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SFA BILL ANALYSIS

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Senate Bill 1208 (Substitute S-2 as passed by the Senate)
Sponsor: Senator John J.H. Schwarz, M.D.
Committee: Health Policy

Date Completed: 6-2-00

CONTENT

The bill would create the "Patient's Right to Independent Review Act" to:

- **Require a health carrier to notify a covered person of internal grievance and external review processes, when the carrier notified the person of an adverse determination (the denial, reduction, or termination of a health care service).**
- **Allow the covered person to submit a request for external review to the Commissioner of the Office of Financial and Insurance Services, who would have to conduct a preliminary review and decide whether to accept the request.**
- **Require the Commissioner, upon accepting the request, to assign an independent review organization to conduct an external review and make a recommendation.**
- **Require the Commissioner to decide whether to uphold or reverse the adverse determination.**
- **Allow a covered person to request an expedited external review if, due to his or her medical condition, the time frame for a standard external review would jeopardize the person's life, health, or ability to regain maximum function.**
- **Require independent review organizations to be approved by the Commissioner, and establish qualifications for independent review organizations and clinical peer reviewers.**
- **Establish record-keeping and reporting requirements for independent review organizations and health carriers.**
- **Require health carriers to include a description of the internal grievance and external review procedures in coverage information given to covered persons.**
- **Allow the Commissioner to order civil fines and license sanctions for violations.**
- **Create the "Cancer Clinical Trials Fund" and require fine revenue to be deposited in the Fund.**

The bill would take effect October 1, 2000.

Application of Proposed Act

Except as provided below, the bill would apply to all health carriers that provided or performed utilization review. "Health carrier" would mean an entity subject to the State's insurance laws and regulations, or subject to the Commissioner's jurisdiction, that contracted or offered to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health maintenance organization, a nonprofit health care corporation, or any other entity providing a plan of health insurance, health benefits, or health services. "Health carrier" would not include a State department or agency. "Health care services" would mean services for the diagnosis, prevention, treatment, cure, or relief of a health condition, illness, injury, or disease.

"Utilization review" would mean a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures, or settings. Techniques could include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning, or retrospective review.

The bill would not apply to a policy or certificate that provided coverage only for a specified accident or accident-only coverage, credit, disability income, hospital indemnity, long-term care insurance, or any other limited supplemental benefit other than specified disease, dental, vision care, or care provided pursuant to a system of health care delivery and financing operating under Section 3573 of the Insurance Code, Medicare supplement policy of insurance, coverage under a plan through Medicare, or the Federal Employees Health Benefits Program, any coverage issued under chapter 55 of Title 10 of the United States Code (which provides for medical

and dental care for members of the armed forces and their dependents), and any coverage issued as supplemental to that coverage, any coverage issued as supplemental to liability insurance, workers' compensation or similar insurance, automobile medical-payment insurance, or any insurance under which benefits were payable with or without regard to fault, whether written on a group blanket or individual basis. (Section 3573 of the Insurance Code, proposed by Senate Bill 1209, would recodify a section governing systems that are similar to health maintenance organizations.)

Notice of Review Process

The bill would require health carriers to give a covered person written notice in plain English of the internal grievance and external review processes at the time the carrier sent written notice of an adverse determination. ("Adverse determination" would mean "a determination by a health carrier or its designee utilization review organization that an admission, availability of care, continued stay, or other health care service has been reviewed and has been denied, reduced, or terminated". Failure to respond in a timely manner to a request for a determination would constitute an adverse determination. "Covered benefits" would mean "those health care services to which a covered person is entitled under the terms of a health benefit plan".)

Except as provided for expedited review, a request for external review could not be made until the covered person had exhausted the health carrier's internal grievance process provided for by law.

