F I S C A L I M P A C T R E P O R T

SPONSOR Park **DATE TYPED** 2/13/04 **HB** 466

SHORT TITLE Cancer Drug Repository Act **SB**

ANALYST Dunbar

APPROPRIATION

Appropriation Contained		Estimated Additional Impact		Recurring or Non-Rec	Fund Affected
FY04	FY05	FY04	FY05		
	See Narrative				

SOURCES OF INFORMATION
LFC Files

Responses Received From
Department of Health (DOH)
Regulation and Licensing Department (RLD –NM Board of Pharmacy)
Commission on Higher Education (CHE)

SUMMARY

Synopsis of Bill

House Bill 466 allows for unused and unadulterated cancer drugs to be donated for use by an eligible individual or entity. It would place the responsibility for developing and implementing the "repository program" with the Department of Health (DOH). HB466 would specify that hospitals, nonprofit clinics and pharmacies could voluntarily accept and dispense the donated cancer drugs to eligible state residents.

HB466 would require medications to be in their original, sealed, tamper evident, unit-dose packaging. An exception would allow the packaging to be opened, but the unit dose seal must still be intact. Medications accepted into the program would be required to have an expiration date longer than six months away.

DOH would be given the responsibility to promulgate recipient eligibility criteria, to develop participation criteria for hospitals, nonprofit clinics and pharmacies that volunteer and to create standards and procedures for accepting, storing and inspecting the donated drugs. Additionally DOH would develop and distribute: recipient identification cards and liability waiver forms;

forms for donors to verify ownership or representation of owner; a list of cancer drugs that are acceptable or unacceptable for donation and the reasons for unacceptability.

Significant Issues

RRD- the Board of Pharmacy relayed the following concerns with the bill:

- Guaranteeing the integrity of the drugs would be problematic unless a laboratory analysis is performed, which is an expensive procedure.
- The Food and Drug Administration may have issues with this practice, since the agency requires manufacturers to perform additional tests to prolong the life of products.

DOH acknowledges that cancer treatment is very expensive and some individuals may not be able to receive treatment due to lack of resources. HB466 would provide a necessary option for treating these individuals.

DOH indicates that overseeing a program to collect and redistribute "cancer drugs", which can cover a broad range of pharmaceutical categories and delivery methods, would be a complex initiative. Issues related to whether collected pharmaceuticals have been properly stored or tampered with, and whether they are "in date" have implications regarding efficacy and safety to the persons receiving these products. Monitoring changes in eligibility status of recipients and the tracking systems that would have to be developed in order to locate and transport appropriate products within the system to meet specific patient needs could also require significant resources to be developed and deployed.

FISCAL IMPLICATIONS

HB466 does not contain an appropriation. Since the program would require funds to staff, develop, administer or monitor this drug repository program, it is not clear how this initiative would be accomplished without detracting from other DOH efforts.

ADMINISTRATIVE IMPLICATIONS

The drug repository program, as described in HB466, would require significant expertise and staff time to accomplish. Without new resources, this would become the responsibility of existing DOH staff, which may not have the capacity or expertise to undertake this initiative.

Some of the duties required as per this legislation would be to track all drugs, to dispense, to perform analysis, and to maintain patient and drug records.

The proposed initiative would require resources and expertise that may not currently be available in DOH.

TECHNICAL ISSUES

DOH notes there may be a conflict with Section 16.19.6.14 of the Board of Pharmacy regulations that prohibit the resale of drugs and indicate that drugs are not to be accepted for return or exchange after taken from the pharmacy where they were sold or distributed.

The Board of Pharmacy would need to promulgate new rules so that pharmacies would be able to accept the donated cancer medications.

OTHER SUBSTANTIVE ISSUES

Patient safety is a priority in most health care professionals' practice. The thought of dispensing a medication where the handling of it could not be tracked may violate the rules of a safe, professional practice.

Cancer patients tend to be some of the most vulnerable patients. Many times their immune systems are severely compromised from the cancer medications and treatment. Even a slight error or alteration of their medication could have a devastating, negative effect.

However, these challenges must be balanced against the importance of HB466, including the potential to save lives and reduce the need to dispose of thousands of dollars of cancer drug medication.

ALTERNATIVES

An alternative could be a memorial to study the issue in the interim and/or perhaps include limited funding for a HB466 “pilot program” on a small-scale basis to better assess feasibility and capacity issues.

POSSIBLE QUESTIONS

1. Would these medications continue to be recycled as long as the expiration date met the criteria?
2. Who will certify storage conditions at individual locales?
3. Who is going to pay for the proper disposal and destruction of unused medications?

BD/lg:yr