5 Medical Care

[Awareness of the Issues]

As for the medical care field, the “First Report Regarding Promotion of Regulatory Reform” (December 11, 2001) states that “in order to realize patient-oriented medical care services, it is essential to improve the efficiency of medical care services by thoroughly streamlining the related procedures, while also raising the quality and ensuring the safety of the services, and from patients' standpoint, it is necessary that transparency is secured in medical care and that they gain greater freedom in making their own choices.” Based on these fundamental ideas, the Report proposed various measures including the promotion of thorough disclosure and publication of medical care information, the promotion of application of information technology in the medical field, the demonstration of functions by insurers, a review of the medical fee system, and promotion of the modernization and efficiency of management in the medical field. In line with the proposals, the "Three-Year Program for Promoting Regulatory Reform (Revised)" was decided on by the Cabinet. Although regulatory reform was carried out in various fields, including the deregulation of advertising, a review of the "205 yen rule," and a review of the pricing method for drugs and medical materials, there still remain some items that have not been implemented, such as examination and payment of medical bills by the insurer.

Based on the recognition that the reform to realize patient-oriented medical care services is incomplete and that ceaseless reform efforts are necessary, the Council for Regulatory Reform has continued their studies, while maintaining the above ideas. While calling for the prompt implementation of measures that are incorporated in the "Three-Year Program for Promoting Regulatory Reform (Revised)" but which have not been implemented, the Council proposes reform measures that are incorporated in the Program but which should be more strictly implemented, and new measures that are not incorporated in the Program as follows.

As for the problem of joint stock companies' entry into medical practice, since the “First Report Regarding Promotion of Regulatory Reform” states that “the desirable management style of medical institutions including a stock company style should be examined in the future,” the Council carried on discussions during the current fiscal year believing that the provision of medical care services by diversifed entities will expand consumer options. However, the Council’s views are still at variance from those held by other parties concerned. The Council intends to continue discussions

aggressively on the matter.

[Specific Measures]

1 Improving the efficiency and upgrading the quality of medical processing by promoting the application of information technology

(1) Keeping medical care information, such as electronic medical records, outside of medical institutions [To be implemented promptly in or after FY2003]

With regard to keeping medical care information, such as electronic medical records, outside of medical institutions, the Ministry of Health, Labour and Welfare Notice (March 29, 2002) states that, "in view of the progress in information technology and legal framework conditions concerning the protection of personal information, such information should be kept at places under the proper control of medical institutions or medical corporations, as such information can be leaked instantly and in volume and as it is hard to identify the source of leakage."

On the other hand, when the volume of data to be kept increases enormously in the future, it may become difficult for individual medical institutions to adequately deal with the maintenance and management of the data, not to mention the operation and maintenance of information equipment.

Therefore, measures should be taken to allow businesses other than medical institutions, etc. to keep medical care information provided that the obligation to comply with personal information and management rules is secured and that the businesses are allowed to see the data if necessary for data management only when the entrusting medical institutions approved.

(2) Protection of personal information in the medical field [To be implemented as soon as possible]

The protection of personal information is insuffient in the medical field. The importance of protecting personal information will increase if the application of information technology is further promoted.

Therefore, a study should be undertaken as soon as possible on preparing guidelines for the protection of personal information in the medical field and necessary measures should be taken.

2 Improving functions of insurers

(1) Examination and payment of medical bills by the insurer [To be implemented in FY 2001 (Measures yet to be implemented)]

The “Three-year Program for Regulatory Reform (Revised)” which was decided upon by the Cabinet should be implemented immediately. The Program says in part that “the examination and payment of bills are originally the role of the insurer, so the insurer should be allowed to choose from various options as follows on its own will: (1) conduct examination and payment by themselves; (2) entrust them to a conventional examination and payment organization; or (3) entrust them to a third party (private sector). In the case of abolishing the transmittal that virtually forces organizations, such as health insurance unions, to entrust examination and payment to the Social Insurance Medical Fee Payment Fund (1948 Transmittal by the Director-General of the Health Insurance Bureau, Ministry of Health and Welfare) or the ministerial ordinance obliging such organizations to submit bills for medical care fees to an examination and payment organization (1976 Ordinance by the Ministry of Health and Welfare) for this purpose, the insurers should be allowed to examine and pay bills by themselves provided that they secure a fair examination system adequate for public insurance and secure confidentiality of information for protection of patients' information. In such cases, the rules for dissolving disputes concerning examination and payment should be clarified. (To be implemented in FY2001).”

