SPONSOR: Neely

This bill allows oncologists and other health care providers to voluntarily notify the Department of Health and Senior Services if they are treating terminally ill patients with off-label drugs for treatment and which drugs they use and for what purposes.

The bill requires the information reporting system database, maintained by the department to include the name, address, and specified off-label usage of a drug for treatment for each oncologist or health care provider who provided the department with this information.

The department must be notified when specified providers intend to run a placebo-controlled clinical drug trial research project and notify the department of the drug or drugs being investigated and for what purpose. Upon notification by the provider the department must provide notice to all licensed oncologists, other health care providers, and nationally recognized cancer research institutions within and outside of the state, of the placebo-controlled clinical drug trial research project, the drug or drugs being investigated, and for what purpose along with a request for voluntary notification to the department as specified in the bill. The department must compile a list of the specified information and provide the sponsor or investigator with the list upon request and for a fee as determined by the department.

This bill requires any sponsor or investigator of a placebocontrolled clinical drug trial research project of a treatment drug for patients with terminal illness conducted in the state to provide prospective trial participants, a list of oncologists and other health care providers in the state who are engaged in the treatment of patients with medical conditions the same as or similar to the prospective trial participant's medical condition through the off-label usage of drugs for treatment. Any sponsor of a placebo-controlled clinical drug trial research project who willfully fails to obtain a trial participant's informed consent will be subject to a fine of \$50,000.

This bill is similar to HB 1020 (2015).