MINUTES FROM THE MEDICAL MANAGEMENT AND PROCEDURES COMMITTEE MEETING

Boston, MA
Sunday, September 27, 1992

The meeting commenced at 8:30 a.m. chaired by Dr. Rodolfo E. Fidelino, Co-Chairman.

Dr. Hanns O. Kretzschmar, Co-Chairman, was not present. The Antitrust Constraints Agreement was read and conflict of interest forms were signed by the members and returned to Dr. Fidelino. During the beginning of the meeting Dr. Fidelino stated that in this meeting and other future meetings of this committee, the paramedical service companies and the insurance laboratories will be represented by one representative from each company. Members present: Drs. Nancy Beecher, Gordon Cumming, Polly Galbraith, James Harris, Max Hefti, Einar Perman, Theodore Plucinski, Robert Quinn,II, John Swanson.

First topic for discussion was the Older Age Group Medical Form introduced by Dr. Robert Pokorski, Vice President of Medical Research, North American Reinsurance Company.

The questions on the form were patterned after long term care history forms used by some companies, while the paramedical side of the form was developed by ASB/Meditest. This form was distributed to those in attendance for discussion, along with recommended changes by Dr. Pokorski. During the discussion emphasis was directed toward the following:

- There is a need for more expansion of the smoking question to include years and amount smoked, reason for quitting and when.
- Questions concerning vision and hearing should also include speech. There is a need to know whether there has been any disturbance in the ability to speak, with full details, and current status.
- Falls and physical injuries in the older ages are important. There should be detail given of all injuries, accidents and any joint replacement that occurred in the last 5 years. Are any supportive devises required, such as crutches, wheelchair, braces, etc., for ambulation?
- On review of physicians consulted, the doctor's name and address should include his/her sub-specialty along with reasons and description of treatment. A complete detailed history would reduce the number of attending physician statements required to properly evaluate the applicant's past history.
- Hospitalization question should be amplified to include emergency room care, nursing home and related home care, along with any physiotherapy, speech therapy, administered.
- Greater amplification of diagnostic tests is desirable to include psychological and cognitive evaluations.
- More amplification on treatment prescribed; the name of the drug, amount, and whether it can be taken without assistance, to determine the cognitive ability.
- An added question could amplify ability to care for him/herself; an explanation of any assistance required at home such as help to prepare meals or food shopping assistance.
- Are there special supportive devises required, such as railings, tub handles, walker, wheelchair, ramps, etc?
- To assess cognitive ability there should be interrogation to evaluate forgetfulness and memory loss. A mini-mental evaluation could be incorporated.
- Automobile driving ability can be helpful. Are you driving, how far, for how long, only local driving or highway driving as well?
- Is spouse alive or dead? If deceased, when and who handles household needs? At an older age, the loss of a spouse can be devastating to the survivor.
- Physical activity question to determine extent of exercise. Daily activity review could be incorporated in a handwritten two to three line explanation to evaluate cognitive and physical ability.
- The new form should have larger print to be more easily read by the applicant.

During the question and answer period the following salient comments were made:

- A Canadian company performs the detailed questioning of the older applicant by a telephone home interview of the applicant done by an experienced Home Office interviewer. It is found to be very informative and better than paramedical technician or examining physician written interviews.

- The current physical examination section of the old form could be improved by asking whether the client was in a wheelchair, used a walker or wore braces. No noted degree of disability is volunteered by examining physician of paramedical technician, as there is no question to request such information.

- Cognitive questions should be asked by the examiner.

- Some companies in the long-term care business have struggled with determining which attending physicians statements should be requested to assess the applicant's insurability. It was felt that more information on the application or the Home Office telephone interview process can reduce the number of APS's significantly.

As part of this presentation William Fisher, 2nd VP and Associate General Counsel at Mass Mutual was invited to participate in the discussion of the older age group medical form. The following is a summary of his comments:

1. Discrimination: An issue to consider is whether the questions in the form are not discriminating and whether the form will be acceptable under state law. In Mr. Fisher's opinion the state insurance departments are reasonable and the form would probably be acceptable.

   - It is considered that "older age" is 65 and older. There is a possibility protective groups such as AARP may have some difficulty with the questions in the form based upon age discrimination laws. However, precedent has been established by existing practices of different questions in the juvenile application, age cut-off by plan, and special priced products.

   - When arriving at a definition of older age, to prevent discrimination charges it would be best to decide on one age and never change it.

2. Filing: The issue of filing with the State Insurance Department was discussed. If the form will be used to supplement the information on the original form, this form does not need to be filed. On the other hand, if the form will be used as an original form it may be necessary to file to make it part of the policy given to the client. Filing the form, however, can raise Insurance Department questions, which suggests it may be better not to file.

   If the form is not filed, it does not become part of the policy which can be a problem in cases of misrepresentation in the future. It's not possible to litigate a case in court if the form is not filed and made part of the insurance policy.

3. Discrimination Against Disability: Legislative action has prevented discrimination against the disabled. Mr. Fisher recommended it would be advisable to give this form to each respective company's law department and policy form unit to assess the degree to which the questions on the form conflict with current legislative restriction or discrimination against the disabled.

4. Antitrust: To determine whether the form is in conflict with antitrust law, the form should be reviewed by ACLI for appropriate resolution of the issue.

