm

Preferred Drug List

For a copy of the most recent preferred drug list, visit:
http://www.dhhr.wv.gov/bms/Pharmacy/Pages/pdl.aspx

State Maximum Allowable Cost (SMAC)

SMAC Review Form:
http://www.dhhr.wv.gov/bms/Pharmacy/Pages/smac.aspx

Please refer questions to Magellan at 1-800-763-7382 or e-mail to StateSMACProgram@magellanhealth.com

Authorized Generics

In 2013, generic drugs which includes authorized generics saved the United States health system $239 billion.[1] An "authorized generic drug" is a listed drug as defined in § 314.3 that has been approved under subsection 505(c) of the act and is marketed, sold, or distributed directly or indirectly to retail class of trade with either labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark that differs from that of the listed drug.[2] In simpler terms, this means that an authorized generic (AG) is the brand company's own identical product but is relabeled and marketed under a generic product name. This differs from a generic drug which contains the same active ingredient, dosage form, strength, and route of administration, and intended use as the brand drug but the inactive ingredients can vary. The generic drug must be approved via the ANDA process by the FDA and must prove its bioequivalence to the brand drug.

The brand company itself, or through a subsidiary, may license the product to another company for marketing in return for royalties. The AG is then sold at a lower cost, and as an alternative generic, to the branded product. This allows brand quality at generic prices. A brand company may choose to do this as a result of a patent litigation agreement, to maintain their market share, or to allow additional competition. A generic company also benefits from this arrangement, in that, it builds their product portfolio and creates additional profits by partnering with the brand company.

An AG may enter the market during a 180-day exclusivity period. The courts have ruled that 180-day exclusivity does not preclude a brand name company from entering with its own generic because it already has approval for its product. Brand companies now frequently launch an AG to compete with the first-filer.[3]

AGs also provide additional Medicaid rebate dollars. Since AGs are listed under a NDA number, the company must adhere to the calculation of a branded rebate. Therefore, the federal rebate may be significantly higher for an AG compared to generics approved via an ANDA. However, the AG and/or the generic approved via an ANDA may or may not be the most cost-effective agent over the brand for Medicaid recipients.

AGs are lower cost alternatives to the brand and may further reduce prices for consumers within the generic marketplace. AGs may enhance competition and offer additional rebate discounts for Medicaid programs. The marketplace for AGs will thrive on the economic notion that consumers demand high quality, lower cost pharmaceuticals.

Some examples of products with an AG are Maxalt, Cymbalta, and Concerta. For the FDA listing of authorized generics, please access the following link: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm126391.htm.

[1] Generic Pharmaceutical Savings Reach Highest-Ever Watermark of $239 Billion in 2013. Available at http://www.gphaonline.org/gpha-media/press/generic-pharmaceutical-savings-reach-highest-ever-watermark-of-239-billion-in-2013/. Accessed March 3, 2015.
[2] List of Authorized Generic Drugs. Available at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm126389.htm. Accessed March 3, 2015.
[3] Authorized Generic Drugs: Short-Term Effects and Long-Term Impact. Available at http://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf. Accessed March 3, 2015.

Upcoming Preferred Drug List (PDL) Changes

Please be advised that the Bureau for Medical Services, based on recommendations made at the January 28, 2015 meeting of the West Virginia Medicaid Pharmaceutical & Therapeutics Committee, is making the changes listed below to the Preferred Drug List (PDL). The complete PDL with criteria is available on the Bureau's website at http://www.dhhr.wv.gov/bms/Pharmacy/Pages/pdl.aspx.

On April 1, 2015, the following changes will be effective:

Drug Class	The following products will become preferred products:	The following products will become non-preferred products and require prior authorization (PA):
Angiotensin Modulators		• Diovan
Antibiotics, Inhaled		• Tobi
Antipsychotics, Atypical		• Fanapt
Epinephrine, Self-Injected	• Auvi-Q • epinephrine	• Epipen • Epipen Jr A non-preferred agent will be authorized upon documentation showing the patient's inability to follow the instructions, or the patient's failure to understand the training for both preferred agents.

Thank you for helping West Virginia Medicaid members retain access to prescription coverage by selecting drugs on the preferred drug list whenever possible.

Safety and Efficacy of Compounded Medications[4, 5]:

An issue receiving increased attention from the media, the FDA, and especially pharmacy payers involves compounded prescriptions. Compounded prescriptions are those situations where a pharmacist combines, mixes, or alters ingredients of a drug to create a tailored medication. While this practice has deep roots in the profession of pharmacy, the need for such compounded medications has been dramatically reduced in the modern era due to the wide array of commercially available medications. There can be legitimate medical needs for compounded prescriptions. Situations involving drug shortages, a patient's inability to swallow a tablet or capsule, or a patient allergy to dyes or inactive ingredients in the commercially available product are examples of when a compounded medication may be helpful. Recently, however, there has been a dramatic surge in the number and cost of compounded medications. Many of these high cost compounds are being aggressively marketed by compounding pharmacies. Often the pharmacy sales force markets to physicians practicing in geographical areas far from the compounding pharmacy. Aside from the cost issue, there are significant safety and efficacy concerns with compounded medications. Unlike FDA-approved medications which have undergone rigorous testing for efficacy and safety, compound prescriptions are often promoted for use where evidence is lacking in terms of administration route, clinical benefit or safety.

In November 2013, as a response to contaminated compounded drug products that led to infections in over 750 individuals and 64 deaths across 20 states from fungal meningitis, Congress enacted the Drug Quality and Security Act (DQSA) and created the new Section 503B of the federal Food, Drug, and Cosmetic (FD&C) Act. The DQSA established an oversight of compounding drugs on a small scale at the state level, while giving authority over the manufacture and distribution of compounded drugs to the FDA.

In February 2015, the FDA released five draft documents regarding drug compounding and repackaging that applies to pharmacies, federal facilities, outsourcing facilities and physicians. The draft documents provide information for compounders that are considering registering as an outsourcing facility under Section 503B of the FD&C Act. Also, industry guidance is provided regarding the repackaging of certain human drug products, the mixing, diluting, or repackaging of biological products outside the scope of an approved biologics license application, and adverse event reporting. Finally, a memorandum of understanding (MOU) between a state and the FDA was also drafted detailing the state's responsibilities regarding investigating and responding to complaints relating to interstate distribution of compounded human drug products. The draft documents are available for public comment for 90 days, with the exception of the MOU, which is available for 120 days.

While final guidance has not been released, the draft guidance provides insight into the FDA's enforcement intentions in order to avoid another mass outbreak due to contaminated compounding techniques. Congress has provided more oversight to the manufacture and distribution of compounded drugs, previously not regulated by the FDA, while leaving smaller scale operations to the purview of the states. There are substantive changes embedded in the new law. Monitoring and responding to the outcome of compounding laws will be critical to Medicaid states to budget pharmacy expenses accordingly and containing costs whilst maintaining quality and evidence supported therapies.

[4]Magellan Rx Management. Safety and Efficacy of Compounded Medications: Paying More for Less? Quarterly Trend Advisory. November 2014;2:1.
[5]Magellan Rx Management. FDA Draft Guidance for Compounding of Human Drugs. Clinical Alert. March 2015;2.