

## Mandated Benefits Review - Senate Bill 1198 - Executive Summary

After reviewing the staff analysis of Senate Bill 1198 - the Cancer Clinical Trials Act - the Pennsylvania Health Care Cost Containment Council does not find evidence to recommend the passage of this legislation at this time. We note that this proposal is only slightly different than Senate Bill 1334 (of 1995), which the Council was asked to review in 1996. At that time, the Council was unable to recommend passage of Senate Bill 1334. Our position on the issue of mandating coverage of patient costs for participants in cancer clinical trials remains unchanged. We make the following points:

- ⊗ No new information was submitted for the current review to alter our original findings. In fact, supporters and opponents re-submitted the identical information as they did for the previous review. The Council, therefore, confirms our original position with regard to mandating coverage of patient care costs for participants in cancer clinical trials.
- ⊗ Clinical trials are experimental in nature. One reason for conducting Phase I and Phase II trials is to determine if the proposed treatment is safe. In Phase III and Phase IV trials, the efficacy of the treatment is studied. In considering mandated benefits, the Council contends that recommendation be reserved only for measures which are of both proven efficacy and cost effectiveness. Since treatments provided in cancer clinical trials are experimental, they cannot be considered to have *proven* efficacy. The Council, therefore, reiterates our 1996 position that one possible option may be to limit coverage to treatments provided in Phase III or Phase IV cancer clinical trials where the safety of the treatment has been established and preliminary evidence suggests the treatment is effective.
- ⊗ Proponents did not provide the needed proof that Pennsylvanians are denied access to clinical trials because of a lack of insurance coverage. While proponents claimed that clinical trials are "the mainspring of progress against cancer," they failed to demonstrate that current insurance reimbursement for cancer clinical trials is inadequate. In fact, proponents recognize that, "Many patients do receive coverage for clinical trials." Therefore, the need for the mandates proposed in Senate Bill 1198 was not proven.
- ⊗ Insurers believe that providing coverage for *established* treatment options for cancer is in the best interest of their subscribers. While insurers may cover the costs of clinical trials, they also note that other parties, such as pharmaceutical companies, may also underwrite the cost of such trials.
- ⊗ The Council is sympathetic to those Pennsylvanians with cancer. We recognize the burden of suffering those afflicted with cancer and their families experience. It was not proven, however, that residents who do not have insurance coverage for their participation in a cancer clinical trial receive inadequate health care or experience financial hardship. For those people who choose not to participate in clinical trials, standard cancer treatments are available.
- ⊗ Senate Bill 1198 does not propose to cover a particular treatment or a particular cancer. Instead, it would mandate insurance coverage of any approved clinical trial for any type of cancer, including trials which are preventive in nature. Because the treatments available in clinical trials vary in cost from under \$100 to over \$150,000, the potential costs incurred by Senate Bill 1198 are not possible to assess with the information submitted to the Council.
- ⊗ Finally, the Council's enabling legislation provides for a preliminary staff review of submitted materials to determine if documentation received is sufficient to proceed with the formal Mandated Benefits Review process outlined in Act 34 of 1993. We conclude that neither supporters nor opponents of the bill provided sufficient information to warrant a full review by a Mandated Benefits Review Panel; nor, given the documentation received, do we believe a panel of experts would come to conclusions different than the ones reached here.

The Council suggests that caution must be used when considering health care mandates. In particular, attention must be given to the cumulative financial effect of enacting mandates. The Council notes the correlation between the number of mandates and the increasing cost of health insurance, the increasing number of uninsured, the incentive for large employers to self insure, and the decreasing number of employees covered by employer sponsored health insurance. As a Council, we are charged with the responsibility to "promote the public interest by encouraging the development of competitive health care services in which *health care costs are contained* and to assure that all citizens have reasonable access to quality health care" (Act 34 of 1993).