

Some of the issues to fix:

- 1 In 0500-change definition of “New Prescription Drug”. Remove ANDA’s and biosimilars where there is already a drug on the market. Any drug approved through an ANDA or a biosimilar are always cheaper than the original drug.
 - 2 In 0501-yes, it needs to be clarified on which m’er is required to file what.
 - 3 In 0502-WAC needs to be added all places the word price shows up. The definition in 0500 is for “price increase” not price.
 - 4 In 0505(2)(d)-WAC also has to be added. Highest and lowest WAC price is not that hard to report, price is impossible because what price is it? We have no control after WAC—and even WAC is not the likely sales price to a distributor.
 - 5 In 0505(3)—Yes, there are some generic patient assistance programs. Let PhRMA take the lead on this though, they do many more so if they are able to clarify anything, it will help our guys as well.
 - 6 In 0520—Same for Trade Secret, PhRMA should take the lead.
 - 7 In 0550--\$400 seems a little high, why is this the arbitrary \$? It should be based on the cost to the department creating a list of all m’er who file and all those that sell and comparing them. There are a lot of m’er so why so high for each? This is not a big issue as we would look bad making too much fuss. Bigger issue should be making the state notify any m’er of the new law, especially prior to any enforcement action.
- In 0473(2)(I)—in (B) and (C) the lists should be based on most costly and greatest increase in the “average cost per dose” or “average cost per patient” basis. Without this language the state will get lists of the most common disease states that the most patients take a drug for. For example, statins are cheap but many many patients take them so the total cost is high while the per pill cost is low. The states goal is to get at the higher cost drugs, not the cheap ones that a lot of patients take.