



**House  
Legislative  
Analysis  
Section**

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**BLUES: ONCOLOGY PANEL**

**House Bill 4323 (Substitute H-1)  
First Analysis (2-14-96)**

**Sponsor: Rep. Maxine Berman  
Committee: Insurance**

***THE APPARENT PROBLEM:***

In 1989 the legislature enacted legislation that requires health insurers, including Blue Cross and Blue Shield of Michigan, to cover federally approved anti-cancer drugs when used in antineoplastic therapy, regardless of whether the specific neoplasm being treated is the one for which the drug received federal approval, as long as certain conditions are met that demonstrate there is evidence the new application is effective. (These new applications are apparently referred to as "off-label indications".) According to testimony by a member of the Michigan Society of Hematology and Oncology, this was the first legislation of its kind nationally and since has been copied elsewhere in the country. The aim of the legislation, obviously, is to provide coverage for drugs that recent research has shown to be effective in new applications. To assist Blue Cross and Blue Shield in implementing this legislation, an ad hoc oncology advisory panel was created to advise the corporation about new drugs and new treatment protocols. A member of the panel has said the panel meets regularly with the corporation's policy makers to discuss new indications for drugs, identify the correct use of new products, or to approve new treatments. Some people feel that this advisory panel should be recognized (and authorized) in statute in order to formalize what has been an effective informal working arrangement between oncology experts and Blue Cross and Blue Shield. At the same time, there have been recommendations for tightening up and streamlining the process whereby appeals of denied treatment claims are dealt with.

***THE CONTENT OF THE BILL:***

The bill would amend the Nonprofit Health Care Corporation Reform Act (MCL 550.1402 et al.), which governs the operation of Blue Cross and Blue Shield of Michigan, to do the following.

-- Create a 3-member oncology advisory panel within the health care corporation whose duties would include advising the corporation about the efficacy, appropriateness, and routes of administration of off-label indications of federal Food and Drug

Administration-approved drugs used in antineoplastic therapy. The panel also would be required to submit within two years after the bill's effective date to the legislative committees on insurance issues and to the insurance commissioner a list of the off-label indications it has recommended and the health care corporation has approved.

-- Require the corporation to publish its acceptance of the review panel's recommendation for approved drugs in its official physician publication within 120 days after its acceptance of the recommendation or within a greater period of time as mutually agreed to by the review panel and corporation.

-- Specify that the corporation would have 60 days after receipt of a completed written or electronically transferred claim to affirm or deny coverage (rather than within "a reasonable time" as now).

-- Establish a somewhat different procedure in the act for cases when the insurance commissioner believed the corporation had engaged in or was engaging in prohibited claims processing and marketing conduct. The changes appear mostly to involve the use of deadlines for certain actions that are not in the act now and to use "a preponderance of the evidence" as the standard for certain actions rather than "probable cause to believe". (See below)

-- Require the corporation to submit to the standing committees of the House and Senate that deal with insurance issues the annual report on complaints that now must be submitted to the insurance commissioner. The report would have to include the previous two-year totals of complaints, dispositions, underlying causes, and measures implemented to alleviate those causes. The report is due by June 1.

Oncology Advisory Panel. The three panel members would have to be members of a hematology and oncology organization within the state identified by the organization as qualified to provide the required advice to the corporation. They would be appointed by the corporation from a list of persons recommended by

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hematology and oncology organization. They would serve for four years, except that of the initial members one would serve for four years, one for three years, and one for two years. The appointments would have to be made within 90 days after the bill's effective date. Panel members would serve without compensation.

**Prohibited Conduct Process.** Under the bill, when the insurance commissioner believed by a preponderance of the evidence that the corporation had engaged in actions that indicated a persistent tendency to engage in prohibited claims processing conduct or had violated or was violating prohibited marketing conduct, he or she would notify the corporation of the specific conduct at issue and allow the corporation 30 days to establish that it was in compliance. Further, the commissioner would have to ensure that the corporation had an opportunity to participate in an immediate informal conference to discuss with the commissioner or a representative the complaint that could be instituted. At that hearing, the issues could be resolved summarily upon agreement of the parties. If the corporation did not participate in an informal conference or the issues were not resolved at that time to the commissioner's satisfaction, the commissioner would provide the corporation written notice of a hearing to be held no later than 30 business days after the scheduled date of the informal conference. The notice would have to identify the corporation's conduct that was alleged to be prohibited and the action the commissioner proposed in response to the conduct. The hearing would be held in accordance with the Administrative Procedures Act. Following that act, the commissioner would issue and serve upon the corporation, and make available to people who appeared at the hearing, a written statement of findings. If the commissioner found by a preponderance of the evidence that the corporation had a persistent tendency to engage in prohibited claims processing conduct or had violated or was violating marketing standards, he or she would include a cease and desist order with the findings. If the corporation violated such an order, or failed to comply within 60 days after being served with the order (or within a greater period of time determined by the commissioner), it would be subject to a civil fine of not more than \$10,000 for each violation, after notice and an opportunity for a hearing, and upon order of the commissioner.

### **BACKGROUND INFORMATION:**

A similar bill, House Bill 4791, passed the House during the 1993-94 legislative session.

### **FISCAL IMPLICATIONS:**

There is no information at present.

### **ARGUMENTS:**

#### ***For:***

The bill would put into statute the oncology advisory panel that has been operating for five or six years advising Blue Cross and Blue Shield of new treatments that need to be covered. An oncologist told the legislature during the 1993-94 session that: "The field of oncology is making rapid advances in the treatment of cancer patients. Some cancers, which fifteen years ago might have been fatal, are being successfully treated with new chemotherapy drugs. Other cancers, such as lung, colon, and breast, continue to be difficult to eradicate, but new therapies offer new hope and longer remissions. Because the field is so dynamic, and because those that we treat are some of the sickest of patients, it is vital that the oncologist be able to use the newest products and protocols available. Physicians in this field must keep current with new drugs and protocols, and it is difficult to expect an insurance company, a regulatory agency or a legislator to maintain this type of knowledge. The Advisory Panel has served this role for BCBSM."

The bill would also streamline the complaint process against the Blues when claims were not acted upon properly. It contains deadlines for action not currently in the act, so that the corporation and state regulators would have to act in a more timely fashion. There is also an opportunity for the legislature to provide more oversight of claims problems, with the requirement that the corporation submit a report annually to the legislature on its complaint system, the nature of the complaints received, and their disposition.

#### **POSITIONS:**

A representative of the Michigan Society of Hematology and Oncology and Michigan State Medical Society testified in support of the bill. (2-13-96)

Blue Cross and Blue Shield supports the substitute. (2-13-96)

The Insurance Bureau has no objection to the bill. (2-13-96)

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■ 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.