

## Philosophy and issues of Japan's medical assessment and guidance/auditing system

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Japan's medical system which is very generous to the professional freedom of medical doctors is supported by the universal health insurance system from the economic side. Health insurance system has been operated under the public contract and therefore it set the "Regulations" and the "Fee Schedule" which doctors had to observe when they performed the insured medical examination and treatment. And, the medical contents of the examination and treatment of the doctors are assessed by the health insurance side. The Ministry of Health and Welfare and the Prefectures sometimes guide and audit the doctors, while there are very few open materials about the actual state of these activities. Their basic philosophy is that doctors should practice adequate medical examination and treatment from the economic and social viewpoints as well as from the medical viewpoint, and these activities have been performed without the obvious and published criteria other than the "Regulations" and "Fee Schedule." Recent amendments of the "Regulations" and the "Fee Schedule" require the creation of open criteria for these activities and the PRO system of the U.S. and so on provide very useful examples but it should be noted that these activities are based on the medical system and health insurance system peculiar to Japan.

**Key Words** assessment, guidance, auditing, health insurance system, Japan

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### 1. INTRODUCTION

Japan's medical system is said to have three freedoms in principle: the freedom of doctors' medical examination and treatment, the freedom of doctors' commencement of practice and the freedom of patients' choice of medical institutions. These are legally based on the Medical Law and the Medical Service Law. The Medical Law provides that doctors are independent in terms of medical examination and treatment, and only subject to the instructions by the administrative agencies in order to prevent grave danger and injury in terms of public

health<sup>1)</sup>. The Medical Service Law provides that hospitals shall comply with the facility/construction standard and the personnel standard<sup>2)</sup> and the sickbeds shall be restricted in accordance with the necessary sickbeds as stipulated for each medical zone<sup>3)</sup>, while doctors can freely inaugurate hospitals or clinics without restrictions, in principle<sup>4)</sup>. Patients are free from any legal restrictions on their choice of medical institutions, and the Medical Law rather prescribes that doctors engaged in medical examination and treatment shall not reject any request for medical examination and treatment without justifiable reason<sup>5)</sup>. Such freedoms are supported from the economic side by the health insurance system under the Health Insurance Law, the National Health Insurance Law, the Health

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Service for the Aged Law and so on. The medical insurance system allows all of doctors and medical institutions to perform the medical examination and treatment under the system, or the "insured medical examination and treatment", if proper procedures are followed<sup>6)</sup>, without any restrictions on patients' acts for receiving medical examination and treatment. As for the contents of the insured medical examination and treatment, however, "adequate" medical examination and treatment<sup>7)</sup> is sought to be done judging also from the viewpoint of medical economy, the medical reimbursement claiming statement containing the contents of insured examination and treatment actually conducted is assessed by the assessment and payment agency<sup>8)</sup>. Doctors and medical institutions are guided and audited by the Prefectures and the Ministry of Health and Welfare<sup>9)</sup>. The above assessment and guidance/auditing, in Japan where nearly all of the medical examination and treatment of its people is performed on the basis of the medical insurance system under the universal health insurance plan, function as a checking system by the third parties covering the entire contents of doctors' medical acts. Further, under such circumstances where the medical expenses continue to rise sharply, they are positioned as an important political means for greater propriety of medical expenses<sup>10)</sup>. However, this checking system is founded on Japan's own medical system, which is a strictly Japanese-style system quite different from the Peer Review Organization (PRO) system of the U.S. and so on<sup>11,12)</sup>, and nearly nothing has been published of the actual state of its application. This paper observes the philosophy, actual state and issues mainly from the aspect of the system of checking the contents of doctors' medical examination and treatment from the medical viewpoint in Japan. The research method was the investigation of the published materials relating to the assessment and the guidance/auditing and the interviews to the persons in charge of these activ-

ities in the Ministry of Health and Welfare and some Prefectures were performed, because there are very few open documents concerning these activities as mentioned above.

