House
Legislative
Analysis
Section

Olds Plaza Building, 10th Floor
Lansing, Michigan 48909
Phone: 517/373-6466

PROSTATE CANCER: REQUIRE TREATMENT INFORMATION

House Bill 4363 (Substitute H-2)
First Analysis (11-9-95)

Sponsor: Rep. Thomas C. Mathieu
Committee: Health Policy

THE APPARENT PROBLEM:

According to the American Cancer Society, cancer of the prostate (a male gland located behind the base of the penis and under the bladder) is the most common kind of cancer among American men, especially African-American men. Whereas one of every ten American men will develop prostate cancer before the age of 85, one out of eight African-American men will develop prostate cancer during their lifetime. In fact, African-American men have the highest rate of prostate cancer in the world. The American Cancer Society estimates that 40,400 American men will die of prostate cancer in 1995, and that approximately 244,000 new cases will be diagnosed (though it should be noted that the dramatic rise in the incidence of prostate cancer in the past decade is largely due to improved detection). In recent years, a number of new and innovative treatments have emerged, but critics say that patients are not always given the information about the existence or benefits and risks of these new treatments that would enable them to make informed choices about their treatment.

Legislation has been proposed regarding informing patients about treatments for prostate cancer that is reminiscent of legislation passed in 1986 requiring that information on treatment alternatives be given to breast cancer patients. .

THE CONTENT OF THE BILL:

The bill would amend the Public Health Code, adding two new sections that would require the Department of Public Health to develop, publish, and make available to physicians, though the Board of Medicine and the Board of Osteopathic Medicine and Surgery, a standardized written summary about prostate cancer treatments and their advantages, disadvantages, and risks. Physicians then would have the option of offering their patients a form indicating that the patient had been given a copy of the summary. Patients who signed the form would be barred subsequently from suing the physician for failure to obtain informed consent, at least with regard to the treatments included in the summary.

Written summary. More specifically, within six months after the bill took effect, the Department of Public Health (DPH) would be required to develop and publish a standardized written summary about prostate cancer treatment. When developing the form, the department would be required to appoint an advisory committee consisting of representatives from "appropriate" professional organizations and patient advocate groups, including a group called Patient Advocates for Advanced Cancer Treatments (PAACT) or its successor. The form would have to be drafted in nontechnical terms that patients could understand, and would have to inform patients about both (1) alternative methods of treating prostate cancer (including surgical, radiotherapeutic, chemotherapeutic, and cryotherapeutic treatments), other generally accepted medical treatment, and investigational treatment known to the DPH "that is within the context of a clinical trial approved by the National Cancer Institute"; and (2) the advantages, disadvantages, and risks of -- and procedures involved in -- each treatment method described in the summary.

Availability of summary, notification of physicians. The department would be required to make the standardized written summary about prostate cancer treatments available to physicians through the Board of Medicine and the Board of Osteopathic Medicine and Surgery. Within ten days after the summary was published, the two medical boards would have to notify each physician regulated by that board that the summary was available.

Optional patient receipt forms. Physicians, both M.D.s and D.O.s, would be allowed to make available to their patients a form indicating that the patient had been given a copy of the prostate cancer treatment summary (or a copy of a DPH-approved brochure containing information substantially similar to that in the department's summary). If physicians made such forms available to a patient, the physician would be required both to have the patient sign the form and to put a copy of the signed form in the patient's medical record.

Civil immunity for physicians. Patients who signed a form indicating that they had been given a copy of the department's prostate cancer treatment summary (or department-approved brochure on prostate cancer treatment) would be barred from bringing a civil action against (i.e. suing) the physician who had provided the summary (or brochure) based on failure to obtain informed consent. However, the immunity would apply only in regard to information contained in the summary (or brochure) pertaining to alternative and investigative methods of prostate cancer treatment, and the advantages, disadvantages, and risks or each treatment method.

MCL 333.17013a and 333.17513a

FISCAL IMPLICATIONS:

According to the House Fiscal Agency analysis of the bill as introduced, implementation of the bill would cost $76,400 the first year, and then $61,500 each year thereafter. The HFA says that it would cost the Department of Public Health about $50,000 a year to develop and print the prostate cancer treatment summary and to update it every two years because of the frequent change in medical information. The Department of Commerce would be responsible for mailing the summaries to physicians. The cost of the mailing for the first year -- for 33,000 mailings at $1.25 per mailing -- would be $26,500; the HFA estimates that the cost of mailings in subsequent years would be $11,500. (10-9-95)

ARGUMENTS:

For:

