# The Korea-US Free Trade Agreement Threatens Federal "340B" Discounts for Medicines for Low Income Americans

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Chapter Five of the pending Korea-US Free Trade Agreement (Korus FTA) creates a set of binding rules for "central level" government programs that set reimbursement rates for pharmaceuticals and medical devices. Through the federal "340B" program, federal legislation and the federal Department of Health and Human Services establishes discounted reimbursement rates for pharmaceuticals and medical devices supplied to programs that serve low income Americans. Unlike the federal Medicaid program, which provides mandatory discounts to state health care programs, the 340b program is not explicitly exempted from coverage from the Korea FTA's pharmaceutical chapter. As described below, the Korea FTA appears to mandate statutory changes in the operation of the 340B program, which in turn may raise the costs of administering 340B.

**Under 340B, the Federal government sets reimbursement prices for pharmaceuticals and medical devices.**

Section 340B of the Veterans Health Care Act of 1992 requires any drug company whose drugs are covered by Medicaid to offer discounts for outpatient drugs to "certain federal grantees, federally-qualified health center look-alikes and qualified disproportionate share hospitals."[1] Providers that qualify for the program are generally those that serve the poor (e.g. inner-city clinics, AIDS Drug Assistance Programs and health facilities on Indian reservations). To participate in the program, pharmaceutical companies are required to sign a Pharmaceutical Pricing Agreement with the Department of Health and Human Services which sets the reimbursement price according to a formula defined in the statute.[2] 340B reimbursement rates are substantially lower than average manufacturer prices for the same medicines.[3]

**The Korea FTA regulates the operation of all "central level" government programs that set pharmaceutical and device reimbursement rates.**

Article 5.2 of the Korea-US FTA establishes rules that apply to a country's "health care programs operated by its central level of government" that set "the amount of reimbursement for pharmaceutical products or medical devices." As discussed above, the 340B program appears to meet this definition. The 340B program

[1] For a full list of programs covered by this program, see 42 U.S.C.§ 256(b). Available at http://www.law.cornell.edu/uscode/42/256b.html

[2] DHHS guidelines specify that the 340B price may not exceed "the Average Manufacturer Price (AMP) decreased by a rebate percentage." The Average Manufacturer Price is defined in the Pharmaceutical Pricing Agreement, and the rebate percentage is statutorily defined by section 1927(c) of the Social Security Act. The complete agreement that firms must sign, and instructions to the companies, are available at: ftp://ftp.hrsa.gov/bphc/pdf/opa/pricingagreement.pdf

[3] DHHS Health Resources and Services Administration. "Compared to a drug's Average Manufacturer Price (AMP), covered entities receive a minimum discount of 23.1% for brand name drugs (except clotting factor and drugs approved exclusively for pediatric use for which the basic rebate is 17.1% of AMP), and 13% for generic and over-the-counter drugs and are entitled to an additional discount if the price of the drug has increased faster than the rate of inflation." See the Glossary of Pharmacy-Related Terms: http://www.hrsa.gov/opa/glossary.htm

does not meet the criteria for exemptions of certain federal programs contained in two footnotes of the agreement. One footnote specifies that the chapter does not apply to "agencies that engage in government procurement," but 340B does not involve direct purchases of medicines and therefore is not covered by this exception. The other footnote specifies that "Medicaid is a regional level of government health care program in the United States, not a central level of government program." The Medicaid exception is narrow, however, and does not apply beyond that program. There is no specific exception for the 340B program in the FTA.

**The 340B program does not comply with all off the Korea FTA's mandates for the operation of reimbursement programs.**

Article 5 of the Korea FTA contains several mandates that the 340B program does not currently comply with.

- Article 5.3(e) of the Korea FTA requires health authorities to "make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination." As stated above, 340B reimbursement prices are set by statute and do not offer any possibility of independent review.
- Article 5.2(c) requires health authorities to "permit a manufacturer… to apply for reimbursement of additional medical indications for the product, based on evidence the manufacturer provides on the product's safety or efficacy." There is no such provision in 340B. Indeed, Federal regulations do not allow manufacturers to request that 340B cover additional indications that are not approved by the FDA (so-called "off-label" indications).
- Article 5.2(b) requires health authorities to "ensure that the Party's determination, if any, of the reimbursement amount for a pharmaceutical product or medical device… is based on competitive market-derived prices," or else to "appropriately recognize the value of the patented pharmaceutical product or medical device in the amount of reimbursement it provides." These are vague standards that are not defined in the agreement. It is at least plausible that a pharmaceutical company could challenge 340B reimbursement prices as not being "market-derived" since they are constrained by mandatory discounts and penalized for increasing market prices. In addition, it appears plausible that a company displeased with the amount of reimbursement offered could allege that the steep discounts required for the program do not "appropriately recognize the value" of patented products.