## 2. BASIC PHILOSOPHY

### 1) Relations with the medical law

The medical system of Japan leaves the contents of the medical examination and treatment by doctors licensed under the Medical Law to doctors' good sense, in principle. That is, a stand is taken that doctors' freedom is respected as to the contents of doctors' medical acts as far as practicable and their medical judgment and technique are relied upon. This is derived from a philosophy that binding doctors by a uniform medical examination and treatment policy would inhibit the medical effect if taking into consideration the character of the medical examination and treatment which should address each and all of diseases and symptoms on the basis of the subtle relations between doctors and patients. However, Japan's medical insurance is a system operated by insurance premiums mandatorily collected under the laws, which provide the insured medical examination and treatment with a character of medical examination and treatment performed under an official contract. The contents of the contract are provided for as the "Regulations for Medical Institutions and Doctors Taking Charge of Insured Medical Examination and Treatment" under the Ordinance of the Ministry of Health and Welfare. It means that the insured medical examination and treatment shall be performed pursuant to the provisions of these regulations and any act not pursuant to them constitutes a breach of contract. These regulations were enacted in 1957 and have been amended stepwise to date.

### 2) Adequate medical examination and treatment

The policy of the insured medical examination and treatment is generally expressed by the terms of "adequate medical examination and treatment",

which means to be adequate not only medically but also economically and socially. These regulations stipulate as a general policy of doctors' medical examination and treatment that ① toward diseases or injuries for which medical examination and treatment are generally deemed necessary by doctors, ② on the basis of accurate diagnosis, ③ medical examination and treatment shall be performed adequately for the maintenance and improvement of patients' health<sup>13)</sup>, and guidance shall be made so that necessities for medical treatment may be intelligible to the patients, with cordiality and courteousness toward patients as the first consideration<sup>14)</sup>. In addition, these regulations stipulate that the medical position shall be firmly maintained<sup>15)</sup> and patients' thought shall be fostered of preventive hygiene and environmental hygiene<sup>16)</sup>. Further, a stand is taken that medical test, medicine administration, injection, treatment and surgical operation should be conducted stepwise after fully considering the necessity by means whose effectiveness is widely recognized in terms of medical science, minimizing medical examination and treatment processes<sup>17)</sup>. And on the assumption that conscientious medical examination and treatment are performed, and adequate medical expenses are claimed, a fee-for-service payment system described later is formed. Accordingly, if this assumption goes contrary and deviated, or incorrect or inadequate claiming is made, the sound operation of the medical insurance system will be inhibited, and conscientious medical examination and treatment will not be performed, resulting in destroying the confidence of the people in medical examination and treatment. In this sense, these regulations aim fundamentally at the maintenance of the medical insurance system formed in expectation of doctors' good sense, and the assessment and guidance/auditing can be positioned as a means to check if the medical examination and treatment have the contents in conformity with these regulations and to cause any corrective mea-

asures to be taken as necessary.

### 3) Protection of patients/elimination of research purposes

These regulations stipulate that if any disease is outside their specialized field or should any doubt be created about medical examination and treatment, doctors shall take a measure to recommend for a change of doctor<sup>18)</sup>, and in addition any special or new therapy may only be applied that has been provided for by the Minister for Health and Welfare, and any medicine shall be banned that is not provided for by the Minister for Health and Welfare<sup>19)</sup>. The special therapy, which is performed by some doctors, means that which is not generally performed, while the new therapy is that which will be introduced into the insured medical examination and treatment when it becomes an established theory in the field of medical science, being widely disseminated. These regulations aim basically at protecting patients from a medical examination and treatment whose effect is uncertain, while there is a stand that the medical examination and treatment for research purposes aimed at the development of new therapies and medicines should be systematically performed as a field other than the insured medical examination and treatment, whose expenses should be separately disbursed as research expenses. However, it usually takes a fairly long period of time before new therapies and medicines are approved of and introduced into the insured medical examination and treatment causing to increase patients' burden up till the approval, which invites some cases where the reimbursement is claimed by means of "transferring" disguised as if insured medical examination and treatment had been performed using a similar approved therapy or medicine, and therefore it is important to introduce effective new therapies and medicines into the insured medical examination and treatment as soon as possible, and in this sense as well, the "Fee Schedule for Reimbursement" provided for by the Minister

for Health and Welfare has been amended at about two-year intervals in the recent years. Also, in 1984, a system was inaugurated under which, out of new therapies, "highly advanced medical treatment" whose safety and effectiveness have been established when it is performed by the medical institutions which have high-level medical bases both qualitatively and quantitatively but not generally disseminated can be handled within the framework of the insured medical treatment in those institutions under an individual approval by the Minister for Health and Welfare<sup>20</sup>. These regulations also stipulate that the medical test is prohibited that is for research purposes especially covering what is necessary for medical examination and treatment only, since it is often performed in practice simply for collecting data for research purposes<sup>17</sup>.