The written notice of the right to request an external review would have to be in plain English and inform the covered person that he or she, or his or her authorized representative, could request an expedited external review at the same time the person or authorized representative filed a request for an expedited internal grievance, if the person had a medical condition where the time frame for completion of an expedited internal grievance would seriously jeopardize the person's life or health or jeopardize his or her ability to regain maximum function, as substantiated by a physician either orally or in writing. The notice also would have to inform the person that he or she, or his or her authorized representative, could file a grievance under the health carrier's internal grievance process, but if the carrier had not issued a written decision to the covered person or authorized representative within 45 days after the date the person or authorized representative filed the grievance with the carrier and the person or representative had not requested or agreed to a delay, the person or authorized representative could file a request for external review and would be considered to have exhausted the health carrier's internal grievance process.

("Expedited internal grievance" would refer to an expedited grievance under the Insurance Code or the Nonprofit Health Care Corporation Reform Act. The Code requires insurers, and the Act requires Blue Cross and Blue Shield of Michigan, to establish an internal formal grievance procedure that includes an expedited grievance process.)

The notice of the right to request an external review also would have to include a copy of the description of both the standard and expedited external review procedures the health carrier would be required to provide under the bill, highlighting the provisions in the procedures that gave the covered person or his or her authorized representative the opportunity to submit additional information, and including any forms used to process an external review.

These forms would have to include an authorization form, or other document approved by the Commissioner, by which the covered person, for purposes of conducting an external review, would authorize the health carrier and health provider to disclosed protected health information, including medical records, concerning the person that were relevant to the external review. ("Health information" would mean information or data, whether oral or recorded in any form or medium, and personal facts or information about events or relationships that related to one or more of the following: the past, present, or future physical, mental, or behavioral health or condition of an individual or a member of his or her family; the provision of health care services to an individual; and/or payment for the provision of

health care services to an individual. "Protected health information" would refer to health information that identified an individual or could be used to identify an individual.)

Request for External Review

Except for a request for an expedited external review, all requests for external review would have to be made in writing to the Commissioner.

Within 60 days after receiving a notice of an adverse determination or final adverse determination, a covered person or his or her authorized representative could file a request for an external review with the Commissioner. Upon receiving the request, the Commissioner immediately would have to notify, and send a copy of the request to, the health carrier that made the adverse determination or final adverse determination.

Within five business days after receiving the request, the Commissioner would have to complete a preliminary review of the request to determine all of the following:

-- Whether the individual was presently or formerly a covered person in the health benefit plan at the time the health care service was requested or, in the case of a retrospective review, was a covered person in the plan at the time the service was provided.
-- Whether the health care service reasonably appeared to be a covered service under the covered person's health benefit plan.
-- Whether the covered person had exhausted the health carrier's internal grievance process, unless he or she was not required to exhaust the process.
-- That the covered person had provided all the information and forms required by the Commissioner that were necessary to process an external review, including the health information release form.

Upon completing the preliminary review, the Commissioner immediately would have to give written notice in plain English to the covered person and, if applicable, to his or her authorized representative as to whether the request was complete and whether it had been accepted for external review. If a request were accepted, the Commissioner would have to include in this notice a statement that the covered person or authorized representative could submit to the Commissioner, within seven days after receiving the notice, additional written information and supporting documentation that the assigned independent review organization would have to consider when conducting the external review. The Commissioner also would have to give the health carrier immediate written notice of the acceptance of the request.

If a request were not accepted because it was incomplete, the Commissioner would have to inform the covered person and, if applicable, his or her authorized representative, what information or materials were needed to make the request complete. If a request were not accepted, the Commissioner would have to give written notice in plain English to the covered person, the authorized representative, and the health carrier of the reasons for its nonacceptance.

External Review and Recommendation

When a request was accepted for external review, the Commissioner would have to assign an independent review organization that had been approved under the bill to conduct the external review and to provide a written recommendation to the Commissioner on whether to uphold or reverse the adverse determination or the final adverse determination. In reaching a recommendation, the assigned organization would not be bound by any decisions or conclusions reached during the health carrier's utilization review process or internal grievance process.

