Testimony
Senate Bill 2087 - Department of Human Services
Senate Human Services Committee
Senator Judy Lee, Chairman

January 6, 2021

Chairman Lee 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 is addressing the medical assistance pharmacy prior authorization program. Senate Bill 2087 will complete some minor clean-up in the 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 ensures compliance with Federal Upper Limit in the aggregate requirements outside of the prior authorization program. Therefore, 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).

Recent federal regulations that were finalized may have a drastic impact on the pharmacy budget. The federal regulations have finalized the definition of line extensions for covered outpatient drugs. In one of many impacts from this final regulation, the rebates for injectables could be based on the costs of the oral version of the medication, and any increases in said rebate would be 100% federal dollars.

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, 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 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) 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% ($250) plus 6% ($30) to CMS, so the net cost to the state for that $1000 medication was now $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 severe potential to significantly impact the amount of drug rebates states will be able to retain.

Using the same $1000 medication example, if the new calculations change the rebate for that drug to increase from $500 to $800, that means the $300 difference in rebate would be the QROA. Still assuming 50/50 FMAP, the payment to the provider would still be $500 federal funds and $500 state funds. The rebate amount would be $800, with then new $300 of that being 100% federal funds plus the previous existing QROA of 6% also being 100% federal funds, and the remaining being 50/50 federal and state funds. This results in the net cost for CMS to be $500 minus $300 minus $280 - CMS will MAKE $80 every time ND Medicaid pays for this medication. The state cost would be $500 minus $220 for a total of $280.

$1000 Drug with $500 Rebate	Pre-QROA (Pre-2010)	With QROA (2010 to Present)	New Rules ($1000 drug with $800 rebate)
State Share	$250	$220	($80)
CMS Share	$250	$280	$280

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). The final rule is large and there are other areas that have the potential to impact individual state programs. If these rules result in existing rebates to change, that would increase the amount of existing rebates that would be considered part of the QROA. 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.