#### 4) Social and economic adequacy

It is stipulated by these regulations<sup>17</sup> that medical examination and treatment shall be performed with due regard to patients' occupational and environmental characteristics, which is quite natural in terms of diagnostics, while they also mention that labor accidents, etc., for which medical expenses are paid under another system, shall be prioritized. It is stipulated that health examinations are outside the scope of insured medical examination, which is the provision to exclude health examinations for employment or pursuant to Tuberculosis Prevention Law and other laws, purporting that those cases without subjective or objective symptoms are not covered by the insured examination and treatment. These regulations stipulate that doctor's home call shall be made only when necessary for medical examination and treatment, which is said to purport to eliminate patients' request for home call without good reason. It is stipulated that the administration of medicines shall be made only when necessary, only one medicine be administered in principle, the administration of the same medicine not be repeated without good reason, and the dosage be minimized

to be, for example, a two day portion at a time in the case of an internal medicine, which has been gradually relaxed having due regard to increased chronic diseases and patients' convenience to allow a 30 day portion or a 90 day portion to be administered at a time for such diseases as stipulated by the Minister for Health and Welfare. It is stipulated that injection shall be performed when oral administration is improper and the rapid effect of medical treatment is especially counted on, and injection combined with internal medicines may be made only when a remarkable effect is obvious and an internal medicine alone does not work. Surgical operation, treatment or physical therapy is stipulated to be done when necessary or a better effect is expected. It is stipulated that hospitalization may be made when necessary for medical examination and treatment, and shall not be made merely by such a reason as recovery from fatigue or inconvenience in visiting hospital.

#### 5) Medical examination and treatment standard

It had been stipulated that the medical examination and treatment of venereal disease, tuberculosis, hypertension, chronic gastritis, gastric ulcer and duodenal ulcer, the medical examination and treatment at the psychiatric department and the medical examination and treatment by antibiotic preparations and various hormone preparations should comply with the standard of medical examination and treatment provided for by the Minister for Health and Welfare<sup>17</sup>, which was exposed to strong criticism as "limited medical examination and treatment"<sup>21</sup>, resulting in the sequentially relaxed or removed limitations from 1961 on and in the abolished limitations also as to the use and dosage of medicines in 1970. With respect to the insured medical examination and treatment, there is no standard of medical examination and treatment stipulated by the administrative agencies or restrictions placed on medical examination and treatment by the administrative agencies at present.

### 3. FEE SCHEDULE FOR REIMBURSEMENT

While the payment methods of the medical insurance include various systems in many countries<sup>22)</sup>, an itemized fee-for-service system has been adopted in Japan since 1943 in principle under which the total sum of the fixed fee is paid for all of individual medical services claimed by doctors or medical institutions. Specifically, a points table of "Fee Schedule" was prepared in which the balance of each medical service was expressed in points, for which the unit price per point was fixed in accordance with the then available commodity prices and wages to produce the payment amount by multiplying the unit price by the points. In and after 1958, however, one point was fixed at ¥10 to simplify the claiming business routines, with the amendment of the Fee Schedule made only through the change of points. The current points table, which was fixed in 1958, is the one that has since been amended stepwise.

The amendment of the points table is decided in the Central Social Insurance Medical Council established within the Ministry of Health and Welfare through negotiations among the Ministry of Health and Welfare, the Japan Medical Association and other pressure groups concerning its specific contents having due regard to the progress of medical science, and the total amount of medical expenses are usually decided along with the decision of the government budget, which causes the criticism that the contents of medical examination and treatment is decided in reverse order from the total amount of medical expenses.

### 4. ASSESSMENT

A system is adopted under which the assessment of the contents of the reimbursement claimed for the insurance by medical institutions and doctors, the power to which belongs fundamentally to the Health Insurance Association and the National