In 1986, the legislature passed a law (Public Act 195) that required a physician administering primary treatment to a breast cancer patient to inform the patient about all generally accepted medical treatments, the procedures involved, and the advantages, disadvantages, and risks of each method of treatment. Prostate cancer is to men what breast cancer is to women, both in its gender specificity and in its significance as a public health concern. Just as women already must, by law, receive information about alternative breast cancer treatment, so, too, it is only fair that men receive information about alternative prostate cancer treatments. Only if prostate cancer patients are made aware by their physicians of all the various treatments available to them, as well as the risks and potential benefits of each treatment, can they give their informed consent to a procedure or course of treatment. Courts have said that informed consent to medical treatment is an essential part of the right of self-determination guaranteed to individuals in our society. Sometimes the necessary information is not provided to prostate cancer patients, and men are led to believe that the course of treatment they are following is the only one that holds any promise. Men have the right and the ability to make these, admittedly hard, choices, but to do so they must have the facts. The bill would address this problem with the simple requirement that a summary of available prostate cancer treatments be available to physicians to give to their patients so that patients can be aware of all the choices available to them in the treatment of their cancer. It also would provide physicians with some limited immunity from lawsuits based on failure to obtain informed consent.

Response:

The bill as written, unfortunately, would not guarantee that prostate cancer patients would obtain the information that they need to make informed decisions regarding the treatment of their cancer. The bill requires the Department of Public Health to develop, publish, and make available to physicians (through their regulatory boards) certain information. But it doesn't require physicians to obtain the information, nor does it require physicians to give the information to their prostate cancer patients. Instead, the bill would allow physicians to make available to their patients -- not the department-written summaries or department-approved brochures on prostate cancer treatments -- but forms indicating that a patient had received such information. The bill also says that if a physician makes such a form available to his or her patients, the physician then is required to have the patient sign the form and put a copy of the signed form in the patient's medical record. What if the patient refuses to sign the form? What if the physician doesn't offer the patient the prostate cancer treatment summary in the first place? Finally, the bill would require the Department of Public Health "as part of the development process" in developing and publishing a standardized written summary about prostate cancer treatment, to appoint an advisory committee consisting of representatives of "appropriate" professional organizations and patient advocate groups, including one specific group. But the bill neither specifies which professional organizations are to be considered "appropriate" (physicians, surely, but which physicians? Oncologists? Radiologists? Others?) nor does it require the department to take the advice of its advisory committee in writing the proposed summary. As introduced, the bill was modeled more closely on the breast cancer treatment information legislation (Public Act 195 of 1986, enrolled House Bill 4549), and made more sense.

Against:

People have raised a number of objections to the bill or the bill's intent. The bill refers to "alternative methods of treatment of prostate cancer . . . and investigational

treatment" that basically still is in clinical trials. Physicians might well be reluctant to give information to their patients about experimental treatments, just as it is not clear that professional medical organizations would consent to include experimental treatments in official literature that they presumably helped develop. Questions also can be raised about the appropriateness of singling out only one or two groups of patients -- breast cancer patients and prostate cancer patients -- who by law must receive alternative treatment information. What about other kinds of cancer patients? Or AIDS patients? Why shouldn't advocates of other serious or chronic diseases seek similar such legislation? Where should the line be drawn?

Against:

In the first place, physicians already have the obligation to give their patients enough information that the patients can give informed consent to treatment. But in the second place, the legislature shouldn't interfere in the physician-patient relationship in this way, no matter how well intentioned. Physicians already do make their patients aware of the nature of the patient's illnesses and the pros and cons of various treatments. But physicians can and do differ over the value of treatments, especially new, evolving forms of treatment, and it is unrealistic to expect that there exists at any one time a single, objective viewpoint on how to treat a complicated disease that can be neatly summarized to apply to everyone. Besides, not all treatments are available everywhere, nor can all patients be treated at the same few facilities. A physician may have more confidence in one form of treatment or may be better trained in one than in another. Doctors and patients need to work together to decide what is best in each case, taking into account special features, including proximity to treatments -- and, with the increase in limiting medical insurance -- accessibility to both facilities and providers, as well as the skills of available practitioners, and the condition and medical history of the patient. Brochures cannot replace physician-patient dialogue. Legislative mandates don't belong in this process, especially since the right of patients to informed consent is well established already.

Response:

While informed consent, with full information on all treatment alternatives, is the ideal, it all too often is just that, namely, an ideal. Many physicians, and perhaps especially specialist physicians, are not willing to view patients as partners in the decision making process. What is more, for many people, a diagnosis of cancer still is so frightening as to impair their ability to assertively question the advice given by their doctors, and so any additional, objective information that can be made available to such patients can only improve the physician-patient dialogue and decision making process.

POSITIONS:

The Department of Public Health is neutral on the bill. (11-8-95)

■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.