Testimony
Re-Engrossed Senate Bill 2190 – Department of Human Services
House Human Services Committee
Representative Robin Weisz, Chairman
March 11, 2013

Chairman Weisz, members of the House Human Services Committee, I am Dr. Brendan Joyce, Administrator of Pharmacy Services for the Medical Services Division of the Department of Human Services. I am here to provide information regarding the fiscal note for Re-Engrossed Senate Bill 2190.

Biological medications are not approved by the Food and Drug Administration (FDA) in the same manner as the more familiar small molecule medications. Instead of being approved under a New Drug Application (NDA), they are approved under a Biological Licensing Application (BLA). Drugs approved under an NDA are subject to generic competition once their patent expires. However, drugs approved under a BLA are not subject to generic competition after their patent expires because the United States Congress has not passed any law allowing the FDA to approve generics for drugs originally brought to market under a BLA.

Biological medications are by far the fastest growing segment for pharmacy costs nationwide, growing 18.4% this past year. Some of the costs are enormous, including North Dakota Medicaid recipients receiving single medications that cost $200,000 or more per year. Examples of such biological medications are:

- Elaprase® for Hunter syndrome – only 2000 patients in the world have the disease, including one on ND Medicaid
- Fabrazyme® for Fabry's disease – only 2200 patients in the world have the disease, including one on ND Medicaid
- Aldurazyme® for Hurler syndrome – only 600 patients in the world have the disease, including one on ND Medicaid

North Dakota Medicaid tracks prescriptions that cost greater than $1000 per month. These medications account for 16% of North Dakota Medicaid's pre-rebate drug spend, and an even higher percentage of the post rebate spend as the effective rebate percent for biological medications is lower than the Medicaid average. It is also worth noting that many of these biological medications are only available through limited distributorship models involving only out-of-state pharmacies.

Given these enormous costs, any additional requirements placed on pharmacists and physicians beyond what is current practice for normal generic substitution will impact the expenditures for North Dakota Medicaid because the generic substitution rate will decrease.. Senate Bill 2190 was amended to remove the additional requirements (page 2, lines 3-6), so the Department did not have a fiscal note attached to the bill. Since the additional requirements were amended back into the Re-Engrossed version of Senate Bill 2190, the Department prepared the fiscal note.

I would be happy to answer any questions.