Within seven business days after the health carrier received notice that the request for external review was accepted, the carrier or its designee utilization review organization would have to give the assigned independent review organization the documents and any information considered in making the adverse determination or final adverse determination. Except as provided below, failure by the carrier or its designee to provide the documents and information within seven business days would not delay the conduct of the external review.

Upon receiving a notice from the assigned independent review organization that the carrier or its designee had failed to provide the documents and information within seven business days, the Commissioner could terminate the external review and make a decision to reverse the adverse determination or final adverse determination, and immediately would have to give notice of that decision to the independent review organization, the covered person, his or her authorized representative, and the health carrier.

The independent review organization would have to review all of the information and documents received from the health carrier or its designee and any other information submitted by the covered person or his or her representative that the Commissioner had forwarded to the organization. Upon receiving any information submitted by the covered person or his or

her representative, at the time the Commissioner forwarded the information to the independent review organization, he or she would have to forward it to the health carrier.

The health carrier could reconsider its adverse determination or final adverse determination. Reconsideration would not delay or terminate the external review. The external review could be terminated only if the carrier decided, upon completing its reconsideration, to reverse its adverse or final adverse determination and provide coverage or payment for the health care service that was the subject of the determination. Immediately upon deciding to reverse its determination, the carrier would have to give written notice of that decision to the covered person, his or her authorized representative, the assigned independent review organization, and the Commissioner. The independent review organization would have to terminate the external review upon receiving the notice.

In addition to the documents and information provided by the health carrier or its designee, the assigned independent review organization would have to consider the following in making a recommendation, to the extent information or documents were available and the organization considered them appropriate:

-- The covered person's pertinent medical records.
-- The attending health care professional's recommendation.
-- Consulting reports from appropriate health care professionals and other documents submitted by the carrier, the covered person, his or her authorized representative, or his or her treating provider.
-- The terms of coverage under the person's health benefit plan with the health carrier.
-- The most appropriate practice guidelines.
-- Any applicable clinical review criteria developed and used by the carrier or its designee utilization review organization.

The assigned independent review organization would have to give its recommendation to the Commissioner within 14 days after the Commissioner accepted the request for an external review. The organization would have to include all of the following in its recommendation:

-- A general description of the reason for the request for external review.
-- The date the organization received the assignment from the Commissioner.
-- The date the external review was conducted.
-- The principal reason or reasons for its recommendation.
-- The rationale for its recommendation.
-- Reference to the evidence or documentation, including the practice guidelines, considered in reaching its recommendation.

Upon receiving it, the Commissioner immediately would have to review the recommendation to ensure that it was not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier. Within 14 days after receiving the recommendation, the Commissioner would have to give written notice in plain English to the covered person, his or her authorized representative, and the health carrier of the decision to uphold or reverse the adverse determination or final adverse determination. The Commissioner would have to include in this notice all of the following:

-- The principal reason or reasons for the decision, including the information included by the independent review organization in its recommendation.
-- If appropriate, the principal reason or reasons why the Commissioner did not follow the independent review organization's recommendation.

Upon receiving notice of a decision reversing the adverse determination or final adverse determination, the health carrier immediately would have to approve the coverage that was the subject of the determination.

Expedited External Review

A covered person or a covered person's authorized representative could make a request for an expedited external review with the Commissioner within 10 days after the person received an adverse determination, if both of the following were met:

-- The adverse determination involved a medical condition of the person for which the time frame for completion of an expedited internal grievance would seriously jeopardize the person's life or health or would jeopardize the person's ability to regain maximum function, as substantiated by a physician either orally or in writing.
-- The person or his or her representative had filed a request for an expedited internal grievance.

