Testimony
Senate Bill 2087 - Department of Human Services
House Human Services Committee
Representative Robin Weisz, Chairman

March 10, 2021

Chairman Weisz and members of the Human Services Committee, I am Brendan Joyce, Administrator of Pharmacy Services for the Department of Human Services (Department). I appear today to provide testimony on Senate Bill 2087, which was introduced on behalf of the Department.

Senate Bill 2087 updates language and will allow the Department to react, if necessary, when federal final regulations regarding line extension products go into effect.

Page 1, Line 9 and Page 2, line 2 involves striking through the phrase “in the aggregate, or.” This language is not necessary in this section of the law as the Department is federally required to comply with Federal Upper Limit in the aggregate requirements outside of the prior authorization program. If implementation of prior authorization on a product would put compliance with the federal requirement at risk, it would not be brought to the Drug Use Review (DUR) Board for consideration.

The remaining changes in the bill on page 1, lines 11 and 12 and page 2, lines 4, 25, and 26 are in response to final regulations posted on December 21, 2020 by the Centers for Medicare and Medicaid Services (CMS). (Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements (CMS 2482-F) Final Reg).

These federal regulations have the potential to impact the pharmacy budget due to their definition of line extensions for covered outpatient drugs. This could result in significant increases in the state share for injectables due to changes in rebate calculations for line extensions.

For instance, Abilify is an antipsychotic medication. The Abilify tablet was approved in 2002 and has been generic for a number of years. Abilify Maintena is a long acting injectable version of the same drug. Abilify Maintena was approved in 2013 and is not available as a generic. With the new rules, the 2002 price of the tablet (< $17) will be used in the calculation of the rebate for the injectable in 2022 (currently > $1700). Any increase in rebate amount that results from this change will be 100% federal funds, otherwise known as the Quarterly Rebate Offset Amount (QROA). QROA has existed since 2010 and has generally averaged less than 6% of total rebates since 2017.

To summarize through an example, let us assume that the Department pays $1000 to the pharmacy for a medication. When we were 50/50 FMAP, $500 of that payment was federal dollars and $500 was state dollars. If the federal rebate was $500 prior to 2010, the Department would send 50% of the rebate ($250) back to CMS for their share, and the Department would keep 50% of the rebate ($250) for the state share, so the net cost to the state for that $1000 medication was $250 in state dollars ($500 payment to pharmacy minus $250 rebate collected).

After 2010, with the QROA, the Department would send 50% of the rebate ($250) plus 6% for the QROA ($30) to CMS, so the net cost to the state for that $1000 medication was now $280 ($500 minus $220 for state share of rebates).

Supplemental rebates for ND started after the 2015 legislative session. Assuming a $300 supplemental rebate was received for the example with the same 50% FMAP, the new split of the rebates would be as follows.

$1000 cost of the drug ($500 federal and $500 state dollars)

$280 federal rebate federal share (50% of $500 rebate plus 6% QROA)

$220 federal rebate state share ($500 federal rebate minus federal share)

$150 federal share of supplemental rebate (50% of $300 supplemental rebate)

$150 state share of supplemental rebate (50% of $300 supplemental rebate)

Net federal cost = $70 ($500 - $280 - $150)

Net state cost = $130 ($500 - $220 - $150)

If the new federal regulations for line extensions changes the federal rebate to $800, the $300 difference between the original federal rebate and the new federal rebate is included in the QROA, so it would be 100% federal funds. Also, with the higher federal rebate, the less room there is for a manufacturer to offer a supplemental rebate, which results in this:

$1000 cost of the drug ($500 federal and $500 state dollars)

$280 federal rebate federal share (as above)

$220 federal rebate state share (as above)

$300 federal rebate new QROA due to line extension rule

Supplemental rebate is gone as manufacturer no longer has margin to offer

Net federal cost = $500 - $280 - $300 = ($80)

Net state cost = $500 - $220 = $280

It is unknown at this point exactly how significant these changes will be when they become effective in 2022, but given some dramatic differences in prices between products that are considered line extensions in the new rule, it has the potential to significantly impact the amount of drug rebates states will be able to retain.

The Department has always taken the QROA into account when calculating net prices for medication reviews, and we will continue to do the same going forward. The most significant impacts will be in medication classes that the Department is prohibited by state law from prior authorizing (e.g. antipsychotics like the Abilify example above). One thing is certain, the Department needs the flexibility to react to

any changes that do occur, and to work with the Drug Use Review Board when necessary for all of the Medicaid program.

This concludes my testimony, and I am happy to answer any questions you may have.