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E-Prescribing for Opiates – No One Can Hide!

Reps. Katherine Clark (D-MA) and Markwayne Mullin (R-OK) recently introduced the Every Prescription Conveyed Securely Act, which would require all controlled substances to be prescribed electronically. Commenting on the legislation to the bill's cosponsors, National Association of Chain Drug Stores President and CEO Steve Anderson said, "[This] is an important step in combatting the abuse and diversion of prescription opioid medications." He added, "Electronic prescribing of controlled substances adds new dimensions of safety and security."

Drug Store News (09/21/17) Salazar, David

Commentary:

The move to electronic prescribing, electronic tracking of prescriptions, alerts for potential abusive problems, and abusive physicians and patients is a byproduct of the Information Age. Controlled substances, including opiates, are covered under federal law so that this does not have to be a state-by-state issue. Previously, the focus was on Class II triplicate prescriptions (e.g., morphine) to maintain a copy in manual records of what was written.

With this bill the focus changes to all controlled substances providing a record of the prescription and dispensing. This is evolutionary, necessary, and a natural progression of medicine/pharmacy to a digital environment. If this is passed, then the next step will be to use this information to improve safety without compromising patient security.

Analytics at Work: A Real World Example

TREND MANAGEMENT

What do Pro Pharma clients request on an ongoing basis? Trend management! Trend models are supported, among other things, by cost accounting, unit cost and utilization increases, provider performance metrics, medication category impact, new entrant impact, age/gender movements, and projections for future growth. All of these analyses are aggregated and provided in Pro Pharma/ProData Analytics cloud-based solutions. So, how is trend managed?

Calculations: Aside from the actuarial models that Pro Pharma/ProData Analytics supports, the alternative problem is to manage trend throughout the year in order to reach targets. Analytics at your fingertips can help with monthly calculations and trends to identify components that require interventions.

First, what is the trend that is associated with management? Trend calculations based on PMPM (per-member-per-month) are commonly composed of the ingredient cost, utilization, and new entrant components. Each of these PMPM components are calculated monthly and summed. The result is compared to prior period trends.

Summing the results of these elements and comparing to prior periods is the trend for management.

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What to Manage? Linking all elements of trend to their respective driver reports provides: the medications incurring the largest price increases for formulary management, financials for utilization trend leads to therapeutic category expansion/new PA targets/formulary planning, provider performance for Comparative Price Sheets and Comprehensive Medication Reviews, age/gender movement period-to-period impact the denominator of PMPM, and financials for new entrants provides a budget impact.

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Results: The results are lower paid PMPM, lower budget PMPM, and lower trend. Management is truly the key!

If You Can't Get a Prescription in One State, Then Try Another

"The New Jersey House Bipartisan Heroin Task Force discussed federal requirements for prescription drug monitoring during its latest roundtable meeting on September 25. Problem – If a doctor in New Jersey refuses to prescribe drugs to a patient suspected of so-called "doctor shopping" to obtain prescription drugs, the patient can travel to New York, Delaware or Pennsylvania to try his luck with a doctor there."

"While almost every state now has a monitoring program up and running to track information about prescription drug sales, patients and prescribing physicians, only a handful have agreements granting out-of-state doctors and pharmacists access to their home state's data. Rep. Tom MacArthur (R-NJ) is among the U.S. lawmakers who said a federal program may be needed, although he cautioned that safeguards must be put in place to protect patients' privacy and health records. "We need to consider a federal program to encourage us to require doctors and states to cooperate and enter the data," said MacArthur, who co-chairs the task force. New Jersey, which created its monitoring program in 2011, has had some success in partnering with other states to share data. It entered into an agreement with Pennsylvania in April to give prescribers and pharmacists access to the New Jersey database and vice versa."

Burlington County Times (PA) (09/27/17) Levinsky, David

Commentary:

The article is correct that each state has a Prescription Drug Monitoring Program, especially for controlled substances. The article is also correct that very few states cooperate in sharing their information. The opiate abuse problem has underlined the need for cooperation between states. How to maintain patient security? HIPAA allows for health care practitioners to share information for treatment, payment, and administration (including utilization review).

Now the states will have to step up and provide the assurances that patients want to allow for tracking of clinical problems such as addiction and abuse. The federal government already tracks

How Do You Tell a Biosimilar from The Reference Product?

The Food and Drug Administration (FDA) offered new draft guidance on statistical approaches recommended for evaluating analytical similarity for biosimilars and functional attributes of the reference product. The guidance includes details on analytical similarity assessment plans, the development of the risk ranking of attributes, the determination of the statistical methods to be used, the statistical analysis plan, and the statistical methods for evaluation.

The FDA recommends "a minimum of 10 reference product lots be sampled, and the lots should represent the variability of the reference product." To allow for meaningful comparisons, the FDA also recommends a minimum of 10 biosimilar lots to be included in the analytical similarity assessment. The FDA recommends the final analytical similarity report should contain differences in age of the lots produced at testing; multiple testing results; assay performance; and differences in attributes that will be considered acceptable.

Regulatory Focus (09/21/2017) Brennan, Zachary

Commentary:

There is a debate as to whether biosimilars are clinically equivalent to the reference product. Clearly there are commercial interests involved. Also, naming conventions and J Coding have occupied a lot of time as various stakeholders argue about differentiating the pioneer reference product from the biosimilar. The new FDA draft guidance may provide some balance to these arguments and make the biosimilars more acceptable to providers as a clinical equivalent to the reference product. Time will tell.

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The parameter of opiate abuse/addiction on the safety of the entire population. Time will tell if this approach is successful.



Pro Pharma'sDisease Maps serve as proxy for the cost changes experienced year-over-year and month-over-month. These analyses allow for targeting the therapeutic categories and medications responsible for the largest changes in drug spend.

Trend Management & Disease Maps

Important client benefits are:

- Identifcation of medications experiencing the greatest cost inflation
- Indentification of therapeutic categories containing opportunities for spend reduction

When coordinated with Physician Profiles, Disease Maps provide solutions to the following:

- Which prescribers and patients drive the drug spend?
- What changes can be made to reduce spend?
- How do we know if spend has been reduced?

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