When the Commissioner received the request, he or she immediately would have to notify, and give a copy of the request to, the health carrier that made the adverse determination or final adverse determination. If the Commissioner determined that the request met the reviewability requirements (after completing a preliminary review), the Commissioner would have to assign an approved independent review organization to conduct the expedited

external review, and provide a written recommendation to the Commissioner on whether to uphold or reverse the adverse determination or final adverse determination.

If a covered person had not completed the health carrier's expedited internal grievance process, the independent review organization would have to determine, immediately after receiving the assignment, whether the person would be required to complete the expedited internal grievance before conducting the expedited external review. If the organization determined that the person had to complete the expedited internal grievance process first, the organization immediately would have to notify the covered person and his or her representative of this determination and that it would not proceed with the expedited external review until the person completed the expedited internal grievance.

Except in regard to the time frames, the process for conducting an expedited external review generally would parallel the process for a standard external review. Within 12 hours after receiving notice from the Commissioner, the health carrier or its designee utilization review organization would have to provide or transmit all necessary documents and information considered in making the adverse determination or final adverse determination to the assigned independent review organization, electronically or by telephone or facsimile or any other available expeditious method.

The independent review organization would have to provide its recommendation to the Commissioner as expeditiously as the covered person's medical condition or circumstances required, but in no event more than 36 hours after the date the Commissioner received the request for an expedited external review.

The Commissioner immediately would have to review the recommendation to ensure that it was not contrary to the terms of coverage under the covered person's health benefit plan with the health carrier. As expeditiously as the person's medical condition or circumstances required, but in no event more than 24 hours after receiving the recommendation, the Commissioner would have to complete the review of the recommendation and notify the covered person, his or her authorized representative, and the health carrier of the decision to uphold or reverse the adverse or final adverse determination. If this notice were not written, the Commissioner would have to provide written confirmation of the decision within two days of providing the notice.

Upon receiving notice of a decision reversing the adverse or final adverse determination, the health carrier immediately would have to approve the coverage that was the subject of the determination.

An expedited external review could not be provided for retrospective adverse determinations or retrospective final adverse determinations.

External Review Decision

An external review decision would be binding on the health carrier except to the extent the carrier had other remedies available under applicable State law. The decision would be binding on the covered person except to the extent he or she had other remedies available under applicable Federal or State law.

A covered person or a covered person's authorized representative could not file a subsequent request for external review involving the same adverse determination or final adverse determination for which the person had already received an external review decision under the bill.

Independent Review Organization

Approval. The Commissioner would have to approve independent review organizations eligible to be assigned to conduct external reviews to ensure that an organization satisfied the minimum standards established under the bill. The Commissioner would have to maintain and periodically update a list of approved independent review organizations.

The Commissioner would have to develop an application form for initially approving and for reapproving independent review organizations. Any independent review organization wishing to be approved would have to submit the application form and include all documentation and information necessary for the Commissioner to determine if the organization satisfied the minimum qualifications. The Commissioner could charge an application fee that organizations would have to submit with an application for approval and reapproval.

An approval would be effective for two years, unless the Commissioner determined before expiration that the organization was not satisfying the minimum standards. If the Commissioner made that decision, he or she would have to terminate the approval and remove the organization from the list of approved organizations.

Standards. To be approved, an independent review organization would be required to have and maintain written policies and procedures governing all aspects of both the standard external review process and the expedited external review process and that included, at a minimum, a quality assurance mechanism in place that did all of the following:

-- Ensured that external reviews were conducted within the specified time frames and required notices were provided in a timely manner.
-- Ensured the selection of qualified and impartial clinical peer reviewers to conduct external reviews on behalf of the organization and suitable matching of reviewers to specific cases.
-- Ensured the confidentiality of medical and treatment records and clinical review criteria.
-- Ensured that any person employed by or under contract with the organization adhered to the bill's requirements.

In addition, the independent review organization would have to agree to maintain and provide to the Commissioner the information required by the bill (described below).

