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FISCAL IMPACT REPORT

ORIGINAL DATE 02/10/09
 LAST UPDATED 02/14/09 HB 369/aHHGAC

SPONSOR Alcon

SHORT TITLE Donation of Cancer Drugs and Medical Devices SB _____

ANALYST Hanika-Ortiz

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY09	FY10	FY11	3 Year Total Cost	Recurring or Non-Rec	Fund Affected
Total		\$0.1 Unknown but could be Significant			Recurring	Various

(Parenthesis () Indicate Expenditure Decreases)

SOURCES OF INFORMATION

LFC Files

Responses Received From

- New Mexico Board of Pharmacy (NMBOP)
- Health Policy Commission (HPC)
- Department of Health (DOH)
- Aging and Long-Term Services Department (ALTSD)
- Retiree Health Care Authority (RHCA)

SUMMARY

Synopsis of HHGAC Amendment

The House and Health Government Affairs Committee Amendment provides that a pharmacist may accept and dispense donated cancer drugs and medical devices that meet storage and labeling requirements; removes the participation of the “board” in DOH’s efforts to adopt rules for the program; and further clarifies that a drug manufacturer acting in good faith shall not be liable for matters related to donation under the program.

Synopsis of Bill

House Bill 369 enacts a new section of the New Mexico Drug, Device and Cosmetic Act and creates the “cancer drug and medical-device repository program” administered for the purpose of allowing a cancer patient or the patient’s family to donate unused cancer drugs and medical devices to uninsured and underinsured cancer patients in New Mexico.

FISCAL IMPLICATIONS

DOH reports it would cost the Department approximately \$891.5 thousand (recurring) to safely redistribute cancer drugs. The projected costs are for 5 additional FTE: 4 pharmacists, a pharmacy technician and a clerk; and includes laboratory costs to make drug-safety determinations. However, these cost projections could be more or less and have not been substantiated by the NMBOP or the LFC. The Board reports only minimal impact on its budget. The bill does not include nor direct an appropriation to DOH for this effort.

The bill will allow a health care facility or pharmacy to charge an eligible patient a handling fee to receive a donated cancer drug or medical device. The fee shall not exceed an amount specified in rule and adopted by NMBOP.

There may be costs associated with investigating and prosecuting violations of provisions adopted pursuant to this new section.

SIGNIFICANT ISSUES

NMBOP reports that a significant amount of unused prescription drugs are destroyed each year that could be re-dispensed to persons who may not have prescription drug health coverage. The re-use of previously dispensed prescription drugs that are in tamper evident packaging and have been held under reasonable storage conditions as determined by a pharmacist, is a viable option for reducing overall prescription drug costs and reducing environmental impact caused by the destruction of pharmaceuticals.

PERFORMANCE IMPLICATIONS

DOH and NMBOP will be required to adopt rules for the implementation and administration of the program.

DOH reports that the bill conflicts with NMBOP regulations, Section 16.19.6.14, which prohibits the resale, return or exchange of drugs. NMBOP will need to promulgate changes to its regulations to allow for pharmacies and health care facilities to accept donated medications.

HPC reports that in 2006, nine states passed laws allowing the donation of unused pharmaceutical drugs. The programs are primarily limited to serving specific eligibility groups (uninsured, indigent, limited resources, cancer, charitable or needy persons abroad). DOH reports that some state laws allow the return of prescription drugs in single use or sealed packaging from state programs, nursing homes and other medical facilities where storage conditions are known.

ADMINISTRATIVE IMPLICATIONS

Health care facilities and pharmacies may elect to participate in the program.

CONFLICT, DUPLICATION, COMPANIONSHIP, RELATIONSHIP

SB 40 allows practitioners to re-dispense donated prescription drugs.

TECHNICAL ISSUES

The bill does not provide a definition for “medical device”.

The bill does not provide a definition for “board”, presumably the NMBOP.

The bill gives regulatory authority for pharmacists and health care facilities licensed and regulated by NMBOP, to DOH. NMBOP suggests Section G read “the department and the Board shall adopt rules necessary for the implementation and administration of the program.” This would allow DOH and NMBOP to adopt rules in their areas of expertise and according to their statutory authority.

NMBOP suggests limiting the program to tamper evident packaging and to a physical inspection of the donated “cancer drugs” by a pharmacist to ensure product is safe for re-use. NMBOP also suggests expanding the definition of “health care facility” to include a requirement that entities be licensed by the Board, in addition to DOH. NMBOP determines adequate storage conditions and the records required for certain prescription drugs.

OTHER SUBSTANTIVE ISSUES

NMBOP notes that studies have shown significant levels of pharmaceuticals in our nation’s water supply including the Rio Grande.

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

Uninsured or underinsured cancer patients may not benefit from safe and unopened donated cancer drugs and medical devices.

QUESTIONS

What is the average cost for one dose of a cancer drug?

AHO/svb:mc