3 Promotion of patient (the insured) choice

(1) Promotion of allowing patients to choose the combined use of public insurance medical care and medical care not covered by public insurance [To be implemented in FY2003 (Implementation in successive steps)]

The Japanese medical care system so far has been administrated based on the fundamental philosophy that "all people can receive a certain level of medical care services anywhere at any time" under the universal medical care insurance system and free access to medical institutions. However, due to improved living standards and diversified values and needs, people are not satified with simply being able to “receive a certain level of medical care services anywhere at any time” and indeed, they want higher level of medical care services. Medical care service providers, for their part, want to be sufficiently assessed in accordance with their ability and quality.

However, amid the need to check the rise in medical fees under the public medical care insurance system, there are limitations when meeting the diversified needs of citizens (patients) and appropriately assessing the quality of medical care

service providers. Meanwhile, a specified medical care coverage system has been introduced with coverage mainly recognized for "highly advanced medical technology" and "selected medical care" and the scope of coverage has been expanded to outpatients without a letter of introduction at large hospital and long-term hospitalization. In order to further ensure sufficient patient satisfaction, the system that allows patients to choose medical care services in accordance with their needs and the system that allows medical institutions to be appropriately assessed through patients' choice should be further promoted by utilizing this framework.

The combined use of public insurance medical care and medical care not covered by public insurance should be further reformed. That is to say, while continuing to secure medical care that is “necessary and sufficient as social security” which citizens can receive adequately regardless of their ability to bear the cost, the Ministry of Health, Labour and Welfare Notice with regard to the current specified medical care coverage system should be reviewed in order to promote combined use of public insurance medical care and medical care not covered by public insurance by, for example, expanding the scope of medical care services for which a medical institution chosen by a patient can charge additional medical fees.

4 Review of the medical fee system

(1) Promotion of the introduction of a lump-sum/flat payment system

With regard to acute inpatient treatment at advanced treatment hospitals, etc., a comprehensive assessment system is slated to be introduced from April 2003. In this regard, consideration should be given to creating incentives for shortening average hospitalization period. **[Conclusion to be reached in FY2002 and measure to be taken in FY2003]**

Introducing a diagnosis-related group/prospective payment system will give medical institutions incentives for providing efficient and effective medical care services and, as a result, will promote the separation of medical institutions by function and contribute to an enhancement of the quality of medical care services through shorter and adequate hospitalization periods and standardization of medical care content.

Therefore, while aiming at standardizing medical care content, shortening the average hospitalization period, and enhancing the quality of medical care services by promoting the separation of medical institutions by function, first, a plan to introduce the diagnosis-related group/prospective payment system with regard to acute inpatient treatment should be drafted and a study should be promoted on introducing the system. In that process, experiences in other countries should be taken into account in order to

make the Japanese system internationally consistent. **[Plan to be indicated and study started in FY2003]**

As for chronic disease treatment, a study should be undertaken on introducing a flat payment system that takes into account patients' daily living activities (ADL), clinical conditions, nursing and care level. **[To be studied in FY2003]**

5 Utilization of various management methods

(1) Review of worker dispatching regulations

Based on discussions at the medical care subdivision of the Social Security Council in March 2002, the Ministry of Health, Labour and Welfare proposed a plan to make it possible to dispatch workers engaged in medical operations to social welfare facilities and the plan is now being discussed at the Labour Policy Council of the ministry.

Therefore, a conclusion should be reached and measures based on the conclusion should be adopted as soon as possible with regard to dispatching workers engaged in medical operations to social welfare facilities. **[To be implemented as soon as possible in FY2002]**

Even if the above measures are adopted, workers are still not allowed to be dispatched to medical institutions. The efficient and appropriate allocation of medical care workers in accordance with the needs of medical institutions and improvements in the medical care providing system will go a long way toward realizing citizen (patient)-oriented medical care services.

Therefore, a study should be undertaken and a conclusion should be reached on dispatching workers engaged in medical operations to medical institutions. **[Conclusion to be reached in FY2004]**

6 Medical care providing system

(1) Review of community medical care program (regulation on hospital bed numbers) [Study to be undertaken starting in FY2002 and measures to be adopted at an early date in FY2005]

Under the current community medical care program, medical institutions (the number of beds) are quantitatively controlled based on the fundamental idea that inpatient medical fees and the number of hospital beds are correlative, as the current public medical care insurance system is based on the fee-for-service system.

However, it is pointed out that the community medical care program is preventing the entry of high-quality medical institutions because the regulation on

hospital bed numbers based on the program does not promote competition among medical institutions and protects even those institutions that do not make management efforts, resulting in making the number of beds at such institutions a sort of "vested interest." It is also pointed out that, in some prefectures, the regional imbalance in the number of beds to population ratio is as much as three times and that the appropriate number of function-by-function beds are not secured in accordance with the actual situation and needs of individual regions.