A clinical peer reviewer assigned by an independent review organization to conduct external reviews would have to be a physician or other appropriate health care professional who met all of the following minimum qualifications:

-- Was an expert in the treatment of the covered person's medical condition that was the subject of the external review.
-- Was knowledgeable about the recommended health care service or treatment because in the immediately preceding year he or she devoted a majority of his or her time to an active clinical practice within the medical specialty most relevant to the subject of the review.
-- Held a nonrestricted license in a state of the United States and, for physicians, a current certification by a recognized American medical specialty board in the area or areas appropriate to the subject of the external review.
-- Had no history of disciplinary actions or sanctions, including loss of staff privileges or participation restrictions, that had been taken or were pending by any hospital, governmental agency or unit, or regulatory body that raised a substantial question as to the clinical peer reviewer's physical, mental, or professional competence or moral character.

An independent review organization could not own or control, be a subsidiary of or in any way be owned or controlled by, or exercise control with a health benefit plan, a national, state, or local trade association of health benefit plans, or a national, state, or local trade association of health care providers.

An independent review organization selected to conduct an external review and any clinical peer reviewer assigned by the organization to conduct the review could not have a material professional, familial, or financial conflict of interest with any of the following:

-- The health carrier that was the subject of the review.
-- The covered person whose treatment was the

subject of the review or the person's authorized representative.
-- Any officer, director, or management employee of the health carrier.
-- The health care provider, the provider's medical group, or an independent practice association recommending the health care service or treatment that was the subject of the review.
-- The facility at which the recommended health care service or treatment would be provided.
-- The developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended for the covered person.

In determining whether an independent review organization or a clinical peer reviewer had a material professional, familial, or financial conflict of interest, the Commissioner would have to take into consideration situations in which the organization to be assigned to conduct an external review of a specified case or a clinical peer reviewer to be assigned by the organization could have an apparent professional, familial, or financial relationship or connection with a person described above, but the characteristics of that relationship or connection were such that they were not a material conflict of interest that resulted in the disapproval of the organization or reviewer from conducting the external review.

Liability. An independent review organization or a clinical peer reviewer working on behalf of an organization would not be liable in damages to any person for any opinions rendered during or upon completing an external review conducted under the bill, unless the opinion was rendered in bad faith or involved gross negligence.

Record-Keeping and Reporting

Independent Review Organization. An independent review organization assigned to conduct an external review would have to maintain for three years written records in the aggregate and by health carrier on all requests for external review for which it conducted an external review during an calendar year. Each organization required to maintain written records would have to submit to the Commissioner, at least annually, a report in the format specified by the Commissioner. The report would have to include in the aggregate and for each health carrier all of the following:

-- The total number of requests for external review.
-- The total number of requests for external review resolved and, of those, the number upholding the adverse determination or final adverse determination and the number reversing the determination.
-- The average length of time for resolution.
-- A summary of the types of coverages or cases for which an external review was sought.
-- The number of external reviews that were terminated as a result of a health carrier's reconsideration of its determination after receipt of additional information from the covered person or his or her authorized representative.
-- Any other information the Commissioner requested or required.

Health Carrier. Each health carrier would have to maintain for three years written records in the aggregate and for each type of health benefit plan offered by the carrier on all requests for external review that were filed with the carrier or that it received notice of from the Commissioner. Each carrier required to maintain these records would have to submit to the Commissioner, at least annually, a report in the format specified by the Commissioner. The report would have to include the same type of information reported by independent review organizations.

Description of Procedures

Each health carrier would have to include a description of the internal grievance and external review procedures in or attached to the policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provided to covered persons. The description would have to be in plain English and include all of the following:

-- A statement informing the covered person of his or her right to file a request for an internal grievance and external review of an adverse determination.
-- The Commissioner's toll-free telephone number and address.
-- A statement informing the covered person that, when filing a request for an external review, he or she would be required to authorize the release of any medical records required to be reviewed for the purpose of reaching a decision on the external review.

