

SB0357/223022/1

BY: Senator Ready

AMENDMENT TO SENATE BILL 357
(First Reading File Bill)

On page 5, after line 6, insert:

“(A) THIS SECTION DOES NOT APPLY WITH RESPECT TO A PRESCRIPTION DRUG PRODUCT THAT IS:

(1) DESIGNATED AS A DRUG FOR A RARE DISEASE OR CONDITION BY THE U.S. FOOD AND DRUG ADMINISTRATION UNDER 21 U.S.C. § 360BB; OR

(2) A LICENSED BIOLOGICAL PRODUCT THAT IS DERIVED FROM HUMAN WHOLE BLOOD OR PLASMA AS INDICATED ON PRODUCT LABELING APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION.”;

and in line 7, after “subtitle]” insert “**(B)**”.