Pharmacy Benefit News

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Specialty Spotlight

FDA Drug Review Processes Are Changing to Meet the Influx of New Generics from National & International Manufacturers

Per Dr. Stephen Ostroff of the FDA: "FDA's generic drug program promotes access to quality affordable medicines by reviewing Abbreviated New Drug Applications (ANDAs) the pathway that allows generic drugs to come to market…the FDA is currently working to efficiently process and approve generic drug applications, at record or near-record levels, so when drug patents expire, less expensive generic options are available... The FDA is undertaking major changes in quality regulation so the public can be confident that we're holding generic drugs to the same standards as brand drugs, **no matter where in the world they are manufactured or tested**."

Source: Ostroff, S., M.D. (2016, February 4). FDA Voice. Retrieved March 08, 2016, fromhttp://blogs.fda.gov/fdavoice/index.php/2016/02/building-a-modern-generic-drug-review-process/

Comment:

The FDA has licensed manufacturers all over the world to make prescription drugs both raw materials and finished product. The largest international supplier of raw materials for generic medications is Israel. The largest international supplier of raw materials for brand medications is India. Historically, the largest supplier of raw materials for benzodiazepines, e.g., Valium, is Italy. The drug market is international and has been for a very long time. A while ago the American public was surprised to find out that medications that were the same as the prescriptive medications in the US were available in Canada and Mexico. International manufacturing of quality medications is a reality. The FDA represents a "seal of approval" that hopefully can match American desires with international commercialism.

Find out more

Look for Seven $1 Billion-Plus Drugs Reaching the Market in 2016

A new Thomson Reuters report predicts there will be seven "blockbuster" drugs launched this year. In comparison 2015 had 11 new blockbuster drugs. Among the seven blockbusters expect Intercept Pharmaceuticals' chronic liver disease drug obeticholic acid and Gilead Sciences' new fixed-dose HIV drug emtricitabine plus tenofovir alafenamide.

Source: Seven $1 billion-plus drugs seen reaching market in 2016. (2016, February 03). Retrieved March 08, 2016, from http://www.reuters.com/article/us-pharmaceuticals-blockbusters-idUSKCN0VC0CG

Comment:
The pharmaceutical industry (PhRMA) is producing innovative drugs quickly and across a broad spectrum of conditions/diseases. While new medications to treat cancer are the largest category, many agents for so-called “orphan diseases” are being produced so quickly that providers are buried in a volume of information that has to be digested in order to prescribe and monitor efficiently.

However, the costs of these medications are so great that current benefit designs require cost shifting of a portion of the cost to patients. As a result, patients are the new payers. They represent a population with infinite demand and finite budgets. As a result, the new blockbusters will face a world at the tipping point of desire over price. Certainly, new financing models will be necessary. Do we pay for them as insurance? As financing similar to that of home and automobile purchases? As financial funds?

Community Pharmacies are Counting on Federal Legislation to Force PBMs to Reimburse at Cost or Cost +

Independent pharmacies nationwide are counting on federal legislation to overhaul reimbursement by insurers that reimburse them for medicines at below cost. The proposed Maximum Allowable Cost (MAC) Transparency Law would rewrite the rules governing PBMs—which process prescription drug claims for insurers, label pharmacies as "in network" or "out of network," and determine how much to reimburse pharmacies.

The measure would oblige PBMs to update their cost lists, explain how they arrive at reimbursement caps, and offer an appeals process for pharmacists to recoup losses when drug prices eclipse reimbursements. Supporters of the measure say that the legislation would lead to more efficient stocking of drugs and provide assistance when negotiating purchases with wholesalers. In the opposition PBM managers cite that the legislation would compromise their ability to control costs for insurers and Medicare.

Source: Douglas, A. (2016, January 30). Small drugstores look for help from proposed new pharmacy rule. Retrieved March 08, 2016, from http://www.mcclatchydc.com/news/politics-government/congress/article57027088.html

Comment:
The goal of the federal legislation is not unlike that of some States, e.g., California, that have passed MAC transparency legislation. Pharmacy Benefit Administrator (PBA) models also contain elements of transparency. For example, transparency rules often include coverage of all generic/multisource/OTC/store brand/private label generics, weekly-to-monthly price updates based on manufacturer price changes, pricing according to cost-based formulae such as Wholesale Acquisition Cost (WAC) or Average Sales Price (ASP), publication of MAC list on the web for reference by pharmacies, and review of drug shortages for price changes.

The goal of these transparency rules is to achieve determinative pricing based on cost plus and to assure the communication of this information to all stakeholders to ensure that purchasing by pharmacies can be based on known reimbursement. This approach is different than the usual methodology that is based on Average Wholesale Price (AWP) discounts that are predicated on subsets of generics covered on the MAC, and published or inflated AWPs used for discounts. At the end of the day, the ACA, Medicare and private insurance are all driving to determinative pricing. The federal legislation may never see the light of day, but cost plus pricing is already a reality.

Disclaimer – Pro Pharma/Pro Data Analytics provides custom MAC lists for public and private Health Plans.

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- Oversight of Benefits
- Trend Management
- Simulation of Benefits
- Gap Analysis
- Infrastructure Reporting

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Pro Pharma Pharmaceutical Consultants, Inc. has assisted payer and providers for over 29 years to maintain quality while controlling costs.

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