Health Insurance Association effecting the payment on the basis of claiming, is performed first by the Assessment Committees of the assessment and payment organizations established in Prefectures, viz. the Social Insurance Medical Fee Payment Fund and the Federation of National Health Insurance Associations<sup>9)</sup>. This Assessment Committee, consisting of representatives of doctors, representatives of the Insurance Associations and representatives of public interest, is arranged to perform assessment and assume responsibility as a consultation body. In the case that an especially large amount of medical expenses is claimed, the assessment is performed in the Special Assessment Committee established at the central level. The assessment, whose criteria are the "Regulations for Medical Institutions and Doctors Taking Charge of Insured Medical Examination and Treatment" and the "Fee Schedule", is based on the documentary assessment of the medical reimbursement claiming statement, in principle. That is, whether adequate medical examination and treatment services have been properly made neither too much nor too little to the "names of disease" in terms of medical common sense, whether medicine administration, injection, treatment, surgical operation and physical therapy have been adequate, whether the frequency and quantity have been excessive, and whether duplication has been made, etc. are assessed, and no payment of the claimed amount is paid against that portion if deemed excessive. However, no published and written criteria are available for being deemed excessive, and if any, it is nothing more than the by-laws of the Assessment Committee. Accordingly, the assessment is only performed of the adequacy of each claim, and its results are considered to be adequate to that particular patient, not to apply in general. However, such work is being done as to comprehend the general trend on whether medical institutions and doctors are handling medical examination and treatment appropriately by means of taking a general view of

the statements from each medical institution and doctor, and the points per day of medical examination and treatment, the points per patient and so on are being observed statistically. It should be noted that each statement is further subject to follow-up check by the Insurance Association. Should there be any doubt or question about the results of assessment, all of doctors, medical institutions and the Insurance Associations may apply for review.

### 5. GUIDANCE/AUDITING

Since the insured medical examination and treatment is a medical examination and treatment under an official contract as mentioned above, it is stipulated that the Minister for Health and Welfare and the governors of Prefectures shall perform necessary guidance in order to acquaint doctors with the contents of medical examination and treatment pursuant to this contract, which doctors must accept<sup>9)</sup>. It is considered that the contents of the guidance pertain to the method of performing adequate insured medical examination and treatment and the business handling routines, especially the contents of the "Regulations" and the "Fee Schedule," coming inevitably to step into the contents of doctors' medical examination and treatment, if without which the guidance will not prove fruitful. The guidance is performed on the basis of the procedures stipulated in 1957. The guidance, consisting of a group guidance and an individual guidance, is regulated to be performed individually as far as possible upon previous notice in writing. The group guidance is performed mainly along with the amendment of the "Regulations" and the "Fee Schedule." In the case of the individual guidance, doctors and the men including the doctor(s) in charge of the Prefectures and, sometimes the Ministry of Health and Welfare meet and talk about the contents of each doctor's medical examination and treatment, the method of calculating the medical reimbursement, the method of processing claiming business

and so on through such documents as the clinical charts, the reimbursement claiming statements and so on, and the administrative agency points out any inadequate point to doctors and advises doctors of any improvement, as a general rule. Should any inadequate claims be discovered, the return of such amount to the insurance association is requested. In addition, data are sometimes collected for the guidance through survey concerning patients as necessary. It is considered advisable that the guidance will be smoothly executed through cooperation of the Medical Association, to which the attendance of men of learning and experience designated by the appropriate organization is stipulated for<sup>9)</sup>.

Auditing, which purports to check whether the insured medical examination and treatment have been adequately performed pursuant to the provisions of the laws and whether the claimed amount of the medical reimbursement has been adequate, etc. is usually conducted by such method that the men including the doctor(s) in charge of the Prefectures ask doctors and medical institutions to report, cause them to appear in person for explanation and enter their premises for inspection<sup>23)</sup>. During the above guidance, injustices or improprieties are discovered in some cases, where the return of such amount and auditing are enforced. Unjust claiming can be classified into: ① Transferred claim in which the contents of medical examination and treatment actually done is transferred to other contents of medical examination and treatment, ② Proliferated claim in which greater amount is claimed than the frequency, quantity and contents actually done, ③ Fictitious claim in which claiming is made on a person who has actually received no medical examination or treatment by disguising as if such had been done, ④ Duplicated claim in which the contents of medical examination and treatment already claimed is claimed once again, and ⑤ Others. Improper claiming is a claim which deviates considerably from the basic philosophy as mentioned above

or is based on inadequate medical examination and treatment acts according to the commonly accepted idea for medicine. Auditing is conducted in accordance with the procedures stipulated in 1953. Administrative measures after auditing include the return of unjustly or improperly claimed amounts to the insurance association, the revocation of insured medical examination and treatment, the warning and the caution. Of these, the revocation of insured medical examination and treatment has a legal effect, which disables doctors and medical institutions from performing insured medical examination and treatment and patients from receiving insured medical examination and treatment, and might be considered as a severe system which is directly connected to the continuity of the practice of doctors and medical institutions in Japan under its universal insurance system.