Therefore, when preparing a community medical care program, fair and strict calculation standards for bed numbers should be established by taking into account the actual situation and needs of individual regions with regard to the function of beds such as acute, chronic, or special disease treatment needs, and measures to bring the number to an appropriate level should be thoroughly implemented. From the viewpoint of ensuring a proper medical care providing system by promoting competition among medical institutions concerning the quality of medical care, such as standardization of medical care content and a shortening of the average hospitalization period, a study on medical care programs, including the desirable regulation on the number of beds, should be undertaken along with a study on the introduction of a diagnosis-related group/prospective payment system, and measures should be adopted.

(2) Improvement of professional medical care workers [To be implemented in FY2003]

In order to meet patients' diversified needs, it is desirable to provide appropriate medical treatment or care based on various specialties (knowledge/skills). In light of the situation, the specialties of medical care workers have been subdivided and their functions segmented. However, it is pointed out that doctors are in short supply in the anesthesiology and pathological diagnosis fields.

Therefore, in order to cope with this situation, a study should be undertaken and measures should be taken to dissolve the shortage of professionals.

(3) Promotion of remote-controlled medical treatment [To be implemented in FY2002]

With information technology advances in recent years, the importance of remote-controlled medical treatment and e-ICU medical care has increased. Awareness has been raised that increasing the opportunity to receive medical care from highly capable doctors will enhance the quality of medical care. However, under a notice issued by the Ministry of Health, Labour and Welfare, remote-controlled medical treatment is positioned only as complementary to face-to-face medical treatment in remote areas. However, remote-controlled medical treatment even for patients not in remote areas has

been requested for an aspect of patient's convenience and the possibility of providing such treatment has increased thanks to information technology advances.

Therefore, while maintaining the fundamental idea that remote-controlled medical treatment is complementary to face-to-face treatment, such treatment should be promoted by, for example, making it clear and thoroughly known that remote-controlled medical treatment is not necessarily limited to remote areas but is available in various cases.

7 Deregulation concerning drugs

(1) Promotion of providing information on drugs [To be implemented in FY2002 (Implementation in successive steps)]

The Execution Order of the Pharmaceutical Affairs Law prohibits advertising ethical drugs aimed at curing cancer, leukemia, and sarcoma to general consumers (patients) other than medicine-related people. A ministerial transmittal prohibits advertising other ethical drugs to general consumers (patients).

These regulations are said to have been established for patient protection due to the "asymmetry of information" between patients and pharmaceutical companies. Since ethical drugs are used based on doctors' prescriptions, patient protection is ultimately ensured by doctors' appropriate judgment. However, in order to realize patient-oriented medical care services, it is necessary to establish a system under which patients can obtain enough information on drugs and receive medical treatment after acquiring necessary knowledge.

Therefore, information such as package leaflets and recall information of ethical drugs that are provided on the Web site of the Organization for Pharmaceutical Safety and Research should be made well known so that general consumers (patients) can obtain sufficient information on drugs, by reviewing the application of the above transmittal. Measures to make it easy for general consumers (patients) to obtain information on ethical drugs should also be studied and adopted.

(2) Promotion of the use of generic drugs [To be implemented in FY2002 (Implementation in successive steps)]

Under the fee system in FY2002, the charge for prescribing generic drugs has been set higher than for prescribing the original drug. Even now, when doctors prescribe a drug in nonproprietary name, the preparation of drugs of the patient's choice is allowed, and when doctors prescribe a drug in proprietary name, the patient can choose a drug of other proprietary name with the doctor's agreement.

In order to further promote the use of generic drugs, while continuing re-evaluation and ensuring the quality of drugs, including generic drugs, the Ministry of Health, Labour and Welfare began publishing information on nonproprietary names, proprietary names, company names, and price, etc. of generic drugs on its Web site starting in April 2002. The system to provide information should be further improved by such ways as promoting the enlightenment of generic drugs and the security of their quality so that patients can make correct judgments.

(3) Deregulation concerning sale of drugs [Study by specialists to start in FY2002 and conclusion to be reached possibly by the end of FY2003]

As a result of the measure to shift 15 product groups of drugs to quasi-drugs carried out on March 31, 1999, it has become possible for general retail outlets, such as convenience stores, to sell nutrition supplement drinks.

In order to make it possible for general retail outlets to sell drugs that satisfy certain standards and whose harmful effects on health are evaluated to be relatively minor by specialists, a study by specialists should be commenced in FY2002 and a conclusion should be reached possibly by the end of FY2003.