Violations

If the Commissioner found that a violation had occurred, he or she would have to put the findings and decision in writing and issue and have served on the person charged with the violation a copy of the findings and an order requiring the person to cease and desist from the violation. The Commission also could order the suspension, limitation, or revocation of the person's license or certificate of authority; and payment of a civil fine of up to $500 for each violation. If the person knew or reasonably should have known that he or she was in violation of the proposed Act, however, the maximum civil fine for each violation would be $2,500. An order under these provisions could not require the payment of civil fines exceeding $25,000.

If the Commissioner found that a health carrier had deliberately refused to pay for a covered benefit, he or she could order a civil fine of up to $25,000 for a first offense, or up to $50,000 for a second offense. For a third or subsequent offense, or if the Commissioner determined that the health carrier had deliberately engaged in a pattern of refusing to pay for a covered benefit, the Commissioner could order a civil fine of up to $1 million or the amount of the carrier's total liability for the covered benefits denied, whichever was greater. The Commissioner also could order recovery of the cost of the investigation, in addition to any of these fines.

A person who violated the proposed Act would have to be afforded an opportunity for a hearing before the Commissioner under the Administrative Procedures Act. After notice and an opportunity for hearing, the Commissioner could by order reopen and alter or set aside, in whole or in part, an order issued under these provisions if, in his or her discretion, conditions of fact or law had changed to require that action or the public interest required it.

If a person knowingly violated a cease and desist order and had been given notice and an opportunity for a hearing, the Commissioner could order a civil fine of $10,000 for each violation, or a suspension, limitation, or revocation of the person's license, or both.

In addition, the Commissioner could apply to the Ingham County Circuit Court for a court order enjoining a violation of the Act.

Fines collected under these provisions would have to be placed in the proposed Cancer Clinical Trials Fund.

Cancer Clinical Trials Fund

The bill would create the Cancer Clinical Trials Fund as a separate fund in the State Treasury. The State Treasurer would have to credit to the Fund all fines collected under the preceding provisions. Money could be appropriated from the Fund to hospitals, outpatient oncology centers, and other facilities in Michigan involved in National Institutes of Health Phase III or IV cancer clinical trials that applied for Fund money to defray partially costs of patient participation in cancer clinical trials not covered by pharmaceutical manufacturers or health carriers. Money could be appropriated in amounts that did not exceed $5,000 per facility per year.

The State Treasurer could invest Fund money in any manner authorized by law for the investment of State money, and earnings would have to be credited to the Fund. Money in the Fund at the close of the fiscal year would have to remain in the Fund.

Legislative Analyst: S. Lowe

FISCAL IMPACT

The bill should have no fiscal impact on this State's major publicly financed health care program, Medicaid managed care. This is due to existing Federal law (Social Security Act Section 1932(b)(4) and Section 1902(a)(3)) requiring extensive internal grievance for managed care plans *and* an external grievance procedure ("fair hearing") that can occur simultaneously with an internal appeal.

As for the general health care system, the real question is whether a statute mandating an external grievance process would result in increased appeals in and of itself. If not, this bill should have little or no fiscal consequences other than for the Commissioner's office. This assumption is based on the fact that such a process already exists in that office for health maintenance organizations and that overall "adverse" determinations appear to be very low (see Inquiry, Fall 1997).

The bill would have an indeterminate fiscal impact on the Office of Financial and Insurance Services. The Office would be required under this bill to take on additional responsibilities for creating and implementing an independent review program, including approving and assigning independent review organizations, and collection and submission of reports and record-keeping for these organizations. According to the Department, this would require the hiring of additional staff to perform these functions. There is currently no information available about what these costs would total or what fund source would be used to cover them.

The bill also would have an indeterminate fiscal impact on the DCIS or the Department of Community Health, as there is no information regarding which one would administer the Cancer Clinical Trials Fund or the amount of revenue generated.

Fiscal Analyst: J. Walker
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