## 6. DISCUSSIONS

The contents of medical examination and treatment under Japan's medical system is virtually checked within the scope of the insured medical examination and treatment, whose basic philosophy was established in 1953 through 1957, not being subjected to any significant amendment thereafter. It is understood that the insured medical examination and treatment in those days, with a policy striving for the dissemination and expansion of medical examination and treatment, aimed chiefly at providing its people with adequate medical examination and treatment in terms of social and economic aspects to ensure that they were given opportunities for receiving medical examination and treatment, for which a system was formulated to accommodate the situation. The idea, as typically seen in "limited" medical examination and treatment, made it the prime objective to provide a uniform and economical medical treatment and examination, rather than dealing with individual symptoms or enhancing the quality of medical

examination and treatment. The assessment standard has been operated with its details remaining unclear to invite doctor's dissatisfaction in many cases at their medical reimbursement being partially cut without sufficient convincing explanation. In addition, the assessment was said to be not subject to regional difference in principle, while, in reality, such assessment was possible that complied with the regional supplying conditions and quality situation of medical examination and treatment. However, now that this objective was achieved, it is sought to address using limited medical resources to provide high-quality medical care meeting patients' disease conditions and needs in an impartial and efficient manner, which would naturally demand a change in the above-mentioned mechanism. For example, the assessment has been performed without such indispensable information available to determine the impartial supply of medical care as patients' disease condition, severity of disease and so on with the days hospitalized, a representative index for greater efficiency, not directly subject to the assessment. Expensive medical examination and treatment is given priority to be directly covered by the assessment, proving fruitful, which causes, on the other hand, the criticism that the progress of medicine is not adequately evaluated but cheap medical examination and treatment are pursued. The point of greater importance is that 100% of an enormous amount of the reimbursement claiming statements undergo assessment to result in unevenness in the assessment by the limited number of committee members, revealing the difference of views among them, which ends up amplifying doctor's dissatisfaction at the assessment results.

The checkup of the contents of doctors' medical care by the third party is a common issue to the developed countries troubled with soaring medical expenses<sup>22)</sup>, which is a matter having the character to directly step into the area undertaken responsibly by doctors, and might probably not only be directly

connected to doctors' income but also lead to the social evaluation of doctor's capability of medical examination and treatment, and thus the operation of which must be handled prudently. It is widely known that in the U.S. a system called "PRO" is taken on a large scale, which clarifies the scope and standard of assessment, being performed with an enormous volume of information accumulated<sup>11,12)</sup>. However, its essence is a "peer review" under the medical expense payment system of the U.S. and an assessment corresponding to it is performed, which poses, on the other hand, the same issues as Japan including the adjustment of regional difference and the reduction of the reimbursement claiming statements covered by the assessment. Between the U.S. and Japan, the medical care system and medical insurance system are fundamentally different from each other, which disables Japan from introducing the assessment system of the U.S. immediately into Japan, arousing doubts on the effect, while, on the other hand, such aspects are seen as to arrive consequently at the same issues as Japan despite of the system difference, which will have a great significance in providing data for review to help improve the Japanese system.

### 7. CONCLUSION

The amendment of the points table of the "Fee Schedule" in 1993<sup>24)</sup> adopted a system to admit, just upon a notification from medical institutions, the medical examination and treatment acts for which the reimbursement claim had been accepted only when the administrative agency approved of it by determining they are provided with sufficient facilities and manpower, which made insufficient the conventional method of assessing the adequacy of claiming. This caused the start of the investigation into the assessment and guidance/auditing systems<sup>25)</sup> which had not been subjected to any significant amendment to their basic philosophy for 30 years in order to cope with the new situation. It

is understood that Japan's medical system and medical insurance system started fundamentally from dependence on doctor's good sense and have given the first consideration to the dissemination of medical examination and treatment to prioritize their social adequacy and economy, while they certainly have been equipped with the flexibility to properly tackle the medical conditions available then under the current of the times, and will be improved to meet the needs of the new times in the climate of Japan by also referring to the cases of foreign countries, for example the U. S., thus attaining the development of their own from now on as well without fail.

### 8. REFERENCES

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- 4) ditto Art. 7.
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