5. Older Age: Terminology is not good. Perhaps there is another phrase or a word to better define the parameters of "older age."

The second topic for Committee discussion was Build, Blood Pressure and Pulse Rate on the ID/Consent Form. In applications for Major Medical insurance coverage, when a paramedical technician is required to draw blood from the applicant without performance of paramedical measurement, one company determined the technician should obtain the height and weight, blood pressure and pulse rate and send it along with the blood kit to the laboratory. The laboratory, in turn, would forward the obtained measurements to the insurance company. Since the insurance company will extend this practice to applicants for life insurance and other companies may decide to adopt the practice, it was considered appropriate to discuss the new procedure at this committee meeting.

At issue was whether a physical measurement received in this manner, then passed through the laboratory for use in the underwriting process without modification of the existing ID consent form, is an acceptable practice to maintain confidentiality of this privileged information.

In an active committee discussion the following observations were made:

- One laboratory legal advisor recommended that as the consent form is signed by the applicant, paramedical information received in this manner remains

confidential and can be used in underwriting the application.

- To speed up the underwriting process, the insurance company would receive the paramedical measurements along with the laboratory blood and urinalysis results via the expert computer system

- The laboratory, as well as paramedical service charges are unchanged.

- A form was designed through the combined efforts of the laboratory, paramedic and client company.

- Bill Fisher suggested the consent form statement be revised to inform the applicant that the paramedical measurement will be sent to the laboratory for delivery to the insurance company.

- HORL believes the procedure is acceptable legally since the laboratory is an agent of the company.

- The general consensus of the committee was that this method for obtaining an abbreviated paramedical measurement was acceptable without modification of the ID form.

The final topic for discussion by the Committee was "Home Brew Test" and FDA Compliance Policy Guide Draft. The speaker was Morton K. Schwartz, PhD, Chairman, Department of Clinical Chemistry at Memorial Sloan-Kettering Cancer Center.

In the last few months the FDA circulated a draft compliance policy guide (CPG) to several manufacturers for their informal comments. The FDA stated in the draft that "it has come to the attention of FDA that laboratories have been manufacturing 'home brew' products, either from product already on the market, or from components, and utilizing these unapproved products for diagnostic purposes." In addition, it states "home brew products are subject to the same regulatory requirements as any unapproved medical device." The FDA compliance policy guide draft has created a reaction of confusion due to the profound adverse effects the proposed policy would have on the laboratories, manufacturers and researchers.

To discuss the implications the guide draft would have on all laboratories (insurance and clinical) and research centers, Dr. Schwartz was invited to guide us through the maze.

"Home brew" is defined as a product derived from products already on the market or from their components

The current opinion is that all laboratories function under the 1988 CLIA regulation. To be in compliance CLIA requires verification of performance specifications for modified or in-house developed products and the laboratory must provide documented results on request. The present FDA guide draft would interfere with this current assumption of CLIA authority. Also to be in FDA compliance it would appear that the CLIA will require use of only FDA approved tests after 1992.

The guide draft would expand the FDA responsibility beyond what was considered to be the manufacture and the sending of products across interstate lines.

The following are a few of the many implications that would result if the compliance policy guide becomes a regulation as currently stated in the draft.

- There would be increased cost to utilize FDA approved procedures.

- Increased cost and delays in completing protocols for product approval by the FDA.

- In the validation process, the FDA regulation requirement must have three other laboratories validate the test. Thereby the proprietary tests in our laboratories would no longer be confidential, A large concern for the labs.

- The FDA validation process also requires Institutional Research Board (IRB) protocol, which none of the insurance labs possess.

- Core test cannot be altered or used for any other purpose than the protocol approval and the purpose for which it was approved by the FDA.

- The draft directive would not only affect the components of the blood profile, but also those of the urinalysis, including hypoglycemic and antihypertensive substances, cocaine, nicotine and others.

- Any test not on the FDA list in the guide draft would not be approved for use by the FDA. Monoclonal antibodies listing in the draft publication excluded several of the tumor markers reported on in the February 1992 Bethesda meeting. Furthermore, many tumor markers would have restricted approval:

  — CEA only approved for colon cancer.

  — M26 and M29-only test for breast cancer.

— CA-125-only approved for ovarian cancer follow-up after surgery.

— HCG-approved as a pregnancy test, but not approved for cancer detection.

— Alpha-fetoprotein (AFP) would not be approved for liver disease.

— Progesterone Receptor in breast cancer is FDA approved but the more accurate and most frequently used marker, Estrogen Receptor, is not.

— PSA-cannot be used for screening.

— There would be no grandfathering of any existing test protocol.

- Finally, satisfying these FDA guidelines could adversely effect insurance company mortality experience.

Summary

FDA drafted regulation when approved will:

1. Increase cost.
2. Increase antiselection.
3. Increase company mortality.

Proposed ways to handle this FDA issue are:

- Keep going as we are.
- Letter from industry (ACLI) to FDA.
- Support CLIA approach.
- Be sure labs document all results.
- Recommend public hearings for concerted comment approach.
- Need political action by writing to Senator Dole, etc.
- CLIA regulation should be followed by insurance labs.
- Need moratorium to wade through the many test procedures affected by FDA draft guide.
- Industry needs small working groups to go to FDA with insurance position.

Rodolfo E. Fidelino, MD
Co-Chairman.